

## **Transcript of FDA Press Conference on Cough and Cold Medicine**

**Moderator: Susan Cruzan**

**January 17, 2008**

**10:00 am CT**

Coordinator: Good morning and thank you for standing by. At this time all participants are all on a listen-only mode.

After today's presentation we will conduct a question and answer session. To ask a question you may press the star 1 on your touch-tone phone.

Today's conference is being recorded. And if anyone has any objections you may disconnect at this time.

I'd now like to turn the call conference over to the host for today's call Miss Susan Cruzan. Ma'am, you may begin.

Susan Cruzan: Thank you. Thank you (Julianne). Good morning to everyone. Welcome to our press briefing today to discuss a Cedar Action announcing recommendations on cough and cold medicines for children under 2.

Joining us today are Dr. Charles Ganley, Director of Office of the Nonprescription Drug Products Office Center for Drugs with FDA and Dr. Lisa Mathis, the Associate Director who is also with the Office of New Drugs, Pediatrics and Maternal Health Staff also with Cedar - the Cedar and FDA.

Following brief presentations we will open up the call to credentialed media and would like you to state your name and affiliation.

Right now I will turn the call over to Dr. Charles Ganley. Thank you.

Charles Ganley: What I'm going to do is to break my comments up into four questions. And questions I'll be addressing are these: What does the Public Health Advisory say? How did we get to this point? Who's been involved with this process to date, and why was this announcement made today?

And then Dr. Mathis will follow with some comments after mine.

The Public Health Advisory issued today, we strongly recommend that over-the-counter cough and cold products should not be used in infants and young children under two years of age because serious and potentially life-threatening side effects can occur from use of these products.

And our today's advisory is based on the FDA's review of the data and discussion at the October 18 and 19 2007 joint meeting of the nonprescription drugs and pediatric advisory committees.

The advisory also notes that we have not come to final decisions on the use of cough and cold products in children 2 to 11 and that we will continue to work within FDA to arrive at a decision.

So how did we get to this point?

After the advisory committee meeting in October, an internal working group was tasked with coming up with some recommendations for some short term decisions which comprised of review and regulatory staff representing many disciplines within FDA.

And they (met to) consider the actions that FDA should take in short term.

And I making that distinction here because there is also some long term plans

that we have to make.

These - many of these drugs are marketed under monographs. And as was noted at the advisory committee, we are going to have to go through a rulemaking process.

What this working group was tasked mainly is what are the things that we should try to address in the short term and do very quickly?

Within the working group there is generally unanimous agreement that the data in the children - in children under 2 years of age raised significant concerns and that cough and cold products should not be used by parents.

However, within the group, there was still debate ongoing as to what the appropriate short term action was for children 2 to 11 years of age. They could not come to a consensus on all the issues they had to consider.

So who was involved in this process to date within FDA?

Well there are representatives from at least 11 different review and regulatory groups with FDA involved in this process.

And as you can imagine, attempting to get a consensus among all those individuals will require some time because there are a diversity of views as to what the process or what the action should be.

Why was this announcement made today? FDA felt it was important that we make our position known on the use of products in children less than 2 years of age while we continue to determine the course of action on the 2 to 11 age groups.

We were concerned that parents might continue to use these products in children less than 2 years of age even with all the publicity that occurred back in October.

And part of this is driven by some surveys that we became aware of in December where some of the - it appeared that the message in October was not generally received by everyone and there may be individuals or parents that may continue to use these products without seeking advice from a health provider.

This announcement will bring this issue back into the public consciousness, particularly since it is cold season now, and remind parents that we do not know the safe and effective dose in children less than 2 years of age.

Now I will point out that this is - FDA has never endorsed the use of these products in children less than 2 years of age. We've always acknowledged that there was no safety and efficacy data. And it was really left to the discretion of health providers to determine whether a product or use of one of these products was appropriate in those age groups.

