FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON PATIENT-FOCUSED DRUG DEVELOPMENT FOR ALOPECIA AREATA

Monday, September 11, 2017
1:00 p.m.

Food and Drug Administration (FDA)
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20903

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Julia

Julie

Katie

Margaret

Maria

Megha

Mia

Miranda

Paula and Rosie Quinn

Ed Reinhart

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Sanguita

Sarah

Diana Smith

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P R O C E E D I N G S

Welcome

MS. CHALASANI: Good afternoon, everyone. Thank you all for being here today. I want to welcome you to FDA's Patient-Focused Drug Development Meeting on Alopecia Areata. My name is Meghana Chalasani, and I work in the Office of Strategic Programs within the Center for Drug Evaluation and Research here at FDA. I will serve as the discussion facilitator for today.

Dr. Tatiana Oussova will provide some opening remarks in a few minutes, but first let me start by asking my colleagues sitting here in the front to state their names and their role within the agency.

DR. MARCUS: Kendall Marcus, Director, Division of Dermatology and Dental Products.

DR. LINDSTROM: Jill Lindstrom, Deputy Director, Division of Dermatology and Dental Products.

DR. OUSSOVA: Tatiana Oussova, Deputy Director for Safety, Division of Dermatology and Dental

Products.

DR. REYES: Melissa Reyes. I'm a Medical Officer with the Division of Dermatology and Dental Products.

DR. OGDEN: Hello. I'm Neil Ogden. I'm the Branch Chief for the General Surgery Devices Branch 1, and we review light-based technologies.

DR. McCORD: Melinda McCord, Clinical Reviewer, Division of Dermatology and Dental Products.

DR. CAMPBELL: Michelle Campbell, Reviewer, Clinical Outcome Assessment Staff.

DR. MULLIN: Hi. I'm Theresa Mullin. I direct the Office of Strategic Programs in the FDA Center for Drugs. Thank you for coming today.

MR. THOMPSON: Graham Thompson, Office of Strategic Programs.

MS. VAIDYA: Pujita Vaidya, Office of Strategic Programs.

MS. CHALASANI: And I think we also have a few other of our Office of Strategic Programs colleagues outside. Shannon Woodward as well.

Now to give you all a brief overview of the agenda today. After Tatiana's opening remarks, we will first briefly provide background on our PFDD initiative and on alopecia. Then we will move into our discussion with those with alopecia and their family members.

Our two main topics are health effects and daily impacts of living with alopecia followed by current treatment options. I will provide some more details about the format at the start of that discussion.

We have time set aside for open public comment later this afternoon. While the primary discussion today is focused on dialogue with those with alopecia and their family members, the Open Public Comment session will give anyone in the audience the opportunity to make a comment. To participate in that, you will need to sign up at the registration table. Participation is first come, first served, up to 15 commenters. We will close that signup at the end of our break around 3:00 p.m.

The time allowed for each speaker will depend on the number of participants who express interest, likely 1 to 2 minutes each.

For a few logistic and housekeeping points, there is a kiosk outside where bagged lunches, snacks, and beverages are available for purchase. Please feel free to bring your food inside the meeting room. Restrooms are located right behind the kiosk. At any point, if you need to get up for any reason, please feel free to do so. As I mentioned, we will be taking a 15-minute break around 2:45 p.m.

This meeting is being transcribed, and a live webcast is being recorded, both of which will be archived on our website. As you may have noticed there are a few media outlets also recording audio and visual. We appreciate that there is a lot of interest in our meeting today. We, too, believe that this is an important meeting.

We have a documentary filmmaker and several photographers, including FDA photographers, to capture this meeting. Please note that if you are asked to participate in an on- or off-camera interview, you may accept or decline that invitation at your own discretion.

Now I would like you all to join me in a moment of silence to remember all of those affected by the 9/11 attacks 16 years ago.

(Moment of silence.)

MS. CHALASANI: Thank you. Our thoughts are also with all of those affected by Hurricane Irma this past weekend.

With that, I would like to welcome Tatiana for opening remarks.

Opening Remarks

DR. OUSSOVA: Good afternoon, everyone, and welcome to this meeting on Patient-Focused Drug Development for Alopecia Areata. I am Dr. Tatiana Oussova, and I am the Deputy Director for Safety for the Division of Dermatology and Dental Products in the Office of New Drugs at the FDA. Our division reviews drugs for the treatment of dermatologic conditions, including alopecia areata.

We are happy to see so many patients, caregivers, and advocates in the audience. I understand we also have many more of you joining us remotely from the Web. Thank you all for being part of this meeting and sharing your experiences with us.

We are pleased to have this opportunity to engage directly with you and to learn more about the symptoms and the health effects that matter most, the impact that alopecia areata has on your daily lives, and what factors you take into account when selecting a treatment.

We believe that it is absolutely critical that patients with alopecia areata and their caregivers have the opportunity to share with the FDA the unique perspective on living with this disease and different concerns about treatment of this chronic relapsing condition. Your insight on benefit-risks, the availability of treatment, and additional needs is truly important to us.

Alopecia areata is an autoimmune disease that causes hair loss. The hair loss usually occurs on the scalp, but can also affect the beard, eyebrows, and other areas of the body. Dr. Melissa Reyes, from our division, will provide more background on the condition and current treatment options in a few minutes.

Alopecia areata is a serious condition with physical, emotional, and social impacts. And we recognize that there is an unmet need for patients. When FDA approves a drug to be marketed, it is our responsibility to ensure that the benefits of a drug outweigh its risks. Therefore, having this kind of dialogue is extremely valuable for us because hearing what patients care about can help us lead the way in figuring out how to best facilitate drug development for alopecia areata and understand how patients feel the benefits and risks of treatment for alopecia areata. For example, what we hear from you today can help us understand how to develop better endpoints for clinical trials to measure those aspects of alopecia areata that are important to patients.

I know we also have representatives from industry, academia, and other government partners in the room and on the Web. While FDA plays a critical role in drug development, we are just one part of the process, and I am glad to see a high level of interest from those of you who also play an important role in the drug development process.

FDA protects and promotes public health by evaluating the safety and effectiveness and quality of new drugs, but we do not develop drugs or conduct clinical trials. Drug companies, sometimes working with researchers or patient communities, are the ones who conduct trials and submit applications for new drugs to the FDA. It is then FDA's responsibility to ensure that the benefits of a drug outweigh its risks.

We are here today to hear the patients' voice, so thank you all for your participation. We are grateful to each of you for being here to share such personal stories, experiences, and perspectives.

I will now turn it over to Dr. Theresa Mullin, who will talk about the FDA's Patient-Focused Drug Development efforts. Thank you.

Overview of FDA's Patient-Focused Drug Development Initiative

DR. MULLIN: Thank you. And good afternoon. With each of these meetings, I usually try to just give a few minutes of context for why we have these meetings. And when we came up with the idea, which we found is a very good idea to have these meetings to hear from patients.

And so 5 years ago, it's hard to believe it was that long ago, but we were reauthorizing the Prescription Drug User Fee Act, which is how the FDA Center for Drugs and Biologics gets most of its funding for supporting new drug review. And we make commitments to things we're going to do to enhance the program during those 5-year cycles.

And so, you know, 5 years ago, basically we were hearing from patient groups, patient stakeholders, during our negotiations, and they were wanting us to better incorporate their views. And so without having a clear idea at that time, we committed to do this.

So we thought we would need a more systematic way to get the patients' perspective and not just one or two patients in advisory committee meetings where those people have to undergo conflict of interest screening and a lot of other things, so we can't hear from the wider community, we really wanted to hear the broader patients' voice because we knew that that was really critical to doing a good assessment of benefits and risks. I mean, after all, the patients are the ones who are going to be taking these drugs. Do they work for the patient? They're going to experience any risks associated with it.

So we really need this information in our benefit-risk assessment straight from patients, and so we thought this would be a way to get it without having to do that conflict of interest screening, do it by disease, not going and focusing on a particular drug.

So at that time, we committed to do at least 20 of these meetings. And basically the review divisions and patient groups between our own internal people and patient groups wanting to have this more, we've had 24 instead of 20, this is the last month of that program, for the last user fee program. So now we're going to reauthorize and move on to the next authorization of PDUFA where we have commitments to further move this program forward and develop guidance so people know what to do with the kind of information that we get in these meetings.

So we'll look at this information, but it's to give the community more tools and information about what to do next, to take what we hear today and build on it so that we have richer trials that better incorporate the patients' voice as well.

Here are the diseases that we've covered over the past 5 years. This is our second-to-last one. We have one more on September 25th. For those of you who don't live in the government, you know September 30th is the end of our fiscal year, so we're coming right down to the wire in terms of that last meeting.

But you can see it's a very wide range of diseases. And every one of these meetings has provided us with things we didn't know, insights, things we never saw in the literature because that's written by the professional people who don't necessarily have the views of the people who have the disease. So it's been very enriching for us.

And every time we run one of these meetings, we take what we learn and put that into a what we call "Voice of the Patient" report. Now, it takes us a little while to produce these reports because not only do we collect and get the transcript from this meeting and our notes that we take ourselves in this meeting, but we leave open the docket so we can get submissions of information from people on the webcast or other things that may occur to people in the room or on the Web that you will send to us after this meeting because it will occur to you that that might be helpful as well.

We put that information together to develop these reports that have been extremely valuable to us. They both serve as an immediate way to capture as authentically as we can what we heard today and the way we heard it from you, and to not only provide that to reviewers going forward when they do get drugs or there is a sponsor that wants to do a development program in this area, we can use it as a resource for ourselves.

We've heard from companies it's a very valuable head start for them in trying to develop ideas for patient-reported outcomes in a disease area. And also we've heard from patient groups that they have found it valuable as well. So we will certainly be producing that in the coming months after this meeting, and we're very much looking forward to hearing from you today.

So with that, I will turn it over to the next speaker. Thank you.

Overview of Alopecia Areata and Current Treatment Options

DR. REYES: So good afternoon, everyone. Can you hear me? No? All right. Hello? Oh, better.

So my name is Melissa Reyes. I'm a Medical

Officer with the Division of Dermatology and Dental Products. I'm also a pediatric dermatologist by training, so it's very exciting for me to see so many of you here today. I look forward to hearing your experience because we often make decisions on what we think is important for all of you, and we do our risk-benefit determinations, but to actually hear your comments, it will be something concrete that we can then take back with our regulatory decision-making.

Now, today, I'm just going to be giving an overview on alopecia areata. It's really just to set the stage for the discussion that's going to come ahead, and so I'm not going to delve too much into the scientific literature. It's really going to be more background information.

So just briefly we'll go over the clinical features of what makes alopecia areata distinct. We'll go over who it happens in, that's epidemiology. And then being the FDA, we'll talk about the treatment options available. And then, most importantly, we'll talk about the impact of the disease on quality of life, and what's why you're all here today.

So alopecia areata, as you know, it's a disorder of the hair follicles. It tends to happen in three different patterns. So there's focal, total, and general. It can affect the nails as well.

In these photos, you can see two individuals who have alopecia areata of the focal pattern. So you can present with a single hairless patch or you can have several hairless patches. Sometimes it can progress and sometimes you can have regrowth with new patches forming.

In the progressive form, you can have it progress to clinically identifiable patterns, such as on the left, which is ophiasis, you have hair loss that's limited to the posterior and the inferior hairline, or you can have the converse, which is called sisaipho, which is you have hair on the bottom, but you lose it on the top and on the back of the scalp.

In cases when it progresses to complete hair loss, it's called alopecia totalis. And if you have complete hair loss, the condition is called alopecia universalis, and this is where you have eyebrows, eyelashes involved, as well as the body hair.

Now, in terms of nail involvement, the reports of nail changes vary based on the study, but 10 to 38 percent of subjects in the studies report that there is some kind of nail finding. This is one of the more common. If you can appreciate the nail pitting, there are small indentations or pits that make the nail plate look a little bit rough in appearance.

Now that we know how alopecia areata can appear, this is what happens. So it's generally accepted that .15 percent of the U.S. population has alopecia areata. This amounts to approximately 490,000 individuals who have it at this time. Most individuals have onset by the time they're 40, and nearly half have onset before the age of 20.

Studies vary in terms of gender distribution, but it's likely that it happens equally in men and women. And I see a lot of young faces here today, so this might be relevant for you. In children, the mean age of onset is between the ages of 5 and 10 years old.

So typically in alopecia areata, the more common is the focal pattern, where you have a hair loss patch, and then over the year, you have spontaneous regrowth over the year. But there are other cases where it does progress. And so there are studies that show that if you have onset of disease before your 20th birthday, you're more likely to have a severe disease pattern.

In studies that look at alopecia totalis and alopecia universalis, most of these individuals actually had appearance of symptoms before the age of 30. So there are a lot of gaps in terms of what we know about alopecia areata. And I'm going to show you next what we do know about it.

So this is the most scientific of my slides, so please be patient, but I wanted to give you a look at what happens on the cellular level. So on the left is a hair follicle from a normal individual, scalp hair, and on the right is from someone who has active alopecia areata. So to orient you on the left, the pink and purple structure is the hair strand. It's connected to the skin at the very bottom, and that's the hair bulb. So you can see on the right, in active alopecia areata, you have a lot of little purple dots, those are the inflammatory white blood cells, and those are the cells that are disrupting the hair bulb. That's where your hair grows. So if you don't have the hair growth, you end up shedding the hair, and that shows up as hairless patches on the body and on the scalp.

So being an inflammatory process, most of the treatments are anti-inflammatory in nature. And so that brings us to treatment. So currently, there are no FDA-approved treatments specifically for alopecia areata, but treatments are done, obviously, and these are mostly treatments that are approved for other indications. So these are topical and systemic treatments that are used off-label.

Being off-label, we actually still rely on expert guidance and consensus in order to manage patients with alopecia areata. And I provide a list here of some of the peer-reviewed guidelines that are published in the scientific literature.

So in terms of treatments, it's usually divided by local versus systemic therapies. So by far, the most common is corticosteroids topically or injected intradermally into the skin. So these types of medications can happen as creams, ointments, gels, and solutions. Second-line treatments are calcineurin inhibitors, immunotherapies, and minoxidil, which is a hair-growth-stimulating solution. And in the literature, there are also reports of many other types of treatments that are tried in alopecia areata, so these include prostaglandin analog solutions, platelet-rich plasma patches, topical retinoids, cryotherapy, and light-based therapy, such as excimer light. Local treatments are usually used as a first-line or for people who have limited involvement.

In terms of systemic therapies, these are considered for patients who have more extensive involvement of hair loss or if they have a really rapid onset of disease or if they have really progressive disease. And so, again, steroids play a part, being one of the major anti-inflammatory medicines we have, and this is typically given by mouth or it can be given intravenously. Immunosuppressants are medications like cyclosporine, methotrexate, sulfasalazine, and azothiaprine, and more recently are the immunomodulators. So this includes TNF-alph inhibitors, JAK kinase inhibitors, and apremilast. Also in the literature are systemic retinoids and statin-based medications.

Now, as I mentioned earlier, the treatments for alopecia areata, a majority of them are not approved specifically for alopecia areata but are used under expert guidance.

Now, the real reason why we're here is the impact of alopecia on quality of life, and so I wanted to share some data regarding that. So there are studies that show that there are social, psychological, and economic impacts due to the disease on individuals. One study showed that up to 40 percent had a lifetime prevalence of having general anxiety disorder and major depressive disorder.

There is also data that suggests that the adult experience is very different from the pediatric experience. So the pediatric population tends to bear a much bigger burden of the psychosocial impacts of alopecia areata.

Now, compared to other skin diseases, alopecia areata is not as well known as eczema or atopic dermatitis and psoriasis, which has gotten a lot of publicity as well, but there are studies that show that the health-related quality of life of patients with alopecia areata are actually decreased to the same amount as people with eczema and psoriasis.

In light of this, I wanted to share a

statement from the Cochrane Review called "Interventions on Alopecia Areata." And so they quote that there's a desperate need for large well-conducted studies that evaluate long-term effects of therapy on quality of life.

So to conclude, that's why you're all here today with us. We are aware that there is an unmet medical need that you all face in terms of treatments specifically for your condition. And so for this meeting today, we look forward to hearing from you directly, hearing from your caregivers and your family about the experience of alopecia areata because it will help us with our regulatory decision-making. And thank you again for taking the time.

The Road from PFDD Meetings to Clinical Trial Endpoints

DR. CAMPBELL: Good afternoon. My name is Michelle Campbell, and I'm a reviewer of the Clinical Outcome Assessment Staff. We're a group here in the Office of New Drugs that looks at outcome assessments that are used to see how a patient feels, functions, or survives. And so this is really where the patient voice comes into play.

So you may be wondering how the information that we use in these Patient-Focused Drug Development meetings, and what do we do with them? Where do we go from here? And how do we take this valuable information and create clinically relevant and patient-focused endpoints for clinical studies? And I hope I can answer some of this in the next few slides.

At the FDA, we believe that Patient-Focused Drug Development meetings are very important. They provide the opportunity for individuals' and caregivers' voices to be heard. Today, you will be sharing your experiences with alopecia in your own words, letting us know the symptoms and impacts that are most important to you.

Drug companies want to hear this perspective because it can help them give ideas on what to measure in clinical studies. They can select or develop questionnaires that measure these important concepts and engage with the FDA as they develop treatments. The information from these meetings can also help support the FDA review of clinical trial questionnaires to confirm that they are adequately capturing the individuals' and caregivers' perspective on health outcomes.

While the Patient-Focused Drug Development meetings provide useful information, we strongly recommend that drug companies and other researchers obtain additional input from individuals and caregivers using focus group or one-on-one interviews, as well as from physicians and other experts to develop their questionnaires. This will help us confirm that questionnaires should include important and relevant information and that the questions and instructions are clear and understandable to those who will complete them.

Another advantage of these meetings is that they help us think about the clinical study endpoints. So what is an endpoint? In the case of a questionnaire, the study endpoint will be how the questionnaire score is going to be measured and analyzed in the clinical study. For example, if individuals with alopecia are reporting the most important benefit of treatment is symptom improvement, then we would use that information to encourage a drug company to select or develop a symptom questionnaire that meets regulatory standards.

The study endpoint could possibly be the change in the questionnaire score during the clinical study which would measure the amount of symptom improvements.

I should note that we know today we're going to hear many things will be discussed, however, we know that not everything will change with treatment, and it could be difficult to interpret results if these concepts measured in clinical trials for approvals. So if we're measuring something, for example, such as financial well-being, it may be hard to detect a benefit from that in the clinical trial setting, even though we know that is important to you.

We encourage drug companies to consider focusing on important concepts that most likely reflect the effects of treatment as key endpoints in the clinical trials.

At the FDA, we have to uphold laws and regulations. With these regulations, there are regulatory standards that require assessments like questionnaires to generate responses that are well defined and reliable and will not potentially lead to misleading -- be able to be described in a misleading way in labeling. To ensure this, we ask that drug companies gather input from individuals and caregivers through interviews and focus groups to develop these questionnaires. And this is really where we capture our patient voice.

We also ask them to form the appropriate statistical testing to support questionnaire development. These methods help demonstrate that the questionnaire is measuring the right thing in the correct way, and that the score is accurate and reliable so that any positive change on the score can be interpreted as a symptom improvement due to treatment.

We recommend that drug companies start the process of selecting or developing questionnaires and seeking the input of the FDA as early and often throughout the drug development process. This will ensure that they gain experiences with the instrument during the drug development process before they proceed into the Phase 3 clinical trials.

