Transcript for FDA Media Briefing on HFA-propelled Albuterol Inhalers

FTS-HHS FDA

Moderator: Christopher Kelly
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Coordinator: Welcome and thank you for standing by. All participants are currently in a listen-only mode. To ask a question during the question and answer session, please press star 1.

As a reminder, today's conference is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the conference over to your host, Mr. Christopher Kelly. Sir, you may begin.

Christopher Kelly: Thank you (Sterling). Good afternoon everyone and thank you for joining us on this call this afternoon. Today the U.S. Food and Drug Administration issued a Public Health Advisory to alert patients, care givers and healthcare professionals to switch to HFA-propelled albuterol inhalers because CFC-propelled inhalers will not be available in the U.S. after December 31, 2008.

And I'd like to refer all of you to our news release that's posted on Website, www.fda.gov and at the bottom of that news release is a link, which will take you to a host of documents related to today's important announcement.

Joining me today is a panel of FDA experts who will discuss further the actions that the FDA is taking in relation to this important announcement today.

On the panel is Deborah Henderson, a Senior Advisor to the Office of Executive Programs for the Center for Drug Evaluation and Research for FDA; Dr. Badrul Chowdhury, Director of the Division of Pulmonary and Allergy Products for CDER, also with FDA; Dr. Sally Seymour, Medical Team Leader, Division of Pulmonary and Allergy Products, CDER; and Theresa Toigo, the Director of the Office of Special Health Issues with FDA.

I'd like to turn the program over now to Deborah Henderson who will speak more about today's announcement. Debbie.

Deborah Henderson: Thank you Chris and thanks to all of you for joining us today. We are particularly appreciative of the assistance the media can provide us in conveying this important public health message to Americans.

As Chris mentioned, today the FDA issued a Public Health Advisory to alert patients who use albuterol inhalers and to their caregivers and healthcare professionals to switch to HFA-propelled albuterol inhalers now.

This is because CFC-propelled inhalers will no longer be available in the United States after December 31 of this year. No CFC-propelled albuterol inhalers may be produced, marketed or sold in the U.S. after December 31.

Patients who purchased CFC-propelled inhalers before December 31 may continue to use them, but no CFC inhalers will be available for sale after that date.

CFC-propelled albuterol inhalers are being phase out because they contribute to the depletion of the ozone layer above the earth's surface and are therefore harmful to the environment.

The phase out of CFC-propelled inhalers is the result of the Clean Air Act and an international environmental treaty, the Montreal Protocol on substances that deplete the ozone layer. Under this treaty the U.S. agreed to phase out production and importation of ozone depleting substances including CFCs.

To comply with the Montreal Protocol, FDA has engaged since the late 1990s in a public rulemaking process to ensure the transition. In conjunction with the rulemaking, FDA took a number of steps to develop and provide information for patients and their healthcare community about the transitions and about the newly developed products.

In a public meeting convened by the EPA in April of this year and in a variety of other forums, FDA learned from our stakeholders that more information about this transition was needed. And so today FDA is utilizing a variety of tools to communicate to the American public.

They include a Public Health Advisory, a press release, targeted public health service messaging through pharmacy distribution systems, questions and answers available in English and Spanish, a consumer article available in English and Spanish, a podcast of the public health announcement, a stakeholder call and of course this media call, an email blast to our stakeholder list which provides a description of the issue and referral to our Website.

And of course we are updating all of the documents currently available on our Website. In addition, FDA will continue to educate stakeholder groups throughout the remainder of the year.

Many patients have already made the switch to HFA-propelled inhalers. The FDA today is encouraging those who have not switched to talk to their healthcare professionals now about switching to HFA-propelled albuterol inhalers. The FDA worked with industry to assure patients that safe and effective CFC free alternatives were developed and adequate supply is now available.

There are currently four HFA-propelled inhalers available to patients that are alternatives to CFC-propelled albuterol inhalers. Three contain albuterol and one contains levalbuterol, a medicine similar to albuterol. Dr. Chowdhury will provide more information about these products in his remarks.

