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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

Reported by: Michael Farkas

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A P P E A R A N C E S

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19 Topic 1 Panel Participants

20 Samantha Cunningham

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22 Sara and Harrison Evans

1 A P P E A R A N C E S

2 (Continued)

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6 Megha Thyagarajan

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8 Topic 2 Panel Participants

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10 Tyrone Folliard-Olson

11 Katie Krueger

12 Katie

13 Gracielle Palma

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15 Open Public Comment Participants

16 Abby

17 Sally Alterman

18 Callie

19 Callie's Father

20 Cheryl

21 Ember Hibbert's Mother

22 Guru

1 A P P E A R A N C E S

2 (Continued)

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4 Open Public Comment Participants (Continued)

5 Lori Jacobi

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9 Mason McGuire

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12 Dr. Michael Sierra

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14 Jonathan Yeagley (Son)

15

16 Additional Participants

17 Becca

18 Ben

19 Callie

20 Chris

21 Danielle and Connelly

22 Doug

1 A P P E A R A N C E S

2 (Continued)

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4 Additional Participants (Continued)

5 Ebony

6 Bob Flint

7 Jennifer

8 Jessica

9 Julia

10 Julie

11 Katie

12 Margaret

13 Maria

14 Megha

15 Mia

16 Miranda

17 Paula and Rosie Quinn

18 Ed Reinhart

19 Ruth

20 Sanguita

21 Sarah

22 Diana Smith

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Meghana Chalasani
Office of Strategic Programs (OSP),
Center for Drug Evaluation and
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Deputy Director for Safety, Division
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Theresa Mullin, Ph.D.
Director, OSP, CDER, FDA

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21 20 DDDP, CDER, FDA

22 21

22 22

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

2 Welcome

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

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

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

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

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

1 Products.

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

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

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

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

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

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

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

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

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

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

12 We have time set aside for open public comment
13 later this afternoon. While the primary
14 discussion today is focused on dialogue with those
15 with alopecia and their family members, the Open
16 Public Comment session will give anyone in the
17 audience the opportunity to make a comment. To
18 participate in that, you will need to sign up at
19 the registration table. Participation is first
20 come, first served, up to 15 commenters. We will
21 close that signup at the end of our break around
22 3:00 p.m.

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

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

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

20 We have a documentary filmmaker and several
21 photographers, including FDA photographers, to
22 capture this meeting. Please note that if you are

1 asked to participate in an on- or off-camera
2 interview, you may accept or decline that
3 invitation at your own discretion.

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

7 (Moment of silence.)

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

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

13 Opening Remarks

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

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

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

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

21 Alopecia areata is an autoimmune disease that
22 causes hair loss. The hair loss usually occurs on

1 the scalp, but can also affect the beard,
2 eyebrows, and other areas of the body. Dr.
3 Melissa Reyes, from our division, will provide
4 more background on the condition and current
5 treatment options in a few minutes.

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

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

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

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

22 I will now turn it over to Dr. Theresa Mullin,

1 who will talk about the FDA's Patient-Focused Drug
2 Development efforts. Thank you.

3 Overview of FDA's Patient-Focused
4 Drug Development Initiative

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

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

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

1 we committed to do this.

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

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

21 So at that time, we committed to do at least
22 20 of these meetings. And basically the review

1 divisions and patient groups between our own
2 internal people and patient groups wanting to have
3 this more, we've had 24 instead of 20, this is the
4 last month of that program, for the last user fee
5 program. So now we're going to reauthorize and
6 move on to the next authorization of PDUFA where
7 we have commitments to further move this program
8 forward and develop guidance so people know what
9 to do with the kind of information that we get in
10 these meetings.

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

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

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

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

21 We put that information together to develop
22 these reports that have been extremely valuable to

1 us. They both serve as an immediate way to
2 capture as authentically as we can what we heard
3 today and the way we heard it from you, and to not
4 only provide that to reviewers going forward when
5 they do get drugs or there is a sponsor that wants
6 to do a development program in this area, we can
7 use it as a resource for ourselves.

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

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

18 Overview of Alopecia Areata and
19 Current Treatment Options

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

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

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

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

18 So just briefly we'll go over the clinical
19 features of what makes alopecia areata distinct.
20 We'll go over who it happens in, that's
21 epidemiology. And then being the FDA, we'll talk
22 about the treatment options available. And then,

1 most importantly, we'll talk about the impact of
2 the disease on quality of life, and what's why
3 you're all here today.

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

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

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

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

7 Now, in terms of nail involvement, the reports
8 of nail changes vary based on the study, but 10 to
9 38 percent of subjects in the studies report that
10 there is some kind of nail finding. This is one
11 of the more common. If you can appreciate the
12 nail pitting, there are small indentations or pits
13 that make the nail plate look a little bit rough
14 in appearance.