So how can you engage with the FDA and how can drug companies and researchers come and talk to us about selecting or developing questionnaires? Currently, we have three pathways enabled to come and discuss with the FDA your clinical outcome assessments.

The first pathway, on your left, is what we call our traditional pathway, and this is through the individual drug development programs, and this would be with an individual drug company where they will come and talk with the Clinical Review Division during their drug developments and discuss possible endpoints, outcome assessments, and what to measure.

The second is through our Drug Development Tool Clinical Outcome Assessment Qualification Program. This is outside of an individual drug development program and is voluntary. This allows instrument developers to come together with patients and other groups and to engage with the FDA to develop an instrument to be able to support multiple drug development programs. And part of the result of this would be having a qualified clinical outcome assessment. Again, this is a voluntary program and that qualification is not a requirement to use a clinical outcome assessment in a clinical trial.

The third pathway is the Critical Path Innovation meetings. Again, this is outside the individual drug development program. It is a meeting that provides general CDER-specific advice. It brings together different members of various offices in CDER to talk about novel or early stages of development. And this is a way to get input on direction to go. And these meetings are non-binding.

We know that Patient-Focused Drug Development meetings are a starting point for developing patient-focused outcome measures and endpoints and that the outcomes of these meetings will support and guide FDA risk-benefit assessment in the drug reviews. We know that individuals and caregiver input ultimately helps determine what is measured to provide evidence of a treatment benefit, how best to measure concepts, and what a meaningful improvement is in treatments.

I thank you for that. And here are some resources for you.

I now turn it back over Meghana so we can start our discussion for this afternoon.

Overview of Discussion Format

MS. CHALASANI: Thank you, Michelle.

Let's see. So our goal today as we start this discussion portion of our meeting is to really foster an open dialogue on personal experiences and perspectives on alopecia areata. Our two main topics for discussion are health effects and daily impacts of alopecia followed by current approaches to treatment. We will kick off each session with a panel of individuals and family members. There are five for the first topic. And I will ask at this time for our Topic 1 panel members to come to the front, please. Right up here.

After the panelists, we will broaden the dialogue to include other individuals and family members here in the audience and on the Web. We have about 150 participants right now joining us via webcast.

The purpose is to build on the experiences shared by the panel. I'll ask a number of follow-up questions, inviting participants to raise their hands to speak. My FDA colleagues may also have follow-up questions.

We will have staff floating around with microphones, and they will come to you. Please state your first name, and just your first name is fine, before speaking. For transparency, we also request that at the time of your first comment that you disclose if you are affiliated with an organization that has an interest related to alopecia or if your travel here today has been funded or if you have significant financial interests in alopecia drug development.

Please keep your responses focused on the specific question or topics at hand and limit it to a minute or so. We have a very large crowd here today, so I am going to ask that you raise your hand and speak if you have something to add to the conversation. If you agree with a particular perspective or experience, please feel free to nod your heads or clap your hands.

We will have some polling questions today. We ask only that only individuals with alopecia or a family member or a caregiver responding on behalf of an individual with alopecia respond. If you are in the room, you will see these very fancy clickers. They were originally on your chairs. Hopefully you haven't lost them yet. And for those on the Web, we do have a platform, and you will be able to respond via the webcast as well.

So as far as the clickers, we'll have a few test questions coming up, but basically when you submit an answer for some questions, you can select only one. For some of them, you will be allowed to submit multiple answers. You will feel a little buzz almost, and that means that our system has captured your response. And we have a few trial questions to test this out for everyone.

These polling questions are not a scientific survey at all; they're truly just to be -- they're meant to be a discussion aid for today. For those joining us via webcast, you can also add comments to the Web platform in addition to participating in the polling questions. Although they may not all be read out loud today, your comments will be incorporated in our final summary report.

As Theresa mentioned earlier, we also have a public docket for this meeting that will be open until November 13th. We encourage you to share your experiences and expand on what we discuss here today through the public docket. The comments will be incorporated into our summary report as well. Anyone is welcome to comment through the docket whether you're here today, joining us via the Web, or you know someone who wasn't able to participate today, but you think they have something to contribute. Please encourage them to submit their comments. You will find the link on the slide here, and we'll also email this link as well as the slides to folks after the meeting to everyone who is registered via the event website.

Engaging with patients is very important to us here at the FDA. If you're interested in learning about more opportunities to engage with the FDA, please reach out to our office of Health and Constituent Affairs or our Professional Affairs and Stakeholder Engagement staff. Their contact information can be found here on this slide. And as I mentioned, we will be posting these slides publicly after the meeting.

A few ground rules for our discussion today. We are here first and foremost to listen to those with alopecia and their family members. We will try to accommodate everyone who wants to speak.

If we don't get your full thoughts on a topic, we encourage you to elaborate in the public docket. We are happy to see participants here today who represent research and drug development. We believe that the input we hear today will be important for you as well. We just ask that you stay in listening mode. Some of you may have requested to participate in the Open Public Comment, and we look forward to hearing your input at that time.

FDA staff is really here to listen. We know that you may have questions about drug development or drug review. If you have specific questions, we encourage you to write them on a piece of paper or an evaluation form, which you can find on the tables outside, and we'll get back to you with more information following the meeting.

As has been described, our discussion today is focused first on the health effects of alopecia and daily impacts, and then approaches to managing those health effects. Our discussion may touch upon scientific treatments; however, the discussion of any specific treatments should be done in a way that helps us to understand the broader issues, such as what health effects are being addressed, and how meaningful is that to patients and individuals and family members?

The opinions expressed here are personal opinions; therefore, demonstrating respect is of paramount importance. We very much appreciate what complex and personal topics we are addressing in this public meeting, and we expect everyone here and on the Web to share this appreciation with us.

We want your feedback on the meeting. What we learn will help us to continue to design and implement patient-focused meetings that are useful to FDA and to individuals and their families. There are evaluation forms on the tables outside, as I have mentioned, and we encourage you to fill those out during the break or after the meeting.

With that, let's begin with a polling question. So folks in the room, take out those fancy clickers. Our first question, it's a pretty simple one, Where do you live? A, Within Washington, D.C. metro area, so including the Virginia and Maryland suburbs; or, B, Outside of Washington, D.C. metro area.

(Using clickers.)

MS. CHALASANI: Does everyone in the room have a clicker, all the individuals or family members? If you don't, please raise your hand and we have folks that can bring you a clicker. Okay. I see a few more responses trickling in here. Let's give it a couple of seconds. Okay. Let's see. We'll try a second. This is why we have these trial questions. Let's go to the second one. Oh, there we go. Oh, we got it. Okay. So 77 percent of you all traveled from outside of the Washington, D.C. metro area. Thank you. I know it's not easy to get to White Oak, Maryland. And then 23 percent of you all are more local. Okay.

So our next question, please? Have you ever been diagnosed as having alopecia areata? A, Yes; B, No.

(Using clickers.)

MS. CHALASANI: 65 percent of you, yes; 35 percent of you, no.

So going forward, I am going to ask that it's one clicker response or clicker per individual with alopecia. So hopefully the 35 percent of you are answering on behalf of someone with alopecia.

Next question, please? What is your age? A, Younger than 6 years old; B, 6 to 12 years old; C, 13 to 17 years old; D, 18 to 29 years old; E, 30 to 39 years old; F, 40 to 49 years old; G, 50 years old or older.

(Using clickers.)

MS. CHALASANI: Yes, yes. Yes, please answer on behalf of the individual with alopecia.

Yes, one more question? Oh, they're not working. Can we get some more clickers, folks? Please let us know if you're having any challenges with the clicker. It should, like I said, do a little buzz or a little vibration right after. Anyone else having challenges with the clicker? Okay.

Wow, I think we have a very nice range of folks in the room here today. So we have 4 percent younger than 6 years old, around 15 percent between 6 to 12 years old, 13 to 17 year olds, and another 15 percent 18 to 29 years old. And then we have a nice range in the other age ranges as well, 28 percent of you all are 50 years old or older as well. Thank you.

I think we have one more polling question in the demographic section. Oh, a couple more.

Do you identify as: A, Female; B, Male; C, Other?

(Using clickers.)

MS. CHALASANI: Okay. Girl power here today. 75 percent female, and then 25 percent male, and 1 percent other. Okay.

I think we have one more actually polling question. Okay.

Where is your alopecia areata located? And so this is a question that you can select as many that apply. A, Scalp; B, Beard, sideburns, or mustache; C, Eyebrows; D, Eyelashes; E, All areas; F, Other areas not mentioned, such as nails.

Please check all that apply.

(Using clickers.)

MS. CHALASANI: Oh, it's still not working?

Can we try another one, Sara, please?

(Using clickers.)

MS. CHALASANI: We have a really nice mix here as well. A little over half of you indicated that you have alopecia located on your scalp. Less than 10 percent, beard, sideburns, or mustache. Close to a half percent eyebrows. 34 percent eyelashes. 63 percent who said all areas, so A through D, as well as the whole body. And then 31 percent said other areas not mentioned, such as nails.

Okay. I think we have a very nice range. I'm going to turn to my colleague Graham and see what the responses on the Web are looking like. We asked them the same exact questions.

MR. THOMPSON: The responses on the Web are very similar, although we have 78 percent say that they're affected on the scalp, and we had about 57 percent said they had been diagnosed as having alopecia areata.

MS. CHALASANI: Thank you, Graham.

Panel #1 Discussion on Topic 1:

Health Effects and Daily Impacts

MS. CHALASANI: Okay. With that, thank you all. Let's start with our first panelist now. I'm just going to turn to Liz, and then we'll just go straight down.

MS. DeCARLO: Hello. My name is Elizabeth DeCarlo. I was diagnosed with alopecia areata at age 13. As one of six children, I'm the only one in my family with this disease. It started with a bad patch on the back of my head the size of a quarter. During that year, it became larger and eventually connected with other bald patches and turned into total loss of hair on my head. I wore a wig to my eighth grade graduation. (Becomes emotional.)

I have no photos to share at this time because I avoided being photographed. It was very traumatic. I looked different. I felt different. I was about to enter high school wearing a wig.

Thank you.

I was always worried that someone would pull my wig off or find out about my hair loss. Three years later my hair grew back, not 100 percent, but I didn't need to wear a wig. The hair that grew back was the same texture and color as my original hair. I had hair for my senior photo. I was happy and regained some of my confidence.

Throughout my twenties, bald patches the size of a quarter and sometimes larger would come and go. I would cover them up with brown eye shadow or spray on hair paint and lots of hairspray. Wind was my enemy.

When I met my now husband, it was difficult for me to tell him that I was losing my hair and that I had a disease called alopecia areata. I never shared my secret with anyone except my immediate family.

At the age of 30, I lost all of my body hair. When I looked in the mirror, I did not recognize the person looking back at me. I had no eyebrows to give structure to my face. I wondered how my husband could love me when I looked like this. I avoided social events, like going out to dinner or meeting up with friends. I was depressed and angry that this happened to me.

Worklife was difficult. I avoided conversations with coworkers especially when they talked about hair. I always felt that people were talking about me.

In 2009, I overheard an insensitive colleague questioning if I was in some sort of religious cult because she noticed that I had no eyebrows or eyelashes and that I was wearing a wig. I left work in tears. I didn't know how I was going to handle the situation. I did not want to go back to work.

With the support of my family, I decided to confront my colleague the next morning and educate her about my condition. After 30 years of struggling, this was the best decision I ever made, and gave me the confidence to tell others about my disease. However, my disease still prevents me from seeking a new career path because

I worry that I may have to face that situation again.

While I have come to terms with my condition through my involvement with the National Alopecia Areata Foundation as a support group leader, I still struggle with the daily physical part of drawing on eyebrows and fixing my wig. The emotional part is somewhat better, but I still deal with the physical part.

Excuse me.

I love to swim, but I don't swim anymore because I'm embarrassed to swim with no hair and concerned that my eyebrow makeup would come off.

Excuse me.

When I'm at a sporting event and I'm wearing my hat with hair, I pretend I have to use the restroom before they sing the National Anthem.

As I get older, I think about the burden of this disease, about applying eyebrow makeup every day and finding a wig age-appropriate and affordable. I worry if I decide not to wear anything on my head. Will people avoid me because they think I might be sick, have cancer, or something contagious? I worry about other illnesses due to the lack of hair to filter out particles in my nose, eyes, and ears.

Alopecia is always on my mind and never goes away. Thank you for giving me this opportunity to share my story.

(Applause.)

MS. CHALASANI: Thank you, Liz.

And now we have Harrison and his mother, Sara.

MS. EVANS: Good afternoon. My name is Sarah Carr Evans. And for those of you who are parents in the room will appreciate we go to great lengths to not have tears in front of your kids, and this is one of the few times that mine has seen any.

I am sincerely grateful for your invitation to be here today. Our family is here today as a first step in our own transition from victims to valiant warriors, fighting against a disease state that lies in wait, unwilling to tell us when it will strike again. We hope Harrison's story will emblazon your spirit -- excuse me -- and compel you to suit up and join us in this battle that we intend to win. And so I begin.

My husband, David, and I have the most amazing son, two of them actually, one who is hopefully quiet in the back room, and the other, who is our 7-year-old, Harrison, that is sitting here with me.

Harrison experienced complete hair loss across his entire body -- scalp, eyelashes, and brows -- at 2-1/2 years of age. His hair loss is attributed to a genetic predisposition that was coupled with a viral trigger. After the first hair loss, Harrison's lashes grew back fully, and parts of his scalp and body experienced regrowth as well. Around 8 months after the initial regrowth, he experienced another full hair loss.

We have been on a cycle of regrowth followed by hair loss ever since. Neither traditional nor non-traditional treatments have reversed his condition. Harrison is no longer receiving any physical treatment. We are focused exclusively on ensuring his emotional, social, and spiritual health, for this is our choice to be here today to support those aspects. And, again, we want for Harrison to feel empowered, not victimized, by this ailment.

There are several physical challenges that Harrison experiences because of alopecia. For instance, athletic activities are affected. Helmets do not fit securely on his head and are exacerbated when he begins perspiring. Sweat, then combined with sunscreen, which is, of course, necessary to protect his pale, bald scalp, exacerbates this condition in situation.

To that end, sunburn is another important physical concern. Since Harrison has very fair, sensitive skin on his scalp, and we live in a typically sunny southern state, we must apply sunscreen to his head on a regular basis, especially in the summer. His teachers often apply or reapply sunscreen before recess and PE, which draws additional attention to his condition. When patches of hair grow back in, the sunscreen sticks to his hair, which can be uncomfortable.

While the physical challenges are, of course, a nuisance, it's the emotional and social challenges caused by alopecia that are our greatest concern. For instance, there is nonmalicious treatment by children and adults. Harrison is often erroneously defined by himself and others as ill or sick because of his physical difference.

He experiences unusual social cues or reactions from strangers, such as strange faces and exceptionally long glances, as well as special treatment because people believe that he has a life-threatening disease. This behavior, though well intended, draws to us unwanted focus on this condition. Further, this special treatment implies that there is something wrong with him. While these are kind gestures in theory, they're internalized by Harrison as reinforcement that he is ill or different.

Also, there is a concern that Harrison will be resented by his peers and others for some sort of special treatment or favoritism that he inadvertently receives because of his condition.

In addition to the nonmalicious treatment, there is, of course, the malicious treatment by adults as well as children. My child has been called directly to his face, "Baldy," and other incredibly hurtful names. I have watched as adults refuse to course correct their children when they have said such hurtful things.

Name calling is sometimes malicious in its intent, but other times there are children who simply believe they're playing around when they call him names or remove his hat from his head unwantingly. He is often reluctant to say anything to them because he doesn't want them to believe he is hurt by their choices.

My greatest concern as a caregiver is that the impact of this disease will have significant effect on his confidence, his self-esteem, and his self-confidence. Specifically, I worry that Harrison will fundamentally believe that he is sick and is less capable than other people around him.

Harrison is the most amazing little gift from God. He is compassionate, he is funny, he is thoughtful and curious, he is artistic, athletic, and spiritual, and most importantly, he is strong physically and emotionally and spiritually. We desperately want for the world around him to experience him because of these amazing traits and not through the lens of a physical difference caused by alopecia.

Again, we are so deeply grateful for your interest in this disease state and for inviting us to be here today. We believe God chose Harrison as a vehicle for change. He and we feel called to lend our voices to this fight against alopecia and all autoimmune disorders. Our armor is on, our words and swords are drawn, and we intend to win this war. Please join us in this battle.

Thank you so much for your time and your interest.

(Applause.)

MS. CHALASANI: Thank you, Sarah and Harrison.

Next we have Samantha.

MS. CUNNINGHAM: Hopefully I can get through this without crying. I definitely felt everything that Liz had to say, and I teared up when she was speaking. And it's difficult to explain 20 years (becomes emotional) -- I'm sorry -- it's difficult to explain 20 years of your life in 3 minutes.

MS. CHALASANI: Take a moment. It's okay.

MS. CUNNINGHAM: Sorry. My name is Samantha Cunningham. I'm a wife and mother to three beautiful little girls. I've had alopecia for 20 years. I started losing my hair at the age of 14. I was getting ready to graduate from the 8th grade and was attending the largest high school in Detroit, Michigan, over 5,000 kids in the high school.

My hair loss started in May with a penny-size, shiny spot in the back of my head. By July, I was completely bald. And by December, I had lost all of my eyebrows, lashes, and body hair. Over the last 20 years, I've never had complete regrowth. My eyebrows typically grow in every couple of years and stay in for a couple of months. And

I've only had regrowth on my head when I was pregnant, and that regrowth consisted of very fine white hair that I would consider peach fuzz, with no real length to it, and it would fall back out 6 to 8 weeks postpartum.

Over the last 20 years, I've dealt with a compromised immune system. I was never a sickly child before alopecia. Now no matter the amount of vitamins I take, I'm guaranteed to become sick if something is going around. I've been hospitalized several times for the flu, pneumonia, strep throat, and a variety of other things that may not cause hospitalization in a normal person. This affects my life because I'm not always able to spend the amount of time I would like to with my children.

Being diagnosed with alopecia at such a pivotal time in my life has definitely affected it. I withdrew from all of my elementary school friends. I spent that first summer in the house. I refused to leave. I cried myself to sleep at night. And I suffered from severe depression. I often hid in my house, in my own house, from people because when they would come to visit, I didn't have a wig on. I judge my relationships with people based on whether or not they know that I have alopecia. I have family members that I have distanced myself from because I couldn't explain what was happening to me.

I loved amusement parks, but I haven't been to one since I've lost my hair for fear that my wig will come off on a ride. My children have never been to an amusement park. I'm always mindful of outdoor activities and I often ride the sidelines over playing with my children. I also feel as though I cannot be seen as a professional at work if I don't have my wig on.

On my best days, I live a normal life, but on the worst, I'm severely depressed and my own worst critic over my appearance. What you have to understand is that often African American women are defined by their beauty, whether or not you are light-skinned or dark, whether you have good hair or bad, whether your hair is long or short, and although people may or may not believe in these things, society does. How does society define a 14-year-old girl that has lost her hair very quickly and has had no time to process it herself? My greatest fear is that my three beautiful daughters will one day lose their hair and Mommy won't be able to explain why.

MS. CHALASANI: Thank you.

(Applause.)

MS. CHALASANI: Thank you, Samantha. Thank you, Samantha.

