UNITED STATES OF AMERICA

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FOOD AND DRUG ADMINISTRATION

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CENTER FOR DRUG EVALUATION AND RESEARCH

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PUBLIC MEETING
ON THE USE OF OZONE-DEPLETING SUBSTANCES
REMOVAL OF ESSENTIAL-USE DESIGNATION
(EPINEPHRINE)

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WEDNESDAY,

DECEMBER 5, 2007

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The public meeting convened at 9:00 a.m. in Advisory Committee Conference Room 10666, 5630 Fishers Lane, Rockville, Maryland, CHARLES GANLEY, M.D., Director, Office of Nonprescription Drug Products, presiding.

PARTICIPANTS:

CHARLES GANLEY, M.D., Director, Office of Nonprescription Drug Products, CDER, FDA
KIRSTEN CAPPEL, Environmental Protection Specialist, Office of Atmospheric Programs, Stratospheric Protection Division, EPA
BADRUL CHOWDHURY, Director, Division of Pulmonary & Allergy Drug Products, CDER, FDA
CLARK NARDINELLI, Supervisory Industry Economist, Office of Policy & Legislation, FDA

PARTICIPANTS (Continued):

MARTHA NGUYEN, Regulatory Counsel, Office of Regulatory Policy, CDER, FDA
ROSE CUNNINGHAM, Office of Executive Programs, Executive Operations Staff, CDER, FDA

PUBLIC SPEAKERS:

ROBERT M. SUSSMAN, Latham & Watkins, LLP, Counsel for Amphastar Pharmaceuticals, Inc., and Armstrong Pharmaceuticals, Inc.
WEITIAN TAN, Ph.D., Senior Director, Scientific Affairs, Armstrong Pharmaceuticals, Inc.
NANCY SANDER, President and Founder, Allergy & Asthma Network, Mothers of Asthmatics
SANDRA J. FUSCO-WALKER, Director, Government Affairs, Allergy & Asthma Network, Mothers of Asthmatics

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(9:38 a.m.)

WELCOMING REMARKS

MODERATOR GANLEY: Good morning, everyone. Why don't we get the meeting started? This is a public meeting on the use of ozone-depleting substances. And it involves a proposed rule regarding the removal of essential-use designation for epinephrine.

First I want to just have introductions here and also thank everyone for coming out on such a terrible morning. The weather isn't really that bad. It's just the traffic is that bad. And that's typical for this area.

It took me an hour and a half to get from White Oak to here. White Oak is where the current new FDA facility is, and that's probably about a nine-mile drive. It was just horrific driving here.

I am Charlie Ganley. I am the Director of the Office of Nonprescription

Products. And I will allow the other folks to introduce themselves.

DR. CHOWDHURY: I'm Badrul Chowdhury. I'm the Director of the Division of Pulmonary and Allergy Drugs at the FDA.

MR. NARDINELLI: Clark Nardinelli, director of the economic staff in the Office of the Commissioner.

MS. NGUYEN: Hi. Martha Nguyen, regulatory counsel in CDER's Office of Regulatory Policy.

MS. CAPPEL: Kirsten Cappel with the Stratospheric Protection Division of the Environmental Protection Agency.

MODERATOR GANLEY: Okay. The purpose of this public meeting is to solicit comments on a proposed rule that would amend the FDA regulation on the use of ozone-depleting substances in self-pressurized containers.

The rule proposed to remove the essential-use designation for oral pressurized

metered dose inhalers containing epinephrine. The rule published in the Federal Register on September 20th in 2007. Information from this meeting, which is required under our agency regulations, will be considered in finalizing this rulemaking.

For the agenda today, we have two speakers. The first speaker will be Mr. Robert Sussman, who is counsel for Amphastar Pharmaceuticals, Incorporated and Armstrong Pharmaceuticals. And I believe he's associated with Latham Watkins, LLP.

Following that presentation, the panel will have an opportunity to ask questions. After that, Nancy Sander or Sandra Fusco-Walker will be speaking. Nancy Sander will be speaking. She's the Director of Government Affairs for Allergy and Asthma Network, Mothers of Asthmatics. And after their talk, we will also have an opportunity to ask questions.

Following that, there will be an

open comment period for any of those here who have an interest in providing comments who didn't like what we asked or want to add something to the discussion. Feel free to do so. And after that, there will be just some closing remarks, and the meeting will end.

It's obvious from the agenda it's not going to be an all-day affair here. And it should last maybe an hour or so. So why don't we get started? Mr. Sussman?