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

1 Studies vary in terms of gender distribution,
2 but it's likely that it happens equally in men and
3 women. And I see a lot of young faces here today,
4 so this might be relevant for you. In children,
5 the mean age of onset is between the ages of 5 and
6 10 years old.

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

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

21 So this is the most scientific of my slides,
22 so please be patient, but I wanted to give you a

1 look at what happens on the cellular level. So on
2 the left is a hair follicle from a normal
3 individual, scalp hair, and on the right is from
4 someone who has active alopecia areata. So to
5 orient you on the left, the pink and purple
6 structure is the hair strand. It's connected to
7 the skin at the very bottom, and that's the hair
8 bulb. So you can see on the right, in active
9 alopecia areata, you have a lot of little purple
10 dots, those are the inflammatory white blood
11 cells, and those are the cells that are disrupting
12 the hair bulb. That's where your hair grows. So
13 if you don't have the hair growth, you end up
14 shedding the hair, and that shows up as hairless
15 patches on the body and on the scalp.

16 So being an inflammatory process, most of the
17 treatments are anti-inflammatory in nature. And
18 so that brings us to treatment. So currently,
19 there are no FDA-approved treatments specifically
20 for alopecia areata, but treatments are done,
21 obviously, and these are mostly treatments that
22 are approved for other indications. So these are

1 topical and systemic treatments that are used off-
2 label.

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

8 So in terms of treatments, it's usually
9 divided by local versus systemic therapies. So by
10 far, the most common is corticosteroids topically
11 or injected intradermally into the skin. So these
12 types of medications can happen as creams,
13 ointments, gels, and solutions. Second-line
14 treatments are calcineurin inhibitors,
15 immunotherapies, and minoxidil, which is a hair-
16 growth-stimulating solution. And in the
17 literature, there are also reports of many other
18 types of treatments that are tried in alopecia
19 areata, so these include prostaglandin analog
20 solutions, platelet-rich plasma patches, topical
21 retinoids, cryotherapy, and light-based therapy,
22 such as excimer light. Local treatments are

1 usually used as a first-line or for people who
2 have limited involvement.

3 In terms of systemic therapies, these are
4 considered for patients who have more extensive
5 involvement of hair loss or if they have a really
6 rapid onset of disease or if they have really
7 progressive disease. And so, again, steroids play
8 a part, being one of the major anti-inflammatory
9 medicines we have, and this is typically given by
10 mouth or it can be given intravenously.

11 Immunosuppressants are medications like
12 cyclosporine, methotrexate, sulfasalazine, and
13 azothiaprime, and more recently are the
14 immunomodulators. So this includes TNF-alpha
15 inhibitors, JAK kinase inhibitors, and apremilast.
16 Also in the literature are systemic retinoids and
17 statin-based medications.

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

22 Now, the real reason why we're here is the

1 impact of alopecia on quality of life, and so I
2 wanted to share some data regarding that. So
3 there are studies that show that there are social,
4 psychological, and economic impacts due to the
5 disease on individuals. One study showed that up
6 to 40 percent had a lifetime prevalence of having
7 general anxiety disorder and major depressive
8 disorder.

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

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

22 In light of this, I wanted to share a

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

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

16 The Road from PFDD Meetings to

17 Clinical Trial Endpoints

18 DR. CAMPBELL: Good afternoon. My name is
19 Michelle Campbell, and I'm a reviewer of the
20 Clinical Outcome Assessment Staff. We're a group
21 here in the Office of New Drugs that looks at
22 outcome assessments that are used to see how a

1 patient feels, functions, or survives. And so
2 this is really where the patient voice comes into
3 play.

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

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

19 Drug companies want to hear this perspective
20 because it can help them give ideas on what to
21 measure in clinical studies. They can select or
22 develop questionnaires that measure these

1 important concepts and engage with the FDA as they
2 develop treatments. The information from these
3 meetings can also help support the FDA review of
4 clinical trial questionnaires to confirm that they
5 are adequately capturing the individuals' and
6 caregivers' perspective on health outcomes.

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

19 Another advantage of these meetings is that
20 they help us think about the clinical study
21 endpoints. So what is an endpoint? In the case
22 of a questionnaire, the study endpoint will be how

1 the questionnaire score is going to be measured
2 and analyzed in the clinical study. For example,
3 if individuals with alopecia are reporting the
4 most important benefit of treatment is symptom
5 improvement, then we would use that information to
6 encourage a drug company to select or develop a
7 symptom questionnaire that meets regulatory
8 standards.

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

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

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

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

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

1 due to treatment.

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

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

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

1 and what to measure.

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

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

1 are non-binding.

