FDA MEDIA BRIEFING ON HEPARIN

Moderator: Julie Zawisza
March 19, 2008
11 a.m. EDT

Coordinator: I would like to thank all participants for holding. All lines will be on listen-only until the question and answer portion of today's conference. I would also like to inform participants today's call is being recorded. If you have objections, you may disconnect at this time.

I am now turning the call over to Julie Zawisza. Thank you. You may begin.

Julie Zawisza: Thank you. Good morning ladies and gentlemen. It is Julie Zawisza here with FDA. I am the assistant commissioner for public affairs. I would like to welcome you to this briefing.

We want to update you on our Heparin investigation this morning. We have some important new developments in the case. So we are going to hear from Dr. Janet Woodcock, who is the director of our Center for Drug Evaluation and Research. And she will provide you with the latest developments. And then we will take your questions.

Dr. Woodcock.

Janet Woodcock: Thank you, Julie.

Well, after weeks of testing and the really (unintelligible), and in some cases, around the clock efforts of scientists, both at FDA and in academic laboratories, the material contaminating lots of Baxter Health Corporation’s

blood thinning drug, Heparin, has been identified. The contaminant is an over-sulfated chondroitin sulfate.

Now chondroitin sulfate itself is a biologically-derived compound. It is commonly available.

However, over-sulfated chondroitin sulfate is not ordinarily found in nature. It is most likely that ordinary chondroitin sulfate is chemically modified to create this compound that is found in the contaminant.

Over-sulfated chondroitin sulfate, unlike common chondroitin sulfate mimics Heparin's activities. And therefore appears to be Heparin when it is subjected to standard tests.

Dozens of people were involved in the chemical analysis work to arrive at the identity of this material. FDA labs in Cincinnati, Ohio and St. Louis, Missouri - along with scientists from the Center for Drugs here at White Oak -- partnered with experts from Massachusetts Institute of Technology.

The teams conducted separate tests on Heparin, collected from Heparin active pharmaceutical samples. They also sought input from Washington University in St. Louis.

By conducting multiple different types of testing, the scientists were able to definitively identify the contaminant as over-sulfated chondroitin sulfate.

As we reported previously, the contaminant now identified as over-sulfated chondroitin sulfate was found in many of the samples of Heparin Active Pharmaceutical Ingredient collected from the Changzhou SPL plant in China. This is the plant that supplied Baxter with its Heparin API.

Over-sulfated chondroitin sulfate was also found in some of the Baxter Heparin lots associated with drug adverse reactions.

Analysis of these samples suggests this contaminant accounted for approximately 2 to 50% of the total content of the API in some of these samples.

Over-sulfated chondroitin sulfate is not an approved drug in the U.S., nor should it be present in Heparin, as found by these analyses.

Now that the contaminant has been identified, FDA can move forward to determine how and when in the supply chain this contaminant was introduced.

At the moment, we don't know definitively whether the contaminant was introduced intentionally, or by accident. FDA continues its investigation to track down the root cause of the contamination. And still to be determined is whether or not the over-sulfated chondroitin sulfate, when combined with Heparin, can produce the serious allergic reactions of the sort reported to Baxter and FDA.

We have an intensive immunologic investigation under way to look into the mechanism in how these reactions may have occurred.

The FDA and the U.S. Pharmacopoeia have agreed to collaborate, to develop compendial tests on an expedited basis. The compendial tests will enable Heparin manufacturers in the U.S. and the rest of the world to detect the presence of trace amounts of the over-sulfated chondroitin sulfate.

It is likely these tests will be more rigorous versions of the tests that we have put out in an expedited way for screening.

Dr. Mack Lumpkin, FDA's deputy commissioner for international affairs and special programs, briefed China's State Food and Drug Administration on these findings that I have discussed earlier this week. The Chinese regulators have agreed to assist us in our investigation.

Now, FDA's unraveling of this mystery comes on the one-year anniversary of our discovery of the contaminant melamine in pet food. As in the melamine case, FDA's identification of a highly unlikely contaminant is a result of rigorous and methodical investigation, combined with the use of sophisticated testing.

Also the Memorandum of Agreement with China, which was signed in December, expedited our ability to get inspectors to Chinas to pursue the investigation there, and collect samples with us with no time loss. And this has been a real improvement.

Before opening the phones to your questions, I would also like to bring you up-to-date on other recent developments.

Additional lots of API have tested positive by both SPL and FDA and these lots have been added to SPL's recall.