Today's announcement also allows us to reaffirm that we agree with the voluntary withdrawal by industry of cough and cold products that have pictures of infants on the front of the package or use of the word infant in the name of the product.

So that concludes my comments right now. And I'm going to turn it over to Dr. Mathis to make some additional comments.

Lisa Mathis

Okay, so this is an important first step in evaluating this group of drugs. And

pending FDA's review of over-the-counter cough and cold medications for children 2 years of age and older, the FDA has the following recommendations.

The first is always remember that these medications do not cure the cold. They don't shorten the time that your child has a cold. And they're only meant to help a child's symptoms.

Also make sure if you choose to give these medications to your child that you look at the active ingredients section of the drug facts label. This will help you understand what active ingredients are in the medication and what symptoms each active ingredient is intended to treat.

Cough and cold medications often have more than one active ingredient. Be very careful in giving more than one over-the-counter cough and cold medication to your child.

Remember that many of the over-the-counter cough and cold products have multiple medications in them.

If you use two medications that have a similar active ingredient, a child could get too much of the ingredient and that could hurt a child.

Also make sure to carefully follow the directions in the drug (strengths) part of the label. These drug directions tell you how much medicine to give and how often you should give it.

Also, only use the measuring device spoon or dropper or cup that comes with the medication. Common household spoons come in different sizes and are not meant for measuring medicines. If you use these, you may not be giving

the right dose.

Also, if you have the opportunity to choose a cough and cold medication with a childproof safety cap you should do so and store these medications out of the reach of children.

Most importantly, call your physician, pharmacist or other healthcare professional if you have any questions about using these medications in children 2 years of age and older.

Susan Cruzan: Thank you Dr. Mathis. We will now open it up to questions again to credentialed media only.

Before I do that, I do want to mention that FDA's press release has been posted on the Web site at [www.fda.gov](http://www.fda.gov). And there are links to the Public Health Advisory and a consumer Q&A column.

We can take the first question now. Thank you.

Coordinator: Thank you. At this time if you would like to ask a question, please press the star 1 on your touch-tone phone. You will be announced prior to asking your question.

To withdraw your question, you may press star 2. Once again, to ask a question, please press star 1. One moment please.

Thank you. Our first question comes from (Peggy Peck) from (MedPage) Today.

Woman: (Please) turn this up.

(Peggy Peck): Yes. Thank you for taking the question. I'm wondering, based on the - what you're saying today, if you could address a pediatrician who was treating patients, infants younger than 2 and describe to that what the advice - what that pediatrician should be - what advice you would give that pediatrician in terms of any kind of medication that would be - would treat symptomatic cough and cold.

Charles Ganley: Right. I think it's important to understand that our announcement today is we're not trying to dictate the practice of medicine and that we understand that health providers on an individual basis have to make certain decisions for the individual patient based on what the facts are presented to them.

However, we do need to recognize here that there is some difficulty particularly in this age group of dosing these products because many of the serious adverse events in the less than 2 age group are related to mis-dosing.

And also in attempting to choose the correct product, there's clearly instances where more than one product are used or it's not clear to the parent as to what the ingredients are in the product.

It's simply not adequate to state what the - give a trade name or something (like that) because there are so many different products out there.

And...

Lisa Mathis Yes. I would like to also add that the pediatrician should probably refer to some practice guidelines by the American Academy of Pediatrics.

And it should be known that the American Academy of Pediatrics as well as

the College of Chest Physicians have for many years recommended against the use of these products in younger children for these exact reasons. We don't know the appropriate dose and there are safety concerns.

(Peggy Peck): Thank you very much.

Susan Cruzan: Can we have the next question please?

Coordinator: Thank you.

The next question comes from (Jennifer Corbett) from Dow Jones.

(Jennifer Corbett): There's this internal working group and that right now the working group is divided on what to do for kids ages 2 to 11.

And I guess what I'm wondering is how you expect to get some consensus.

I mean you've had - you've been looking at this for almost three months. And I'm wondering, you know, how a longer time period would help you come to consensus.