HFA-propelled albuterol inhalers, the newer inhalers, are not currently available in generic form and therefore may be more expensive than CFC-propelled albuterol inhalers. Manufacturers of the HFA versions have created financial assistance programs and eased income restrictions for low-income patients. Physicians, pharmacies and manufacturer Websites are also offering coupons for those who face a higher co-pay for these products.

For more information about these financial assistance programs, please visit the following Websites; www.inhalertransition.org, www.transitionnow.org and www.pparx.org.

I will now mention a few critical pieces of information for patients and healthcare providers concerning the use of the new HFA-propelled inhalers.

Because these inhalers are different, it is important that patients know how to use them properly and follow the directions.

Patients should know first the inhalers contain the same medicine they have always taken. However, the spray from the new inhalers may taste different and the spray from the new inhalers may not feel as strong as that from the CFC-propelled inhalers. But patients should know that that doesn't mean that they're not working. Even though the spray tastes and feels differently, the inhalers are still working.

Because they are different and because the force of the spray is smaller, it is important to clean and prime the inhalers in order for the right dose of medicine to be delivered. Patients should be reinforced with the knowledge that they need to follow the directions very carefully that come with each of the various inhalers.

Health professionals should reassure their patients that the new inhalers do contain the same medicine they have always taken. Healthcare professionals should explain that even though the spray from the new inhalers may taste and feel differently, it is still working. And finally, they should remind patients that it is important to clean and prime their inhalers so that they get the right dos of the medicine.

Dr. Chowdhury will provide additional information in his remarks. Thank you very much.

Christopher Kelly: Thank you Debbie. I'd like to turn the program over now to Dr. Chowdhury for additional comments. Dr. Chowdhury.

Badrul Chowdhury: Thank you and good afternoon. For the next 10 minutes or less I will talk about the issue that is leading up to this conference call. As you heard before which is giving you background on the December 31, 2008 end date after which CFC-propelled albuterol MDIs cannot be sold in the U.S.

Albuterol MDI is one of the top 10 prescribed medications in the country with approximately 52 million prescriptions every year. These are drugs that are used as reliever medications, which means they relieve shortness of breath in patients with asthma and another lung disease called Chronic Obstructive Pulmonary Disease or COPD.

Being a reliever medication, patients rely on these drugs for breathing difficulty and the drug is rightfully very important to them.

Over the last couple of years, we have been communicating this upcoming phase out to the public. Today's call with you is another one in that direction with the aim of reaching a larger audience.

I'll briefly go over four aspects we're talking about and then go over them one at a time. First, I'll talk about the ozone depleting substances and the Montreal Protocol that you've heard from our previous speaker.

Then I'll talk about in a very broad sense the general framework under which CFC drugs are removed in the U.S., especially mentioning albuterol.

Third, I'll talk about the public outreach activities that have been happening for the last couple of years. And finally talk about some current issues that you've heard before regarding CFC-propelled albuterol MDIs.

The first issue is the Montreal Protocol on ozone depleting substances, which you heard before. CFCs have been used in industry since the 1930s. And from 1981 it has been used in medicine, the first ones being (Ventolin) MDI and (Proventil) MDI which are albuterol MDIs.

Back in 1978 based on information that was known about the same time that CFCs deplete ozone high up in the atmosphere, the U.S., through authority of the U.S. EPA and FDA created some rules limiting the use of CFCs because they're harmful to the environment.

When the Montreal Protocol came into being in 1987, the U.S. signed on to it two years later in 1989 and since then the U.S. has been in a leadership role leading the phase out effort and policies behind those internationally and globally.

The aim of the Montreal Protocol is to reduce the production of all ozone depleting substances, CFC being one of them. The idea here is to get rid of every use because one use of one area of one drug of albuterol here may in a single entity seem to be small, but adding up they become cumulatively large; therefore the aim is to eliminate all use of CFCs.

Under the Montreal Protocol there's provision for allowing some essential use, starting in 1996. Essential use really means that they are essential. This means: 1) that it is necessary for health, safety, and critical functioning of society; and 2) there are no economically feasible alternatives.