There may be additional recall information coming out as a consequence of this. These do not affect the large volume of Heparin that is already off the market in the U.S., but may involve other forms of Heparin.

FDA's Office of Regulatory Affairs continues to identify, hold, and examine all shipments of Heparin imported into the country. And will collect samples of those that are of concern. So we are confident that, at the borders, we have a good system in place.

On adverse events, fortunately, since Baxter's expanded recall on February 28, we have received no reports of deaths related to allergic reactions to the Heparin that occurred after that date.

On our last call, there were many questions about deaths and adverse events and when they occurred and so forth. The information is too complicated to present over the phone. And therefore we are going to be posting that on our website for people to look at so that they will have the numbers and the timing of the reports of deaths and when the deaths occurred and so forth.

As was said last time, we feel that doctors and patients now can be confidant that the product on the market for the large volume uses of Heparin - for example, in dialysis and so forth -- has been tested and is safe. However, we do ask that if any adverse events are observed that are serious by doctors or health care professionals, they be reported to the FDA. And information on how to report is on the FDA Web site.

And now I will turn this back to Julie, and thank you.

Julie Zawisza: Thank you Dr. Woodcock. Before we take your questions, I would like to introduce several people from the FDA from around the table here who are also available to answer questions.

And we have Dr. Murray Lumpkin in China who is our deputy commissioner of our Office of International and Special Programs. So thank you very much for dialing at the late hour, Dr. Lumpkin.

We also have Joe Famulare,, who is the deputy director of the Office of Compliance in our Center for Drugs. And we have Dr. Moheb Nasr, who is the director of the office of New Drug Quality and assessment in our Office Center for Drugs. And we have Domenic Veneziano, who is the director of the Division of Import Operations and Policies in FDA's Office of Regulatory Affairs.

Did I miss anyone? I have everyone. OK. Good.

Operator, let's take the first question.

Coordinator: Okay. I would like to inform participants, if you would like to ask a question, press star one on your touch-tone phone. That’s star one to ask a question. And our first question comes from Peggy Peck. Peggy, please state your affiliation.

Julie Zawisza: Before we get started, as always, I want to remind folks that we will take one question and then one follow-up, Okay?

Peggy Peck: Yes. Thank you very much. This is Peggy Peck and I want to thank you for taking my question.

Dr. Woodcock, you mentioned that this drug - the over-sulfated chondroitin sulfate is not approved in the United States. Is it approved (unintelligible)? What can you tell us about this drug?

Janet Woodcock: Well, it isn't a drug. It is a chemical compound.

Peggy Peck: A chemical compound.

Janet Woodcock: It is derived. It's is a GAG as we talked about before. It is a member of a family of compounds that are like Heparin. Heparin-like compounds.

It is used in the United States and elsewhere as a dietary supplement. It is biologically derived (unintelligible). It is purified from animals. And, it should not be in Heparin. And it obviously should not be in the form it is in. And I don't know of any intravenous use of such product.

Peggy Peck: So on follow-up, is this the chondroitin this is commonly sold for joint ailments. You see it in health food stores and such?

Janet Woodcock: That is sold as a dietary supplement. Yes, it is in there. It also would be in food. I mean, it is normal body constituent. And, um, yeah.

Peggy Peck: (But) this form, the hyper-sulfated form…

Janet Woodcock: No, the (joint)....

Peggy Peck: That is what I'm trying to find out, this form. About this...

Janet Woodcock: Yes, this form - I'm sorry. I didn't understand. Chondroitin sulfate is, you know, a dietary supplement. The hyper-sulfated chondroitin sulfate would be an experimental compound. It would be something that people have taken to drink, let's say, and sulfanated it - add more sulfate groups to it to change its properties in various ways.

And yes, there are scientific papers about this. There are, you know, various laboratories around the world have done experiments on this - on hyper-sulfating all the different compounds (and seeing) what their activities might be.

Peggy Peck: Is it a most critical experiment?

Janet Woodcock: Not too much. No.

Peggy Peck: Not too much, or not at all?

Janet Woodcock: Not to my - to my knowledge, you know, there certainly isn't as extensive clinical on the biological properties of these hyper sulfated GAGs of different kinds, including chondroitin sulfate.

Julie Zawisza: Next question please.

Peggy Peck: Thank you.

Coordinator: Okay. Our next question comes from Ricardo Alonso-Zaldivar. Please state your company name.