And can you say, are you leaning in any direction? I mean do you have any advice for like say parents of children like 3 to 6 where there was some discussion of that age group at the panel?

Charles Ganley: The working group is coming up with recommendations. This they're going to be presenting them to - or there'll be presenting the memo to the Center Director in mid February or late February.

And the center director - Center of Drugs Director will make a decision after

that.

And part of this is driven by we recognize that for products that may be coming onto the market for next year's cold season are going to be packaged and manufactured in early spring.

So if we want specific recommendations out there, we know we have to get them out by that timeline.

As far as consensus, there is - I don't want to suggest that there's total disagreement. There is - there's some issues where there's clearly disagreement.

And it comes down to, you know, process and how do we do it, whether it's through guidance and things like that.

Those are legal issues that have to get resolved. There are some other issues about, you know, what to do right now with products that may have dosing down to 2 years of age.

There's not a consensus on that among the individuals on the group. And that's what they're going to have to try to resolve.

If there's still a difference of opinion that --those differences will be presented to the Center Director and she will make a decision.

Okay, thank you.

(Jennifer Corbett): Okay. Thank you.

Susan Cruzan: Thank you. Can we have the next question please?

Coordinator: Thank you. Our next question comes from (Gardiner Harris) from New York Times.

(Gardiner Harris): Hi. I just - can you give us a sense as to - it doesn't sound like you're doing anything sort of different than what you've done before. You've never suggested that the drug should be used in children under 2.

I think the industry has already voluntarily not only withdrawn products in children under 2, but I think they said that they were going to change the label from, you know, consult a doctor to do not use in children under 2.

So are you announcing anything new today? And also, if you could give us a little bit better sense as to where the - what are the issues that are being - that are where the disagreement is going on in this working group?

Charles Ganley: You have a lot of questions there (Gardiner).

(Gardiner Harris): I'm sorry doctor.

Charles Ganley: Well I think the you know, are, - you're correct in saying that we've never recommended the use of these products because we'd rather acknowledge for this age group that we do not have data to support a safe and effective dose.

The reality of the situation is that these products are used quite a bit in this age group. And in many instances, parents are using them without getting advice from a health provider.

And I'll refer you back to two - some two pieces of information you can go

check. One is the NPR Harvard Survey that came out in December. And we can provide that to you although it's readily available on the Web site.

And there's a chart, Chart 10 in there where the question was which of the following best describes your reaction to the recent news about the safety and effectiveness of over-the-counter cold and cough medicines in children?

And for parents of children under 2, 20% planned to continue to use, 26% were undecided, and 15% have not heard about discussions. So that accounts for 61% of the parents in that survey who have children under 2.

That's really troubling to us. And so one of the purposes was to get this information out more broadly.

The other piece of information was presented at a December workshop presented by NIH, FDA and CHPA with the use of adolescent - the use of over-the-counter drugs in adolescent children.

And a Dr. (Sanders) presented some information in one of his presentations where he did a survey among parents who were aged 16 to 25 who had infants less than 12 months of age.

Eighty-three percent or 86% of them considered OTC cough and cold medications appropriate for children less than age 2 without consulting a physician.

That's the problem we're trying to address today. Okay. So...

(Gardiner Harris): Okay, thanks Dr. Ganley. I mean I threw in that other question that you probably won't be able to answer about if you can give us some sense of

where the disagreement going forward lies. Is there any way that you can give us more hints?

Charles Ganley: Well I think the - it's the disagreement probably resolves - revolves around, you know, the one - it pertains to the one question that was dealt with, what do you do with these products now.

And you know they're - for both the 2 to 6 and the 2 to 5 and 6 to 11 year age groups that the committee voted on.

And I don't know if you recall the votes, the vote was 13 to 9. And the 2 to 5 is that we should do something now to not make these products available. And for the 6 to 11 age group, it was 15 to 7 in favor that leaves them available to - for parents to use.