Next, we actually have comments from Deirdre Nero. Deirdre is located in Miami, Florida. I'm not sure how many times she rescheduled her flight, but her latest rescheduling was trying to get her here by 11:30 a.m. Unfortunately, the airports are closed, and she wasn't able to join us in person. However, she did send us her comments, and so my colleague Sara Eggers will be reading on her behalf.

Just kind of hold it. Just hold it with you. Yeah.

DR. EGGERS: Again, my name is Sara Eggers, and I'm speaking on behalf of Deirdre Nero, and I'm reading her comments exactly.

"Hello. My name is Deirdre Nero. I'm an attorney and live in Miami, Florida. It has been 19 years since I first found the bald patch on my head that would completely change the course of my life. It was during my junior year of college while blow-drying my very thick long hair. Little did I know then that the significant impact alopecia areata would have on my life. I am now 40 years old, and I've been living with some form of this autoimmune disease for almost half my life.

"I started with alopecia areata patchy bald spots at age 21. For about 9 years, it was just patchy. Sometimes I had just one or two small patches, and then other times I had lots of patches and/or large patches. At age 30, I lost all the hair on my scalp, alopecia totalis. And at around age 35, I lost all of my hair everywhere on my body, alopecia universalis, including leg hair, arm hair, pubic hair, armpit hair, all scalp hair, nose hair, eyebrows, and eyelashes. I've had every single form of alopecia and experienced what they all were like.

"At times, my hair inexplicably started to grow back in a very patchy and random fashion on my head and parts of my body, only to fall out again for no apparent reason, a perfect example of the completely unpredictable course of this disease, which can cause significant emotional distress.

"I would not define my condition as well managed. Right now, I have zero hair on my body. For a time, I was able to keep eyebrows and some eyelashes by getting steroid injections directly into my eyebrows every 4 to 6 weeks and by using Latisse on my brows and lashes. About a year ago, it completely stopped working, and I lost all eyebrows and eyelashes.

"When I lost my eyebrows and eyelashes, I suffered the most. Your eyebrows and eyelashes not only protect your eyes, but they add character, definition, and expression to your face. Without eyebrows, your entire face changes and becomes unrecognizable. Not recognizing yourself in the mirror is a very difficult thing to deal with and causes an identity crisis. Having no lashes not only make your eyes look small and strange, but also cause problems, such as constant discomfort in the eyes. I always feel like I have sand or debris in my eyes.

"I also lost my nose hair and have a lot of issues with runny nose and sneezing. Taking allergy medicine every day does nothing to help this problem.

"This disease has changed me. It changed my life, my mind, and my heart. It made me weak and vulnerable, battered my self-esteem, and heightened my insecurities. As a woman, a lawyer, and a business owner, I strive to present a confident image to the outside world. I spent many years in constant fear of being discovered as a bald woman, fearing being thought of as sick, bizarre, ugly, or worse.

"I worry that I will always be like this and never be normal again. It is very difficult to live your life feeling different and abnormal. I worry that my partner will not find me attractive. I worry that if I ever have children I will pass this disease to them. I worry that if I do try medications, that they will have terrible side effects and I will get sick, and maybe they just won't work, and I will have spent a lot of money and gotten my hopes up.

"I don't like to swim, go to the beach, or do sports or exercise. Wearing a wig during these activities is pretty much impossible or at least uncomfortable. So in order to do these things, I must -- I need to be bald. Sweating is uncomfortable, as it pours directly into the eyes since I have no eyelashes or eyebrows. Being bald outdoors can be painful, especially since the head skin is very easily burned, even when wearing a lot of sunblock.

"As an adult woman, 40 years old, living with alopecia since 21, one of the most significant impacts has been on my love life and sexual and romantic relationships. Living in fear of being rejected, not found to be attractive, unfeminine, et cetera. I had a wig fall off during sex, which makes you not want to wear it at all, but then I've also had a man ask me to wear a wig for sex because without it, they don't find me sexually attractive.

"As you can imagine, it is devastating to experience and hear these things, and makes the entire prospect of having a healthy sexual relationship seem impossible and stress inducing. It is something we don't talk about much because it can be embarrassing, but it is such an important part of life for an otherwise healthy adult woman.

"This is a disease that not only alters the way you see yourself, but the way the outside world sees you and treats you. For me, it has been a constant battle. There hasn't been a day since I found that first patch 19 years ago that I have not wanted to scream or cry when looking in the mirror or thought that I am damaged, abnormal, unfeminine, or ugly because of my hair loss, not a single day that I haven't worried about how a client, colleague, friend, or love interest might see me and judge me.

"Many say to me that it is only hair or at least it's not cancer. These comments, while often well meaning, are insensitive and usually make me feel even worse. It is a disease that has a tremendous physical and emotional burden which is often not well understood by those who are not experiencing it themselves.

"I want to thank the FDA for giving the alopecia areata community the opportunity to discuss these burdens in this forum and hopefully help give the medical community a better understanding of what it means to be living with this disease."

On behalf of Deirdre Nero, thank you.

(Applause.)

MS. CHALASANI: And now we have Megha.

MS. THYAGARAJAN: So I wanted to start off by saying thank you guys so much for like choosing us and letting us talk about our story.

So I just want to ask some simple rhetorical questions. When you go to school or work, what do you do? Before you meet a person, what is something last minute you do? Before you step out of your car, what do you do? The answer to these simple questions is adjust your hair. Now, to say alopecia is not a big deal, well, then that's the funniest joke of 2017 because having alopecia is one of the best and worst experiences that a person can ever have.

My name is Megha Thyagarajan. I'm in 9th grade, 14 years old, and I've had alopecia since 1st grade. The only hair left on my head is, so to say, baby hair. It has a soft texture, and the amount of my hair is so very few, it's like a newborn's head. Even when I did have hair, it didn't grow past my shoulders. My mother shaved me once, but it never grew past that.

Now, many of you understand the emotional roller-coaster alopecia provides and the impact it gives to a person. I want to share with you my experience and what I personally went through.

When I got alopecia, I was around 6 years old, soon turning 7. Now, at a very young age, kids don't understand sensitivity. People always came up to me and yelled, "Are you a girl? Why don't you have hair? You look weird." Of course, at such a young age, I can't explain my condition, and their insults hurt. My best friend even dropped me with the words, "I don't want to be your friend because you're bald," and the way that hurt is unexplainable.

Without hair, the feeling different has always been there. I put up barriers refraining myself from coming close to my friends. I pretend like I'm the most confident person, but the simplest things hurt me.

I believe people regard me differently due to my hair, or the lack of hair, and that makes me feel terrible about myself. My personal relationships have always depended on the fact that I don't have hair.

Although after all that pain and emotional scars, I have never had the thought of wearing a wig. Wearing a wig has never been a solution to these ever-so-constant problems. My self-confidence has risen, yeah, and I couldn't care less what others think of me. I go to school with a wig that isn't combed and untidy once a year just to make fun. I make jokes about being bald on a constant basis.

Yeah, it has changed me as a person, and I'm describing that it can be good, but the amount of times I have thought about self-harm and just not existing in general is unexplainable. I blame so much things, such as my cockiness, how I'm irritating, annoying, to alopecia. I believe my personality has become different, and I wouldn't be the same without hair, so due to that fact I have many emotional conflicts with my hair. And many don't understand how hard it is to talk about it.

I'm frequently called a boy. I'm on the ski team. I was listed as the last girl. The professionals started asking my coach, "Are you sure this is a girl?"

And one other experience, I was in the bathroom, one woman came in, and she's like, "Is this the lady's room?" She saw my mother and then just shut her mouth and went to the stall. See, those are simple things, but they hurt me so much. It strikes me emotionally a lot and sometimes I can't handle the pain. So as I said, I've refrained from many things on an emotional level due to alopecia.

I stopped karate. I stopped so many different events because I had alopecia because I was so scared about how people would judge me. There have been times I've broken down and cried for hours and then wondering why I even deserve a life. But all-in-all, I try to surround myself with positivity so others can understand it isn't always miserable. For people with this condition, getting the right doctor and the right treatment is the key to a positive outlook.

My biggest worry is when I grow up and I dream about finding a person to spend my life with, go on adventures with, and just live as happily as my parents do, when I need a partner, that no one is going to find me attractive, and personality will mean nothing, as looks will always mean more. No matter my success, I won't be regarded as beautiful or pretty or even come close to that type of status. Recently, wearing makeup lets me have a fake exterior of nothing as ugly as I believe so.

This condition, even though I've never regarded it as something bad, I reason it will cost me so many things. The world is changing and beauty is becoming so important. My fear is that I will have to change who I am just unnaturally to be accepted, to hide my condition, as there is no cure, to wear wigs. Changing who I am is definitely something I don't want to do.

So if there is no cure, maybe the future holds hiding your true self is good for image, and I would never be myself again. Changing who I am is a worry greater than I could ever fear.

Overall, alopecia has a great impact on everyone, whether you have this condition or you live with someone who does. It changes who you are, whether people realize it or not. And a cure needs to be found because it's never something you should take lightly.

(Applause.)

MS. CHALASANI: Thank you, Megha.

And can we have one more round of applause for all of our Topic 1 panelists, please? Thank you.

(Applause.)

MS. CHALASANI: Thank you all, and to our panelists again.

So by a show of hands, how many of you heard your or your loved ones' experiences reflected by the comments that we heard today?

(Show of hands.)

MS. CHALASANI: Wow. For those of you that are on the Web, everyone's hands just went up. Great. Thank you guys so much again.

Large Group Facilitated Discussion: Topic 1

MS. CHALASANI: So to get us started with our afternoon discussion, I'd like to look at one polling question to get us started. The first one we're going to ask that the responses are provided by pediatric and young adult individuals with alopecia. A caregiver or family member can respond on behalf of an individual.

So what aspects of your alopecia areata are most bothersome to you? So for this question, please feel free to choose up to three answers: A, Patchy hair loss; B, Widespread hair loss; C, Location of my hair loss; D, Repeated episodes of hair loss and regrowth; E, Unpredictability of when or where hair loss will occur; F, Skin sensitivity, such as to sun, temperature, or sweat; G, Itching, burning, or stinging; H, Brittle, spotted, pitted, rough, or rigid nails; I, Other health effects that may be associated, such as thyroid disease.

We will ask the same question again for the adults in the room with alopecia, so feel free to start thinking now.

(Using clickers.)

MS. CHALASANI: Okay. Let's see. So we have 56 percent of you that said the most bothersome aspect of their alopecia is the widespread hair loss. Then we have 41 percent that said skin sensitivity, such as the sun, temperature, or sweat. That's very, very important for us to hear. Thirty-nine percent said unpredictability of when or where hair loss will occur. And then we have a nice range for all of the other aspects as well.

I would like to ask the same question of the adults now in the room, the same question, please.

So for the adults, what aspects of your alopecia areata are most bothersome to you?

(Using clickers.)

MS. CHALASANI: Okay. We have a nice range here as well. Similar to what we heard from the pediatric and young adults, 56 percent said the most bothersome is the widespread hair loss. And then once again similar to what we heard from the younger folks in the audience, we have 53 percent that mentioned skin sensitivity to sun, temperature -- such as sun, temperature, sweat as being the most bothersome. After that, we have 42 percent for location of hair loss as well. And then a nice range as well. Very interesting. Thank you. Thank you all for participating.

So I'd like to spend some time expanding upon what we heard from our panelists. All of them, especially Deirdre, talked about her patchy hair loss. Is there anyone in the audience that would like to kind of speak a little bit more about this aspect and how it's most bothersome to you?

DOUG: Should I stand? Is it on? Okay. Thanks for bearing with me here. Doug is the first name.

MS. CHALASANI: Thank you.

DOUG: I came here from Denver, Colorado, for this meeting.

MS. CHALASANI: Welcome, Doug.

DOUG: So I will just say just a couple things. I've had the condition for 9 years. It's resulted in the loss of a marriage, my career, and two of my family members no longer speak to me.

There has been a personality change. It was an appearance change.

So the National Cancer Institute says 39 percent of the population will have cancer in their lifetime. There are hundreds of FDA-approved cancer treatments. There are zero approved FDA treatments for alopecia. So a little tough love for the drug companies and the folks that have a nice job and a pension is that this is more than statistics, this is lives. And friends ask me why I don't fix it. I say there's no money in it. We're in no person's land. There's no money in alopecia treatments for -- and it's a business. So I would say maybe an alopecia XPRIZE or some type of contest may start invoking some interest and maybe a curious new approach to a therapy.

So sorry to be a little stinging in the comments, but I think, you know, this is a challenge to really make a direct connection. And charts and statistics and things are fine, but if you're experiencing it, it just seems like another day to exercise.

But thank you very much. I appreciate it.

MS. CHALASANI: Thank you. Thank you. I do want to highlight that this is not a scientific survey, it's just meant as a discussion tool, mostly just to help me ask you the right questions.

A couple more comments on the patchy hair loss. I think we have, oh, one right here.

DANIELLE: Hi. My name is Danielle. And what's your name?

CONNELLY (ph): Connelly.

DANIELLE: We are from Arlington, Virginia. And I actually have two sons that have alopecia. Connelly was 3 when he was diagnosed. And I have one at home who is currently 3, and he was 2 when he was diagnosed. And both of them have alopecia areata. And I want to echo what Sarah and Harrison have experienced here.

And I want to say that watching your child go through alopecia is one of the hardest things you'll ever go through. And I don't want to cry in front of my kid, but it tears you apart watching your son get in the bathtub and the hair just come out and fill the water and it go down the drain, and you can't do anything about it.

And you go to the doctor, and you look for a solution, and they say try vitamins, change the diet, try an injection. We don't want an injection. I don't want to put something in my child's head that's going to hurt him. I don't want to give him a vitamin. I want something that he can take and will actually stop the hair loss, but not stop his growth.

And I want to do something for him that's going to help him in the long term and be something that's not going to be something that he's going to have to do for the rest of his life. And I want something that's really going to be able to make a difference in his life without being a long-term solution that he's going to have to take every day.

So that's all I wanted to say.

MS. CHALASANI: Thank you. Thank you. That's really important. And we will spending a lot more time in the second half during the topic, too, hearing from you all, what you really want, and what would be really meaningful in regards to treatment options.

One more comment on the hair loss?

JULIE: Hi. My name is Julie. My hair fell out when I was 11, and it's come out -- come and gone for years, but mostly gone. And it's been all over my body. I look around and I see all of these beautiful bald heads today, and I just -- (becomes emotional) -- I actually -- I'm really jealous because I wish it was all gone. I wish every hair on my body would leave and that I wouldn't have to constantly manage my hair because it's, you know, the mole hair, the chin hair, but nothing else, you know.

And it affects relationships. You know, I don't have romantic relationships because I'm concerned about, "What is he going to think?" I don't wish to -- you know, I have -- he has to be something special to even think about it, but I'm generally it's not worth the effort. And generally I don't think about it because it's -- I have way more important fish to fry, you know? And it's just hair and you put it -- you know, you bury it deep, right? But the patchy hair loss is a major issue.

MS. CHALASANI: Thank you, Julie. I think you raise a very important point, that we actually read a lot in the comment summaries that you shared with us. So I'm going to ask for a show of hands for those in the room, how many of you, when you experience your patchy hair loss, your preference would almost be that it would just all be gone, as Julie said? It's better to have it all or nothing?

(Show of hands.)

MS. CHALASANI: Okay. Wow. For those on the Web, I want to say around 50 hands went up really quickly. Okay.

Thank you so much for that, Julie. Thank you.

Could we hear from folks a little bit about the skin sensitivity, such as to sun, temperature, or sweat? I know Sarah spoke about Harrison's experiences. A couple in the back.

MIA: Hi. My name is Mia. My mom and I, we came from Midlothian, Texas, today. And I am currently a junior in high school, and I'm in the marching band, and it's -- sorry -- at the beginning of marching season, I was expecting the summer to be really, really hot, and so we were trying to prepare for that. And so we stocked up on sunscreen and hats, which are very, very annoying to me. I don't like having a hat on my head, especially when I'm doing something that requires -- or something athletic to where I'm sweating because then it gets really irritating and it rubs against, and it's just annoying to me.

But I noticed recently with football season starting, whenever we go out to perform in our marching show during halftime, the hats that we have to wear, they don't stay on my head because of the sheer amount of sweat that comes out because I don't have anything to like hold it in. And it gets into my eyes and just that's a really big thing for me, is that I can't do some of these things because I can't go swimming. And I have like a swim cap, you know, like Olympic swimmers have to use, so that way like my head doesn't get burned in the water. And so that's just something that's really important to me.

MS. CHALASANI: Thank you. Thank you.

I think we have one comment here.

MARIA: Hi, there. I'm Maria. I live in Delray Beach, Florida. Also a member of the Board of the National Alopecia Areata Foundation. So that's, I guess, my full disclosure.

I have patchy alopecia. I've had it since I was 14, so I can certainly relate to many of the comments that were made. As far as the skin issues, that's one of my biggest issues beyond the hair loss, is I have extremely sensitive skin to the sun, to fragrances. It started probably when I was early twenties, I had eczema very severely, and over time, I've been able to kind of keep that under control, but I am extremely sensitive to the sun to the point -- and it's unfortunate because I live in Florida -- but I do have to be very careful to wear a sunscreen of SPF 70 and above. My preference is 100. But I also do break out, you know, from fragrance in lotions or, you know, detergents, or even soaps, I have to be very careful. So it's just something I definitely attribute to the alopecia.

MS. CHALASANI: Thank you, Maria.

Do we have -- we'll take one more comment here. Sure, two.

MR. FLINT: My name is Bob. And along with a full disclosure, I am the chair --

MS. CHALASANI: A little closer to your -- just hold it up a little closer.

MR. FLINT: Oh. I'm the chair of the board for the National Alopecia Areata Foundation. And I have had alopecia areata universalis since I was 3. And I won't tell you how many years ago that was, but it's more than 60.

In my childhood and young adulthood and even later than that, I was foolish enough not to think that I would ever have sun-damaged skin. I now go to my dermatologist twice a year and he freezes sun-damaged spots off my head. You might notice that I have a number of obvious ones that he just treated last week coincidentally. I think there were 12. I think inevitably I will have skin cancer because I don't think you can get all of it off. I've damaged too much over the years. And it's something I never thought about, nor my parents ever thought about, but it is something for all of us to think about with our kids.

And one second comment just very quickly. I've heard it said twice. (Becomes emotional.) My biggest fear as a parent is I'm going to pass this on to my children, and that really hurts. Thank you.

MS. CHALASANI: Thank you, Bob. Thank you.

And I think we're taking one more comment from right behind Bob.

CHERYL: Hi. Cheryl. I'm from Northern Virginia. And full disclosure, I work very closely with the National Alopecia Areata Foundation. So skin sensitivity. My skin is very sensitive. I work with the Virginia Renaissance Fair, and we're outside in May and June when the sun is very bright and beats, and I get burned probably -- I try not to get burnt really well. I have a really big hat, a really, really big hat, that I wear. But hats are very important.

And I really like hats, I really like wearing hats, because I can change the hat to go with my outfit. I can accessorize with the hat. But it is sometimes annoying that I have to think about, "Oh, do I have a hat to wear today? Did I remember to pack my hat?" if I stay the night somewhere. I used to travel for work. Did I remember my hat? Do I have to go find a store to buy a hat? Did I remember my sunscreen? Did I remember my lotion? Because I'm very sensitive to different types of lotions, and I will break out, like Maria said. So that's my two cents.

MS. CHALASANI: Thank you, Cheryl. Thank you.