Ricardo Alonso-Zaldivar: Hi. I am with the L.A. Times and thanks for taking my question.

On the last call, Dr. Woodcock, you said that once you identified the compound that it would give you at least some theories as to how it got in there.

Could you, you know, could you bring us up-to-date on what goes on now?

I mean is it the kind of compound that would normally be found in the raw materials from which Heparin is derived. And, you know, would sort of have to be eliminated in the purification process?

Janet Woodcock: No and that's - this compound is not, to our knowledge is not naturally occurring. And therefore,(it would be) easily hyper - or over-sulfated chondroitin sulfate would not be part of something that would be purified away during the purification process.

Ricardo Alonso-Zaldivar: Okay go so that's the gist of it. That it is something that would have been deliberately added in then, right.

Janet Woodcock: We cannot rule in or out whether this is accidentally or deliberately introduced into the product, okay. What we know is that it is something that we are 99% sure is not a natural component that got in there as part of the purification process.

Julie Zawisza: We still have not linked this contaminant to the adverse events.

Janet Woodcock That is correct.

Ricardo Alonso-Zaldivar: But whether accidentally or deliberately added, it would have to be something that was added in?

Janet Woodcock: It didn’t come straight from the (pig) if that is what you are asking. So that would be very improbable.

Julie Zawisza: Thank you. Let's take the next question.

Ricardo Alonso-Zaldivar: Thank you.

Coordinator: Our next question comes from Bruce Japsen. Please state your affiliation.

Bruce Japsen: Hi. Thanks for taking the call. Bruce Japsen with the Chicago Tribune.

I think what everyone is going to wonder here is whether indeed this is a counterfeit situation, or a safety situation. I mean we've had other situations where dietary supplements have been passed off as drugs and sent to the United States by counterfeiters.

But how would you describe it to the American people here? What it is that should be a concern. I mean, if indeed this has happened, is this not the first time a foreign substance has been put into, a U.S. pharmaceutical from a U.S. - into the U.S. supply chain?

Janet Woodcock: So you have two questions. One is intent here and then secondly is this the first time a contaminant has been added to a pharmaceutical made outside…

((Crosstalk))

Bruce Japsen: Yeah. And introduced into a U.S. supply chain. I mean, we know that there is certainly, you know, people in their basements or whatever making counterfeit drugs and shipping them to the U.S.

But this is a situation that something was introduced into a drug company's supply chain. Have we ever seen that before?

Janet Woodcock: We are continuing to investigate how this got in, okay. We can't go any further than that, alright. What we are telling you today is that it does not appear to come straight from the (pig). It doesn't appear to be a natural

contaminant that got in there, all right. We do not know how it was introduced or why.

As far as, have their ever been other deliberate adulterations in the drug supply chain? Yes, there have in the past. And that's why we have - we try to have a very strong network of testing and inspections and controls of the drug supply.

Julie Zawisza: Thank you. Let's take the next question.

Coordinator: The next question comes from Heidi Splete. Please state your affiliation.

Heidi Splete: Hi. I am Heidi Splete, Internal Medicine News. Thanks for taking my question.

You said earlier, just reiterating that doctors and patients don't need to be concerned about this. Is there anything further, as far as safety that people ought to know?

Janet Woodcock: Well, I would say, as usual with any medication there are benefits and risks. The medications must be used wisely.

As far as the quality of this medicine, we are doing everything possible to make sure that the quality is tested before it gets out into the U.S. drug supply.

And so, for people who are taking Heparin that has been used in dialysis, or cardiac surgery and so forth, we are sure that these supplies have been tested.

(For all) our uses of Heparin, the testing is going forward on those uses.

So right now, people should not be alarmed. We have not received any more reports, as we said, of fatalities of this type since the recall on February 28.

But we all should always be vigilant, and we always encourage doctors and health professionals to report to the FDA if adverse events are observed.

Heidi Splete: Okay. Thank you.

Julie Zawisza: Next question.

Coordinator: The next question comes from Susan Heavey. Please state your affiliation.

Susan Heavey: Hi. I am with Reuters. Just to go back to where this compound came from. I know Dr. Woodcock has said you don't know (if it didn't come) straight from the pig. Is there a chance it was chemically made and it didn't come from animals at all?

Janet Woodcock: The entire chondroitin sulfate would be chemically synthesized is what you're asking?

Susan Heavey: Right. Instead of animal - instead of derived from an animal. Is that a possibility that you're looking into?