MR. SUSSMAN: Okay. I am Bob Sussman. And we appreciate the opportunity to be here. I am with the law firm of Latham and Watkins. And today we are representing Amphastar Pharmaceuticals and one of its wholly owned subsidiaries, Armstrong Pharmaceuticals.

With me today is my colleague from Latham and Watkins John Manthei and Weitian Tan, Dr. Weitian Tan, who is the Senior Director of Scientific Affairs for Armstrong.

Armstrong is a manufacturer and

distributor of epinephrine metered dose inhalers distributed over the counter, which at the present time use CFCs as the propellant. Although we disagree with some of FDA's conclusions, we do not oppose FDA's determination that the essential-use status for epinephrine, MDIs, should be eliminated.

We are here to address one narrow but fairly important issue, which is the effective date for phasing out CFC epinephrine. FDA has proposed an effective date of December 31st, 2010.

We are asking that that effective date be postponed by a year to December 31st, 2011. This will provide us with sufficient time for development and approval of an OTC, non-ODS, HFA-based epinephrine MDI before the current OTC product is phased out.

This additional year will permit the transition of patients from the existing CFC formulation to the non-CFC formulation and, as a result, will eliminate a one-year

gap in which there is no OTC epinephrine formulation on the markup.

We recognize that epinephrine MDI is not the drug of choice for physicians treating asthma patients. Nonetheless, this product serves a vital role in serving this patient population and is relied upon by as many as 1.7 to 2.3 million people with asthma.

A significant portion of these people according to FDA face barriers to health care. FDA has estimated that between 9 and 14 percent of OTC epinephrine users face barriers to health care. This is a population of between 150,000 and 320,000 people. So it is not a trivial population.

When FDA published its proposed rule, it did specifically request comment on whether the effective date should be December 31, 2011 or December 31, 2012, as opposed to December 31, 2010. And in requesting comment on that issue, FDA did identify a number of challenges that would have to be met in

implementing an OTC ODS epinephrine phase-out.

First, FDA indicated that new avenues of communication would need to be opened to reach all OTC epinephrine users since many purchasers do not interact with a health care provider to purchase this OTC medication.

FDA also indicated that many OTC epinephrine users may need to be provided information to help them select a position. And then FDA indicated that some users who face economic barriers to health care may need additional time to avail themselves of free or low-cost health care and prescription drug programs.

So I think there is a recognition by FDA that if the outcome of this rulemaking is simply to withdraw the current OTC product from the marketplace without any replacement, there is going to be disruption. And there is certainly going to be a very substantial patient communication challenge.

I think FDA's premise in the proposed rule was that there would not be a non-ODS epinephrine product on the market. However, we believe based on our current development time line that the availability of an OTC non-ODS product is on the horizon.

We met with FDA on March 27, 2007 to discuss our proposed non-ODS epinephrine MDI and our proposed clinical development plan. And based on feedback from FDA during this meeting and further internal analysis, we anticipate being able to successfully develop and receive approval for our non-ODS epinephrine product by the beginning of 2011, which would mean that it would be in the marketplace by the end of 2011, before the phase-out of the ODS product.

We think in light of the potential availability of a non-ODS product by 2011, it makes sense to delay the effective date by one year in order to eliminate the difficult task of immediately transitioning patients off of

the OTC product, which could be doubly difficult if, in fact, an OTC product returns to the marketplace a year or two later.

This transition will require patients to see a physician and obtain new medications for their asthma. As I mentioned before, a large number of patients who use OTC epinephrine lack access to health care. And FDA itself has estimated I think in the preamble to the proposed rule that removing the OTC product from the market would result in 40,000 to 120,000 more hospitalizations for asthma annually and up to 440,000 more asthma-related emergency room visits each year.

If we have a seamless transition from one OTC product to another, I think we can avoid some of this disruption and burden on the patient community.

In short, removing OTC epinephrine from the market and attempting to switch patients to prescription medications will have

significant costs and health consequences. The alternative is to extend the effective date by one year so a non-ODS OTC product is available before the phase-out.

Therefore, we would like to ask FDA to revise its final rule to substitute a phase-out date of December 31st, 2011 for the current proposed phase-out date of December 31st, 2010.

Thank you. And I'm happy to answer questions.

MODERATOR GANLEY: Okay. I'll just look to the panel. Are there any questions that panelists have?

DISCUSSION

DR. CHOWDHURY: I have just one quick question. I thought you mentioned you were the only manufacturer for the epinephrine MDI for the U.S. market. Can you please confirm and state that you are the only manufacturer of epinephrine MDI for the U.S. market and requiring CFC for this product?