And so there's a lot of ways that you could cut that is that you could say that those products should be taken off the market or that you just put in labeling that says do not use or whatever.

And that's where the debate really lies as to, you know, what can we do there and what should we do?

There are differences of opinion in that within the individual involved. And that's one of the issues that has to get resolved.

Many of the other issues, they have come to agreement. They know what - you know, they know what they want to do. The question is, how do you implement that? So...

(Gardiner Harris): Thanks. Okay.

Susan Cruzan: Thank you. We can take another question.

Coordinator: Thank you. Our next question comes from (Elizabeth Lapetto) from Bloomberg News.

(Elizabeth Lapetto): Hi. Good morning. So as I understand it, what sparked all of this were four deaths over the course of six years in Baltimore. And then all of the pediatric chiefs in Baltimore got together and advised parents not to use these over-the-counter medicines in children under the age of 6.

And I guess I feel like the question is only half addressed, you know. You have recommended that parents not use these over-the-counter drugs in children under 2.

But how are you actually going to implement that? I mean is that - aside from the labeling change, are these going to be kept behind the counter, these children's cold medicines? What is actually happening here?

Charles Ganley: Okay first of all, the products that were more or less marketed and directed to children under 2 -- and we characterized those as the ones that may have had a picture of an infant or if they had infant in the name okay -- many of those have already been withdrawn, okay?

So - but one of the issues is there are many products out there that are suspensions that have dosing directions down to 2 years of age and can carry through adult, okay.

So simply addressing, you know, saying that those products should no longer be available doesn't necessarily take care of the problem in the less than 2 age

group. Because parents still may be inclined to use products that are labeled for children to through adulthood.

So the purpose of this is also to get the message out to parents that they should not use these products okay. If they go to a health provider and the health provider, you know, provides some advice that they should use them, that's not what we're getting directed at here okay?

There are clear indications to us that some parents may decide to use these for whatever reason based on past experience with kids that they already had or whatever. You know, we don't know all the intricacies that go into this.

(Elizabeth Lapetto): Right.

Charles Ganley: So it's important that that message gets out.

So what was your other question?

(Elizabeth Lapetto): I mean are you going to suggest that these, you know, that the suspensions that can be used in the younger infants be placed behind a counter or something like a - you know, like the Plan B birth control pill?

Charles Ganley: Well again, that's something that we're going to have to address, you know, in the spring.

We're going to address - as we noted in the health advisory, we're still considering how to proceed on that. And we will address that in the spring.

(Elizabeth Lapetto): Okay. Thank you.

Susan Cruzan: Okay, thank you. Next question please.

Coordinator: The next question comes from (Erin Smith) from CNN Money.

(Erin Smith): Hello everybody. Thanks for taking my question. The warnings issued today mentioned side effects that are serious and potentially life threatening. But they don't go into further detail.

And I was just wondering if you could explain the physiological effect of these side effects and how they might actually kill the patients?

Charles Ganley: Well I'm not sure that's purpose of this conference. There is a review in - you know, the background material that was presented to the advisory committee. And the reviewer was (Deta Toiserkani).

And if you want-- she has two reviews here. One involves the, you know, looking at death in children less than 6 years of age. And the other involved the serious adverse events reported in children less than 6 years of age.

Now clearly, you know, some of these serious adverse events may be related to physiologic effects.

When you think about the adverse events that are reported in children -- and it's no different in adults -- in children, it's a little different though -- you can generally categorize them into three things.

One is that there may be a miss-dosing or a mis-dosing adventure. There may be an accidental ingestion. Or they are may be just intrinsic side effects related to the pharmacologic action of the drugs.

And I think the thing is that you have to remember that and, you know, we have to keep reminding ourselves that these are OTC drugs and they're, you know, relatively safe and these events are rare.

But, you know, they can be harmful just as easily as a prescription drug okay. And so, there's pharmacologic action that could occur.