I do want to ask really quickly, for the 23 percent of you that mentioned other health effects that may be associated with their alopecia, would you mind sharing what those health effects may be? I think we have a few hands that went up.

MARGARET: Hi. Margaret. I'm from Niskayuna, New York. And I've had alopecia for 71 years. I got it when I was about 18 months old. And I really am concerned about the connection between thyroid disease, Hashimoto's syndrome, which I've had also since I was a child, and alopecia, because my son, who also has alopecia universalis, has had Hashimoto's since he was 10. At least that's when it was diagnosed. And I just feel there's a really strong connection there.

And it would be great because I can get autoimmune blood tests for my thyroid, I've never had one for the alopecia, but I know my thyroid antibodies are through the roof, and when I do certain things, they come down. Like I'm seeing a functional doctor now, and I've seen online a bunch of parents are putting their kids on gluten-free diets and their numbers are coming down.

So it's like I'd love to know if anybody is working on that connection because I really think there's -- for people like me, it's a strong connection. I had the patchy alopecia until I was 18, and then during a stressful time in my life, bang, it was gone, it was all gone. And it was really, really hard, I can relate to everything everybody said.

And when my son was 10 and got a spot -- you know, my other issue is doctors and how they relate to us because they have no information, they have no good information, and they don't get training, and what do you do when you've got a disease with no cure? And they say things like, "Well, what do you expect? That's who he's got for a mother." That's what they said to me.

And I read the other day somebody told -- some doctor told a woman that her child's hair is just going to grow back, so don't worry about it. And all of us who have children with alopecia know, "Lots of luck, lady. What are the odds of that?" So those are kind of my issues. And I really appreciate what you're doing here today.

MS. CHALASANI: Thank you. Thank you. And some of the comments that we heard, we did hear some frustration with the diagnosis process and the lack of knowledge in the medical community, and this meeting is a platform that we can help communicate a little bit more about alopecia areata.

Other comments on the other health effects, something other than thyroid disease possibly?

Jennifer here.

JENNIFER: Hi. I'm Jennifer. And I've had alopecia areata since I was 29. I'm 32 now. Some of the health concerns that I've seen from several dermatologists that I've visited have said that a couple of conditions that I have may have affected my alopecia. I have celiac disease, and they have said that they are little studied, but some have said there's a connection.

I also have endometriosis, and they have said that there is a connection possibly there.

And I'm also deaf. And they have said there's probably a connection there.

But also wearing a wig and a cap is really hard because it makes (inaudible), it gives me a headache, and it's hard to even wear a wig because it sort of bunches up behind my head. I really have no choice. So, yeah.

MS. CHALASANI: Thank you, Jennifer. Thank you.

I want to encourage all of -- we do have to move on from this question to another question, but I do want to encourage all of you to expand on everything that we've heard today here in the public docket comments, as we've mentioned. Please encourage participation on the docket.

Okay. So our next question, and we're going to do it in a similar format, we're going to ask to hear from the pediatric and young adult folks first.

What do you find to be the most bothersome impacts of your alopecia areata on your daily life? Please choose up to three answers. A, Time or cost of daily maintenance; B, Refraining from activities, such as school, work, sports, or social activities; C, Self-consciousness or embarrassment; D, Bullying or discrimination; E, impact on relationships with family and friends; F, impact on intimate relationships; G, Physical impacts, such as pain or difficulty concentrating; H, Emotional or psychological impacts, such as anxiety, fear, depression; or, I, Other impacts not mentioned.

(Using clickers.)

MS. CHALASANI: Okay. So we have an overwhelming majority, 81 percent, who selected that the most bothersome impact is the emotional or psychological impacts, followed by 67 percent who said self-consciousness or embarrassment. In the forties, we have refraining from activities, such as school, work, sports, or social activities, as well as bullying or discrimination. And then we have a nice range in all of the other options as well.

I'd like to ask the adults in the room the same question now. Once again, what do you find to be the most bothersome impacts of alopecia areata on your daily life? And you can choose up to three answers for this question.

(Using clickers.)

MS. CHALASANI: Okay. Some similarity. Also in the 80 percent we have H, which is the emotional or psychological impacts, such as anxiety, fear, or depression; followed by self-consciousness or embarrassment. Thirty-seven percent for both refraining from activities as well as for impact on intimate relationships, which I think is understandable.

I'd like to ask folks in the room to expand a little bit on the emotional or psychological impacts. If you feel comfortable doing so, I think I'd like to hear a little bit from the pediatric or young adults’ perspective first, and then we'll follow with adults. So it's okay, I see a hand right there.

CALLIE (ph): Hi. I'm Callie. I am 28 years old, and I have had alopecia universalis since I was 18 months old. This is actually the first time I've ever really met anybody else with alopecia. As a kid, I can't even begin to describe the impact that it had on me growing up, the amount of bullying and torment I faced, and I still deal with a lot of anxiety and depression. (Becomes emotional.) You know, it's just -- it's like indescribable, the amount of torment you face as a child especially, but even as an adult. And you get it from other children, other adults. That's about it.

MS. CHALASANI: Thank you. That's a very important point. Thank you for sharing.

In the back. Sara, I think we also have -- go ahead. Thank you.

UNIDENTIFIED: Hi again. So being in high school right now, I'm pretty fortunate that I live in a town where it's like a small town, so I kind of know a lot of people. And I have a really good support system, like my friends and my family are amazing. And I just know that, for instance, a couple of weeks ago we had our first day of school, and just -- I just remember sitting in my room and like dreading it because I was like, great, I've got to go meet new people again. I have new teachers who don't know what's going on. So I know that for me personally, that's a big thing.

And going out in public -- I told my mom this a while ago -- but it's like you've got to mentally prepare yourself for people to stare at you. Before I lost my hair, I had people stare at me because I am mixed, and so my parents aren't the same race, and so people stared at me because of that, because I had like long curly hair. So people stared at me because of that. So I was used to people staring, but not having hair now, it's a different kind of staring.

And I find it funny with children. I find children like hilarious when they see me in stores because they're like, "Wait a minute, she doesn't have hair," and it's like, "No, no, I don't." And trying to explain that to a child, it's just I find children hilarious in stores.

But just emotional effect on me personally, like I couldn't imagine going to a different school and being new and not knowing anybody at all who doesn't know what's going on in your life. So for me, that's a big part of it.

MS. CHALASANI: Thank you. Thank you for sharing that. I think we have over here.

SANGUITA (ph): Hi. My name is Sanguita. I'm Megha's mom. As Megha said, she got alopecia when she was in her first grade. It was kind of very difficult for us coming from India. When I heard that she had alopecia, the first thing that I did is, "Oh, I'm in America, I have all the treatments available." And I went about searching about it. And also it was a lot of turmoil for me to go through as a mom what the child is going through. And I didn't know that there is no cure.

And so as soon as I found there is no cure, the first thing I did is I stopped all the activities for her because I didn't know what is going to be affecting it. And the next thing I did is me and her teacher, Mrs. Alexando (ph), we worked with her to counsel her to be a very strong person emotionally and psychologically in the sense that never get depressed or never do anything, be a go-getter, forget about anything in life. You are what you are, and made her strong. Even though I know she is strong, there's always a part of her which suffers. I mean, the psychological thing, the first time I went to the NAAF conference in Los Angeles is when I saw all the kids in the swimming pool, everybody bald, I knew I'm not alone.

(Laughter.)

(Applause.)

MS. CHALASANI: Thank you, Sanguita.

I'd like to hear a little bit about -- oh, I see Sara. Maybe we'll take one more. Okay.

BECCA (ph): Hi. I'm Becca. I'm 14 years old, and I just started my first year of high school, so I'm a freshman. It's hard to wake up and have to go to school every day because you know you're different. And I play sports. I play volleyball and basketball, and even just walking onto the court -- like going to school, I have my makeup, and I feel just a tad bit more beautiful, but still I feel like I'm hiding myself from everyone. And I can't wear my makeup on the court. So I automatically feel ugly and secluded. So it's scary just to walk out and practice. And for games, it's even worse because the whole school is there and they see me without eyebrows and eyelashes. And I wear hats, but those are very hot, and I get extremely sweaty. And I have really bad heat waves on the court which affects how I play.

And I just every day -- there isn't a day that goes by that I don't wish I had my hair again because I felt extremely confident with it. It was beautiful curly brown hair, and I loved it. And I just wish I had it back because it helps me, it would help me every day just to go to school and to play sports. So thank you.

MS. CHALASANI: Thank you, Becca. You are beautiful.

(Applause.)

MS. CHALASANI: I'd like to ask the adults in the room now a little bit about their emotional or psychological impacts. And I'll ask you to keep one question in mind, which is, How have the impacts changed as you've gotten older? For example, has an impact become more bothersome as you've grown older or maybe less bothersome as you've grown older? I think we have --

MIRANDA: Hi. I'm Miranda. I have had patchy alopecia areata since I was 5. I do find that the issues I deal with as I've aged change, although I still -- I used to get haircuts, well, until I was about 8, and as a young adult, I know I have two sisters, and they both have brown hair, and so I noticed I was definitely very depressed. I was very hard on myself. I don't know, I think it's also part of the personality.

But I know I was -- my parents are very supportive, but I isolated myself a lot. Actually, I know I suffered a lot with body image issues. And I was actually hospitalized for anorexia for a couple of years. And that definitely was a very low point that I don't think I would have had if I was maybe more confident as a young adult and didn't face like, you know, kids picking on me, but -- and which also affected my family because parents have to treat you and take you to -- you know, back and forth and visit you.

But as an adult, I'm working actually in Bethesda actually in health research, and I found that I've accepted my condition a lot more. I do find that the wigs have made me more confident. I definitely don't go in public without one, or not to National Alopecia Areata Foundation event. I do a lot of volunteering with them because up until I was out of college, I avoided even the foundation because I didn't want to face other people who were upset.

And the wig has been very helpful for me. I have become very confident, but I do -- like, you know, you cry a lot with this disease. Thank you.

MS. CHALASANI: Thank you. Thank you for sharing.

Do we have -- oh, lots of hands. I'm going to let Pujita pick one.

JULIE: Okay. I'm going to try not to cry this time. Again, I'm Julie. The thing that --

you asked the question specifically, what's changed from when you were young to where you're an adult, and -- well, first of all, you know, like I've done a lot of personal growth, and what I've realized is that the emotional and psychological issues are not external. You know, like it actually comes from my immune system, and it -- you know, like, as human beings, we tend to think that what we are thinking has something to do with what's going on around us in our environment. And then when you have reactions to life that have nothing to do with your environment, you have to question it.

Research is now proving my point. You know, there's lots of new research that's coming out that's showing that the immune system is actually responsible for behavioral issues and behavioral side effects of health issues. And when you have chronic anxiety and chronic depression and you have chronic aggression, and you have these things, they actually come from the immune system.

And what I'm most afraid of about standing here in front of the FDA and talking and having all of us talk is that we're going to miss the point. This is not the hair disease. I'm afraid that we're going to sit here and we're going to talk about the symptoms of having no hair. I don't care if I have hair or not. Honestly, what I care about is that my immune system is fixed. I care that I'm not sick anymore.

And I think that, you know, like, yes, did I get bullied when I was a little kid? Sure, I did. It also made me the most confident person in the room because I was stronger than that, and I wasn't going to let my hair stop me. But, you know, like that's not the point. The point is, is that we need research and solutions for an immune problem. And I literally 5 years ago was so sick that I couldn't stand up. (Becomes emotional.) Okay, I'm going to cry.

MS. CHALASANI: Thank you, Julie.

JULIE: And I saved myself. Not one damn doctor did that for me, not the FDA, not a doctor, not a drug company. I saved myself. I stopped eating gluten, I stopped eating tomatoes. I found the drugs, I found the supplements, and the things that were going to change my life, and I did it. And I can't point the finger to anybody else that did that for me. So that's -- that's -- now I'm --

(Laughter.)

MS. CHALASANI: Thank you, Julie.

JULIE: And I'm very grateful for this panel, and I'm very grateful for the opportunity and the willingness of the industry to turn this around. So --

MS. CHALASANI: Thank you. Thank you, Julie.

We are cutting really close to our break time, so I'm going to quickly turn to Graham and Shannon and see what our webcast responses have been like. Similar to what we've heard in the room? Anything different?

MS. WOODWARD: So for the previous question, we did have some comments in regard to asthma, also experiencing allergies associated with food, and new episodes of patchy hair loss that specifically occur when getting sick.

For impacts, a lot of people discussed societal perceptions. One caregiver discussed her daughter being referred to as a boy on numerous occasions. Also depression and anxiety were mentioned as well. A lot of adults mentioned anxiety with meeting new people and workplace discrimination and how there's been a shift in them caring more about how their peers feel about them versus their perception at work as they've gotten older.

MS. CHALASANI: Thank you, Shannon.

I'm going to turn to my FDA colleagues here. Any follow-up questions at this point?

(No audible response.)

MS. CHALASANI: No? Okay. Once again, I just want to do a quick plug-in for the docket comment reminder. I think we've barely scratched the surface as far as the daily impacts and what you guys experience day-to-day. So please go to the public docket and expand on what you've shared so far.

And quickly before we go to break, I have a couple of points I'd like to make. One is that some of the topics that we're talking about today are sensitive, and one of the topics that we've heard and may continue to hear about is self-harm or suicide ideation. We want to remind you to seek any help if you need it. We have the information for the National Suicide Prevention Lifeline up here on a slide, and we just want to put that out there.

And one other announcement is the National Alopecia Areata Foundation has a couple of photographers here. And we didn't really allow them to come all the way up to the front because we didn't want to disturb the meeting while we were proceeding, but if you're comfortable being in a photograph, they've asked that you kind of stay on the panel and where you are during the break, and then the photographer will be able to come up and take a picture. But it's at your discretion. If you don't feel comfortable doing so, you're more than welcome to take your break.

And we'll see you guys back at 3:00 p.m. And if you are planning to get lunch, feel free to bring it into the room. This is a very relaxed, informal setting.

Thank you.

(Break.)

Panel #2 Discussion on Topic 2:

Current Approaches to Treatment

MS. CHALASANI: Hello, everyone. I think we're going to get started, if everyone could start taking a seat, please. And for those of you trickling in with food, please feel free to munch away.

Okay. So our Topic 2 Discussion is going to focus on current treatment options and ideal treatments for alopecia. Similar to how we had our Topic 1 discussion, we're going to have five Topic 2 panelists kick off our discussion.

So I'm going to let Katie get started.

MS. KRUEGER: Hi. I'm Katie. And I am one of the millions of victims of alopecia. When I was just 10 years old, I was diagnosed with alopecia areata. I began my long road of treatments with a prescribed topical that I used for about 6 months. Following the topical, I began receiving dozens of corticosteroid injections in my scalp every month for 9 months.

As my condition progressed and became alopecia totalis, I found myself willing to give it one more shot. So my mom found a specialist in Chapel Hill, and as a last resort, I began on folic acid, methotrexate, and prednisone. However, the methotrexate caused me to be constantly sick, and the prednisone made me tired and lacking energy.

For the 3 months that I was on the prednisone, I dragged myself around and slept as much as I could. The 6 months total that I was taking the methotrexate, I was constantly sick and drowsy. This began to affect not only my sports and social life, but my schoolwork as well. I began to think that all of these treatments and their coexisting side effects were simply not worth the slim possibility that one day I might retain some hair growth.

Throughout this journey, my parents have been my backbone and outlet of unending support. While they were always there to hold my hand, at the end of the day, they made it quite clear that decisions pertaining to my treatment were ultimately my decision. This experience has forced me to grow up faster than most kids my age. However, it has allowed me to inspire others and impact their lives in ways that I couldn't have if lived a normal teenage life.

I won't sit here and lie to you all, though. Being a teenager without hair is no cakewalk. While it has been a truly humbling experience, I would give anything to get my hair back. Today I use an over-the-counter topical called Rogaine and essential oils. I also wear a wig. An ideal treatment for my lifestyle would consist of something you can do at home, preferably a pill with limited doctor visits so I don't have to miss too much school.

My hope is that one day there will be an easily accessible treatment that will result in a well-managed condition. I've never known my condition to be well managed, so to speak. Alopecia is an unpredictable disease. One can never know or predict the extent of its future harm or doings. I live every day with slight hope of a miracle while also fearing its progression to universalis.

I miss the carefree lifestyle that I once lived. I used to wake up every morning, look in the mirror, and not think twice about the fact that I had hair. Everyone I knew had hair, so what made it so special? Well, it was very much so when I began to lose it all. You never truly know what you have until it’s gone. One morning I had hair, and the next, I was watching it all fall out. This may seem to many as no more than a superficial cosmetic issue. However, I can assure them that they would not think the same if it were them in the state of vulnerability.

So as my time comes to a close, I hope that I made somewhat of a difference in all of your perspectives going forward. While a mere 3 minutes is not even close to enough time to explain the hardships that people with alopecia endure, I sincerely hope that you are all able to get a glimpse of the importance of this disease.

MS. CHALASANI: Thank you, Katie.

(Applause.)

MS. CHALASANI: And we have Katie again.

KATIE: Hello. My name is also Katie. And I am a senior at West Valley High School in Yakima, Washington.

Two months after my 13th birthday in early March of 2013, I began to notice my initial hair loss in the shower after soccer practice. My first visit to my local dermatologist resulted in about 50 cortisone shots in my head and many tears. I also visited my local naturopath and started a gluten-free, dairy-free, and sugar-free diet, as my mom did some research and found that in some cases a clean diet can help encourage regrowth. However, this wasn't the answer for me.

As amazing as my local doctors are, they couldn't give me the answers I so desperately needed, as I was in a race against time trying to stop my rapid hair loss. During the summer going into my 8th grade year, my family traveled to Seattle to seek treatment from a doctor at Children's Hospital. She then diagnosed me with alopecia areata, with no treatment plan currently in place that works for all patients.

In August, as I was gearing up to start school, my mom, nana, and I went and traveled again to Seattle in search of a wig. I took the first month off of school, quit soccer, and began wearing my wig. I was reluctantly adjusting to my new normal and the new looks my peers gave me as they walked past me in the halls.

Going through my 8th grade year, I continued the steroid shots along with multiple different types of vitamins. I traveled to Oregon to seek different opinions from doctors connected to OHSU, but he could not offer me any new advice.

In November, my family found a different doctor over in Seattle, claiming he had the latest technology to cure hair loss, and agreed to try to the treatment on me. The treatment, called PRP, is commonly used for male pattern baldness, but at this point in time I was willing to try anything to get my hair back. The treatment consisted of drawing blood, spinning it with nutrients, and then inserting 250 numbing shots around a certain area of my scalp and ending in 200 deep-tissue shots with the new blood. I chose to receive this treatment twice.

After no results, we headed back to the drawing board and eventually found out that I was anemic, which is the lack of iron. My family thought that this could possibly give us some sort of relief, as I had maybe 150 hairs still left on my head. I received treatment from my local naturopath, who prescribed me iron infusions weekly. Eight weeks later, I was bursting with energy, but unfortunately still without regrowth.

We hit our rock bottom both physically and mentally during the summer of 2014, headed into my freshman year of high school. My dad booked a family trip to the beautiful Rochester, Minnesota, where I visited the well-respected Mayo Clinic. We thought they could give us the type of answers we needed, but after multiple exams, I was prescribed methotrexate, a form of chemotherapy.