Janet Woodcock: We can't really speculate on that. That would be much more expensive to do that obviously, than simply chemically modify chondroiton sulfate.

Susan Heavey: Thank you.

Julie Zawisza: Next question.

Coordinator: Next question comes from Anna Mathews. Please state your affiliation.

Anna Mathews: I am with the Wall Street Journal.

Julie Zawisza: Anna, could you speak up please?

Anna Mathews: I am with The Wall Street Journal. So it is not yet clear whether this substance is derived - is a chemically-altered version of something derived from animal cartilage, or if was made sort of from scratch.

And do you know if that - if it is from pig cartilage? Because Baxter has said that they believe the substance was from pigs.

Janet Woodcock: We are not able to tell whether it - which animal - what animal it would emanate from at this point in our testing.

Anna Mathews: Are you sure it does emanate from an animal? Or you are not sure of that either?

Janet Woodcock: As I said, synthesis from scratch of this would be very expensive. Is that Dr. - I will ask Dr. Nasr to comment on that.

Moheb Nasr: Yeah, this is Moheb Nasr.

I think we can say the following: that over-sulfated chondroitin sulfate was chemically made by modifying the existing and abundant chondroitin sulfate that comes from a variety of animal sources.

Anna Mathews: From cartilage?

Janet Woodcock: Yes, it is ordinarily purified from animal cartilage.

Moheb Nasr: Yes.

Julie Zawisza: Thank you. Next question please.

Anna Mathews: Thank you.

Coordinator: Next question comes from Brian Hartman. Please state your affiliation.

Brian Hartman: I am with ABC news. I am just wondering if you have any idea, you know, with the (pet food) we all are obviously thinking about the pet food and melamine when we think about this.

Is over-sulfanated chondroitin sulfate, is this something that is cheaper - much cheaper than Heparin to produce? I would assume it is, right.

Janet Woodcock: Well, the base compound chondroitin sulfate is a very abundant and inexpensive compound.

Julie Zawisza: Is that it, Brian?

Brian Hartman: That's all. Thanks.

Julie Zawisza: Next question.

Coordinator: The next question is from Marc Kaufman. Please state your affiliation.

Marc Kaufman: I'm with the Washington Post. And it was said...

Julie Zawisza: Marc?

Marc Kaufman: …it was asked earlier if this at this point with be - could be determined to be counterfeit.

Julie Zawisza: Marc, we are having trouble hearing you.

Marc Kaufman: Okay. Can you hear me now?

Julie Zawisza: We're having some technical issues, but...try again.

Marc Kaufman: Okay.

Julie Zawisza: I don't hear you at all.

Marc Kaufman: Can you hear me better?

Julie Zawisza: Yes. Thank you.

Marc Kaufman: Okay. You had said - someone had asked earlier whether or not if this was to be declared to be a counterfeit. And (unintelligible) that question was specifically answered. So I was wondering if you could tell us whether or not you think that would be an accurate description at this point.

And as a related thing, if it turns out that this is counterfeit, and was either intentionally or unintentionally put in there, what kind of authority does the FDA have to respond in a foreign country?

If this was in the United States, obviously there could be criminal penalties. Could there be such things in foreign countries?

Janet Woodcock: This is Janet Woodcock. I will turn this over to Joe Famulare from our office of compliance in a minute.

But the counterfeit (unintelligible) can be a little confusing, because we don't know how this got in there. There is Heparin in this product, all right. However, it is contaminated or adulterated with this other over-sulfated chondroitin sulfate. So that's the status of it right now.

Joe Famulare: I think that is accurate, what Janet Woodcock said. Right now we are looking at it as an added material, or a contaminant, or an adulterant that should not be there, so I think it is premature to use that other terminology at this point of our investigation.

As far as, you know, as far as our authority in another country, I think as Dr. Woodcock pointed out, we are working with the Chinese authorities to work through this investigation. It is open right now. And we will be able to - particularly with the benefits we have, using the MOA, work through these issues.

We have done them in the past. And as you correctly point out, there's a difference than if we were doing it here in the United States. But we can use various cooperations to further the investigation.

Julie Zawisza: That was Joe Famulare in our Office of Compliance. Dr. Lumpkin did you have any further remarks? Or Dr. Woodcock?

Murray Lumpkin: No, I think Joe handled it fine. Thank you.

Julie Zawisza: You're welcome. Okay, anything further? Okay. Next question please.

Coordinator: The next question comes from Drew Armstrong. Please state your affiliation.