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

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

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

16 Overview of Discussion Format

17 MS. CHALASANI: Thank you, Michelle.

18 Let's see. So our goal today as we start this
19 discussion portion of our meeting is to really
20 foster an open dialogue on personal experiences
21 and perspectives on alopecia areata. Our two main
22 topics for discussion are health effects and daily

1 impacts of alopecia followed by current approaches
2 to treatment. We will kick off each session with
3 a panel of individuals and family members. There
4 are five for the first topic. And I will ask at
5 this time for our Topic 1 panel members to come to
6 the front, please. Right up here.

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

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

17 We will have staff floating around with
18 microphones, and they will come to you. Please
19 state your first name, and just your first name is
20 fine, before speaking. For transparency, we also
21 request that at the time of your first comment
22 that you disclose if you are affiliated with an

1 organization that has an interest related to
2 alopecia or if your travel here today has been
3 funded or if you have significant financial
4 interests in alopecia drug development.

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

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

22 So as far as the clickers, we'll have a few

1 test questions coming up, but basically when you
2 submit an answer for some questions, you can
3 select only one. For some of them, you will be
4 allowed to submit multiple answers. You will feel
5 a little buzz almost, and that means that our
6 system has captured your response. And we have a
7 few trial questions to test this out for everyone.

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

16 As Theresa mentioned earlier, we also have a
17 public docket for this meeting that will be open
18 until November 13th. We encourage you to share
19 your experiences and expand on what we discuss
20 here today through the public docket. The
21 comments will be incorporated into our summary
22 report as well. Anyone is welcome to comment

1 through the docket whether you're here today,
2 joining us via the Web, or you know someone who
3 wasn't able to participate today, but you think
4 they have something to contribute. Please
5 encourage them to submit their comments. You will
6 find the link on the slide here, and we'll also
7 email this link as well as the slides to folks
8 after the meeting to everyone who is registered
9 via the event website.

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

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

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

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

18 As has been described, our discussion today is
19 focused first on the health effects of alopecia
20 and daily impacts, and then approaches to managing
21 those health effects. Our discussion may touch
22 upon scientific treatments; however, the

1 discussion of any specific treatments should be
2 done in a way that helps us to understand the
3 broader issues, such as what health effects are
4 being addressed, and how meaningful is that to
5 patients and individuals and family members?

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

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

20 With that, let's begin with a polling
21 question. So folks in the room, take out those
22 fancy clickers. Our first question, it's a pretty

1 simple one, Where do you live? A, Within
2 Washington, D.C. metro area, so including the
3 Virginia and Maryland suburbs; or, B, Outside of
4 Washington, D.C. metro area.

5 (Using clickers.)

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

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

22 (Using clickers.)

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

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

7 Next question, please? What is your age? A,
8 Younger than 6 years old; B, 6 to 12 years old; C,
9 13 to 17 years old; D, 18 to 29 years old; E, 30
10 to 39 years old; F, 40 to 49 years old; G, 50
11 years old or older.

12 (Using clickers.)

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

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

22 Wow, I think we have a very nice range of

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

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

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

12 (Using clickers.)

13 MS. CHALASANI: Okay. Girl power here today.
14 75 percent female, and then 25 percent male, and 1
15 percent other. Okay.

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

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

1 Please check all that apply.

2 (Using clickers.)

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

4 Can we try another one, Sara, please?

5 (Using clickers.)

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

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

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

1 alopecia areata.

2 MS. CHALASANI: Thank you, Graham.

3 Panel #1 Discussion on Topic 1:

4 Health Effects and Daily Impacts

5 MS. CHALASANI: Okay. With that, thank you

6 all. Let's start with our first panelist now.

7 I'm just going to turn to Liz, and then we'll just

8 go straight down.

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

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

1 Thank you.

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

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

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

19 At the age of 30, I lost all of my body hair.
20 When I looked in the mirror, I did not recognize
21 the person looking back at me. I had no eyebrows
22 to give structure to my face. I wondered how my

1 husband could love me when I looked like this. I
2 avoided social events, like going out to dinner or
3 meeting up with friends. I was depressed and
4 angry that this happened to me.

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

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

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

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

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

10 Excuse me.

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

14 Excuse me.

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

18 As I get older, I think about the burden of
19 this disease, about applying eyebrow makeup every
20 day and finding a wig age-appropriate and
21 affordable. I worry if I decide not to wear
22 anything on my head. Will people avoid me because

1 they think I might be sick, have cancer, or
2 something contagious? I worry about other
3 illnesses due to the lack of hair to filter out
4 particles in my nose, eyes, and ears.

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

8 (Applause.)

9 MS. CHALASANI: Thank you, Liz.

10 And now we have Harrison and his mother, Sara.

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

16 I am sincerely grateful for your invitation to
17 be here today. Our family is here today as a
18 first step in our own transition from victims to
19 valiant warriors, fighting against a disease state
20 that lies in wait, unwilling to tell us when it
21 will strike again. We hope Harrison's story will
22 emblazon your spirit -- excuse me -- and compel

1 you to suit up and join us in this battle that we
2 intend to win. And so I begin.