Medical use of CFCs for inhalers certainly met those criteria.

Now moving on to the second topic is the general framework of removing drugs. And as you heard before, the FDA has gone through extensive public

discussions, rulemaking processes and we had open public discussions in Advisory Committee settings where experts are brought in and discussions happen (in scientific) issues.

These discussions between 1997 and2002 set some general frameworks to determine if a product is no longer essential. It was decided and agreed upon with large public input to have some criteria to be met and these criteria are pretty straightforward: 1) the availability of acceptable alternatives; 2) adequate supply and production of the alternatives; 3) adequate U.S. post-marketing data; and 4) patients are adequately served by alternate products.

As you heard before for albuterol, these criteria were met. And they were met a couple of years ago with introduction of non CFC albuterol products. First one that came to the market in the U.S. was Proventil HFA MDI, which was marketed since 1996 and Ventolin HFA MDI, which was marketed in the U.S. since 2002.

Around 2004 the FDA had Advisory Committee meetings, which are the public meetings I mentioned earlier. FDA proposed rules, and held public meetings around those rules, discussing the phase out and for albuterol, as you heard before, the decision was (ultimately) made to phase out albuterol effective December 31, 2008. And that final rule was in 2005.

So from 2005 onward, the end date was there and was criticized quite extensively. Let me pass on to the third topic talking about what has been done to make people aware of this transition.

As I mentioned earlier, proposed rules and other activities where decisions were made were very much in the public domain: Advisory Committee meetings, proposed rules, public hearings, and things like that.

And for CFC MDIs in general, which was 1997 and 2002 that this happened. For albuterol, specifically, this happened in the proposed rule published in 2004 and subsequently finalized in 2005.

In 2005 when the rule was finalized, we at FDA posted an MDI transition web page with various links. Major medical professional societies and others covered the rule in their publications and outreach programs to make the information available to their membership which was quite large.

And there were stakeholder groups in the U.S., which included various (professional) societies, Patient Advocacy Groups and others who also took this news on and had public outreaches.

Now one thing is to understand and talk about the penetration of the market.. In 2005 when the rule was finalized, there were still CFC albuterol MDIs in the market and in large supply. As you've heard before, there were financial reasons for people to buy CFCs because of the pricing differential and the CFCs were available.

Leading up to this year, the market penetration of HFA albuterol MDI has been around 5 to 10%. Over the years manufacturers of CFC albuterol MDIs have stopped manufacturing and today there is only one manufacturer and the market has gradually switched over to HFA albuterol.

As of today, approximately 65% of albuterol MDIs in the U.S. are HFA-propelled and the rest of about 35 to 40% are albuterol CFC MDIs. In general, the transition is very much happening and is happening now with the albuterol CFC MDIs gradually being phased out.

Regarding the CFC to HFA albuterol switch, there's couple of issues that I want to touch on again. The first one, which is important, is the pricing and financial aspects.

CFC albuterol MDI has been generic and with the CFC albuterol MDI going away as a generic drug and the available alternatives are not generic, there is ultimately an increased price. As you're aware of, we from the FDA did not have influence on setting prices and this is a free market.

And we do all we can as the prices being computed and for HFA albuterol MDI. We have done so. Currently there are four alternates in the market and the expectation is that with competition the prices will come done. Also there is no barrier to the development of generic albuterol HFA MDIs and we expect industry to be innovative and so a generic can come to the market.

Well you've heard about some points regarding switching from CFC to HFA albuterol. I want to touch on one or two of those again. First, we have determined through clinical studies which were the basis of approval of the HFA albuterol MDIs that they are substitutes in the clinical sense to the albuterol CFC MDIs so that patient medical needs are adequately served.

These are different products. They may taste different. The spray/mist may be softer. HFA albuterol inhalers may clog and require regular cleaning and they require priming. The important point here is for patients, healthcare providers and others (and a way for media to get to a larger audience) is to understand the that there are differences in the cleaning and priming instructions for the albuterol HFA MDIS and to use them properly so that they don't have problems and understand what the differences are.