When first hearing of this, my parents were very reluctant to put a 14-year-old girl on something as invasive as this, but we were left with no other options. Oral pills ended up hurting my stomach horribly, so a month in, we switched to injections, which my mom was kind and brave enough to give me weekly. A year into the treatment, I had maybe a fourth of an inch growth scattered around my head, but in May of 2015, my dad came in contact with Dr. King in hopes of getting me on a new breakthrough drug.

In July, my dad and I made the wonderful journey to New Haven, Connecticut, where I was prescribed Xeljanz. Two months later, we traveled back to visit Dr. King for a checkup with new regrowth of 1-1/2 inches. It seemed as if my body had all of a sudden knew how to produce hair again and was growing rapidly.

The following March, less than a year later, we traveled back to Seattle, but this time with an appointment scheduled to get my extensions. Xeljanz freed me from the prison chains of my wig and gave me a chance to live like a normal teenager. I can now attend sleepovers and swim parties, I can now walk outside without the fear of it being so windy, it could catch my wig and pull it off.

Although I did not regain my passion for soccer, I am currently a cheerleader at my local high school during my senior year and now can finally feel normal again. It took have a dozen treatments to find a key, but I am forever grateful for each step of this journey.

Thank you.

MS. CHALASANI: Thank you, Katie.

(Applause.)

MS. CHALASANI: And now we have Tyrone.

MR. FOLLIARD-OLSON: Hello. My name is Tyrone Folliard-Olson, and I'm a husband and new father in Minneapolis, Minnesota. I have had alopecia areata since I was 13 years old, so for the past 20 years. I've been an advocate for the alopecia areata community since 2013, when the National Alopecia Areata Foundation created the Legislative Liaison Program.

My bald spots started out small and sporadic and shifted around my head, but I was able to cover them with hair. In my early twenties, they became larger and more static, and at 23, my bald spots became so large that I had little choice but to shave my head. Over the next 2 years, I lost my eyelashes and eyebrows.

I only receive treatment for my eyebrows. I don't treat my scalp because of the large surface area that would require treatment and because of the lack of a reasonable treatment, and I don't treat my eyelashes because I'm not aware of any effective treatments. As funny as it may sound, I also miss my facial hair very much, but alopecia makes that impossible, and as the token male, I thought I would say that.

(Laughter.)

MR. FOLLIARD-OLSON: In an ideal world, I would be able to fully regrow my scalp hair, eyebrows, eyelashes, and facial hair. That is what the phrase "well-managed" means to me, full hair regrowth. As such, I do not feel as though my alopecia areata is anywhere near well-managed.

Throughout my teenage years, as we've heard, I also took multiple treatment options for my bald spots on my scalp, including steroid injections and topical creams. The injections, hundreds at a time sometimes, were incredibly painful, but neither the injections nor the creams did much to combat my alopecia. At most, these treatment options stimulated peach fuzz over a period of many months, which was nowhere near the outcome that I was seeking. Over time, I stopped using any treatment, as they were not effective and the injections were not worth the pain. The natural ebb and flow of my alopecia did far more to regrow hair than either of these treatments.

At 23, as my bald spots became unmanageably large, I came to terms with shaving my head and being bald. I had the luxury of being a man in a society that deems this aspect acceptable, so luckily it wasn't too difficult to transition.

However, when I lost my eyebrows, I was devastated. For me, I saw my eyebrows as the last defining feature on my otherwise bald head. After a couple of years of struggling with no eyebrows, I happened upon a treatment option through an old acquaintance, and I began receiving monthly Kenalog injections in my eyebrows. I have since received eyebrow injections every month for the past 8 years.

These injections work moderately well. On average, the injections allow me approximately 75 percent of my eyebrows, although my eyebrow hair continues to fall out and regrow in unexpected patterns. I continue to have patchy eyebrows, which for me is far from ideal.

The injections are quite painful. The monthly dermatology appointments are an inconvenience, and without good health insurance, I likely wouldn't be able to afford the monthly injections, but for me, all of that is worth it in order to maintain some semblance of eyebrows. As a side note, my eyebrows are currently more full than they've been in years.

My hope is to one day have the ability to regrow and maintain hair that is lost in an effective, painless, inexpensive, and relatively quick manner. I hope to one day to have eyebrows, eyelashes, and facial hair.

Thank you.

(Applause.)

MS. CHALASANI: Thank you, Tyrone.

And now Andrea.

MS. ALBERTI: Hello. So I have had alopecia areata in some form as a result of my autoimmune disease since I was about 4 years old. Most of my childhood, it was just alopecia areata, and at the time, I was lucky to have thick curly hair to hide most of the spots. And with the spots that we couldn't hide, me and my mother slowly worked down the line of topical treatments that were offered by our dermatologists. First it was Rogaine, and then on to ascorbic acid. And once I got to middle school, it was leaving class every month to drive to the Cleveland Clinic -- (becomes emotional) -- excuse me -- to get corticosteroid injections.

Did any of these treatments actually work? They may have for a time, but, really, what's the point of treating a spot you have when it does nothing to prevent the spot that comes next? It feels like a game of cat-and-mouse that we are constantly playing until it got too hard to keep up.

By the time I was 14, I had lost nearly all my hair, and hiding it was no longer an option. At this point, we treated in topical treatments for an internist, a long list of supplements, a thyroid medication, highly restrictive diet, and, of course, antidepressants. And I say "of course" because the mental health effects of alopecia I had on me were more detrimental than the alopecia itself.

I cannot express to you how much developing alopecia totalis delivered a blow to my self-esteem, my self-image, and my ability to focus on schoolwork as a teen. Even as an adult, it has had a fundamental effect on my personality and the way I carry myself in public.

Over the course of my youth, I have gone to multiple dermatologists, holistic doctors, endocrinologists, internists, therapists, and others I can't even remember. All of them had different methods of treatments, but, frankly, it seems like the method was to throw any idea they had at the wall and to see what would stick, and nothing ever really did. Any hair that may have grown would eventually just fall out again after a couple of months.

By the time I started high school, wearing a wig was the only real solution we had left. There was no more managing my alopecia. As far as I'm concerned, you cannot alopecia any more than you can manage the weather, and all you can do is prepare for it.

Looking back, treating my alopecia with

topical treatments feels like a total waste of time to me. At least with a wig, I know it's going to be there every day. Am I happy about this solution? Not at all. Wearing a wig has its own laundry list of issues and inefficiencies that I could list here as well, so many, in fact, that it had actually compelled me to produce a documentary about it, which my sisters are currently filming for me as we speak.

But at the end of the day, I believe the only treatments that I would even consider using are ones that treat the autoimmune cause of alopecia, not just the effects of it. Everything else is just a Band-aid.

MS. CHALASANI: Thank you, Andrea.

(Applause.)

MS. CHALASANI: And now we have Gracielle.

MS. PALMA: I already cried so much today, I thought I wouldn't cry anymore when my time came, but I don't think that's going to happen. And I was very afraid to be the first, but now I see I'm even more to be the last one. (Becomes emotional.)

So I want to thank everybody first because I think everybody that came before me today couldn't have talked any better and expressed everything that I felt. I'm newly married. I married in February. My husband is here, and I think that it's going to be the first time he truly can understand and feel what it is (inaudible) issue because I was never able to express and tell him in truly words how it is.

So my name is Gracielle Palma. I'm 37 years old and I'm from Brazil. And I was first diagnosed with alopecia when I was 17 years old. Over the years, I tried to keep the alopecia under control with a variety of treatments, and today I will try to summarize a little bit of all I went through throughout those years.

So as probably the majority of you, my treatment was the topical minoxidil. It was very mild, pretty much no side effects, but it didn't work very long. After minoxidil stopped working, my doctor at the time prescribed adrenaline. It was a dark brown substance. It would stain everything, leave my skin very sensitive, and my clothes and my pillows, it was all ruined.

When adrenaline become ineffective, my doctor decided to try cortisone injections. Once a month, I would go to the doctor's office and had countless injections in my head. Needless to say, it was not pleasant.

After a while, the cortisone injection also stopped working, and the doctor had the great idea to combine the cortisone injections with liquid nitrogen cryotherapy. So every month, after the 100 self-injections in my scalp, the doctor would apply the subzero liquid nitrogen on top of it on my scalp.

The only way I can describe, it was torture. The liquid would burn my skin that was already hurting from the injections, and would leave the skin like with many blisters after that. The 20 hours after the treatment was horrible. I couldn't barely sleep because I couldn't lie my head on the pillow. When the skin started to heal, it would itch constantly, and the dead skin would peel off of my head.

There come to a point, as many of us heard today, that I couldn't take it anymore, so I stopped treatment for a while. At this point, I had went to three different doctors in two different cities. And my last option, the doctor, the new doctor specialist I found, was the cortisone pills. My doctor alerted about the possible bad side effects, but still I want to try.

On the picture, in 2019 (sic), that was me after the cortisone treatment. I put so much weight, I stopped healing, and even if I cut my finger on a paper cut, it would not heal. My menstrual cycle got irregular, and I had no change in the hair grow. So I decided to discontinue the medication, and the result was that in a couple weeks the alopecia areata went to totalis and later to universalis.

In my experience, all these treatments I tried had the same downsides. The medication did not prevent new hair loss from developing. It become ineffective after a while and was at least very uncomfortable, but the majority was very super painful.

At this point in time, I was dealing with alopecia about 8 years. I was traumatized and depressed. To be honest, the emotional toll it took on me was harder than the actual treatment. So I decided I would rather go bald and learn to live with that instead. I bought a wig and move on.

I did not seek any treatment for 11 years. But recently through a friend, a mutual friend that I have on Facebook, and I start sending her some pictures and asking her what she was doing, and I learned about the Xeljanz. I'm being on the treatment with Xeljanz with Dr. King for 4 months, and for the first time, I have hope again that I will have my hair back. I've never been with not wig in front of anybody that I did not know, but I'm very happy, and I want to share with everybody in the community. I see 6 percent of my hair is growing, my brows are coming back, under the tattoo that now is kind of out of place.

(Laughter.)

MS. PALMA: It seems silly, but I couldn't be any happier that my eyelashes are back, my eyes feel protected, and I feel like sexy again because I can.

(Applause.)

MS. CHALASANI: Thank you.

MS. PALMA: I'm very lucky because I was pretty healthy throughout the whole process. Aside of alopecia, I didn't have any other major symptoms. And the medication has no side effects for me so far. And that was a very important point for starting the medication again. I did not want to go from any treatments that was painful that would hurt me or that would me make more sick than the alopecia was. For me, the main downsides from the treatment which are going now is that currently the medication is not approved by FDA for alopecia, so get the health insurance to pay for it is a hassle. They, of course --

it's very expensive, they don't want to pay for it if it's not approved.

I hope the research community keep investing and studying to keep people suffering from this heartbreaking condition to get better, this medication or any new treatment. There is a huge community. We need new treatments. We need new hope. We need to get better.

Thank you for the opportunity.

(Applause.)

MS. CHALASANI: Thank you to all of our Topic 2 panelists. I think you guys have really illustrated what treating alopecia is like today and really highlighted the unmet medical need, both in the pediatric and young adult population as well as the adult population today.

One thing that Andrea said that really resonated with me was that -- and I'm going to have to paraphrase here, and feel free to jump in on your mic -- was that you said managing alopecia is like managing weather, you can't, so you can only work around it? Is that -- prepare for it, yes, exactly. How many of you feel like that in the room?

(Show of hands.)

MS. CHALASANI: Okay. Oh, I want to say 100 hands up in the air maybe for those on the Web. Thank you. Okay.

So let's jump into one polling question. So similar to Topic 1, I'm going to ask -- kind of parse apart the pediatric and young adult responses from the adults.

So first, for the pediatric and young adults, have you ever used any of the following drug therapies or medical devices to treat your alopecia areata? So currently or in the past. And please feel free to check all that apply. A, Topical corticosteroids; B, Injectable corticosteroids; C, oral corticosteroids; D, Other topical treatments, such as minoxidil, Rogaine, anthralin, immunotherapy, such diphencyprone/DPCP; E, Immunomodulatory therapies, such as Xeljanz or Jakafi; F, Light treatment, such as laser or phototherapy; G, Other prescription medicine, such as psychiatric or pain medication; H, Other drug therapies or medical devices not mentioned; and, I, I am not using any drug therapies or medical devices.

(Using clickers.)

MS. CHALASANI: As you're responding, I do want to give you a brief mini agenda for the rest of the afternoon. We are going to be talking a little bit about the drug therapies and medical devices now, but there is a question after this for the non-drug therapies as well. We are very much interested to see what else you're supplementing your management approaches with, such as dietary modifications and so forth.

And then we'll be wrapping the discussion after talking a little bit about the downsides with a hypothetical clinical trial scenario as well. And so that's when I'm really going to ask all of you what's most important to you as well.

Okay. So let's take a look at these results. We have 89 percent topical corticosteroids, followed by 63 percent for other topical treatments. Following topical, we just have a very nice range of approaches that have been tried in the room. H, 41 percent for other drugs therapies or medical devices. So after the adults have a chance to take this question as well, we'll definitely come back, and I'm interested in hearing what those other drug therapies or medical devices may be.

Could we ask the adults the same question now, please? So adults in the room, have you ever used any of the following drug therapies or medical devices to treat your alopecia areata? Once again, please check all that apply.

(Using clickers.)

MS. CHALASANI: Okay. Slightly varying results from the pediatric and young adult population. So we have 77 percent for both topical and injectable corticosteroids, followed by D, other topical treatments, and then 41 percent for oral corticosteroids, 36 percent for other prescription medicines, such as psychiatric or pain medication. Okay. Okay. Thank you all.

Large-Group Facilitated Discussion: Topic 2

MS. CHALASANI: So let's start with the topical medications, and I'm going to kind of lump the topical corticosteroids with option D, the other topical treatments. And I think from the panelists, we've heard a range of benefits that they've seen from these topical treatments. We heard that there was no benefit at all, that they didn't see any results. Some mentioned that they saw some fuzzy hair, I think, so very minimal. And then other folks said that they saw results for a limited amount of time, so for a short time, and then no effect again. So I'm really interested to see if folks in the audience have other experiences that can kind of expand upon this, on this concept.

JULIA: Hi. My name is Julia, and I was diagnosed with patchy alopecia probably about 5 years ago. And I used topical, injectable, and other topical treatments, such as Rogaine, probably for about 2 years. And then one day I just said I'm doing anything else, this is it, I'm not doing another injection. And at that point, I started --

MS. CHALASANI: Sorry, Julia, would you mind just holding your mic a --

JULIA: Sure. Thank you. I started to accept my diagnosis. I decided no more treatment. I decided to use it as a tool to help other individuals that have lost their hair. I started to wrap my head with fabrics and scarves, which was a lifesaver for me.

I started a project where I teach individuals how to wrap their heads with fabrics and scarves, and for me, it has been the greatest uplifting thing that I've done for myself. And I feel confident. I feel happy.

But I know the journey that everyone in this room that is affected by the disease. I'm not saying it's been easy, but I've tried to overcome. So I just wish the best for everybody, that you find your good place. Thank you.

MS. CHALASANI: Thank you, Julia. Thank you.

(Applause.)

MS. CHALASANI: I think we have a comment over here.

RUTH: Hi. My name is Ruth. And I have a 10-year-old daughter, Bailey, right here. My daughter was diagnosed with alopecia areata right before her third birthday. It was terrifying. I had hoped that it was ringworm. Of course, took her to the dermatologist, who first prescribed topical steroids and the Protopic. We were on it for 3 months. No effect at all. As a matter of fact, her hair continued to fall out.

Then I read about Richard Strick, who used to be on the Medical Advisory Board for NAAF. So at that time, we lived in L.A. I took my daughter to UCLA to see him. And he told me about a topical immunotherapy chemical agent that he was using very successfully since the 1970s. It's called DNCB, dinitroclorobenzene, again, not approved by the FDA. Controversial, I think. I think there are a lot of parents through the years who have told me that it's possibly carcinogenic. It failed the AIMS test, but so did Selsun Blue shampoo.

And during that first episode where my daughter lost about 40, 50 percent of her hair in the ophiasis pattern, within 3 months, she regrew her hair. She had a full head of hair for 7 years. We just dealt with patchy hair loss, and we continued to use the DNCB. When we stopped using the DNCB, the hair loss continues and it gets bigger.

In the last 9 months, we recently moved to New York. We moved to New York fall 2014, but in the last 9 months, my daughter once again started losing over 75 percent of the hair on her head. We increased the use of DNCB, and as most people know, it is a form of topical immunotherapy. It causes severe itching. I don't think there's ever been a night in my daughter's life that she hasn't experienced an itch on her head.

The effects have not been as severe as what many have probably read about, blistering and pus. I think I've just learned how to use it and to toggle it. I've become the DNCB expert. But it would be nice for my daughter to have some form of therapy where the hair will just stay and that she doesn't have to scratch her head for every day of her life. So that's been our experience with DNCB.

(Applause.)

MS. CHALASANI: Thank you. Thank you so much for sharing that. We received a few panel comment summaries about this treatment as well.

Another quick raise-of-hands question for you. And let me say it before -- let me lay it out a little bit. So I'm hearing two different kinds of meaningful benefit. I'm hearing folks that would see a stop in progression, so they just don't lose more hair as a meaningful benefit. Are there folks in the room that would agree that that is meaningful, just if you're taking a treatment and it just what you have is what you have?

(Heads nodding.)

MS. CHALASANI: No, I'm seeing people saying no. No, that is not meaningful benefit. So meaningful benefit would be regrowth.

(Heads nodding.)

MS. CHALASANI: Yes. So now I'm seeing -- for folks on the Web, I'm seeing a lot of head nodding up and down. Okay, great.

So quickly to go back to the pediatric and young adults, we had I think it was around 40 percent -- testing my memory here -- that said that -- that mentioned other drug therapies or medical devices. I think we heard one so far. Are there other drug therapies and medical devices that folks are trying? I think we have Megha up here. And I will just like to highlight that if it's non-drug therapy, such as diet changes and so forth, we do have a polling question to get a little bit into that.

Go ahead.

MEGHA: So I did something called ayurvedic treatment. It's an Indian treatment. I spent over a month in India inside a hospital. And so what it did was like they gave me medicine and I was like on a strict diet. I wasn't allowed to get exposed to the sun. I had to stay in the hospital. And like it was a really -- they had like different things where you had to be massaged in oils and stuff that was supposed to help like circulate things in your body. And then they had a lot of different things. But like all-in-all it was like -- it was really hard because I was only 9 years old when I went through it, and I barely could eat anything. I couldn't go outside. And I couldn't -- I literally couldn't do anything. I was -- and the medicine was like so bad, I couldn't even eat it. Like there were days where they said you can't eat anything until like literally the end of the day.

And it was like -- it was hard because it's not something a kid should do. Like we tried because there was some -- a lot of people said it worked for them. It didn't work for me. But it was a really hard experience all-in-all, but, yeah.

MS. CHALASANI: Thank you, Megha. Thank you. That's really helpful.

One other -- well, the medical devices. We didn't really hear any comments thus far about folks who have tried light treatments, such as laser or phototherapy. Has anyone in the audience tried this treatment and willing to share an experience perhaps? Okay, perfect.

GURU (ph): Actually, I wasn't going to talk about the light treatment, but I can.

MS. CHALASANI: And you can talk about the other thing you wanted to talk about as well.

GURU: Well, I can talk about light also because we've tried that, too. My name is Guru. I'm from Dallas, Texas. I have a 7-year-old, 8-year-old daughter now, Mia (ph). She got alopecia when she was 2 years old. And, like Megha, we're also from India.

