Transcript of FDA Press Conference on FDA's review of Prilosec and Nexium

FTS HHS FDA

Moderator: Susan Cruzan
August 9, 2007
12:30 pm CT

Coordinator: Please standby for the FDA Conference Call it will begin in approximately three minutes.

Please continue to standby for the FDA Conference Call it will begin in approximately three minutes. Thank you.

Good afternoon and thank you all parties for standing by, I would like to inform you that your lines will be on a listen only until the question and answer session of today's conference.

The call is being recorded, if you do have any objections you may disconnect at this time.

I would now like to turn the conference over to Ms. Susan Cruzan, thank you ma'am you may begin.

Susan Cruzan: Thank you (Carol), this is Susan Cruzan with FDA's Office of Public Affairs, thank you all for joining us today.

This is part of FDA's ongoing effort to make information available today about FDA's review of Prilosec and Nexium.

Joining us today are Dr. (Paul Salsman) the Associate Director for Safety Policy and Communication and FDA Center for Drug Evaluation and Research.

And Dr. (Julie Bites), the Director of the Office of Drug Evaluation III.

When we open it open to questions, Dr. (Joyce Clovick) is also available to answer questions she is FDA's Cedar Deputy Director for Gastroenterology Drugs.

I will now open - give it to Dr. (Salsman) for some brief comments and then we will open it up to questions for credentials media.

Thank you, Dr. (Salsman).

(Paul Salsman): Thank you Susan and good afternoon today the FDA posted an early communication about an ongoing safety review that we are currently conducting related to omeprazole branded as Prilosec in the United Stated as esomeprazole branded as Nexium.

As I think all of you know both of these products belong to a class of drugs know as proton pump inhibitors that are used by millions of people both in this country and around the world to treat the symptoms

and disease - still this is related to gastric and esophageal problems associated with the excess production of stomach acid.

And as you know I think PTI's work to reduce the amount of gastric acid that is produced.

On May 29th of this year the manufacturer of both of these products AstraZeneca informed us of early results from one clinical study involving Prilosec and the analysis from a second still ongoing study of Nexium.

In these studies AstraZeneca was attempting to ascertain whether drug therapy with either of these drugs or surgery was most effect in relieving and preventing a recurrence of symptoms in patients with several Gastroesophageal Reflux Disease commonly referred to as GERD - G-E-R-D.

The results from the study of Prilosec in analysis from an ongoing study of Nexium raised initial concerns on our part that that the long term use of Prilosec or Nexium may have increased the risk of heart attacks, heart failure or heart related sudden death in those patients taking either one of the drugs compared to patients who received surgery.

Since May 29th AstraZeneca has submitted to the FDA a large amount of additional data some of it as recently as July 25th.

Upon initial examination and review of all of the available data that we have to date, FDA has concluded preliminary that these data do not

suggest an increased risk of heart problems in patients treated with either of these products.

We have been in communication with our colleagues in the United Kingdom in New Zealand in Australia as well as Canada and their independent reviews as well of the similar data support findings.

As a result at this time we are recommending that health care providers and patients are not alter either their prescribing practices or taking of these drugs or at any time discontinuing the use of these products.

This early communication is really part of an ongoing commitment on the part of the FDA to inform both healthcare providers as well the public about emerging safety issues that impact public health.

Again as all of you know back in March we issued a guidance document referring to how we communicate emerging safety issues to the public.

Early communications maybe to disseminate before during the time that the view (unintelligible) take the information on this plant case (unintelligible) in the midst of such review.

And as planned once we complete such a review we will communicate our final conclusions and any resulting recommendations to the public.

So with that I'm happy by way of introduction to answer any questions.

Susan Cruzan: (Carol) we can open this up to questions now for (Credential Media).

If we can have people provide their name and affiliations we would appreciate that, thank you.

Coordinator: Thank you, and at this time if you would like to ask a question please press star 1 on your touchtone phone, you will be prompted to record your name.

Once again it's star 1 if you'd like to take a - ask a question.

Susan Cruzan: And while we're waiting for the queue I just want to make sure everyone knows that this information is posted on FDA Center for Drug Evaluation and Research site, and a med watch support was also sent on this.

Coordinator: And the first question comes from (Deidre Henderson), of Boston Globe, your line is open.

(Deidre Henderson): Hi thank you very much for doing this call.

Dr. (Salsman) I was hoping that you might be able to shed some light on just how the FDA is handling these emerging safety questions about drugs.

A number of us on this call were at the Avandia Advisory Committee Meeting, and that was triggered by Meta Analysis.