MR. SUSSMAN: We are. Let me clarify that Wyeth Pharmaceuticals has marketed and still markets Primatine Mist, which is a brand OTC epinephrine product. We are, in fact, the contract manufacturer for Wyeth. So at this point in time, we are the sole manufacturer in the U.S. And I think that situation is going to continue.

MODERATOR GANLEY: Yes. I just had a few questions. What is the expiration date on the current product manufactured by Armstrong or Amphastar? The rulemaking talked about a two-year expiration date. And that's how they project it or that's how we project it, publications on a rule, and they arrived at the December 2010. Is it a two-year date? Do you know?

MR. SUSSMAN: Weitian, is it two years? Yes.

MODERATOR GANLEY: The other thing is I had an opportunity to look at some of the comments submitted to the public record. And

it was interesting to see some of the comments of, you know, older individuals, who use this product in lieu of HFA albuterol, for example.

Does Amphastar have information on the populations who actually are using these products in terms of their age and socioeconomic status? Because I got a sense that these are individuals who could afford other things but they felt that this medication was better for them.

MR. SUSSMAN: Well, yes. I personally cannot speak to that issue.

MODERATOR GANLEY: If you could check back with them?

MR. SUSSMAN: Yes, yes.

MODERATOR GANLEY: And they could submit something to the record.

MR. SUSSMAN: Yes. We will do that.

MODERATOR GANLEY: The other thing is that in your background or the material you provided, the projection was to submit an NDA

by October 2009 --

MR. SUSSMAN: Right.

MODERATOR GANLEY: -- assuming that it would be approved sometime within the next ten months, towards the end of 2010. So what is that lag period? There is a lag period there of five months or so. And so if the date for this rule was to maintain at December 2010, you potentially could have had an approved product available.

MR. SUSSMAN: You know, actually, I think, looking at our comments, what we said is that we would file the IND no later than the end of March 2009 and then we would spend the duration of 2009 manufacturing and testing stability batches, validating the manufacturing process, and initiating clinical trials.

So we would anticipate submitting the NDA by October of 2009. And we are kind of assuming that we would get approval sometime in mid to late 2010. And I ought to

say that is really a very, very ambitious time frame. And everything would have to go exactly right if there were some hitches in the FDA approval process.

If there were some hitches in our stability work and our efforts to develop the new delivery system and optimize the manufacturing process, we could be thrown off track.

So I think the bottom line is it is barely doable by the end of 2010, but if we're delayed and we're into 2011, we face this 2010 cliff event.

MODERATOR GANLEY: So I guess the company would not manufacture product until it received a letter of approval if the NDA was going to be approved. So it would not be packaging and manufacturing?

MR. SUSSMAN: I would think so, yes.

MODERATOR GANLEY: You need to go to a microphone, I believe, to do that and

also state your name and affiliation.

DR. TAN: Okay. My name is Weitian Tan. I am Senior Director of Scientific Affairs at Armstrong, the manufacturer of epinephrine today. Okay. So I mentioned that I want to make additional points.

Even we have the product approved by FDA by the end of 2010, we still are facing a transition to consumers from CFC to HFA. Thinking about the transitional issues, even the product is approved by the FDA by the end 2010, if we have another year, then I think the entire market can transition, just like the albuterol HFA when transition from CFC to HFA will take a few years. So the one-year transition is real aggressive.

Thank you.

MODERATOR GANLEY: Are there any other questions from the panel? Sure.

MS. CAPPEL: In just thinking through the time frame, then, if you were to get approval and then you start producing the

product, you're transitioning patients within several months.

I mean, I guess sort of I'm thinking from the time frame. I mean, if the effective date is 2011 and you just start producing it in 2011, then you're sort of -- patients are required to transition, then, within months almost. Okay. I just --

MR. SUSSMAN: No. That's right.

MS. CAPPEL: Okay. Okay. Thanks for that clarification.

MR. NARDINELLI: Well, as the economist, I have to ask this question. Do you have any idea of how the price might differ for the alternative product from current product?

MR. SUSSMAN: I don't have an answer to that. I do know that over in the world of albuterol, the HFA product has been more expensive than the CFC product. But that is a different market. And here we would be in all likelihood, the sole supplier.

And I don't know how that would impact pricing of the product. Weitian, do you have any thoughts on that? I think that's down the road.

MR. NARDINELLI: Sure. I thought I'd ask.

MR. SUSSMAN: Yes, yes. Okay?