3 My husband, David, and I have the most amazing
4 son, two of them actually, one who is hopefully
5 quiet in the back room, and the other, who is our
6 7-year-old, Harrison, that is sitting here with
7 me.

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

17 We have been on a cycle of regrowth followed
18 by hair loss ever since. Neither traditional nor
19 non-traditional treatments have reversed his
20 condition. Harrison is no longer receiving any
21 physical treatment. We are focused exclusively on
22 ensuring his emotional, social, and spiritual

1 health, for this is our choice to be here today to
2 support those aspects. And, again, we want for
3 Harrison to feel empowered, not victimized, by
4 this ailment.

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

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

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

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

20 Also, there is a concern that Harrison will be
21 resented by his peers and others for some sort of
22 special treatment or favoritism that he

1 inadvertently receives because of his condition.

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

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

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

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

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

18 Thank you so much for your time and your
19 interest.

20 (Applause.)

21 MS. CHALASANI: Thank you, Sarah and Harrison.

22 Next we have Samantha.

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

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

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

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

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

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

17 Being diagnosed with alopecia at such a
18 pivotal time in my life has definitely affected
19 it. I withdrew from all of my elementary school
20 friends. I spent that first summer in the house.
21 I refused to leave. I cried myself to sleep at
22 night. And I suffered from severe depression. I

1 often hid in my house, in my own house, from
2 people because when they would come to visit, I
3 didn't have a wig on. I judge my relationships
4 with people based on whether or not they know that
5 I have alopecia. I have family members that I
6 have distanced myself from because I couldn't
7 explain what was happening to me.

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

16 On my best days, I live a normal life, but on
17 the worst, I'm severely depressed and my own worst
18 critic over my appearance. What you have to
19 understand is that often African American women
20 are defined by their beauty, whether or not you
21 are light-skinned or dark, whether you have good
22 hair or bad, whether your hair is long or short,

1 and although people may or may not believe in
2 these things, society does. How does society
3 define a 14-year-old girl that has lost her hair
4 very quickly and has had no time to process it
5 herself? My greatest fear is that my three
6 beautiful daughters will one day lose their hair
7 and Mommy won't be able to explain why.

8 MS. CHALASANI: Thank you.

9 (Applause.)

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

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

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

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

4 "Hello. My name is Deirdre Nero. I'm an
5 attorney and live in Miami, Florida. It has been
6 19 years since I first found the bald patch on my
7 head that would completely change the course of my
8 life. It was during my junior year of college
9 while blow-drying my very thick long hair. Little
10 did I know then that the significant impact
11 alopecia areata would have on my life. I am now
12 40 years old, and I've been living with some form
13 of this autoimmune disease for almost half my
14 life.

15 "I started with alopecia areata patchy bald
16 spots at age 21. For about 9 years, it was just
17 patchy. Sometimes I had just one or two small
18 patches, and then other times I had lots of
19 patches and/or large patches. At age 30, I lost
20 all the hair on my scalp, alopecia totalis. And
21 at around age 35, I lost all of my hair everywhere
22 on my body, alopecia universalis, including leg

1 hair, arm hair, pubic hair, armpit hair, all scalp
2 hair, nose hair, eyebrows, and eyelashes. I've
3 had every single form of alopecia and experienced
4 what they all were like.

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

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

20 "When I lost my eyebrows and eyelashes, I
21 suffered the most. Your eyebrows and eyelashes
22 not only protect your eyes, but they add

1 character, definition, and expression to your
2 face. Without eyebrows, your entire face changes
3 and becomes unrecognizable. Not recognizing
4 yourself in the mirror is a very difficult thing
5 to deal with and causes an identity crisis.
6 Having no lashes not only make your eyes look
7 small and strange, but also cause problems, such
8 as constant discomfort in the eyes. I always feel
9 like I have sand or debris in my eyes.

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

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

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

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

21 "As an adult woman, 40 years old, living with
22 alopecia since 21, one of the most significant

1 impacts has been on my love life and sexual and
2 romantic relationships. Living in fear of being
3 rejected, not found to be attractive, unfeminine,
4 et cetera. I had a wig fall off during sex, which
5 makes you not want to wear it at all, but then
6 I've also had a man ask me to wear a wig for sex
7 because without it, they don't find me sexually
8 attractive.

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

17 "This is a disease that not only alters the
18 way you see yourself, but the way the outside
19 world sees you and treats you. For me, it has
20 been a constant battle. There hasn't been a day
21 since I found that first patch 19 years ago that I
22 have not wanted to scream or cry when looking in

1 the mirror or thought that I am damaged, abnormal,
2 unfeminine, or ugly because of my hair loss, not a
3 single day that I haven't worried about how a
4 client, colleague, friend, or love interest might
5 see me and judge me.