And just to take an example, if you have a decongestant which is a certain type of drug, it - if too much of it is taken, it can cause very rapid heart rate. Okay?

Whether that leads to a serious adverse event, you know, may depend on an individual in other circumstances okay?

(Erin Smith): Okay.

Charles Ganley: I don't think we're here to talk about all the different pharmacologic effects that can occur with these drugs.

I think clearly, you know, these are drug products that have pharmacologic effects that when taken in certain amounts that may be excessive or there may just be some sensitivities on the individual part could lead to serious adverse effects.

It's no different than, you know, what we see with prescription drugs. They just may have a - you know, the OTC drugs may just have a different side effect profile and have a safer margin of error.

(Erin Smith): All right.-I just - right now I've got a story referring to serious or potentially life-threatening side effects but it doesn't really mention what they are.

And I didn't really want to cause unnecessary anxiety to the public. I just wanted to go into a little bit more detail.

I mean, I can look at these other reports, but they be you could just tell us, you mentioned something about very rapid heart rates seen I guess. I didn't really get all the details on that.

But I just want to give, you know, parents a little bit more of an idea of what they're dealing with and what the physiological effects might actually be -- the side effects. That's all.

Lisa Mathis            I think -- this is Lisa Mathis. And some of the adverse events that we have seen do include deaths, convulsions or seizures, rapid heart rate and decreased levels of consciousness. Those are the specific adverse events that we have seen and have reported.

(Erin Smith):        Okay, thank you.

Susan Cruzan:        Okay. Can we have our next question please?

Coordinator:         Thank you. Our next question comes from (Elizabeth Crawford) from The (Panshee).

(Elizabeth Crawford): Hi. Thank you. I just want to clarify that this recommendation, is it a change from the advisory committee's recommendation in August that said not to give OTC cough, cold products to children under 2 unless the healthcare provider specifically directs parents to?

Those parents if...

Charles Ganley: I don't understand your question.

(Elizabeth Crawford): Sure. If a healthcare provider recommends a parent use this product, is that okay? I mean, you said in August only use this if a healthcare provider directs you to.

Charles Ganley: Right. Again - and Dr. Mathis may want to add some points about, you know, what the various societies have recommended.

Generally FDA does not dictate the practice of medicine okay. But our recommendation here is that they not be used.

Health providers can always make a decision on a case by case basis for a patient whether they want to use a product off label or not.

And that's not unique to these products. And I'll just turn it over to Dr. Mathis who has some - may have additional comments about recommendations.

Lisa Mathis Sure. The FDA is recommending that these medications not be used in children 2 years of age and younger. But you should also be aware that the American Academy of Pediatrics as well as the College of Chest Physicians have for decades recommended against the use of these products in younger children as well. And that they are more closely tied to the actual practice of medicine.

As Dr. Ganley said, we don't regulate the practice of medicine.

(Elizabeth Crawford): Great. Thank you.

Susan Cruzan: Thank you. May we have the next question please?

Coordinator: Thank you. Our next question comes from (Alexis Grant) from the Houston Chronicle.

(Alexis Grant): Hey. That list is pretty extensive of the drug makers that already pulled their products. But I'm wondering if there are any medicines specifically for toddlers and infants that are still available on the shelves or whether you're more worried about drugs that could be used for kids under 2 that are specifically marketed towards them?

Lisa Mathis: This is Lisa Mathis. Of course one of the things that we are concerned about is that many of the cough and cold medications that are on the shelves even for adults are liquid. So they are pediatric friendly.

We want to make sure that people understand that they should not be giving these medications to children 2 years of age and younger.

And then Dr. Ganley may wish to elaborate. But many of the products for - that were specifically marketed towards patients 2 years of age and younger have been voluntarily recalled.

There may still be some products out there because this was a voluntary recall. I - do you want to elaborate on that?

Well yes. I think the - you know, when we had the Advisory Committee, despite the recall or the voluntary recall by the manufacturers prior to the Advisory Committee, even after the Advisory Committee, folks who worked - have been working on this project within FDA had noted that some of them still remained on the shelves in the Washington area.