MODERATOR GANLEY: I just have one other question. The technical barriers that are challenges for the company now are primarily manufacturing and developing a product. Is that correct?

MR. SUSSMAN: Right, right.

MODERATOR GANLEY: Okay. Thank you.

I will now invite the next speaker up: Nancy Sander, who is the President of Allergy and Asthma Network, Mothers of Asthmatics.

MS. SANDER: Thank you very much for the opportunity to be here this morning and talk to you about two sets of surveys that

we did regarding the essential-use status of the OTC epinephrine at a time when the nation is midway through a mandatory transition from metered dose inhalers containing CFC to non-ozone-depleting alternatives.

And I want to say that the transition for most patients is going very well. Those patients who have received educational information and who have met with their physicians tend to be doing better than those who have not had that experience.

And so as an organization, we continue to help families through that educational process. We have a great deal of experience now in dealing with their concerns and their problems when they do call us. We actually help them through that transition process. And what I distributed to you today is our "Smart Moves to an HFA Inhaler Program" that was funded through a contract with Sepracor.

When you posted in the Federal

Register this meeting, we as an organization contacted a public research firm here in Washington, D.C. and drafted a survey that would be used with patients. We also drafted another one that would be used with medical professionals.

And after that time, we did secure funding for the patient surveys from TEVA. And so what I am going to do right now is go over the surveys that we conducted first with medical professionals and then with the patients. And I believe our findings will demonstrate that CFC-propelled OTC epinephrine does not present a public health benefit worthy of continued essential-use exemption.

Just to give a little bit of information for those who don't know who we are, as a nonprofit organization founded in 1985, we have had great successes in helping patients with a variety of different issues from being able to carry their own inhalers, students being able to carry their own

inhalers while at school, also going through the transition, dealing with indoor air quality issues, knowing what inhalers are on the market while the transition is taking place, without illegal mass manufacturing of nebulizer medications. And so, you know, our three core areas of expertise are education, advocacy, and outreach.

So the first set of surveys that I'm going to talk to you about are surveys that were conducted at annual conferences of the American Academy of Pediatrics; the American College of Allergy, Asthma, and Immunology; and also, most recently, last week or a couple of days ago, I guess it is, at the American Association of Respiratory Care. All of these surveys were conducted after we saw the Federal Register announcement.

These surveys I should also mention informed. There was a short paragraph at the top of this one-page survey that informed the person taking the survey that FDA was looking

at the essential-use issue and wanted their comments. Eight hundred and nine medical professionals completed one-page surveys consisting of 17 questions.

I will flip to my cheat sheet here. When asked, "Do you recommend the use of OTC epinephrine to your asthma patients?" you can see overwhelmingly they don't.

Respondents were also asked to check statements that they agreed with. And there were 13 statements that they could agree or disagree with, but the following statements that you are going to see on the next few slides will not add up to 100 percent because they could select more than one item that they agreed with. They pretty much agreed that OTC epinephrine inhalers are antiquated therapy.

Also it's an urban legend, I guess I should say, that stated that OTC epinephrine inhalers keep patients out of the emergency room and out of the hospital, but our survey showed that only a small number of medical

professionals actually feel that way or see that as part of their experience.

They overwhelmingly agreed that asthma is not a do-it-yourself medical condition or one that can be easily self-diagnosed and treated. They agreed that asthma is a potentially life-threatening condition and should be treated by a medical doctor and not at the checkout counter.

Medical professionals who say OTC epinephrine inhalers work as well as prescription inhalers were also in the minority. And I should mention that national guidelines also do not recommend or do not make that statement either.

The availability of OTC epinephrine inhaler implies an effective alternative to prescription-only medications. More than half of the medical professionals felt that it was sending the wrong message.

Medical professionals do not consider OTC epinephrine inhalers essential,

primarily because they don't recommend them. It's antiquated therapy. Asthma is not an OTC condition. And they had concerns about implications.

Now, of course, when we were doing this survey, we could only remain neutral, but the overwhelming comments that people would give is if essential-use exemption is given for OTC epinephrine, it would present a quandary for how they were going to deal with patients who had already made the transition who were going to be wondering why they had to make the transition, why their drugs had to make the transition at their expense, by the way, and a special exemption was given to an OTC product that was, by all definitions, inferior.

One person actually said, "You know, I'm not advocating for asthma to be treated with OTC medications, but if you're going to put epinephrine OTC out there for patients, you should at least give them the

good stuff, instead of the garbage. So they had very strong feelings is my point.