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

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

19 On behalf of Deirdre Nero, thank you.

20 (Applause.)

21 MS. CHALASANI: And now we have Megha.

22 MS. THYAGARAJAN: So I wanted to start off by

1 saying thank you guys so much for like choosing us
2 and letting us talk about our story.

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

13 My name is Megha Thyagarajan. I'm in 9th
14 grade, 14 years old, and I've had alopecia since
15 1st grade. The only hair left on my head is, so
16 to say, baby hair. It has a soft texture, and the
17 amount of my hair is so very few, it's like a
18 newborn's head. Even when I did have hair, it
19 didn't grow past my shoulders. My mother shaved
20 me once, but it never grew past that.

21 Now, many of you understand the emotional
22 roller-coaster alopecia provides and the impact it

1 gives to a person. I want to share with you my
2 experience and what I personally went through.

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

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

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

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

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

21 I'm frequently called a boy. I'm on the ski
22 team. I was listed as the last girl. The

1 professionals started asking my coach, "Are you
2 sure this is a girl?"

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

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

22 My biggest worry is when I grow up and I dream

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

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

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

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

7 (Applause.)

8 MS. CHALASANI: Thank you, Megha.

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

11 (Applause.)

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

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

17 (Show of hands.)

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

21 Large Group Facilitated Discussion: Topic 1

22 MS. CHALASANI: So to get us started with our

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

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

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

22 (Using clickers.)

1 MS. CHALASANI: Okay. Let's see. So we have
2 56 percent of you that said the most bothersome
3 aspect of their alopecia is the widespread hair
4 loss. Then we have 41 percent that said skin
5 sensitivity, such as the sun, temperature, or
6 sweat. That's very, very important for us to
7 hear. Thirty-nine percent said unpredictability
8 of when or where hair loss will occur. And then
9 we have a nice range for all of the other aspects
10 as well.

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

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

15 (Using clickers.)

16 MS. CHALASANI: Okay. We have a nice range
17 here as well. Similar to what we heard from the
18 pediatric and young adults, 56 percent said the
19 most bothersome is the widespread hair loss. And
20 then once again similar to what we heard from the
21 younger folks in the audience, we have 53 percent
22 that mentioned skin sensitivity to sun,

1 temperature -- such as sun, temperature, sweat as
2 being the most bothersome. After that, we have 42
3 percent for location of hair loss as well. And
4 then a nice range as well. Very interesting.
5 Thank you. Thank you all for participating.

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

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

15 MS. CHALASANI: Thank you.

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

18 MS. CHALASANI: Welcome, Doug.

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

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

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

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

1 day to exercise.

2 But thank you very much. I appreciate it.

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

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

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

12 CONNELLY (ph): Connelly.

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

20 And I want to say that watching your child go
21 through alopecia is one of the hardest things
22 you'll ever go through. And I don't want to cry

1 in front of my kid, but it tears you apart
2 watching your son get in the bathtub and the hair
3 just come out and fill the water and it go down
4 the drain, and you can't do anything about it.

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

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

21 So that's all I wanted to say.

22 MS. CHALASANI: Thank you. Thank you. That's

1 really important. And we will spending a lot more
2 time in the second half during the topic, too,
3 hearing from you all, what you really want, and
4 what would be really meaningful in regards to
5 treatment options.

6 One more comment on the hair loss?

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

18 And it affects relationships. You know, I
19 don't have romantic relationships because I'm
20 concerned about, "What is he going to think?" I
21 don't wish to -- you know, I have -- he has to be
22 something special to even think about it, but I'm

1 generally it's not worth the effort. And
2 generally I don't think about it because it's -- I
3 have way more important fish to fry, you know?
4 And it's just hair and you put it -- you know, you
5 bury it deep, right? But the patchy hair loss is
6 a major issue.

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

16 (Show of hands.)

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

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

21 Could we hear from folks a little bit about
22 the skin sensitivity, such as to sun, temperature,

1 or sweat? I know Sarah spoke about Harrison's
2 experiences. A couple in the back.

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

16 But I noticed recently with football season
17 starting, whenever we go out to perform in our
18 marching show during halftime, the hats that we
19 have to wear, they don't stay on my head because
20 of the sheer amount of sweat that comes out
21 because I don't have anything to like hold it in.
22 And it gets into my eyes and just that's a really

1 big thing for me, is that I can't do some of these
2 things because I can't go swimming. And I have
3 like a swim cap, you know, like Olympic swimmers
4 have to use, so that way like my head doesn't get
5 burned in the water. And so that's just something
6 that's really important to me.