Recently though we haven't seen that okay. But again, we don't - you know, outside the beltway, where not, you know, we're not privileged to what may be going on out there.

And so I think, you know, one of the options that we have is to have our field investigators go out to do some random checks to see if these products are still out there and then determine a course of action.

(Alexis Grant): Thank you.

Susan Cruzan: Can we have the last question please?

Coordinator: Thank you. Our last question comes from (Rob Stein) from Washington Post.

(Rob Stein): Yes, thanks very much. I was wondering if you've gotten any additional reports of adverse reaction to these products since the advisory committee meeting.

And I was also wondering are you - as part of your continued deliberations, are you - could you formally ban these products in children this young and not just issue a recommendation for how they should be used?

Charles Ganley: Let me just - when you're saying banning the products in children younger than 2, is that...

(Rob Stein): Well yes, there are products that are still on the market that are - you said that are labeled for kids down to age 2.

So I'm wondering, can you - is that one of the options that you're considering

is taking some formal action to stop that practice?

Charles Ganley: Well I think that got - gets back to (Gardiner Harris)'s question earlier about what are the, you know, the difficult - or what are the disagreements between, you know, what to do.

You know, one obviously one of the options is for us to say is that, you know, there shouldn't be products marketed with, you know, to children, you know, in the 2 to 6 age range.

And if you're going to create a product such as a suspension that may be pediatric friendly that you're going to have to put some type of labeling on their suggesting that it not be used or do not use or something else okay?

Those are the things that have to be decided I think you know, by this working group in the short term as to, you know, how we're going to address these products.

Now I'll just step back and say that - you know - and part of this was just a discussion at the Advisory Committee, many of these products are marketed under monographs which marked - monographs are regulation.

And so as was noted at the Advisory Committee, the path forward in the long term is to create an amendment to those regulations stating that these products should not be - or have not been found generally recognized as safe and effective in children 2 to 11 years of age okay?

So as this process moves forward in the rulemaking process, there will be an amendment to the monograph that addresses, you know, what the long term is.

And a lot of it is going to depend on - you know, and it's sort of separate from what happens in the short term because we may make some decisions in the short term okay but - that may or may, you know, that may take some action against these products or not.

But the long term action is we're going to have to come out with an amendment that says that these cough and cold products or the ingredients are generally not recognized as safe and effective. And that's more of the legal way for us to address that right now.

(Rob Stein): And have you received any additional reports of that?

Charles Ganley: (Unintelligible). We'll be quite frank about it. We haven't kept tabs on what's been coming in. I don't think we expected to have, you know, additional information that'd be much different than we already have.

And I think with - there may be some publications coming out in the future that we may have an interest in. And so those are the things that may provide us more useful data. So...

(Rob Stein): Okay, thank you.

Susan Cruzan: That concludes our call. I think Dr. Ganley will wrap up with our three main points for advice to consumers.

Charles Ganley: Right. And again, I think the thing we want to make clear today is that we are strongly recommending that over-the-counter cough and cold products should not be used in infants and young children under 2 years of age.

And again, part of this is based on some concerns that parents that have

children in those age groups may continue to use them without seeking advice from a health provider.

The second thing is that we are continuing to make some decisions as to what we plan to do in the short term with products that may be directed to children 2 to 11 or have dosing instructions for children 2 to 11. And we hope to have something available in the spring.

And the last thing as if parents with children in the 2 to 11 age range decide to use the products to please follow the advice that Dr. Mathis mentioned earlier on.

Susan Cruzan: Thank you so much. This will conclude our call. I just want to remind you that FDA's press release with links to the Public Health Advisory and a consumer Q&A are posted on FDA's Web site.

And if you do have follow-up questions, myself Susan Cruzan and (Chris Kelly) will be happy to address your questions by email. Thank you so much. Have a great day.

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