And as a 2-year-old and someone from India, anytime anybody sees, especially folks, current parents or other relatives, sees a child with no hair or hair falling off, everybody has got some kind of advice, some kind of oil that they have used, and they want to treat them with diet or with homeopathy or, you know, they know one doctor in this particular city in India who has treated this in the past successfully, and so on. So for the first 1, 2 years when she had this condition, we've gone through a series of different things that we wanted to try. Ayurveda was one. It wasn't as -- I'm sorry, Megha, for what you had to go through, but it wasn't as much as what she mentioned, but there was some kind of oils that we tried, some oral medicines. And then homeopathy was another thing that we tried for maybe 2, 3 months. We didn't see any results.

Light treatment was something that we tried one time. It was with one of the dermatologists in India. I forget what it was, it was either UVB or UVA or one form of light treatment that was applied on one spot on my daughter's head one time. It severely blistered her scalp, and we just stopped it after that.

Yeah, so I would say -- and probably many parents might relate to this -- as a parent who is exposed to this for the first time, you hear a lot of different things, and you want to try and fix this. As a parent, I felt, both my wife and I, very helpless that we're not able to do something to our daughter, whose hair just was falling off every day for a period of 1 year. So we went through a lot of different things that we tried. And we now for the last 4 years or 5 years are not doing any drug therapies. We do some other things, and we can talk about --

MS. CHALASANI: Sure.

GURU: I'll be open to talk about it during that time. Thanks.

MS. CHALASANI: Great. Thank you. Thank you.

So one other question for folks in the room. How long do you try a treatment before you decide that there is an effect or no effect? That hand went up really quickly.

UNIDENTIFIED: I think I can -- good afternoon. I'm a parent of a young boy that has alopecia areata universalis. He was first diagnosed at the age of 12. I brought him to Hopkins, was told it would be highly unlikely that it would progress to universalis. Within 6 months, it did.

So to answer your question, for the last almost 5 years, we've tried A through H, and we almost systematically would think, well, what is the trigger? Is it lack of vitamin D? Is it histamine levels? Is it fungal? So we would try different approaches, whether it be topical, the cortico shots, or we would try Chinese medicine. We did acupuncture. We did Yoga. We did diet. We did gluten. We did everything.

I then petitioned Pfizer for hardship case and we tried the JAK inhibitor 1, 2, and 3 drug for Xeljanz. And for 5 years this was a little boy who wouldn't sing, who wouldn't ride his bike, who just got the lead for Hamilton, his school's show, because he has hair because of the Xeljanz.

So I did try everything over a 5-year period as scientifically and as accurately as I could, eliminating things, focusing just on what we thought his trigger was. We're really no longer interested in what his trigger is or was. Is it stress? Again, is it a lack of a vitamin? Was there some traumatic event? We don't know, and at this point we don't really care, we just have a little boy who's singing again on stage because he's got hair. Thanks.

MS. CHALASANI: If I could just -- sorry -- just a clarifying question. I know you mentioned that you've tried A through H in 5 years -- I know this is a little bit of a difficult question to put you on the spot, but would you mind parsing apart like --

UNIDENTIFIED: Not a bit.

MS. CHALASANI: Okay. Like maybe how many months perhaps you may have tried like the topical -- like kind of giving a little bit of background, and if that was a decision you and your loved ones --

UNIDENTIFIED: I can lead this.

MS. CHALASANI: Okay.

UNIDENTIFIED: It's really important, I believe, a child at 3 or 4 cannot, but a child at 12 who is trying to build his identity is. I also, before I get down to -- I want to say that my son, Charlie, knows that he may not be on the Xeljanz forever. He does understand that there are risks involved. But if it gives him time to build from the inside out his confidence, he's willing to do it.

So when he was first diagnosed, we started with the topical shots, and that was for about 6 months. It worked. He had about eight patches in the back. He also had the ophiasis, which a woman over here was saying over here your daughter has, and that's the hardest to treat. That was the last -- that was the most stubborn part. We didn't really get a great response there, but the shots did work for about 6 months.

For about a year, everything was fine, nothing happened. Very suddenly then he started losing his hair again. Within 3 months, he lost his eyelashes, his eyebrows, and every hair everywhere. So the injectable shots I would say at that point we tried for 6 months. It was enough.

We did do the Rogaine when the hair was back in. So we had stopped the injections, but we thought almost prophylactically to use the Rogaine. Did it work? I don't think so.

The Xeljanz, Charlie has had an incredible response. We also (inaudible) dermatology, and he has got the villous hairs all over his body. He responded very quickly. And it's been now 4 months.

MS. CHALASANI: Great. Thank you. Thank you so much.

UNIDENTIFIED: Sure.

MS. CHALASANI: One more comment I think back here.

KATIE: Hi. My name is Katie. I'm 35. I live in D.C. I originally got alopecia areata in my mid to late twenties, where I lost my eyebrows and my eyelashes. The dermatologist -- I did the injections in my eyebrows, which helped them grow in patches, and at that point, I was using makeup to fill in my eyebrows, and it just kind of got annoying when there are just patches and I kind of had to fill it in, and it made it more obvious than just with no hair and the makeup. I've since gotten the microblading and love it. I highly recommend if you can afford it.

I then started getting patches. So I had the topical creams, Rogaine, the cream somebody else was talking about where it turns everything brown and it burns and you have to like work your way up to 10 minutes. And that I probably used for maybe I made it 3 months, but just, A, nothing ever happened, and, B, it just -- you had to put rubber gloves on to put it on, it stained everything, it smelled. So that wasn't worth it to me, especially since there were no results.

With the eyebrows, again, I probably went every 4 to 6 weeks to my dermatologist for those. Rogaine I probably took for about -- I used for probably about 6 months, but at that point I think is when the rest of my hair started falling out, and then at that point I think I knew that it was just more work and more emotionally -- more emotional work to have the treatments when I wasn't seeing any results. I don't even think I had any response to the injections in my scalp either.

So, anyway, I found no treatment was the best path for me.

MS. CHALASANI: Thank you for sharing that.

I'm hearing 6 months and less.

KATIE: I just want to make --

MS. CHALASANI: Sure.

KATIE: Sorry. One more thing, with treatments in the future, if there are things that seem to work better, for me, it's not going to be a win or something I'll even consider trying if the most I'm going to get is 50 percent of my hair back. I think even 75 percent I would really have to think hard about it. I'm really going to not try anything unless it's like 90 percent or more of my hair scalp on my head.

MS. CHALASANI: Thank you for sharing that. That's a really important point. And we actually have a scenario question that's going to tease that apart, I think, but we will have to adjust the scenario question based on what you just told us already.

I'd like to turn to the Web really quick and see what our polling results for this question look like on the Web, Shannon.

MS. WOODWARD: So we have a lot of similarities in terms of we had some comments that are seeking treatment beyond the cosmetic portions of the disease and don't really get to the causes. A lot of discussion about use of topical and essential oils as well as injections. A lot of people related to the comment of this being a cat-and-mouse game in regards to treatment. And we did get one comment in regards to use of a medical device called a laser cap as well.

MS. CHALASANI: Thank you, Shannon.

Could we have our next polling question, please? So let's take a look at some of these non-drug therapies. So I didn't tease this one apart, this is for everyone in the room: pediatric, young adults, and adults.

Besides the therapies that we've already mentioned, what else are you doing to manage any symptoms or manifestations you experience because of your alopecia areata? So for this question, you can check all that apply: A, Temporary cosmetic measures, such as a wig, hat, hair weave, makeup, the microblading that we've heard about; B, cosmetic procedures, such as hair transplants or permanent makeup -- just kidding, let's throw the microblading into B -- C, Dietary and herbal supplements; D, Diet modifications; E, Over-the-counter products; F, Complementary or alternative therapies; G, Other therapies not mentioned; H, I am not doing or taking any therapies to treat my alopecia areata.

And, right, so this is for the pediatric population, the young adults in the room, as well as the adults. This is for everyone.

(Using clickers.)

MS. CHALASANI: Okay. So 71 percent of you are using temporary cosmetic measures, such as wigs, hats, weaves, or makeup to manage your alopecia. And then we have a nice range for all of the other options as well, 47 percent for dietary and herbal supplements, which we've heard a lot about the diet changes similar to D, in diet modifications. F, we have the complementary and alternative therapies. I think we heard a little bit about the Ayurveda, which I think this falls under this bucket here. Twenty-four percent who are saying that, "I'm not doing or taking any therapies to treat my alopecia." Twenty-six, over-the-counter products. And then 22 percent are the cosmetic procedures.

Thank you. We do find it interesting to learn about this to see what you guys are supplementing your medical product approaches with.

So I'll take a couple minutes to ask you all, what kind of benefits are you seeing from these that you're not seeing from your medical products, such as your drug therapies or your light treatments, for example?

(Show of hands.)

MS. CHALASANI: A few hands went up. So what kind of benefits are we seeing here? Yeah.

UNIDENTIFIED: My daughter, Mia, had alopecia, got it -- I don't even know what you call it. We're still new to this. It hasn't been a year yet. We started off with the injections, and then we found out her thyroid levels were out of the park on different scales or whatever. Went to go see an endocrinologist. And he was Irish, so his accent just made everything sound better for what he said. I'm not even going to lie. I was just like, "Whew!"

(Laughter.)

UNIDENTIFIED: And him telling her that she was freaking beautiful just made me cry, and for him to tell her that, you know, these injections you're doing might be good for you, but you can also maybe be infertile, and all this other stuff, just really made us think about it, like, is her hair worth that? And so that was where we switched over to, you know, the biotin and the vitamins.

And there are different organizations that give wigs free to kids for, you know, X amount of time. And so she has a wig. She chooses to wear it when she wants to wear it. It's an accessory just like her different glasses, and I love that.

And so that's how we decided, was, you know, what were the side effects of what the medicine was, you know, compared to, you know, maybe these vitamins will help. Somebody told her wash your hair upside-down, rub your head, do this. So we're trying these things that I know won't cause other problems. And so that's why we did it. And, you know, we love her.

And the big thing that I wanted to say before, she recently broke up with her boyfriend, which is okay, whatever --

(Laughter.)

UNIDENTIFIED: -- but when his mom told me that he thought that they would get married and, you know, that kind of thing, it just made me cry because I knew that somebody would love her without hair.

And I just needed to know that as a parent, and it just made me think that, okay, I didn't need to make her take these injections, which we can't stand needles, we are not -- all these injections in her head and everything else, I didn't have to do that, that somebody else would love her as much as we did. So that's why we went this way. Is it making a difference? Probably not, but it is what it is. That's how we're looking at it.

MS. CHALASANI: Thank you.

I think Rosie and Rosie's mother.

MS. QUINN: Hi. I'm Paula Quinn, from Chicago. My daughter is Rosie. So she was diagnosed at 2-1/2. And I remember we went to see this fabulous pediatric dermatologist, and we were asking, "What is it? How do we stop it?" and he says, "Do you have a crystal ball?" And I said, "Actually, I don't. Where do I find one?"

So at that point, we did the topicals for a year, and then Rosie said, "You know what, Mom? I like being bald. I'm okay with this." She's like, "Are you okay?" And I'm like, "If you're okay, I'm okay." So we're in the 24 percent that's just kind of focusing on her confidence, her inner soul, because that's what's going to carry her through life. Hair, wig, head scarf, therapies. I think as a parent we didn't want to drug her up and give her shots in the head. We just want her to be a good person and feel good about herself and love herself. And she's teaching us about being Rosie and being a happy little girl. And she wants to say something. You know, she's the better talker. So here you go.

ROSIE: Hello. My name is Rosie. And I have a little things to say to you about the medicine that we're going to have the FDA make for us.

(Laughter.)

ROSIE: So I ask that they make safe medicine for kids to take. And I hope that it's edible and --

(Laughter.)

ROSIE: -- and that you can mix it with chocolate sauce.

(Laughter and applause.)

MS. CHALASANI: Thank you, Rosie. I don't think anyone else could have described a more ideal treatment.

(Laughter.)

MS. CHALASANI: I love chocolate as well.

One more comment and then -- okay, yes.

MS. EVANS: Rosie, I think Harrison would agree with you, too, especially the chocolate sauce part.

I wanted to share this with you all. So as a caregiver, a parent, to a child with alopecia, these are the notes that I have taken today in blue ink. This is showing our level of desperation. We will do anything for our kids to try to take this pain away, and the pain in addition to the autoimmune, that you're right, we have to solve the autoimmune first. But as a caregiver, it's the pain that we are so afraid of for our kids, and that know in this room if you are a child with alopecia, we mean it as a mom and as a dad when we say we would take this on in a second if we could take it away from you, because it is awful as a parent to observe.

But as you hear these laundry list of

therapies, and as a psychologist, I will tell you, this sounds nothing different than what we were dealing with in the '20s and the '30s with depression. The willingness people would go through to try things that today sound ridiculous to try to solve a problem, we are willing to go through those lengths. We consider putting needles in our children's head and listening to them scream, we consider the opportunity that perhaps they will never have a child of their own, because it might take away the pain.

When I listed off for this panel discussion all of the things we have tried for Harrison over the years, I was actually embarrassed to show the list to my husband because I knew he would look at some of those as nothing short of witchcraft, but those are the things we're willing to try, those are the things we're willing to go to.

Someone in my city actually suggested that we leave Atlanta, where we've lived our whole lives, and move to Sarasota because they knew somebody who had alopecia, and when they went to Sarasota, alopecia went away. Talk about a non-traditional therapy.

(Laughter.)

MS. EVANS: Just move. Maybe it's the pollution. Maybe it's the antibiotic I took. Maybe it's all those things when I was pregnant that I did to cause this. But we are desperate.

And there are a lot of malicious people out there who are willing to take advantage of our vulnerability, and it is those people that we have got to get the word out to as well, that it is not tolerable to send your child to India. These people did the best they could for their child. Whoever takes these people in and says, "Yes, we can fix this for you," those people need to be shut down. It is not acceptable to allow these kids to be tortured and take our money.

You guys have got to take the lead and make the word known what it is to have alopecia, what will work, what will not work, and what will not be acceptable in this country for treatment for kids.

(Applause.)

MS. CHALASANI: Thank you, Sarah. Thank you.

I think we'll take one final comment up here from Chris, and then I want to move on to the next polling question.

CHRIS: I just wanted to say it's not like we're having a note-off or anything, but these are the amount of notes that I've taken.

(Laughter.)

CHRIS: My name is Chris. My wife is Jen, you heard from her earlier. I'm her cheerleader. Jen has had five open-heart surgeries, yet I looked at her for the first time in actual pain as they injected steroids into her eyebrows that she lost recently.

Skipping all of the things that she's tried and have not worked, one of the most interesting things that we're dealing with right now is she met a new dermatologist. He was previously the chief of residency for dermatology at the Mayo Clinic, and somehow he landed in Milwaukee, Wisconsin. And after talking about a couple things, he said, "You know what? I can see that this is expanding and expanding and expanding, and I think that we have to find a way to try and actually stop this."

So that was the first time we had -- we had actually -- she had been in remission for 2 years, and it was the first time we had heard about JAK inhibitors. And so he mentioned that we should look into Xeljanz.

Having a heart disorder, trying the other immunosuppressants are dangerous because she had an artificial valve, and she's at high risk of infections. And her cardiologist is even game to try Xeljanz just because the risk profile is so much lower. She'll still have to be monitored.

But, so we started the process to get Xeljanz, and her insurance -- this is kind of where it gets back to the panel -- the insurance company said, "Actually, what we would like you to do is try methotrexate," and the one that starts with an L that I was trying to remember, which is like really dangerous, and because Xeljanz is not approved for alopecia areata, and as you know, nothing is.

So we're at this crossroads now. An interesting thing is one workaround may be the fact that I'm sort of a geek, and I noticed that methotrexate and the L one have contraindications for five of the other medications that she had to start taking for anxiety and depression since starting to have alopecia areata. That could be our workaround to get prior auth for the Xeljanz. There are no side effects that are immediately noticeable that her dermatologist thinks compared to the prednisone or any of the other things we've tried.

So I think it's really important for us to have an FDA-approved medication, medications, not just for the practical use, but for the financial as well.

Thank you.

(Applause.)

MS. CHALASANI: Thank you, Chris. Thank you. I think you raised several really important points. I would like to just keep in mind that we do want to focus our conversation on treatments more broadly. This isn't necessarily the most appropriate platform to talk about one specific medical product.

I think we have a couple more comments. Back here?

EBONY: My name is Ebony. I am a legislative liaison for the National Alopecia Areata Foundation, and I'm from Michigan. I was diagnosed with alopecia areata at the age of 4. I began wearing wigs at the age of 9. So I've had alopecia for 22 years now. I've been wearing wigs for 15 years.

There has been a lot of talk about different medications being developed trying to bring back lost hair follicles and things like that, and just watching myself go through this entire process, and even so watching my mother -- (becomes emotional) -- watching my mother have to see me suffer as a young kid, there's been -- I've been through a lot as a child.

Not only have I gone through hospitalizations with asthma and other autoimmune diseases, but I've gone through the bullying, I went through the teasing, kids snatching off my wig in school, snatching off my hats on the school bus heading home. And a lot of these teachers don't do anything about the kids who are being bullied when they have to wear head coverings.

And that's one thing that really irritates me, is when you get into these schools, they enforce all these ridiculous dress codes. Now I understand to a certain degree, there are some children who will try it, they will push you to your limits to where they wear stuff that's inappropriate, but if you have a child who cannot help their condition, if you have somebody who cannot help what they're going through, why would you make things more difficult for them?

My mom would have to visit these schools each and every single year explaining to these officials why I'm going through this and what she is going through as a parent. And I wish she was here right now. She couldn't make it this weekend, but just to sit here in the gap for so many young people is an honor and a privilege to be able to do something about this because I really want to see our kids happy.

You don't go to school to get bullied, you go to school to get an education, and it is up to the parents to educate their children before getting to school that there are other children who have different conditions that separate them from all the other kids.

Education does not start at school, it starts at home, and it's all about getting into your children's business and learning exactly what they're doing, understanding why they're doing it, and telling them it's not fair and it's not right, and even get into these schools and explain the same thing to them because these officials, they -- some of them helped me, some of them did work with me and my mom, but the rest of them just basically gave me hell for no reason all because I looked different.

I started wearing wigs very early, and it was very hard to adapt because I constantly dealt with rejection and people just giving me a hard time for no reason. I come from a small city, so everyone assumed that I had cancer because I wore wigs, and, in fact, the disease cancer by itself doesn't cause hair loss, it's the medicine in the chemotherapy. And I wish people would understand that because this autoimmune disease, we can't help that. Like we're not sick, we just can't grow hair.

I've tried topical creams. I've tried topical shampoos, and they smell really, really bad. They didn't do anything for me as far as growing my hair back. But hopefully you guys are able to develop something where we can have our hair in its entirety. The last time I saw it was I was just 15 years old. It fell out for the final time, and honestly I'm okay with it. If it comes back, okay. If not, I'm perfectly fine with it.

MS. CHALASANI: Thank you. Thank you so much for sharing that point.

(Applause.)

MS. CHALASANI: Okay. One more because Sara is giving me her "please" face.

BEN: Hi. I'm Ben. I'm from Boston. I just wanted to say that I've had alopecia since I was 2 years old, and I've tried many different treatments. And in the past 2 years, I started taking Xeljanz with Dr. King, and I have had total hair regrowth on my body except for my head, and it has completely changed my life.

MS. CHALASANI: Thank you for sharing that, Ben.