7 MS. CHALASANI: Thank you. Thank you.

8 I think we have one comment here.

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

13 I have patchy alopecia. I've had it since I
14 was 14, so I can certainly relate to many of the
15 comments that were made. As far as the skin
16 issues, that's one of my biggest issues beyond the
17 hair loss, is I have extremely sensitive skin to
18 the sun, to fragrances. It started probably when
19 I was early twenties, I had eczema very severely,
20 and over time, I've been able to kind of keep that
21 under control, but I am extremely sensitive to the
22 sun to the point -- and it's unfortunate because I

1 live in Florida -- but I do have to be very
2 careful to wear a sunscreen of SPF 70 and above.
3 My preference is 100. But I also do break out,
4 you know, from fragrance in lotions or, you know,
5 detergents, or even soaps, I have to be very
6 careful. So it's just something I definitely
7 attribute to the alopecia.

8 MS. CHALASANI: Thank you, Maria.

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

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

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

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

20 In my childhood and young adulthood and even
21 later than that, I was foolish enough not to think
22 that I would ever have sun-damaged skin. I now go

1 to my dermatologist twice a year and he freezes
2 sun-damaged spots off my head. You might notice
3 that I have a number of obvious ones that he just
4 treated last week coincidentally. I think there
5 were 12. I think inevitably I will have skin
6 cancer because I don't think you can get all of it
7 off. I've damaged too much over the years. And
8 it's something I never thought about, nor my
9 parents ever thought about, but it is something
10 for all of us to think about with our kids.

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

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

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

19 CHERYL: Hi. Cheryl. I'm from Northern
20 Virginia. And full disclosure, I work very
21 closely with the National Alopecia Areata
22 Foundation. So skin sensitivity. My skin is very

1 sensitive. I work with the Virginia Renaissance
2 Fair, and we're outside in May and June when the
3 sun is very bright and beats, and I get burned
4 probably -- I try not to get burnt really well. I
5 have a really big hat, a really, really big hat,
6 that I wear. But hats are very important.

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

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

20 I do want to ask really quickly, for the 23
21 percent of you that mentioned other health effects
22 that may be associated with their alopecia, would

1 you mind sharing what those health effects may be?

2 I think we have a few hands that went up.

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

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

21 So it's like I'd love to know if anybody is
22 working on that connection because I really think

1 there's -- for people like me, it's a strong
2 connection. I had the patchy alopecia until I was
3 18, and then during a stressful time in my life,
4 bang, it was gone, it was all gone. And it was
5 really, really hard, I can relate to everything
6 everybody said.

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

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

22 MS. CHALASANI: Thank you. Thank you. And

1 some of the comments that we heard, we did hear
2 some frustration with the diagnosis process and
3 the lack of knowledge in the medical community,
4 and this meeting is a platform that we can help
5 communicate a little bit more about alopecia
6 areata.

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

9 Jennifer here.

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

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

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

22 But also wearing a wig and a cap is really

1 hard because it makes (inaudible), it gives me a
2 headache, and it's hard to even wear a wig because
3 it sort of bunches up behind my head. I really
4 have no choice. So, yeah.

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

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

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

17 What do you find to be the most bothersome
18 impacts of your alopecia areata on your daily
19 life? Please choose up to three answers. A, Time
20 or cost of daily maintenance; B, Refraining from
21 activities, such as school, work, sports, or
22 social activities; C, Self-consciousness or

1 embarrassment; D, Bullying or discrimination; E,
2 impact on relationships with family and friends;
3 F, impact on intimate relationships; G, Physical
4 impacts, such as pain or difficulty concentrating;
5 H, Emotional or psychological impacts, such as
6 anxiety, fear, depression; or, I, Other impacts
7 not mentioned.

8 (Using clickers.)

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

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

1 to three answers for this question.

2 (Using clickers.)

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

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

18 CALLIE (ph): Hi. I'm Callie. I am 28 years
19 old, and I have had alopecia universalis since I
20 was 18 months old. This is actually the first
21 time I've ever really met anybody else with
22 alopecia. As a kid, I can't even begin to

1 describe the impact that it had on me growing up,
2 the amount of bullying and torment I faced, and I
3 still deal with a lot of anxiety and depression.
4 (Becomes emotional.) You know, it's just -- it's
5 like indescribable, the amount of torment you face
6 as a child especially, but even as an adult. And
7 you get it from other children, other adults.
8 That's about it.

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

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

13 UNIDENTIFIED: Hi again. So being in high
14 school right now, I'm pretty fortunate that I live
15 in a town where it's like a small town, so I kind
16 of know a lot of people. And I have a really good
17 support system, like my friends and my family are
18 amazing. And I just know that, for instance, a
19 couple of weeks ago we had our first day of
20 school, and just -- I just remember sitting in my
21 room and like dreading it because I was like,
22 great, I've got to go meet new people again. I

1 have new teachers who don't know what's going on.
2 So I know that for me personally, that's a big
3 thing.

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

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

20 But just emotional effect on me personally,
21 like I couldn't imagine going to a different
22 school and being new and not knowing anybody at

1 all who doesn't know what's going on in your life.
2 So for me, that's a big part of it.