Now I'm getting to the patient and parent survey. I want to just briefly switch over to my methodology piece over here. If you just bear with me for a second?

In our patient surveys, we had 822 surveys that were completed. These were telephone surveys. Six hundred were patients that were adults, and then 222 were parents. All the surveys were completed between November 9th and 21st using a non-probability list sample.

All numbers are given in percentages. Some columns will not add up to 100 percent because of rounding. And I think I have given you everything from our methodology there.

We based this on certain assumptions that were not only in the Federal Register but also in common belief, another urban legend, that OTC medications or

epinephrine users are poor African American and Hispanic populations who live in inner city or rural areas, don't have medical insurance, and their access to medical care or medications is limited and, therefore, this population would no longer be served if the essential-use exemption were removed. We sought to find out how many answers we could get to whether it is an urban legend or in reality.

This is our sample sizes. These are the demographic regions that demonstrate that we got a pretty good representation from all over the country. The vast majority of our respondents were female. And this is in keeping with just about every survey that we do with patients.

So they're female. And they're largely between the ages of 21 and 64. And they're primarily white followed by blacks or African Americans. So this does not add up to 100 percent because people had an opportunity

to select more than one answer there as well.

The number of OTC epinephrine inhalers that patients said they used in the last 12 months were between 1 and 3. The majority of them were between one and three. But I would like for you also to pay attention to the minority of them, who said there were nine or more.

They used these, despite the fact that 95 percent are paying for other prescription medications. I could list all of the others. However, they are all the ones that you already know.

But, just to give you a feeling for bronchodilator use or albuterol use, I should say, 54 percent of patients -- these are adult patients -- and 64 percent of parents indicated that they have prescriptions for albuterol. But, again, 95 percent do have prescriptions for other asthma medications.

They also said that they see doctors and that they have been diagnosed by a

medical professional. This is the frequency and the time period that they have seen, but the great majority of them have had a visit within the last 12 months with their primary care physician. It's not on this slide, but 39 percent of adults and 40 percent of parents say they have never consulted with an allergist.

Thirty-eight percent and 29 percent say that they have used more than the recommended dose of OTC epinephrine. And I want you to think about what that means for a moment. This is the same for adults and for children four years of age and older.

You start with one inhalation. You wait one minute. If not relieved, use one more. Do not use again for three hours. Children under four years of age ask a doctor. See a doctor if you're not better in 20 minutes. You get worse or you need 12 inhalations in any day or use more than 9 inhalations a day for more than 3 days a week.

You know, if this was albuterol, certainly this would be cause for me to be seen right away and certainly, according to the guidelines, would put me in a very serious level of care.

So, you know, when we are looking, we're still looking at all of this data, but when we look at it together, we see that there are indicators that some of these patients may not have an appreciation for the seriousness of their condition.

For example, when they report having to use more than the recommended dose of the OTC epinephrine in response to symptoms, they also are reporting that they are going to the emergency room and a significant number are being hospitalized.

So this is not something where we see that this drug is actually keeping people out of the emergency room or out of the hospital. The survey actually suggests that these patients are probably tolerating more

symptoms and compromised lifestyle than necessary.

So we asked, why are you choosing to use an OTC epinephrine if you have access to these other medications and you do have access to care? And so there are issues. The things that they said are, you know, the doctor recommended it.

The cost issues, we lump those three items together there. I can correlate them. Well, I will do that in a moment and then I only use it when I am having a bad asthma attack.

And then the last one is concerning insurance issues. And it's a multitude of issues from no insurance to no prescription coverage, they lost their inhaler, and the insurance won't pay for a new one. It's those kinds of issues.

On page 53720 table 1 from the Federal Register, there's a listing of the most frequent reasons cited by sole OTC

epinephrine metered-dose inhaler users. When we compared it to the statistics that we have in our findings, easier and quicker to obtain were only 10 percent of patients and 10 percent of parents versus the 55 percent in the table.

More reasonably priced, 5 percent gave that as a reason, in both parents and patients, as opposed to the 41 percent in the table. I don't have health insurance. Instead of the 25 percent in the table, it was 5 percent and 3 percent, patients and parents, respectively. I don't want to go to a doctor was listed in the table as 25 percent, but in our findings, it was 4 percent and 1 percent.

So we're finding that some of these urban legends are around because perhaps people haven't looked hard enough. And, indeed, when we were looking for these answers before doing this survey ourselves, we could not find a lot of really reliable information either.