In conclusion then, I would say that the phase out of ozone depleting substances including CFCs is one of the best described success stories of international cooperation which will have lasting impact on the earth and all living beings on the earth.

The phase out of albuterol CFC MDI and its replacement for albuterol agent for MDI is a major success story at international level and also the domestic level in the U.S. The transition has already happened largely. No problems in other developed countries as well as in the U.S. with approximately 65% of the market turned over.

Today we are very close to calling this completed. And in fact in the next couple of months the transition will be completed. Thank you very much.

Christopher Kelly: Thank you Dr. Chowdhury. (Sterling), we'd like to move now to any questions that we may have from the media, if you could arrange that for us please. Thank you.

Coordinator: Okay. To press - to ask a question, please press star 1. To withdraw your question, please press star 2. Please allow one moment while we wait for questions.

Our first question comes from Justin Blum with Bloomberg News. Sir you may ask your question.

Justin Blum: Hi. Thanks for taking my question. I couldn't hear very well on the speakerphone there and so I'm just not completely clear. Did you say 65% of the albuterol inhalers now sold have switched over already to the new type?

Badrul Chowdhury: Yes. That is correct. And actually the albuterol market in the U.S. is monitored very closely by our drug shortage folks in the U.S. FDA. On the international area there is a medical technological company, which is assigned to (embody) the whole Montreal Protocol. And they come up with a report just a couple of weeks ago and those and our estimates are that 65% of the albuterol is in the U.S. driven by HFA propellant.

Justin Blum: Sixty-five, six five?

Badrul Chowdhury: Approximately that number. Yes.

Justin Blum: And so in the U.S. what is the remaining 45%? What brands are still out there?

Badrul Chowdhury: Yes. The remaining is the CFC-propelled albuterol. As you probably know, a couple of years ago there were multiple manufacturers of albuterol CFC MDIs. Over time they'll gradually go out. So as of now, there's only one manufacturer in the U.S. and that is Armstrong that markets albuterol CFC MDI in the U.S.

Justin Blum: So one manufacturer has 45% of the market?

Woman: Thirty-five.

Badrul Chowdhury: Thirty-five approximately; 45 would be I think not correct at this stage. I said 65% is HFA. The rest would be 35% of CFC.

Justin Blum: Oh, okay. And last question if I could. Could you just repeat the number of prescriptions written annually in the U.S. for these inhalers?

Badrul Chowdhury: Yes. Approximately 52 million prescriptions per year is written in the U.S. for albuterol total, CFC plus HFA per year.

Christopher Kelly: Thank you. We'll move to the next question.

Coordinator: Our next question comes from Lisa Richwine with Reuters. You may begin ma'am.

Lisa Richwine: Thanks. I had similar questions and just want to clarify that number. About 52 million prescriptions per year in the U.S. for albuterol inhalers?

Badrul Chowdhury: That is correct.

Lisa Richwine: Okay. Five two, 52?

Badrul Chowdhury: Five two.

Lisa Richwine: Okay. Great. Yeah, we're having a little trouble hearing you.

Badrul Chowdhury: Sorry.

Lisa Richwine: That's okay. And the one manufacturer, Armstrong, do they have a brand name for their inhaler just so, you know, patients can know if they're taking it or not.

Badrul Chowdhury: No. As I said before, it is a generic.

Lisa Richwine: It's a generic.

Badrul Chowdhury: It's a generic. There's no branded name to it.

Lisa Richwine: Okay. Okay. That's all I need. Thanks.

Christopher Kelly: Next question.

Coordinator: Our next question comes from Cheryl Thompson of American Journal of Health System Pharmacies. Ma'am you may begin.

Cheryl Thompson: Hi. Thank you. Would you explain why there is no generic HFA-propelled albuterol inhaler? The drug itself has been off patent for years. So what's the problem?