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

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

15 And so as soon as I found there is no cure,
16 the first thing I did is I stopped all the
17 activities for her because I didn't know what is
18 going to be affecting it. And the next thing I
19 did is me and her teacher, Mrs. Alexando (ph), we
20 worked with her to counsel her to be a very strong
21 person emotionally and psychologically in the
22 sense that never get depressed or never do

1 anything, be a go-getter, forget about anything in
2 life. You are what you are, and made her strong.
3 Even though I know she is strong, there's always a
4 part of her which suffers. I mean, the
5 psychological thing, the first time I went to the
6 NAAF conference in Los Angeles is when I saw all
7 the kids in the swimming pool, everybody bald, I
8 knew I'm not alone.

9 (Laughter.)

10 (Applause.)

11 MS. CHALASANI: Thank you, Sanguita.

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

14 BECCA (ph): Hi. I'm Becca. I'm 14 years
15 old, and I just started my first year of high
16 school, so I'm a freshman. It's hard to wake up
17 and have to go to school every day because you
18 know you're different. And I play sports. I play
19 volleyball and basketball, and even just walking
20 onto the court -- like going to school, I have my
21 makeup, and I feel just a tad bit more beautiful,
22 but still I feel like I'm hiding myself from

1 everyone. And I can't wear my makeup on the
2 court. So I automatically feel ugly and secluded.
3 So it's scary just to walk out and practice. And
4 for games, it's even worse because the whole
5 school is there and they see me without eyebrows
6 and eyelashes. And I wear hats, but those are
7 very hot, and I get extremely sweaty. And I have
8 really bad heat waves on the court which affects
9 how I play.

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

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

19 (Applause.)

20 MS. CHALASANI: I'd like to ask the adults in
21 the room now a little bit about their emotional or
22 psychological impacts. And I'll ask you to keep

1 one question in mind, which is, How have the
2 impacts changed as you've gotten older? For
3 example, has an impact become more bothersome as
4 you've grown older or maybe less bothersome as
5 you've grown older? I think we have --

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

15 But I know I was -- my parents are very
16 supportive, but I isolated myself a lot.
17 Actually, I know I suffered a lot with body image
18 issues. And I was actually hospitalized for
19 anorexia for a couple of years. And that
20 definitely was a very low point that I don't think
21 I would have had if I was maybe more confident as
22 a young adult and didn't face like, you know, kids

1 picking on me, but -- and which also affected my
2 family because parents have to treat you and take
3 you to -- you know, back and forth and visit you.

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

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

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

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

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

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

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

22 And what I'm most afraid of about standing

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

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

19 MS. CHALASANI: Thank you, Julie.

20 JULIE: And I saved myself. Not one damn
21 doctor did that for me, not the FDA, not a doctor,
22 not a drug company. I saved myself. I stopped

1 eating gluten, I stopped eating tomatoes. I found
2 the drugs, I found the supplements, and the things
3 that were going to change my life, and I did it.
4 And I can't point the finger to anybody else that
5 did that for me. So that's -- that's -- now
6 I'm --

7 (Laughter.)

8 MS. CHALASANI: Thank you, Julie.

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

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

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

19 MS. WOODWARD: So for the previous question,
20 we did have some comments in regard to asthma,
21 also experiencing allergies associated with food,
22 and new episodes of patchy hair loss that

1 specifically occur when getting sick.

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

12 MS. CHALASANI: Thank you, Shannon.

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

15 (No audible response.)

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

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

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

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

5 Thank you.

6 (Break.)

7 Panel #2 Discussion on Topic 2:
8 Current Approaches to Treatment

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

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

19 So I'm going to let Katie get started.

20 MS. KRUEGER: Hi. I'm Katie. And I am one of
21 the millions of victims of alopecia. When I was
22 just 10 years old, I was diagnosed with alopecia

1 areata. I began my long road of treatments with a
2 prescribed topical that I used for about 6 months.
3 Following the topical, I began receiving dozens of
4 corticosteroid injections in my scalp every month
5 for 9 months.

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

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

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

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

21 My hope is that one day there will be an
22 easily accessible treatment that will result in a

1 well-managed condition. I've never known my
2 condition to be well managed, so to speak.
3 Alopecia is an unpredictable disease. One can
4 never know or predict the extent of its future
5 harm or doings. I live every day with slight hope
6 of a miracle while also fearing its progression to
7 universalis.

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

20 So as my time comes to a close, I hope that I
21 made somewhat of a difference in all of your
22 perspectives going forward. While a mere 3

1 minutes is not even close to enough time to
2 explain the hardships that people with alopecia
3 endure, I sincerely hope that you are all able to
4 get a glimpse of the importance of this disease.

5 MS. CHALASANI: Thank you, Katie.

6 (Applause.)