So we asked another question. If you could trade your child's over-the-counter inhaler for a free prescription inhaler to treat asthma symptoms of coughing, wheezing, and shortness of breath, would you be interested? And you see that the yeses outweigh the nos. And the six percent didn't know or refused.

I think that one was of the parents, and this one is of the patients. Yes. So same question asked of patients. They were a little more inclined to accept the offer.

Our conclusions. Overwhelmingly, physicians and medical professionals from the American Academy of Pediatrics; the American College of Allergy, Asthma, and Immunology; and the American Association of Respiratory Care do not recommend OTC epinephrine. The vast majority of users of OTC epinephrine are insured and have access to prescription medications. The vast majority have access to

physicians. And overwhelmingly, patients and parents don't think removal of OTC epinephrine will seriously affect them.

When we have our complete set of slides available, we will send those to you, but in the short period of time, we were unable to get it as complete as we would like to.

What we would like to say is that of the comments that were made earlier today regarding price, the question about price, to Mr. Sussman is important for, you know, communicating the transition. It will be important to people as they are making the transition.

It was a question from the beginning of the CFC to HFA transition and has been throughout. And we deal with families who are struggling with price all the time. So you will need to expect that.

You will need to really spend a lot of time in patient education. You will need

to have a real strategic plan to transition your patients because we are finding that those who transitioned without a plan are the ones who are struggling the most today. And in many cases, they are making decisions that are in their own best interest. So we would encourage Armstrong to work very carefully, very cautiously as you make that transition, and move forward.

So thank you. If there are any questions, I will be happy to try and answer them.

MODERATOR GANLEY: Do panelists have questions?

DISCUSSION

DR. CHOWDHURY: I will ask some questions and get some clarifications. One point is you are commenting very globally on the medical necessity of epinephrine as an OTC product. I just wanted to get a clarification.

Are you specifically talking about

the CFC epinephrine or the comment that you were raising actually will also translate to even an alternate product, which will be potentially HFA epinephrine OTC, in the marketplace?

MS. SANDER: You know, we don't know what the new product is going to look like. And we don't know what the new delivery system will do and if there will be advantages or disadvantages. And so as patient advocates, we have to look at -- you know, we have to look at what is best for patients based on what we know of today. And if it was simply another form of, you know, this product with an HFA on the market today, I don't know that any of this information would change.

I would expect that there are going to be a number of people who are not going to be able to use the new propellant or feel like they can't make that transition to your products, just like there are many who feel that they can't make that transition right

now.

So I would have to say that given equal product, it would apply.

DR. CHOWDHURY: Thank you.

Now one or two specific questions. You mentioned funding sources and as it applies to both the studies: the professional surveys and all the patient and parent surveys. Can you confirm that?

MS. SANDER: Yes. Thank you very much. I'm sorry. I meant to clarify that earlier.

We began the survey process before we had any funding for anything. And very late, perhaps two weeks ago, I think it was, we were able to secure funding from TEVA that would help support the patient survey. And I believe it may have contributed to the ACAA, just one of the surveys, the physician surveys.

DR. CHOWDHURY: Thank you.

Another question that I will ask

now is, for the professional surveys, you received a series of questions. Can you tell us who actually formulated the questions and how you went about to ask the questions and was there any way the epinephrine manufacturer was involved in that or not?

MS. SANDER: No. No manufacturers of any medications were involved in the construction of any questions on any surveys. And that is our policy forever.

MR. NARDINELLI: Let me just ask a broader question along the same lines. You mentioned fuller slides on survey results. Will you be submitting, though, the full statistical package, you know, showing the sampling frame, all of the associated statistics for the surveys?

MS. SANDER: Yes, we will be. It just was not a whole lot of time to get that done before coming here. You know, it's like a killer.

MS. NGUYEN: I have one

clarification. Table 1 that you cited from FDA's proposed rule, I just wanted to clarify that these were not frequent reasons identified by FDA. These were reasons identified by Wyeth that they used for their internet survey in 2005 of Primatine users.

MS. SANDER: Thank you for that clarification.

MS. NGUYEN: And, to follow up, I assume that we will receive this information, but I was curious to see how you were able to identify asthma patients and parents of asthmatics in your patient survey.

MS. SANDER: Well, I can read what was given to me. And I hope I can find it fast enough. Okay. These are notes at the bottom of one of these pages. So I am going to read them verbatim. This was being directed to me personally. So it's not very -- anyway, I'll just read it.

"The listed sample was purchased from a variety of different sources, including

brokers like Survey Sampling International, Marketing Systems Group, and All Media. One of the lists used for this study was compiled using product registration and marketing efforts from pharmaceutical, medical, and other companies.