Badrul Chowdhury: It is a matter of time when a generic company is able to make exact duplicate of a product. It is true albuterol as a molecule is a very old molecule. But in the (metered) inhalers, there are many other things besides albuterol.

One of the major things is a propellant which we just talked about. An HFA propellant is new. With the CFC we have experiences going back to 1980s. With HFA it is new. And when the MDIs, the metered dose inhalers were formulated to have HFA because HFA is very different than CFC, lots of components of the inhaler devices had to be changed. Lots of (other excipients) which are inactive ingredients in the drugs had to be changed. So essentially they are substantially different than the CFC albuterol MDIs and they're different.

So it is a matter of time when the generic manufacturers are able to make exact duplicates of the albuterol HFA MDI. There's no technical barrier. The products are out there. And we expect that it will happen anytime soon. And if you historically go back and look at the albuterol CFC MDIs, there was

substantial lag period between the introduction of the (innovator) and the generic, 10 years lag. Thank you.

Cheryl Thompson: Thank you.

Coordinator: Our next question comes from Lynne Peterson. Ma'am you may begin.

Lynne Peterson: I'm also having trouble hearing today. But I'm just a little puzzled on the emphasis on now. This happens on the 31st of December and we've already switched over 65, two thirds of this whole market. So why this emphasis on now?

Badrul Chowdhury: Well I think now should not be in my view taken up as a minute or a day. It is a well broad spectrum of time. And as I mentioned earlier, the rule of the end date being December 31, 2008 was out there from 2005.

And the transition for the last couple of years was rather slow which is not a surprise because the albuterol CFC MDI, which is generic was there and the price computation obviously had to roll in that.

And over the years, primarily end of last year to early this year CFC manufacturers some of them have stopped manufacturing and also the Armstrong who is manufacturing CFC albuterol with end date known to everybody is winding down.

So it really is early part of this year the market switched from approximately 5 to 10% HFA albuterol MDI to approximately 65% HFA MDI. It's a pretty short time period. The (unintelligible) says it happened without lot of people knowing about it which is ideal and it just happened in this way.

The final 35% or so are the ones who have probably not heard about it or as individual patient level or as a large (unintelligible) level may not have learned about it. And this (coming into very close). Only six months to go. So we are bringing this to you and through you to help reach a larger audience to make sure that the ones that have not heard about it hear about it and they can plan the transition and transition soon.

Christopher Kelly: Thank you. Next question.

Coordinator: Our next question comes from Justin Blum with Bloomberg News. Sir you may ask your question.

Justin Blum: Thanks for taking my question again. I'm just trying to understand why is it so important to notify doctors and patients about this? If a doctor writes a prescription for albuterol after the end of the year and lets say the doctor had been writing the prescription for generic, writes the prescription again early next year, won't the patient - when the patient goes to the pharmacy, get one of the newer approved versions? Does the prescription - does the way the prescriptions are written have to change?

Badrul Chowdhury: No, you are correct in that. It really does not have to change. And if a physician writes a specific brand of drug, then that drug will be dispensed. The important point here which you heard the previous speaker bring up and I also bring it to bring it up here is the fact that average for all CFC MDIs has been there in the market for long time. Years.

And there is only one albuterol CFC MDI. By one I mean (unintelligible) which were basically identical products and generics to those. But CFC has properties which are very forgiving. Therefore, CFC MDIs were easy for

patients to (unintelligible) handle and years and years of experience patients they are very aware and very used to how to handle those.

As you heard before that HFA albuterol MDIs (unintelligible) are safe and effective. But because of the change of the propellant, they are different products. And HFA is perhaps not as forgiving as CFC is.

For example, CFC in industry as many may know has been used as a cleaning agent, has been used for cleaning computer circuitry boards and other things. And each of those inhalers when the drug comes out through a pinhole size orifice, the albuterol given by CFC is coming out (really almost) at the same time.

Whereas HFA is not as good a cleaning agent. So when the drug comes out the pinhole size orifice, has some residual HFA left in there which can ultimately lead to clogging and then the drug will actually physically not come out.