Here you guys are communicating information from clinical trials including placebo controlled trials and one that is 14 years - a 14 year study.

So, how does the FDA decide that in this case it's early communication via Web and email and phone call versus advisory committee?

(Paul Salsman): I think communication for us is always an evolving process, and I think this early communication is part of that involving process.

We are - we constantly are receiving new information from adverse event reports and clinical trial data from meta analysis from all sorts.

And we look the results of these case reports these studies on an individual basis we said their potential public impact and import of both the practitioners and consumers.

I think that you know, each as we progress in our thinking related to how to inform the public and practitioners about emerging information each experience we have in Avandia is certainly one experience we've had some (constructs) about you know, when and where and how we should inform that public.

(Deidre Henderson): One tiny follow up, should the public expect any changes to direct to consumer advertising for these drugs?

(Paul Salsman): Not based on this announcement - no.

(Deidre Henderson): Thank you.

Coordinator: (Lisa Richwine), Reuters, your line is open.

(Lisa Richwine): Hi, thanks for taking my question I think somewhere in the statement I can't find the exact wording right now.

But you referred to these studies as a small study they were small but long term, can you tell us how many patients were in the studies, and then give us of the (unintelligible) of heart attacks or any other events?

(Julie Bites): I guess we would say that the review of these studies and all other available data is ongoing at this time.

So we're not prepared to reveal any of the specifics, also we do plan to upon completing our review provide the public with a more comprehensive overview of what has been found in them.

Oh, this is Dr. (Julie Bites).

(Lisa Richwine): Okay, thanks.

Coordinator: (Gardner Harris), New York Times, your line is open.

(Gardner Harris): I think my question has sort of been answered but let's just sort of restate it.

You seemed to have come to a very different decision with these studies and these drugs than you did with Avandia.

Obviously you had the results of the Avandia studies for at least a year that meta analysis before there was any public announcement.

In this case it sounds like a matter of a little more than a month has passed, and you're obviously still involved in the analysis.

Why - what seems from the outside to be two very similar circumstances why are you handling them in such different fashion?

Is there something about the Avandia situation that lead you to rethink how you do this?

(Paul Salsman): Yes I think there is nothing particular about either circumstance simply I think it gardenered and its just an evolution in our thinking as to you know when we should be communicating information as we are receiving the results of clinical trials.

And at what point in our review and analysis we should be communicating information to the public.

(Gardner Harris): Okay, and Avandia obviously you - your initial analysis was that there seemed to be little concern - certainly not enough to alert the public.

I think it's fair to say that the advisory committee disagreed with that, there should be an alert here.

Any thought that this process might play out similarly?

(Paul Salsman): Well it's actually at this point hard to know whether this process is going to play out similarly or not until we really completed our analysis.

There is always the potential for taking any issues once we've completed our view through a public advisory committee without an enlarge measure, depend on what we learned by completing our analysis and what are conclusions with these - their completed such analysis.

Susan Cruzan: Thank you next question.

Coordinator: (Sue Sutter), Scriptworld Pharmaceutical News, your line is open.

(Sue Sutter): Hi thank you for taking my question, have you asked the manufacturers of any of the other PTI's on the market to go back and look at their data for (unintelligible) events or to submit you know pulled analysis to you?

(Paul Salsman): Yes, well at the present we are in the process of accumulating as much data as we can about all these products.

Susan Cruzan: Next question please.

Coordinator: (Jennifer Smith), FDA Week, your line is open.

(Jennifer Smith): Thank you for taking my call, just wondering if this is the first time that FDA has issued this early communication notice. And if the Internal Drug Safety Board has also looked at the (unintelligible) or this is one of the first - I guess first projects of both the risk communication panel that was newly formed?

(Paul Salsman): Sorry, could you repeat the question again.

(Jennifer Smith): Sure no problem, wondering if this is the first early communication that FDA has done concerning a product, concerning letting the public know that there is not a definitive answer to their next product.

I guess it's dangerous but is the (unintelligible) indications is the first time FDA is doing this?

(Paul Salsman): Well this - it is the first time we actually have a communication tool that it's entitled in early communication about an ongoing safety review.

However for the last two years we have issued over 60 public health advisories and health care provider sheets of emerging health concerns that will have been brought to our attention even through adverse events reports that we've received, through postmarking of clinical trials that have been conducted.

(Jennifer Smith): So how is this different, I'm sorry I don't see that how is this different from a public health advisory from what you had just mentioned.

(Paul Salsman): You know I just think it's - I think it's just earlier in the process of our evaluation.

(Jennifer Smith): Okay, so this is the earliest yet that FDA has done concerning a product?