"Individuals on the list had signed up for coupons, newsletters, samples, and trial offers related to asthma. These individuals have specifically asked for more information about asthma or asthma products. In addition, these consumers stated that they or someone in their household is actively suffering from asthma."

"All of those lists were then randomized. And then certain questions were asked to make certain that we were talking to OTC epinephrine users."

MS. NGUYEN: Thank you.

Was the survey conducted entirely in English or did you have translators in case some respondents had language barriers?

MS. SANDER: Only in English. We're a poor nonprofit organization with a short time frame. But we did ask them to purposely look for representation from across the board. And we did specifically look for African American and Hispanic populations to be included in our survey.

And we do have an Hispanic outreach division of our organization. So, you know, that's part of what we do all the time.

Thank you.

MODERATOR GANLEY: I just have a few questions also. I was actually a little surprised by the survey results with regard to both situations. I'll give you some examples.

My perception would have been since you're at these various conferences and generally people would follow guidelines, it seems that there are health providers out there that think these products worthwhile.

I mean, I understand the majority may not, but, you know, in some of the cases,

the percentages range from 60 to 80 percent. So there's still a fair percentage of health providers that think there is some value to this product.

You can look at things different ways and --

MS. SANDER: Right, absolutely. And that's one of the things that you will probably see more of in the next set of information that we bring to you.

There were certain questions where they were very perplexed. They were operating under the belief, the urban legends belief, that there may be some patients out there who have no other choice. And for those patients, they wanted to be very compassionate.

But what we found from the patients themselves is that they're seeing doctors. It's not about access to medications or access to care. It's not about those things. And if you're really, really poor, you have access to free prescription medications and free medical

care.

And so, you know, what we are beginning to see is that we have a bigger job about educating uninsured or people who are poor or, you know, we have a bigger job to do about educating people with what their options are.

The other thing that we found surprising about physicians is that they were not certain what the guidelines said about epinephrine. And so we felt like they may not be paying attention.

MODERATOR GANLEY: Yes. I think the other thing, if I understood the questions and answers, is the question regarding whether asthma is a life-threatening condition. I think the numbers were around the 80 percent range if you look in the 3 different meetings that you were at. And so that it suggests that 20 percent don't think it's a life-threatening condition, which to me is a little surprising in itself.

MS. SANDER: And that should be treated by a medical doctor, not at the checkout counter of a local store. So a fault with that question would be it's conditional.

MODERATOR GANLEY: Will you be providing the questionnaires and all that information aside from the slides?

MS. SANDER: Yes.

MODERATOR GANLEY: I guess the other thing is, you know, even with the individuals who used these products, when you offered them a free product, 27 percent did not take that offer. So did anyone follow up and ask them why they would turn down something for free that would, you know, also treat a condition?

MS. SANDER: I'll tell you, if we had the funding, we could ask more why kinds of questions. But what early indicators are as we're studying this -- and we're still studying it -- is that mixed in this group are people who are not happy about having made the

HFA transition. And maybe that may be reflected in there.

We don't really know the answer to that question, but there are people are struggling with HFA albuterol. And we work with them on a daily basis to help them find the one that will work for them.

MODERATOR GANLEY: Yes. I think if you read the comments, some of the comments, I think that is evident in some of the comments where they really are not happy with the HFA albuterol --

MS. SANDER: Right.

MODERATOR GANLEY: -- and are more comfortable with the epinephrine for some reason.

MS. SANDER: Right.

MODERATOR GANLEY: Okay. I don't have any more questions. Does anyone have any?

(No response.)

MODERATOR GANLEY: Okay. Thank

you.

MS. SANDER: Thank you.

MODERATOR GANLEY: Okay. The next part of the meeting is the open comment and discussion period. If there is anyone in the audience who would like to make any comments, this is your opportunity to do so. So are there any takers here?

OPEN COMMENT & DISCUSSION PERIOD

MS. FUSCO-WALKER: Sandra Fusco-Walker, Allergy and Asthma Network, Mothers of Asthmatics.

I am curious if OTC epinephrine is revised and they come out with one that is ODS, is that an OTC product automatically or is it a prescription product? It's a new drug.

MODERATOR GANLEY: Yes. I don't really think we would say anything at this time regarding that. That would obviously be a review issue once an application comes in.