Very important for the patients to know that using HFA albuterol they therefore have to clean that small hole from where the drug comes out in the plastic piece. Run water through the mouthpiece, wipe with a towel and dry it. If you don't then the drug will not come out.

Pretty important to know this point - the other points as well. (Unintelligible) this point for the physician to know, for the pharmacist to know so the patients know so when they walk out with their albuterol HFA MDI which is actually different. They're to care for it differently so that they do not have the situation with a clogged inhaler.

Justin Blum: One follow up question. When does FDA expect the generic version of the new type of albuterol inhaler to come on the market?

Badrul Chowdhury: I think it's very difficult to actually project a date because as you know that it is the companies who do these innovations and bring, you know, to the market. As far as we can tell you, there is no technical barrier for making generic.

And we also understand it is not necessarily very easy to make a generic. And given the example of the CFC albuterol MDIs, it took 10 plus years. So we expect companies who are manufacturing to be innovative and make the generic and bring to the market. And we can hope for it to be happening soon but we cannot give you exact timeline.

Justin Blum: What's the earliest they could bring it to market under the rules about when - how long exclusivity lasts?

Badrul Chowdhury: Exclusivity has got (unintelligible) and we probably all know the numbers which is couple of years after the drug comes out which is six years or so. But I think also once you consider there are patent issues, which we also have some rules here and more importantly the technical issues of actually being able to make a generic MDI.

Christopher Kelly: Thank you. Move on to the next caller please.

Coordinator: Our next question comes from Jeff Evans with Internal Medicine News. Sir, you may ask your question.

Jeff Evans: Hi. I was wondering if there's any other similar concerns for MDIs with other aerosolized active drugs other than albuterol if those are being switched over as well to HFA-propelled inhalers.

Badrul Chowdhury: I will say there is actually no concern and also do the (unintelligible). For albuterol I will say there's not a concern. (Unintelligible) we are sharing with you and hoping it will actually happen well.

With other drugs, there are many other drugs, which are (unintelligible) by albuterol. The couple of them which was not reformulated and they simply were gone and there was a rule, which finalized the movement of them. There are approximately eight drugs in this category that will happen couple of years ago.

Going forward, in the U.S. as of now, there are eight (unintelligible) inhalers that use CFC as a propellant and they will be again gradually switched over to HFA MDI and FDA has proposed rules on those. And we do not anticipate really problems in that. But we again want to make sure the transitions happen taking into account to (unintelligible) patients' health and safety.

Jeff Evans: Thank you. Next caller please.

Christopher Kelly: Our next question comes from Lisa Richwine with Reuters. Ma'am you may ask your question.

Lisa Richwine: Hi. Thanks for letting me ask another question. Since you've referred to the price several times, do you know what the price difference is between a generic CFC-propelled inhaler and the HFA version?

Badrul Chowdhury: I cannot really quote you the exact price difference but one can easily look up some (unintelligible) Internet drugstore.com and others.

Lisa Richwine: Okay. And I may have misunderstood you earlier I think you had said that there were no barriers to generics now. I mean if a company wanted to apply today for a generic HFA inhaler, could they go ahead and apply or is there some kind of patent or exclusivity protection of the brand names right now?

Badrul Chowdhury: Again I'm not very much an expert on those areas. I said there's no technical barriers.

((Crosstalk))

Lisa Richwine: No technical barriers.

Badrul Chowdhury: …of an alternate. Exclusivity and patents have to be sorted out…

Lisa Richwine: Okay.

Badrul Chowdhury: …in different areas.

Lisa Richwine: Okay. And just one last quick thing. Does the CFC inhalers also have to be cleaned the way the HFA inhalers do or is it that different?

Badrul Chowdhury: No actually it's a very interesting question. I'm glad that you asked it again. I mentioned it earlier. Actually CFC was extremely good cleaning agent by itself.

Lisa Richwine: Okay.

Badrul Chowdhury: So therefore it was not required that those were to be cleaned. Actually there were no instructions to clean them.

Lisa Richwine: Okay.

Badrul Chowdhury: And with HFA, it's actually very important to clean them.