UNIDENTIFIED: We did try a few other things when he was younger, but as a lot of you have said, they're painful, and as a parent, I let it be in my control until he was old enough to speak up. And I couldn't put my children through pain for something that really didn't help. So the Xeljanz is the only thing that has actually helped us.

MS. CHALASANI: Thank you. Thank you for sharing that.

I think I kind of want to move to the next polling question. And so this one we did parse it apart separately for pediatric and young adults. And I think it's going to cement some of the concepts that we've already been hearing a little bit so far this afternoon.

So for the pediatric and young adults in the room, for the therapies that you use, what do you consider to be the most burdensome downsides? And so for this, please choose up to three answers: A, How the medication is administered, such as a topical cream or an injection; B, Difficulty in accessing treatment, for example, insurance; C, The treatment only provides minimal benefit; D, The treatment is effective only for a short time -- short term, sorry; E, Change in the texture or color of my hair; F, Bothersome side effects of the treatment; G, Concern about serious risks of the treatment; H, Uncertainty about long-term effects of the treatment; I, Other downsides not mentioned.

(Using clickers.)

MS. CHALASANI: Okay, a very wide range here. So 51 percent highlighted difficulty in accessing treatment, for example, insurance, as one of the most burdensome downsides, followed by, C, The treatment only provides minimal benefit, and then A, How the medication is administered, such as topical cream and or an injection. And we've heard downsides for both the cream and the injections so far this afternoon. Followed by 39 percent for uncertainty about long-term effects of treatment. That's very interesting as well. And then we had folks who indicated treatment is effective only for short term as well as concern about serious risks of the treatment.

Thank you.

Could we ask the adults the same question, please? So for the adults in the room, for the therapies that you use, what do you consider to be the most burdensome downsides? You can choose up to three answers for this question.

(Using clickers.)

MS. CHALASANI: Okay. Different results,

that's for sure, but I'm going to have to go back and forth to compare, my memory is not that good. B, 64 percent for difficulty in accessing treatment. So that was one of the most burdensome that we heard in the pediatric and young adult population as well. Followed by 52 percent for the treatment only provides minimal benefit. Okay. Followed by 40 percent for both the treatment is effective only for short term and, H, Uncertainty about long-term effects of treatment.

So I think one of the top three from the young adult and pediatric, which is, A, How the medication is administered, is not as much of a burdensome downside in the adult population, if I remember that correctly. And then we had zero percent for E, which is change in the texture or color of your hair. That's interesting and good for us to know as well. Okay.

I think we could easily talk about this for a very long period of time, this question itself, but in the interest of time, I'm going to ask all of you for a favor. Please note this question down. It's very much of interest to us. But then please go to the public docket that we've been talking about throughout the afternoon and tell us a little bit more about why you selected what you did for your most burdensome downsides. I think some of the concepts and topics we've heard so far have hinted at it, but any examples and specific experiences that you can share with us would be really helpful.

Really quickly on the Web for this question, what are seeing on the Web?

MR. THOMPSON: Very similar results to in the room. We had about 31 percent talking about how the medication is administered; 62 percent for difficulty in accessing treatment; and between 30 and 50 percent for the other responses.

MS. CHALASANI: Okay. Thank you. So, yes, please, please, please expand upon this question in the public docket responses. I do want to make sure that we have enough time to discuss our scenario question, which I think is on the next slide.

So this is a purely hypothetical scenario that our planning group put together. I'm going to read it out loud, and we just really want to hear what your first thoughts are that are coming to your mind, what kind of follow-up questions you may ask. Is this something that you would try? Would you participate in this clinical trial, for example?

So imagine that you have been invited to participate in a clinical trial to study an experimental treatment for alopecia areata. Your doctor believes that you may be a good candidate for this medication. This experimental treatment is a weekly self-injection.

Early research in animals and people show that this treatment may reduce patchy hair loss on the scalp by up to 30 percent in some people. The purpose of this study is to better understand how well this treatment works and its safety.

More common side effects of this therapy may include fatigue, headaches, weight gain, sore throat, and gastrointestinal issues. Rare, but more serious, side effects may include liver problems, cancer, stroke, infertility, or birth defects.

This clinical study will last 18 months, and clinical visits will occur every month for the first 12 months, and once every 2 months in the remaining 6 months. Visits will involve routine blood work.

So what are some of the first thoughts that are coming to your mind as you hear this scenario?

(Show of hands.)

MS. CHALASANI: Not as many hands went up this time. I think I have Rob up here.

UNIDENTIFIED: I think the only thing we're all thinking is, 30 percent?

(Laughter.)

UNIDENTIFIED: You're going to get 30 percent? Without any side effects, I wouldn't take part in it. I don't know.

(Applause.)

MS. CHALASANI: I think that's helpful, and I think we heard some participants who said it would have to be at least 90 percent I think is what we heard earlier. Okay.

A few other comments from folks in the audience?

UNIDENTIFIED: So I'm coming at this from -- oh, should I stand? I have a child, so there are a couple things that would have to change for this. First off, coming at this from a pediatric perspective, it could not be an injection. It would have to be topical or it would have to be oral.

There would have to be a -- it would not have to be a reduction, it would have to be baseline and forward. So we would have to see an increase in hair here, not reduction. So baseline up.

And the side effects could not be gastro-intestinal issues, could not be weight gain, could not be -- those side effects are not acceptable.

MS. CHALASANI: Thank you. That's very helpful for us to hear.

UNIDENTIFIED: So this clinical trial is not acceptable.

MS. CHALASANI: Okay. That's very helpful for us to know.

(Applause.)

MS. CHALASANI: Let's take one more right here, and then I'm going to change the scenario up a little.

DANIELLE: (Off microphone.)

MS. CHALASANI: Okay.

(Laughter.)

UNIDENTIFIED: Way to go, Danielle.

(Laughter.)

UNIDENTIFIED: No, I would not participate in this clinical trial. The side effects make it completely unacceptable. And the fact that it's only reducing patchy hair loss by up to 30 percent is totally not worth it, and it's not worth it to have to go through injections.

MS. CHALASANI: Okay. I think that's very helpful for us to hear back as well.

So let me change up the scenario question a little bit. I'm going to change the second sentence of the second paragraph to, "Early research in animals and people show that this treatment may increase hair growth on the scalp by 50 percent in some people." Now, what kind of responses? I'm still seeing folks shaking their head no.

I think Bob may have a comment right here. Rob.

UNIDENTIFIED: I still think it's a risk-benefit analysis. 50 percent doesn't do it for me. I don't want half of my head covered with hair. I'm sorry. That's not going to look good.

(Laughter.)

MS. CHALASANI: Okay.

UNIDENTIFIED: It's got to be much bigger. And the questions I would ask my doctor are, the rare but serious side effects, quantify that for me. Is it liver disease in one of a million? Or is it 100,000 in a million?

MS. CHALASANI: Those are really great questions. Let me see, one thing that you said that really resonated with me is that you said half of the hair came back on your scalp. What if

-- I don't know if this is scientifically possible -- but say that the regrowth was your eyebrows, 50 percent of your eyebrows, would that make a difference, the location of where the hair regrowth is?

UNIDENTIFIED: (Off microphone.)

MS. CHALASANI: No? Okay. Sorry, 50 percent --

(Laughter.)

MS. CHALASANI: No half eyebrows. Okay. Okay. And I have a feeling it's going to be similar for eyelashes as well. But let's take a few comments to see. I think we have one hand back there. And then I'll change the scenario question once more. We'll eventually get there.

MS. SMITH: Hi. My name is Diana Smith. I'm a support contact and a legislative liaison with NAAF. And I got alopecia when I was 5 years old. I think a lot of the resistance here is that you still have to somehow manage yourself 50 percent hair loss. You know, if you get one eyebrow instead of zero, that's still drawing on one in the morning, that still hasn't made a drastic change in your self-management of the disease. And that's not the ultimate goal for me of treatment, and I feel like a lot of people would agree with that. So --

(Applause.)

MS. CHALASANI: Okay. And for those on the Web, there's handclapping and a lot of head nodding up and down.

I will change the second paragraph, second sentence once more. Let's try it. "Early research in animals and people show that this treatment has a 25 percent chance, so 1 in 4 people, may see 90 percent regrowth of hair." So there's a 25 percent chance of you receiving this benefit, but the benefit is 90 percent hair regrowth. Some hands are going up.

JESSICA: I'm Jessica. I'm from Michigan. I've had alopecia since I was 10 months old. I feel like if I were to do something like this, infertility would not be an option. I would never do anything that would make me not be able to have children in the future. So if that was something that they said, I would 100 percent not do it, no matter how much came back.

(Applause.)

MS. CHALASANI: Okay. That's helpful. Thank you.

I think we have some hands back here.

UNIDENTIFIED: So, I mean, I'm 15, so, yeah, infertility, like not an option for me because I kind of want kids. Sorry. But also like liver problems. I'm young. I shouldn't be having liver problems. So cancer, not really worth my hair. So, and then for it to fall out again if I go through chemo and lose it because of that. So it's not worth it to me.

MS. CHALASANI: Okay. Let me take one more, and then I'm going to turn to my FDA colleagues to see if they have any questions as well.

SARAH: Hi. I'm Sarah. I kind of wanted to piggy-back off of what she just said, is I don't think that we should have to apologize for not wanting a side effect. We just want a treatment.

I shouldn't say, "Sorry, I do want to have kids. Sorry, I don't want to have cancer." Likely, yes, there is going to be side effects. We're aware of that, but something to this extent to what we're already dealing with is not fair and it's not acceptable. So I don't think that we should have to preface it or side effects to not be those and apologize for that.

(Applause.)

MS. CHALASANI: I think that's a really good point. Thank you so much for sharing.

Do my FDA colleagues here at the table -- I think Dr. Kendall Marcus?

DR. MARCUS: I first want to make a comment or provide some clarification, and then I just want to sort of build on these types of questions. And I think people understand, but I really don't know to what extent people understand, that we regulate drug research. We don't direct drug research. We don't financially invest in drug research. We regulate it. It's very much what I would call -- and I've actually been told not to say this before

-- it's a collaborative relationship with drug sponsors and people developing the drugs. It's really people don't like it when I say that, maybe a better word would be "interactive." We are experts in drug development. We can give excellent advice to drug sponsors.

But two comments have struck me today. One is from the young man who said taking Xeljanz was life changing because he now has hair everywhere else but his head. And so what I hear from him is a very positive risk-benefit for a treatment that did not work optimally for him.

And then the other comment that struck me is your comment just now about risk and benefit, which is what we do on a regular basis. We assess the risks of a product that are administered to patients for any given condition, and the benefit that they receive.

Successful therapy for different diseases and conditions often build on themselves, and the first success is not necessarily a complete success in terms of getting a drug that is, you know, 100 percent effective by whatever definition of "effective" that is used. And it's never 100 percent safe. You know, when I started working at FDA, I stopped using the term "safe and effective" and started using "risk and benefit."

And so I hear all of you in terms of what you want, but as a regulator, we have to make decisions about less than optimal, often less than optimal outcomes, and this is one of the things that we're trying to get a sense of from you.

And so, I mean, before we convened this meeting, I didn't really understand the importance and the impact of eyebrows, and I think that I've made that clear to people. I mean, it's life changing, and that's quite remarkable to me. And tattoos just don't cut it. I mean, it's a workaround, but it's life changing.

And so with that in mind, I hear all of the reaction, I hear the immediate pushback to the scenarios that we're giving you, but these are the types of decisions we have to make if that's the product -- you know, if the development program doesn't deliver that 100 percent. And you really have to start somewhere. You all clearly know, you all painfully know, that there are no approved treatments.

And if we're all going to continue to try and move forward and work on this, it's helpful for us to understand, you know, really drill down on, is regrowth of your body hair without regrowing your scalp hair, is that a win? Would you consider that a win? Would you --

(Applause.)

DR. MARCUS: So, yeah. So I'm just providing that to you to give you some of the context for me and what I'd like to hear as we get feedback from these types of scenarios.

And, Katie, I believe you said something about hair extensions. And so that -- I assume that you have to have enough hair regrowth to be able to get hair extensions. Any idea what percentage -- I mean, this is -- so, to me, you've had a win, but it wasn't 90 to 100 percent regrowth of your hair. But it sounds like it changed your life.

KATIE: Right. So when I got extensions the first time, I had 100 percent growth around my head. And it needed to be -- in order to work with getting the extensions that I bought, which were the glue-on extensions, they go on like probably 25 to 50 pieces of your hair. And it has to be long enough in order to be able to hold the extension. So, yeah, you do have to have a certain length, a certain amount of regrowth. But if you only have 75 to 90 percent with the length and the strength, you can use the extensions and the length of the extensions to cover up whatever you don't get.

DR. MARCUS: Right.

KATIE: So it was a huge win for me.

DR. MARCUS: Okay. Yeah. So I don't think I've actually asked a question here. I've just provided you with a comment. But I wanted you all to understand more where we're coming from and what kind of information from you is helpful for us as we try to do our job.

MS. CHALASANI: So I know it wasn't a

question, but folks still want to respond to your comment, I think. So let's hear what some folks have.

UNIDENTIFIED: Hi. Thank you. My son is on Xeljanz, and it's been successful. But we realize that there are potential side effects with it, and he sees Dr. King every 6 months, and he has blood work done. And I think that's sufficient for us, as parents, to know that if that blood work shows something that, you know -- shows that there's a liver problem or there's something else, then we will address the situation at the time.

So I think if the customer is aware of when he starts taking a drug of the potential side effects, we can deal with it and make the decision, you know, from that, from there.

MS. CHALASANI: Thank you.

One or two more comments, and I think we'll have to --

MR. REINHART (ph): Hi. My name is Ed Reinhart. I'm the proud father of Katie. I apologize. Kendall, thank you so much for those comments. We're part of the Dr. King fan club. Xeljanz changed our lives. And what I would encourage you -- and we came all the way from Yakima, Washington, to let the FDA know that -- Xeljanz is an FDA-approved drug, but it treats pain.

And what I would let you know that alopecia is also painful. And I would really encourage you to open it up. Because right now our insurance company doesn't cover Xeljanz, so I have to go to Canada. Where right now if I went in the United States, it's $4,000 for 60 tablets, I go to Canada, and it's $1,000. The same drug, from Pfizer, but we found a way, and it's a miracle drug. And you're right, it's not going to work for everybody, but we also have blood exams every 3, 4 months to keep track of it. But it's a start.

And we know it's not a solution, but when I look at my daughter, it really has changed her life. So I would encourage the FDA to approve Xeljanz for alopecia. I would really make a big difference to us. Thank you.

(Applause.)

MS. CHALASANI: Thank you, Ed.

Kendall.

DR. MARCUS: I just want to make the point again that we regulate drug research. We can't approve a drug without a drug development program and an application. And I hear you. I'm not trying to discourage you. I just -- I'm trying to help people understand the process, and we're one part of the process. But that's not to discourage you, that's just I want people to understand our role in all of this.

MS. CHALASANI: Thank you, Kendall.

I think we have --

MS. CUNNINGHAM: Again, I'm Samantha, from Detroit. For me personally, I would be willing to -- when I look at all the things that my parents have paid for that are not approved by the FDA, with unknown side effects, with, you know, witch doctors coming out of the blue, you know, with diagnoses and ways to cure alopecia, and all the different things that we've gone through, that to know, to at least know, what the possible side effects are, to know that I can go and have blood work done, and that they can tell me if I'm starting to have gastrointestinal issues or that if I'm starting to have liver issues, and then I can choose to end the treatment, is a win for me.

To have all these unknowns -- and I did them as a child -- to have all these unknowns, you know, to try and possibly cure my alopecia, but to know that I have a chance, that I may have a 75 percent chance or a 90 percent chance of regrowth, is something I'm willing to do.

MS. CHALASANI: Thank you, Samantha.

We are cutting it really close on time right now, and we do have to more forward with our Open Public Comment session portion of the afternoon. I just want to make another plug-in for the public docket. You've seen the questions, change the scenario, and send it back to us. Anything that you can expand on, elaborate on, provide us more insight into your daily life and your experience would be very informative and insightful for us here at the FDA.

And, once again, we will send you this link via email as well. We'll share it with the National Alopecia Areata Foundation. Please send us those comments. We do read them all and incorporate them into our summary report.

So at this time I'd like to turn the mic over to Sara Eggers, who will facilitate the Open Public Comment portion of the meeting.

Open Public Comment

DR. EGGERS: Good afternoon, everyone. This is the aspect of -- can everyone hear me?

(Chorus of noes.)

DR. EGGERS: No. I think they're -- can you hear me now? Okay. Yeah.

So this is the portion of our program where, particularly if you signed up, actually we have 16 people have signed up. We want to make sure we get you out on time, and so that we can wrap up the meeting. So we're going to ask everyone to please stick to 2 minutes, and I will have to stop you. Hopefully, if you're a self-advocate or a parent in the room, and what you have said is resonating with what others have said, you can strike yourself off of this and that will make sure that everyone gets their time.

As we did earlier, if you could please disclose whether your participation has been supported financially or if you have a financial stake in any kind of drug development for alopecia areata or if you are associated with any organizations that have an interest in alopecia areata, that would be helpful for us for disclosure.

So we are going to go through this list. I'm actually going to ask you to go to the microphones if you're able to. We might have a couple people, a couple kids, who are a little -- Rosie's good? Okay. Okay.

We have so many folks today, so come to the microphones. I'm going to actually call you out right now. I'm going to call Ember Hibbert, Jonathan and Jennifer Yeagley, and Dr. Michael

Sierra to start to come up to the front. Come up to those microphones that are there and just stand in line, and we'll start with you, and then I'll call up another round.

MR. YEAGLEY: I'm Jonathan Yeagley. Should I just start?

DR. EGGERS: Yeah. Is Ember here?

(No audible response.)

DR. EGGERS: We'll start with Jonathan, and then, Ember, if you want to come up, you go ahead.

MR. YEAGLEY: Okay. My name is Jonathan Yeagley. I'm from Berwyn, Pennsylvania. Mr. Reinhart, who -- we're all big fans of Dr. King. My son got alopecia in 7th grade. In March of 2016, we found Dr. King. He started us on Xeljanz. By Christmas of that year, he was able to take off his hairpiece. We went through all the topicals, the injections, and, you know, we couldn't be more happy with the effect that Xeljanz has had on us. I'm amazed that they haven't gone through -- I don't know if it's in trial now or it hasn't progressed any further.

But Mr. Reinhart hooked me up with a doctor in Canada who wrote a prescription for us. I travel 7 hours, I drive 7 hours to Buffalo, cross a bridge, go half a mile to a Walmart to buy the drug. It costs me $1,250 a month as opposed to $3,900 a month at our local drug store. That's $15,000 a year versus $47,000 a year in the United States, which I think is just outrageous.

Insurance, we have a good insurance plan. Our insurance does not cover it. And I think that's, you know, part of the fact that -- I mean, it's a horrible disease, my son will tell you. He's had a horrible experience with it. But we have to make medicine more affordable. I realize that's not the purview of the FDA, but the only -- you know, we have to speak out about it. So that's what I wanted to say.

DR. EGGERS: Thank you. Thank you.

JONATHAN: Hello. I'm Jonathan as well. In 2nd grade, I was first diagnosed with alopecia, and then it slowly grew back a little bit, but by 6th or 7th grade, I had to wear a hairpiece. And until last semester -- I'm 19 years old, I'm a sophomore in college, and last semester was the first time I could finally go without my hairpiece. So I went all through high school, all through 7th and 8th grade with my hairpiece. And as many of you people know, it's just awful. People look at you like all the time. Like I'm still paranoid that people are constantly looking at me.