MS. FUSCO-WALKER: So it's not

automatically over the counter is what I am trying to --

MODERATOR GANLEY: Well, there would have to be some reason why we would think it -- you know, the default, really, in the regulatory world here is something, is OTC, unless there is some reason it should be Rx. Okay?

And so we have a current product that is OTC right now. And so we would have to be able to explain if we did not feel it should be OTC anymore why it should be Rx.

Okay? But the default of our regulatory process is that things are OTC unless we think it needs a prescriber or it can't be used by an individual.

MS. FUSCO-WALKER: Okay.

MODERATOR GANLEY: That's a very sort of basic answer to it.

MS. FUSCO-WALKER: Right. And that's my question because it's presently OTC in its form. It's actually a new drug with

the HFA, et cetera, as the albuterol has had to be redone, you know, the --

MODERATOR GANLEY: Right.

MS. FUSCO-WALKER: -- CFCs had to be changed over. And if there's a transition that has to happen and this product, for some reason, it's decided it's going to be a prescription product, it wouldn't make any difference on a date because people would have to get a prescription anyway. It wouldn't be transitioned to the same product.

MODERATOR GANLEY: Yes. I don't think we're in a position to answer that question.

MS. FUSCO-WALKER: Thank you.

MODERATOR GANLEY: Is there anyone else who would like to make any comments into the record here?

(No response.)

CLOSING REMARKS

MODERATOR GANLEY: The only other thing, in closing, I just want to thank the

two speakers and appreciate the comments. The comment period has been extended to December 19th. So if there are additional comments that individuals or groups would like to make, we encourage you to get it in by that date.

I know Martha is going to work over the Christmas holiday on this rulemaking and looking at all of those comments. And I certainly will be, too, in some regards, I guess.

But if there are comments or any issues that you need to address with the agency prior to that, you can either contact myself or contact Martha. If there are economic questions, you can contact Mr. Nardinelli. And Dr. Chowdhury is always available to answer questions, too.

We can be located if you go into the HHS directory. There are methods to find our e-mail addresses, and you can send us an e-mail.

These are for questions and

clarifications. These aren't to submit comments to us. Okay? We don't want your comments sent directly to us. We want them sent to the docket. Okay?

Mr. Sussman?

MR. SUSSMAN: We have had trouble accessing the comments that have been submitted to the docket. You mentioned some comments that have been submitted by patients.

We have been checking the docket. And we haven't really found anything there. It would be useful to be able to review these comments before we submit our final comments.

I don't know whether there's any way to expedite putting things in the docket, but that would be very helpful.

MODERATOR GANLEY: Martha, is there any? I have not found an easy way to access the docket.

MS. NGUYEN: No. And we have I think an internal access. But I will check with Dockets to see if -- I know they have a

backlog from both of our rulemakings. So I will check with them to see if they can speed up the process, but that's very valuable to hear that it's difficult from the outside.

Yes, Rose?

MS. CUNNINGHAM: It's available printed.

MS. NGUYEN: Yes. And so the reading room is available if you would like to review the comments in person here. We'll look into that.

We do encourage everyone if you have more comments and especially more data to submit those. We did extend the comment period with the specific purpose of being able to wrap it around this meeting so that we can get more comments from you and anyone else who is interested in this issue.

MODERATOR GANLEY: Okay. Let's turn to Rose here to see if there is anything else we need to do before we conclude the meeting.

MS. CUNNINGHAM: No. I want to thank everybody for coming. On the agenda and on this slide, it has the Web site that you can go to. We will be providing the slides and also the transcript once it is available. We had given them 14 days to do the transcript. We are going to try to get it a little earlier, but I can't promise that.

The slides that you just saw will be available on the Web site.

MODERATOR GANLEY: I'll just ask Martha. Martha, most of the comments we received from you have been in a .pdf or electronic format.

MS. NGUYEN: I have been creating those.

MODERATOR GANLEY: I see. And, Rose, is this a Web page that's directed -- it's for this proposed rule?

MS. CUNNINGHAM: It's for the proposed rule. It's in connection with this meeting. And you just click on the meetings,

and everything comes up. If you would like, we can see about getting some of the comments put in there.

MODERATOR GANLEY: I think if we have them in electronic format, we may be able to actually post them on that Web page if we can --

MS. CUNNINGHAM: We can do that.

MODERATOR GANLEY: Yes. So we will try to do that, then, and keep the constant vigil.

Okay. Thanks, everyone. I appreciate your efforts in getting here today. I know it was very difficult. And I hope you have a safe trip home or to your work. Thanks.

(Whereupon, the foregoing matter was concluded at 10:41 a.m.)