(Paul Salsman): Yes I think it's fair to say that.

(Jennifer Smith): Okay, okay great, and one more think to I was asking whether or not the Drug Safety Board has looked at - has looked at the information internal drug safety board, or this was something - this was a - this

announcement was crafted with consultation with the newly formed risk communication panel.

(Paul Salsman): The newly formed risk communication panel doesn't exist yet.

(Jennifer Smith): Oh.

(Paul Salsman): But it's - so it's forming but the answer to the first part of your question is yes, the data that were available to us on July 12th, which is when the board met to consider the question of early communication, the day that we had at hand at that time were presented to the board.

(Jennifer Smith): And that was the May 29th data as well - just the May 29th data at that July 12th meeting or the following follow up data as well.

(Paul Salsman): You would actually receive between May 29th and July 12th some additional data as well.

We also received towards the end of July, I guess July 25th some additional information as well this is you know part of this process that it is somewhat of a moving target for us and that we are accumulating a more information as we all conducting our analysis.

(Jennifer Smith): The moving target would be I think you were saying earlier just as the two drugs and now you're looking at the entire class of (unintelligible) drugs out there.

(Paul Salsman): Our primary focus is on these two drugs.

(Jennifer Smith): Okay primary but you also are kind of extending your scope as well, would that be fair to say if you know the target these two but you're still looking at overall.

(Paul Salsman): We are of course interested in the date (unintelligible) are some word products, yes.

Coordinator: Your next question comes from (Ed Silverman), (Pharmalot), your line is open.

(Ed Silverman): Hi, thanks for taking the question.

I'm just wondering you're saying that this is an early communication tool, but it's a moving - the process is a moving target and you've not completed the review.

And I'm wondering to what extent are you worried that by saying today to the medical community to patients nothing has changed that maybe there is going to be scare, particularly in the context of what happened with Avandia.

(Paul Salsman): Well we are always - we always tried to make our communication as factual as possible and as balanced and as neutral in tone as we possibly can to reflect what it is that we know about a product at the time of the announcements.

We are always cognizant and aware of and concern about the potential consequences of our announcements and that is why that we are very explicit in this statement that prescribers as well as patients should not

change their either prescribing patterns or use patterns based on that we received some initial information and are conducting an analysis.

(Ed Silverman): But the other shoe hasn't dropped yet, so it's possible that some will - some people, some doctors, some patients will react and say, well maybe we should wait and see what they finally decide.

(Paul Salsman): I'm afraid I can't engage in that speculation as to how people will necessary react to it.

But our hope is that our words speak for themselves.

(Ed Silverman): Okay, thanks.

Susan Cruzan: All right, thank you, next question please.

Coordinator: (Gary Heybrid), the News Journal, your line is open.

(Gary Heybrid): Hi, when do you think you'll have your analysis completed?

(Paul Salsman): We're hoping by - about three months is our planned completion.

(Gary Heybrid): With three months from today?

(Paul Salsman): Yes.

(Gary Heybrid): Thanks.

Susan Cruzan: Could we have another question please?

Coordinator: (Mark Bloom), (unintelligible) Today, your line is open.

(Mark Bloom): Hi, good afternoon, now you received this information on May 29th and you - it was somewhat alarming but you just now put a safety warning out of May 29th.

Then you received some more information on July 12th which I presume was less alarming. And then on July 25th, which I presume was even less alarming. But on neither of those days you put out some information.

What was the timeline, when did you become less alarmed, and if you had not become less alarmed when would you have put some information out?

(Paul Salsman): Well this is - great question (Mark).

Woman: Yes I think it's a combination also you need to consider the fact that there was a lot of - the initial May 29th submission was an early analysis, it wasn't fully complete.

So, what was coming in over time was more and more data to complete this picture.

(Paul Salsman): We - just so you know we - it wasn't July 12th when we received additional data it was actually the first and second week of June.

So right after we received this the initial information from AstraZeneca within that week we were receiving additional data because we were not only very concerned about the initial results, but also concerns that

there was a lot of missing information and some you know real legitimate problems with what they had submitted to us.

So it - we were I'll be blunt with you, we were cognizant right from the earliest submission about whether and how we should say something and we were at the same time we were receiving and reviewing new information at a - as it arrived, we were also internally discussing at what point we should say something and what we should say.

So, there is a lot going on internally in the months of June and July regarding both and new information that we were receiving and how we should communicate it.

(Mark Bloom): But when do you become less alarmed?

(Paul Salsman): I think - I don't there is a point and time when we - I could say became necessarily less alarmed.