Drew Armstrong: Yeah, I am with Congressional Quarterly. Actually I had a question for (Joe). Again, I am wondering if you could characterize the cooperation by the Chinese government and their regulators there.

Have they been very cooperative, somewhat cooperative? Could you go into a little bit of detail and the attitude there?

(Joe Samulari): I think we should go primarily to Dr. Lumpkin, who is right there on the ground level.

Drew Armstrong: Oh, yeah. My mistake. Thanks.

Julie Zawisza: Dr. Lumpkin.

Murray Lumpkin: Yes, that is no problem. I would characterize it as very cooperative on this. And as Dr. Woodcock said, it is quite a different scenario than we had a year ago with melamine. Some of the specific examples, the Chinese government was extremely quick in doing the Visas when we asked for them to help get our inspectors into China as quickly as possible.

And inspectors from the state's Food and Drug Administration here in Beijing accompanied our inspectors during the time they were here in China.

I have been in China this week. I was supposed to have been here anyway, but because I have been here, I have been in contact with our counterparts here at the State Food and Drug Administration. They have been extremely helpful and interested in our data and in sharing what they have been doing with us.

Julie Zawisza: Thank you, Dr. Lumpkin. Let's go to the next caller.

Coordinator: The next question comes from Elizabeth Weiss. Your line is open. Please state your affiliation.

Julie Zawisza: Beth?

Coordinator: Elizabeth, your line is open. Check your mute button.

Julie Zawisza: How many more people are on the line, Operator?

Coordinator: How many more questions?

Julie Zawisza: Yeah, queued up.

Coordinator: About seven more questions queued up at this time.

Julie Zawisza: We will do our best. I am not sure if we can get through all of them, but we will try. If Elizabeth Weiss comes back, could you put her in?

Coordinator: Sure. And our next question comes from... Okay. Our next one comes from Anna Edney. Please state your affiliation.

Anna Edney: Hi. I am with Congress Daily. Dr. Woodcock. I just wanted to clarify. I think you sort of went over this. But you mentioned that modifying the chondroitin sulfate is expensive.

Is it more expensive than manufacturing the API?

Janet Woodcock: No, what - I don't - I you are asking if you could make chondroitin sulfate from scratch? In other words, not get it from an animal, but synthesize it from scratch. And I said that would be expensive. Modifying it or sulfanating it would not be that - I'll ask - I'll refer that to Dr. Nasr.

Moheb Nasr: Yeah this is Moheb Nasr.

Chondroitin sulfate by itself is certainly not expensive. It is abundant and cheap. We are defining it by making it over-sulfated chondroitin sulfate would not be that expensive either.

Julie Zawisza: Next question.

Coordinator: Next question comes from (Kate Trainor). Please state your affiliation

(Kate Trainor): Hi, I am with the American Journal of Health System Pharmacy.

This has been partly addressed. Dr. Woodcock has said that the large volume usage of Heparin, all the products have been tested and found safe.

So you are working on other products? Are you referring to Heplock Flush Solution? And how did you go about getting confirmation from the manufacturer that they have been tested?

Janet Woodcock: What we are doing is, you know, in our investigation is looking at the API sources of Heparin, okay, because those go into all these different distributed products. You know, it might be a small amount of Heparin in this or that or the other thing.

To our knowledge, we haven't had any adverse events reported unusually with this - with these types of devices and so forth that have small volumes of Heparin.

However, our strategy is to go to the source where the API - the source of Heparin – and test that. Because that would then be distributed out to, you know, various other manufacturers to use. So that's the strategy we are pursuing and we are pursuing that very aggressively.

(Kate Trainor): Okay, how much more testing do you think remains to be done of Heparin out there right now in the U.S.?

Joe Famulare: This is Joe Famulare. We have a regular program of testing - both within FDA and with companies that have already agreed to do testing as part of their screening before using the API in manufacturing their product. So that will go on as we continue on to develop more robust methods that Dr. Woodcock mentioned in her preliminary remarks.

And so that companies will be testing. And we will correlate that with (unintelligible) folks in ORA. As, Dr. Woodcock mentioned, that will be looking to sample at the border where we don't have any evidence of testing and clearing any particular material coming in.

Julie Zawisza: Thank you. Next question.

Coordinator: Next question, Justin Blum. Please state your affiliation.

Justin Blum: Hi. This is Justin Blum with Bloomberg News. Thanks for taking the call.