And I thought last semester that everything would be fixed right away when I have all my hair back, which is not true. It takes a lot of time to grow from being shy and just trying to like seclude myself all the time. And it's slowly getting better, but it is a slow progress. And I know that you guys can't have Xeljanz just affordable like that, but it has changed my life.

I thought it would change right away, but it's slow progress, and I sort of feel guilty that I'm one of the few people in here able to have this drug. And I really wish it would be affordable for everyone because I know what you guys are going through. And I feel that one day there is going to be a solution, just hang in there.

And I want to thank you, Dr. King, for really being the man, helped me out.

(Applause.)

DR. EGGERS: Thank you, Jonathan.

Ember. Ember, would you like to say something?

UNIDENTIFIED: This is Ember. She's 12 years old. She's had it about 3 years. And I have to say the hardest part is trying to get the wigs. (Becomes emotional.) The insurance will not cover it unless it is hair loss due to chemotherapy. And all the wigs for kids and everything, you can only get one a year. She's a child. She plays volleyball. It's a pain in the butt. But we're making the best.

And do you want to say anything?

(No audible response.)

UNIDENTIFIED: No? Okay. You're good.

(Applause.)

DR. EGGERS: Thank you, Ember. And if I can point out, Ember and her family have been here --

UNIDENTIFIED: Hello?

DR. EGGERS: Let me just -- Ember and her family have been here -- they were the first to arrive today, and it was just such a sight, such a pleasant sight, to see such enthusiasm for this meeting starting with Ember and her family, who came I believe at around 11:00. Okay.

(Laughter and applause.)

DR. EGGERS: Okay. Yes. And you are? Michael Sierra.

DR. SIERRA: Yeah. How are you going? I work for LEO Pharma. I am here not only to represent LEO, but also I have alopecia. I had it since 2005. Shaved my head in 2006. And it's been moving around ever since. Lost an eyebrow, and the fingernails are starting.

I think it's a real privilege to be here and be talking about alopecia. I know at least in Leo, used a lot of time to push for looking at not only the other skin indications we're looking at, but also alopecia. We have a JAK inhibitor that's in development, and we're looking at potentially systemic antibodies and biologics that could be used in treatment.

We've been associated with the NAAF since 2014. And I'm not really -- I mean, I'm in a position now where my hair doesn't really bother me, but the stories that I've heard today from these young people and adults really moves me. And I know that you've probably been as moved as much. And I think that it's really necessary that we, as the pharmaceutical industry, and also the FDA, look at how we can bring treatments to really support and help these families moving forward.

Thank you.

(Applause.)

DR. EGGERS: Thank you, Michael.

And now we have Callie and Jamie, Callie and Jamie C.

CALLIE: Hi. I'm Callie. I'm a terrible speaker and I'm really nervous, so I apologize in advance. I lost all my hair by the age of 3. I started wearing my first wig in 1st grade. I went through years of kids tearing off my wigs and my hats. By the age of 15, I was so severely depressed that I attempted suicide. Luckily, it wasn't successful. I still struggle daily with anxiety and depression.

About 3 years ago, my dad found an article about Dr. King and Xeljanz and reached out to him, and we started seeing him, and he prescribed Xeljanz, and this is the first time that I've ever had any hair growth at all. And for me, just the eyebrows and eyelashes was like completely life changing. So also a part of the Dr. King fan club. But that's all I want to say.

(Applause.)

UNIDENTIFIED: I'm also nervous. I'm Callie's dad. You know, this has been a long journey of treatments that didn't work. People talked about witch doctor I don't even call them treatments. And I think this is where the FDA can really come in, where we recognize that you can't recommend drugs or you can't -- I think one of the things that's really important is to possibly sort of influence the pharmaceutical community to do research, JAK inhibition works. There's an opportunity for expanding upon the work that's been done by Pfizer. And I think the opportunity for doctors like Dr. King to promote these types of things and move forward to sort of stimulate this research I think is real instrumental for what the FDA can possibly do.

It's been life changing for Callie, even though she still does not have total hair growth on her head, but she does have hair growth. And the eyebrows and eyelashes, it's been amazing, it's been life changing for her. And it's really important, I think to try to influence the research that's being done.

We understood last night from Dr. Christiano (ph) that there's actually work being done with NIH funding some of this sort of stuff, so I think this is something where the FDA can come in and sort of stimulate this opportunity to do more research in this area of things that actually work. Because we've seen all the things that don't work, from tar ointments on the scalp to, I mean, just unbelievable things that you can't even imagine are not even scientific, and it's just like, "Are you kidding me?" And as a parent, you just shake your head, you just can't understand it. But thank you for the opportunity.

(Applause.)

DR. EGGERS: Thank you very much.

We have Dory Kranz. Dory? Dory Kranz? Dory Kranz?

MS. KRANZ: We have a Lori and a Dory. I'm the Dory. My name is Dory Kranz, and I am CEO of the National Alopecia Areata Foundation. It's a nonprofit voluntary health agency serving the 6.8 million people -- we have different numbers than you guys do -- in the U.S. that either have had or will experience alopecia areata in their lifetime based on a 2.1 percent lifetime risk.

I'm also a board member of the National Health Council, which is the united patient voice for more than 133 million Americans living with chronic disease or disability. And on behalf of both organizations, I thank you, the FDA, for recognizing the importance of bringing the voice of the patient into your benefit-risk process for new treatments. It's heartening and we are really grateful for the whole PFDD initiative.

(Applause.)

MS. KRANZ: You've already heard from the most important participants, the people who live with alopecia areata, but as a patient advocate, I just wanted to reinforce some of the things that we are hearing from the community and that are documented in a paper entitled, "Alopecia Areata is a Medical Disease," that was just accepted for publication by the Journal of the American Academy of Dermatology, and when it is published, I'm going to share it with you.

Alopecia areata is a life-altering medical disease. It's an autoimmune disease. And it warrants treatment like any other autoimmune disease. There is a large unmet need for safe and effective treatments. And as you've heard today, it has a profound impact on quality of life.

Rates of depression and anxiety are high. And the psychosocial impacts affect choices about participation in sports, educational attainment, career path, social contacts, and intimacy, as you heard today. And because of the significant nature of the psychosocial impacts and the proven effectiveness of integrated behavioral health and primary care, we're working to have behavioral health integrated into dermatologic care, not just for alopecia areata, but for all diseases that have a high psychosocial burden.

And lastly, I wanted to tell you, the FDA, that preparing for this meeting, from the moment we knew that it was a possibility in 2012, has changed the way that we, as a patient advocacy group, engage patients in our work for the better, including in our partnership with industry on treatment development. So even before we got to this meeting, this meeting helped our community to find its voice in the research and treatment development process.

And one specific example, we are grateful to be working with the FDA as well as patients, industry partners, key opinion leaders, and treatment -- health economics outcomes research experts on the development of a patient-reported outcome instrument that this meeting will inform as well as many other things to demonstrate the patient benefit to payers so that treatments are covered by insurance and accessible and affordable for everyone who needs them.

So, anyway, thank you for this whole initiative and this opportunity.

(Applause.)

DR. EGGERS: Thank you very much, Dory.

We have Gary Sherwood? Gary Sherwood? Mason McGuire is on deck.

MR. SHERWOOD: I'm Gary Sherwood. I'm NAAF's Communications Director. I'll keep it brief. I've never been so proud of this community as I have been today. It's been an absolute privilege just to be in the same room with all of you. And you all just make me so proud of what NAAF does every day. Thank you.

(Applause.)

DR. EGGERS: Thank you.

Mason?

Abby is up next.

MR. McGUIRE: I'm Mason McGuire. I was diagnosed with alopecia when I was about a year old. And it really hard going through all the treatments. When I was about 13, I went through and had the cortico injections into my head and the topical solutions, and I saw little to no success with that.

When I was 15, my mother -- sorry -- found Dr. King, and we got an appointment over there and got on the drug Xeljanz, and it was completely life changing. I haven't seen much eyebrows or eyelashes came back in, but my scalp has for the most part came back in. So I would like to thank Dr. King for that.

(Applause.)

DR. EGGERS: Thank you.

We have Abby.

ABBY: Hi. I'm Abby. I'm a legislative

liaison with NAAF, and my dad used to be on the board. I'm from Louisiana. And I lost all of my hair -- or I got patchy alopecia when I was 6, and I started getting the steroid injections, but they actually made my hair fall out faster, which is something I don't know if anyone said today, but I have heard that from other people.

Since I was 6, I haven't had any hair regrowth, but I didn't lose my eyelashes till I was in high school. So that was -- I never had eyebrows really after I was 6, but that was something pretty traumatic because I kind of held onto my eyelashes and would put a lot of mascara on them, and then I felt like my face had no definition after that.

And another thing I wanted to touch on was like the wig costs. So the medicine is super expensive. I may be willing to take it if I knew that maybe 90 percent of my hair would grow back. But I also -- I have chosen to wear wigs, I did it from the age of 6 to 19, but now I work abroad in international development, and I interact with a lot of people, and so I've chosen to, but the wigs are around $4,000 to $5,000, and you have to get a new one -- I mean, you don't have to, but every 2 to 3 years. There are less expensive wigs, but these are like regular hair wigs, I mean, human hair wigs, so, you know, you can do anything with them that you want, whereas with synthetic, you can't do as much. So that's something. They're not covered by insurance for the most part. And I'm really fortunate that I can afford that, but I know that so many people aren't.

So I just wanted to add that. Thanks.

(Applause.)

DR. EGGERS: Thank you very much. Thank you.

We have Sally Alterman. Sally Alterman?

MS. ALTERMAN: Hi. I'm Sally. I was diagnosed when I was 56, and I'm 67. My issue for this group is, number one, I would like to salute all the parents because your support of your children and your giving them of their self-worth and their self-image and their self-concept is the most important thing of all.

I think that -- I think I'm losing my voice. I think that after you listen to the heartfelt thoughts of the people that have alopecia for hours, sometimes you get a little numb to that, and I would like to be sure that everybody goes home and really thinks back upon the pain and the heartfelt admissions that are coming from the people in this room.

And if we can do anything to help these children that have to go through the social media, that have to go home and look at their emails and look at their cell phones and listen to the bullying, and they can never escape this. And this is really the biggest issue that I think needs to be addressed today that hasn't really been hit.

(Applause.)

DR. EGGERS: Thank you.

We have Sarah Seward? Or Seward, sorry.

MS. SEWARD: Hi. I'm Sarah Seward. I am a legislative liaison with NAAF. I think the biggest thing -- (becomes emotional) -- sorry, it's going to happen -- I think the biggest today that -- I thought that I was in a much better place than I am. Today ripped off a Band-aid that I thought I was dealing with -- I thought I had a grasp on this unpredictable disease. I was diagnosed when I was 21. I lost all my hair in 2 weeks. I am grower and I'm a shedder, so I lose in patches -- I'm so sorry.

DR. EGGERS: No, it's okay.

MS. SEWARD: I lose it in patches, and then it grows back, and then I lose it again, and it grows back. So I'm on this crazy roller-coaster that we're all on. I'm on a pretty strict 3-month cycle. I do have other autoimmune diseases. Thank you. So with me, I can kind of feel when it's going to happen. My lymph nodes swell up to the size of golf balls, and I always get sick, like I always get a cold, and then I know that it's going to happen.

Alopecia changed my life in the sense that when I was first diagnosed, I was a hairdresser, and I changed my complete career because I was told that I needed to wear a wig to work in order for my clients to trust me. I went through a deep depression. I didn't know who I was. I didn't feel like a woman anymore. I had it taken away from me, and I let it be taken away from me.

I attempted to commit suicide and was at a peak low until I found NAAF. The National Alopecia Areata Foundation saved my life. Every single one of you had a part of saving my life. My biggest thing today is that I look around and I see all of these children, and I think about what I went through at the age of 21, and I cannot even imagine to put myself into their shoes and how strong they are.

But the thing is, is that we're human, and we don't always have to be strong. We think that we just have to put on this front for everyone, and it's not necessary. We can do this together, and there's a lot of us, and we all need to have that support behind us. And I'm just so grateful for this experience. And I've heard a lot of people say -- talk about these life-changing experiences.

And being a legislative liaison, this is something that we have worked for from the beginning. And here we are. This for me is a life-changing experience right now, and I am so grateful.

(Applause.)

DR. EGGERS: Lori Jacobi?

MS. JACOBI: Right here.

DR. EGGERS: Okay. Hi.

UNIDENTIFIED: Lori, not Dory.

MS. JACOBI: Hi. My name is Lori Jacobi. I'm from California. I am a legislative liaison and an Advocacy Committee member with the National Alopecia Areata Foundation. I want to thank Gary and all of the great folks with NAAF. They've made me a stronger person.

At age 52, 13 years ago, my hair started to fall out. At 1 month into it, I had to get a wig. I couldn't work in a profession where I was at a university without being more professional.

Within 3 months, all of the hair on my body was gone, and my life had changed forever. I eventually lost that job, and it didn't ever dawn on me that it was probably due to my appearance, but in retrospect, that was probably what was going on with that.

I have since finished my bachelor's, my master's. I got six certificates in human resources. I finished my teaching English as a second language, and I passed my CBEST test. And I never had the chance to really get into education because I always had to be the provider of benefits with a full-time job, so I couldn't do the student teaching.

I eventually did retire this past year, and we've moved to a new community where I feel confident enough in my new community to go in public without my wig. It's funny how when you're in one scenario with all the friends you've always known, and even if they know you wear a wig, it's hard to be you in public in that scenario. In my new home, in a new community, I feel okay to be myself now, and that feels really good.

Also, over the past couple months, I've become a substitute teacher in my retired life, and it's great to be able to go into a school with my cap on, or if I get too hot, I can take my cap off, and the kids go, "What happened to your hair?" and I go, "I don't know. It just fell out." And they go, "Oh, okay," and they go on with their life.

(Laughter.)

MS. JACOBI: But I feel like I'm giving them maybe some inspiration, maybe some diversity training, that hopefully things will come to an end. But thank you so much.

(Applause.)

DR. EGGERS: Thank you.

Karen and Marianne? Karen and Marianne?

UNIDENTIFIED: I'll make it really quick. Everyone else said amazing things. And thank you for everything that you've all said.

My son was diagnosed when he was 16. He is now 24. He did lose everything, but now it's almost all regrown. It's about 90 percent regrown. So I guess what I would say, to add to what's already been said, is just that for those who have the patchiness, if there's any type of treatment that could help fill in, you know, the remaining spots that would be safe, that's the main thing I wanted to say, is I think my son wouldn't opt for anything that's risky to the immune system, but if there was some type of drug that could come out that was very, very safe because he wouldn't want to risk all the side effects.

DR. EGGERS: Thank you so much.

UNIDENTIFIED: Thank you.

(Applause.)

DR. EGGERS: And then I have Cheryl.

UNIDENTIFIED: It's kind of low here. I just want to thank you for everything today and the opportunity to see what a wonderful group we have and how they've all come together.

My daughter is 24, diagnosed at 14. She's in Florida. I wish she could be here with us. She's safe. But she has alopecia universalis. It started like pretty much everybody else's, a lot of it just fell out, and she had alopecia universalis at 16. The torture, the stuff she's been through, and all the kids that -- just nasty. It's more than any child should ever have to go through.

But at this point, she's dealt with it. She struggled through it. And she's at the point in her life now where she wears wigs, she doesn't wear wigs, it's back and forth, it differs. Whatever day it is, it depends on how she feels. She's tattooed her eyebrows. She has tattooed on her eyeliner. Just because she doesn't want to be able to have to -- she just -- you wipe your forehead, you don't realize you wiped off your eyebrows. So for her, that was important.

So if she did get her eyebrows back, if she got her eyelashes back, that would be a big bonus to her, but not if it were something that meant that she was going to have all kinds of issues with her immune system. So that's really important to her.

At this point, she's going to be 25, and when she gets to 26, she's going to have to start paying for it. And if it's not something that a child can afford or a lot of other people can afford, what is the point? Because if it's not covered, those are things that are very important to us as well as the effectiveness and the fact that it doesn't cause problems from an autoimmune standpoint, are there other issues?

I appreciate it, and thanks for everything today.

(Applause.)

DR. EGGERS: We have Cheryl. I have just Cheryl. I don't have a last name.

Okay. Hi, Cheryl.

CHERYL: Hi. You've already heard from me today, and I'm going to keep it short because I know we all want to get back on the road and go home.

Guys at the FDA, I would just implore you to research and find an acceptable treatment that doesn't have all the side effects, and also something that's going to be covered, because a lot of us don't have the money to pay for $3,500 a month for a medication that might not even work for everyone. I mean, I'm not going to put out that money if I don't know it's going to work.

That's all I had to say. Thank you.

(Applause).

DR. EGGERS: Thank you, Cheryl.

That is what I have on the Open Public Comment. And so with that, I will turn it over to Tatiana. I will remind you that we have evaluation forms, and we very much appreciate all the feedback we get. So thank you very much.

DR. OUSSOVA: Wow, what a meeting.

GURU: Excuse me. Sorry. I didn't sign up for the Open Public Comment. Is it okay if I make one quick comment?

DR. OUSSOVA: Sure.

GURU: So I'm Guru again. My daughter is 8. She had alopecia when she was 2. I heard a lot of parents talk today, and I don't want to repeat what they said, I can relate to everything. And I also heard a lot of excitement and some life-changing stories from young adults and adolescents about JAK inhibitors, and it's great that that's in development, but I really hope I'm not in the minority here.

As a parent of a child who is still young, my daughter is 8, I would be concerned if the only drug that's under development is something that I have to give my daughter every single day for the rest of her life. I would be concerned if the unpredictability of the disease does not get addressed. I really wish that there is more research into fundamental understanding of autoimmunity and to ultimately fix or reverse the cause of this condition.

That's all. Thank you.

(Applause.)

DR. OUSSOVA: Thank you.

Closing Remarks

DR. OUSSOVA: And then my closing remarks, I just wanted to say that I think this was a very important meeting for all participants, including FDA, patients, researchers, and the industry representatives. And I hope you will feel as positive about this meeting as we do.

For us here at the FDA, it was a very good, very informative meeting. And I would like to thank you all for participating in this meeting today, for sharing your personal stories, your experience, and perspectives.

The psychological impact of the disease, as you described today, is enormous, and the need to develop therapies is immense for alopecia areata, and we understand that. We look forward to incorporating what we have learned today into the agency's thinking and understanding of how patients feel benefits and risks of alopecia areata treatments.

We are also looking forward to receiving commonsense suggestions from you all, from the industry, academia, patients, advocates, and these suggestions and comments will further inform our decision-making process while we move forward with developing new treatments for alopecia areata, and it will benefit our collaborative efforts in the area of new drug development for alopecia areata.

And I would like to assure you that all your voices were heard today. And I'm sure that other players in the drug development process heard you as well. The need for more therapeutic options for all age groups is evident. And I'm hopeful that the combined efforts of researchers, the industry, and the FDA one day will provide the patients with an effective treatment option. Thank you all. And I wish you safe travel back home.

(Applause.)

(Whereupon, at 5:09 p.m., the meeting was adjourned.)

CERTIFICATE OF NOTARY PUBLIC

I, MICHAEL FARKAS, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

MICHAEL FARKAS
Notary Public in and for the
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SEPTEMBER 25, 2017 DEBORAH ARBOGAST