Lisa Richwine: Okay. Great. Thanks for clarifying that.

Christopher Kelly: Next question please.

Coordinator: Our next question comes from Lynne Peterson with Trends in Medicine. Ma'am you may ask your question.

Lynne Peterson: Hi. Thanks for taking the extra questions. Two questions. What if people stock up on the CFC because they really don't like the HFA? How long is the shelf life if they did that? Should there be a warning? Does it wear out?

Badrul Chowdhury: I think you're meaning CFC-propelled MDIs.

Lynne Peterson: Yes.

Badrul Chowdhury: They can purchase and they can use it for their personal use and they can do so as long as (unintelligible) and expiry period of the product is on the box. It is right there. And this expiry period I can not exactly quote the number right now but they're usually years or beyond. One year or two year, something like that.

Lynne Peterson: And I have a follow up question please. Do you - what about elderly patients who use these especially COPD patients who are not very nimble with their

fingers? Are they going to have trouble with cleaning the HFAs? Is there a safety issue here?

Badrul Chowdhury: No there is not. I mean cleaning instructions are pretty straightforward and if you would take a product label and see the (patient) instructions, you would actually see it

It basically is in a broad term taking the metal, which is a canister out of the actuator with a simple small pull. It comes apart. And the other piece, which is a plastic piece, which is called actuator, is to put it under warm running water and let the water run through. Then simply drying it.

And a person who can use an MDI which means taking up the hand and press it, they should have the hand capability to clean it because cleaning it probably requires less of hand coordination than using an MDI. And certainly family members and others can help.

Deborah Henderson: But it certainly makes a very - raises a very good issue and one of the reasons we really wanted to get this message out to patients and their healthcare providers is that we want healthcare providers to be aware that there are additional steps and that these are a little bit different to use.

And so when you're working with patients, whether they're elderly or patients with COPD or whatever, that you want to take into consideration that there's some extra steps that they may need to take and they need to be educated about that.

Christopher Kelly: Your next question please.

Coordinator: Once again if you would like to ask a question, please press star 1. Our next question (unintelligible) with NBC News. Ma'am you may ask your question.

Woman: This is sort of a follow up on an earlier question. But has there been any determination made as to whether there will be greater patient resistance to making the change either because of the extra cleaning needed with the HFAs or because of the taste differences? I would think that once patients get used to one thing that works for them, they're reluctant to make the change.

Badrul Chowdhury: Yes. And it is true that once somebody gets used to one medicine there is some reluctance to change and that's the reason we're reaching to you, reaching to stakeholders and others to educate. Because there's a good reason which is a larger societal need to make this change.

And often medications, yes, they feel different, they taste different, they need slightly different instructions for maintaining and cleaning them. But they are safe and effective medications. And (education) people will adopt, accept and there's are not really very different than the (unintelligible) inhalers. It is slightly different.

Woman: I guess my question really is have you done any testing to see if there's going to be resistance because sometimes if people resist an idea, they simply don't use the medication.

Badrul Chowdhury: If you're asking was any formal testing done…

Woman: Yes.

Badrul Chowdhury: …the answer is no there was no formal testing done. But these products when they came to the market, they were in the market for a couple of years

when we put the proposed rule and had open public meetings to discuss this issue. At those meetings during the proposed rules these issues were discussed. And one, two or multiple individual patients may resist to that, but the larger societal stance, these were accepted.

Deborah Henderson: We have certainly been in close contact with our stakeholders around this throughout this whole transition process and, you know, what we have heard from them loud and clear is that they needed more information about these products and how to use them but less about resistance and just that they needed more information and to be educated about the differences in the products and that's why we're reaching out today.

Christopher Kelly: Thank you very much. Operator, this is going to conclude our media call for today. I would like to thank everyone for participating and for helping us get this important message out about this transition.

If you have follow up questions, it's best to reach me by email at christopher.kelly, that's K-E-L-L-Y, @fda.hhs.gov and I'd be glad to assist you. And thank you again for participating today.

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