There is one thing you said, Dr. Woodcock, that seems like it could be a contradiction. Which is that, the substance, chondroitin sulfate, was intentionally modified. Yet at the same time you are saying you don't know if it was intentionally introduced.

If it wasn't intentionally introduced, why would it have been intentionally modified and added?

Janet Woodcock: As I said, people are experimenting with these different GAGs to make other - make products and chemicals and so forth. It is possible this could have accidentally contaminated a (unintelligible). But we do believe it was chemically modified.

Justin Blum: Okay. And then a follow-up question, which is I know you've touched on the cost issue before. But do you have a sense of how much cheaper it might be to substitute this contaminant for the equivalent amount of the actual raw Heparin?

Janet Woodcock: No. We don't have any quantification on that.

Justin Blum: But it would be cheaper?

Moheb Nasr: Yes.

Julie Zawisza: That was Dr.?

Janet Woodcock: Yes.

Julie Zawisza: Nassar.

Janet Woodcock: It obviously depends on market conditions for all the different ingredients. So we don't - w can't give you any numbers.

Justin Blum: Okay.

Janet Woodcock: That is somewhat beyond our scope anyway.

Julie Zawisza: Exactly.

Janet Woodcock: (Unintelligible) beyond the scientific investigation.

Julie Zawisza: Next question please.

Coordinator: Next question, Walt Bogdanich. Please state your affiliation.

Walt Bogdanich: New York Times. Since it is cheaper to make than regular Heparin, is it your operating hypotheses that it was most likely counterfeit?

I mean, you certainly have some inclination at this point as to what - whether it was intentionally added or not, based on the fact that it is less expensive.

Janet Woodcock: Well, as I said in my opening remarks, we don't have any evidence, one way or another whether it was accidentally or intentionally introduced. There is a very broad investigation and very active investigation going on and that's all we can say about that.

Walt Boganich: Okay.

Julie Zawisza: Thanks, Walt. And we will take one final question this morning.

Coordinator: Okay. Last question, Rob Foreman. Please state your affiliation.

Rob Foreman: Yes, I am with the CBS Early Show. And I believe the last two questioners, stole my thunder. So if anyone else has one, please move on. I would be very interested in whether there is any profit in, you know, what they would say, the bar watering the stuff down.

Julie Zawisza: We don't have that information at this time.

Coordinator: Okay. We will take one more then from Daniel Poppy. Your line is open.

Daniel Poppy: Hi. Thanks. Can you say a little bit more about how the MOA has helped (expediate) the investigation? You sort of said a little bit about it, but can you provide more detail?

Julie Zawisza: Dr. Lumpkin, are you still with us?

Murray Lumpkin: I am. I think the - it (unintelligible) done in several ways. The example that I mentioned first about the ability to get the Visas to get our inspectors in was one that helped us get the samples as quickly as possible.

I think we have also had ongoing discussions with our Chinese colleagues, as the investigation has progressed.

This is the kind of relationship that did not exist during the time of melamine about a year ago. We continue to work with our Chinese colleagues, and they have stated many times that they will continue to work with us on this, until we find out what happened here and who was responsible for what happened.

Daniel Poppy: And one follow-up. Is there talk of adding Heparin to the designated API list, that is done annually?

Murray Lumpkin: You know, I think that is a very interesting question. Actually, the discussions that we have had, Heparin has become kind of an example of how the MOA actually works in a real live situation, as opposed to having to look at the designated products.

So we decided adding it or not adding this to the list is really rather immaterial. It is indeed the living example of the MOA working.

Daniel Poppy: Thanks.

Julie Zawisza: Thank you. With that, we will conclude this briefing this morning. And I would like to thank all of you for joining us. And thank you to our speakers, Dr. Woodcock, Dr. Nasr, Joe Famulare, Dr. Lumpkin, Domenic Veneziano.

If you have follow-up questions, please call Heidi Rebello in the press office at 301-827-6243. If you would like to listen to this briefing on the instant replay, here are the numbers. Toll-free: 800-843-4802. International callers, 203-369-3835.

And as Dr. Woodcock mentioned, please check our web site today. I think today, right.

((Crosstalk))

Julie Zawisza: We hope to have today updated information on the adverse events - timing of the events themselves and when they were reported to the FDA.

There is a lot of work going on here behind the scenes, as you have heard. So we promise to keep you updated. As we can make information public, we promise to do that. And with thank you again for participating. And you have a pleasant day.

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