I think that...

(Joyce Colbert): (Unintelligible).

(Paul Salsman): ...yes, I mean (Joyce Colbert) was just saying something to me.

You know I think we were just at all stages of this process we were taking in the thoughtful careful and prudent approach to receiving analyzing, thinking about this information both in terms of what it said and how it is that we would say something.

And I would not cast this in terms when we became either more or less alarmed; the question for us has always been what to say and when to say it.

Susan Cruzan: Next question please.

Coordinator: (Jessica Lake), the (Tangie), your line is open.

(Jessica Lake): Hi my questions involve - I had most of my questions already answered.

But I was wondering if you're also recommending AstraZeneca or anyone else to anymore studies about the other PPI's, I think you kind of answered that but...

(Julie Bites): I don't think we're ready to really get into that sort of discussion at this point.

(Paul Salsman): Yes I think...

(Julie Bites): The (unintelligible) is still ongoing.

(Paul Salsman): Yes I think until we really complete our review it's too early to be asking for additional space, particularly in light of the fact that they data that we're looking at already coming from fairly long term studies.

I think it's appropriate at these carefully before we make additional recommendations about further studies.

Susan Cruzan: And that was Dr. (Bites) and Dr. (Salsman), and we have time for one more question please.

Coordinator: (Jennifer Smith), FDA Week, your line is open.

(Jennifer Smith): Hi thanks again, I just want to double check a couple of timelines Dr. (Salsman), you were mentioning to at the public health advisory the same that's been going on to the double check the last two years, or was it two or twelve I wasn't too sure on that.

(Paul Salsman): It's the last two years that we've been doing in public health advisories and...

(Jennifer Smith): So you're saying now with adverse reaction clinical trials as well.

But I mean in a sense if you were - for these advisories you were just waiting I guess for later, for more studies were coming in as our later timeline, before you issued this public health advisories, compared to this early communication?

(Paul Salsman): Usually when we have an early - our public health advisors and our health care provider sheets usually are - have announced labeling changes, new data where we feel strongly that the information has the potential to impact prescribers or, the way patients are using information.

And this earlier communication that were talking about today is basically I considered more of a notification that...

(Jennifer Smith): Okay.

(Paul Salsman): ...we are indeed involved in the analysis of new data that we are in receipt of it, and that we'll be looking closely at it and let the public know that a timeline by whereby they can expect our conclusion as related to these analysis.

(Jennifer Smith): Okay, last but least, you also mentioned about this in talk when you were receiving data.

So if you were receiving data May and then June, why wait until July 12th to have the Internal Safety Board look at this?

(Paul Salsman): Well we actually had the board look at on July 12th for a very bureaucratic reason actually the board was scheduled to meet on that day.

They of course couldn't look at the data that we receive subsequent to that in later July, but we felt this was the board is constituted within the center to help us dissolve communication policy and to help guide us and guide the center directly and making decisions about when we communicated and what we communicate, we thought this was a perfectly appropriate venue.

And given the fact that as I mentioned data and information was coming in pretty much throughout the month of June, the July 12th date just worked very nicely for consideration of this issue.

Susan Cruzan: And (Carol) if you have one more question we can take that, thank you.

Coordinator: (Tony Vickeon), the Pink Sheet, your line is open.

(Tony Vickeon): Yes thank you, I think this is answered earlier I just want to clarify it, did you say that direct to consumer versions of Prilosec are not impacted by this communication is that correct?

(Paul Salsman): That is correct.

(Tony Vickeon): Thank you.

Susan Cruzan: Do we have any further questions?

Coordinator: (John Bell), International Medical News, your line is open.

(John Bell): Yes thanks for taking my call I was wondering why AstraZeneca - I mean I'm assuming when they need the initial two studies you're saying they didn't control if a patient aged or previous history of heart problems.

And I'm assuming that in these 14 new studies and especially the four they were placebo controlled that they did control for these things.

And I wondered if you could tell me what kind of analysis they did you know specifically - thanks.

(Julie Bites): All right again, I don't think were going to be able to talk to you in very great detail about any of the studies at this time.

This will have to be deferred until we provide you the complete analysis.

Susan Cruzan: And that was Dr. (Julie Bites) and that will conclude our call today.

If you have further questions you can follow up with the FDA's press office, Susan Cruzan or (Rita Chappelle), and I'll give you (Rita's) email it's Rita.Chappelle@FDA.hhs.gov - C-H-A-P-P-E-L-L-E.

Thank you everyone for joining us, have a great day.

Coordinator: This concludes today's conference you may disconnect at this time, thank you.

END