7 MS. CHALASANI: And we have Katie again.

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

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

21 As amazing as my local doctors are, they
22 couldn't give me the answers I so desperately

1 needed, as I was in a race against time trying to
2 stop my rapid hair loss. During the summer going
3 into my 8th grade year, my family traveled to
4 Seattle to seek treatment from a doctor at
5 Children's Hospital. She then diagnosed me with
6 alopecia areata, with no treatment plan currently
7 in place that works for all patients.

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

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

20 In November, my family found a different
21 doctor over in Seattle, claiming he had the latest
22 technology to cure hair loss, and agreed to try to

1 the treatment on me. The treatment, called PRP,
2 is commonly used for male pattern baldness, but at
3 this point in time I was willing to try anything
4 to get my hair back. The treatment consisted of
5 drawing blood, spinning it with nutrients, and
6 then inserting 250 numbing shots around a certain
7 area of my scalp and ending in 200 deep-tissue
8 shots with the new blood. I chose to receive this
9 treatment twice.

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

19 We hit our rock bottom both physically and
20 mentally during the summer of 2014, headed into my
21 freshman year of high school. My dad booked a
22 family trip to the beautiful Rochester, Minnesota,

1 where I visited the well-respected Mayo Clinic.
2 We thought they could give us the type of answers
3 we needed, but after multiple exams, I was
4 prescribed methotrexate, a form of chemotherapy.

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

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

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

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

16 Thank you.

17 MS. CHALASANI: Thank you, Katie.

18 (Applause.)

19 MS. CHALASANI: And now we have Tyrone.

20 MR. FOLLIARD-OLSON: Hello. My name is Tyrone
21 Folliard-Olson, and I'm a husband and new father
22 in Minneapolis, Minnesota. I have had alopecia

1 areata since I was 13 years old, so for the past
2 20 years. I've been an advocate for the alopecia
3 areata community since 2013, when the National
4 Alopecia Areata Foundation created the Legislative
5 Liaison Program.

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

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

22 (Laughter.)

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

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

21 At 23, as my bald spots became unmanageably
22 large, I came to terms with shaving my head and

1 being bald. I had the luxury of being a man in a
2 society that deems this aspect acceptable, so
3 luckily it wasn't too difficult to transition.

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

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

19 The injections are quite painful. The monthly
20 dermatology appointments are an inconvenience, and
21 without good health insurance, I likely wouldn't
22 be able to afford the monthly injections, but for

1 me, all of that is worth it in order to maintain
2 some semblance of eyebrows. As a side note, my
3 eyebrows are currently more full than they've been
4 in years.

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

10 Thank you.

11 (Applause.)

12 MS. CHALASANI: Thank you, Tyrone.

13 And now Andrea.

14 MS. ALBERTI: Hello. So I have had alopecia
15 areata in some form as a result of my autoimmune
16 disease since I was about 4 years old. Most of my
17 childhood, it was just alopecia areata, and at the
18 time, I was lucky to have thick curly hair to hide
19 most of the spots. And with the spots that we
20 couldn't hide, me and my mother slowly worked down
21 the line of topical treatments that were offered
22 by our dermatologists. First it was Rogaine, and

1 then on to ascorbic acid. And once I got to
2 middle school, it was leaving class every month to
3 drive to the Cleveland Clinic -- (becomes
4 emotional) -- excuse me -- to get corticosteroid
5 injections.

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

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

22 I cannot express to you how much developing

1 alopecia totalis delivered a blow to my self-
2 esteem, my self-image, and my ability to focus on
3 schoolwork as a teen. Even as an adult, it has
4 had a fundamental effect on my personality and the
5 way I carry myself in public.

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

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

22 Looking back, treating my alopecia with

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

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

15 MS. CHALASANI: Thank you, Andrea.

16 (Applause.)

17 MS. CHALASANI: And now we have Gracielle.

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

1 emotional.)

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

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

18 So as probably the majority of you, my
19 treatment was the topical minoxidil. It was very
20 mild, pretty much no side effects, but it didn't
21 work very long. After minoxidil stopped working,
22 my doctor at the time prescribed adrenaline. It

1 was a dark brown substance. It would stain
2 everything, leave my skin very sensitive, and my
3 clothes and my pillows, it was all ruined.

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

9 After a while, the cortisone injection also
10 stopped working, and the doctor had the great idea
11 to combine the cortisone injections with liquid
12 nitrogen cryotherapy. So every month, after the
13 100 self-injections in my scalp, the doctor would
14 apply the subzero liquid nitrogen on top of it on
15 my scalp.

16 The only way I can describe, it was torture.
17 The liquid would burn my skin that was already
18 hurting from the injections, and would leave the
19 skin like with many blisters after that. The 20
20 hours after the treatment was horrible. I
21 couldn't barely sleep because I couldn't lie my
22 head on the pillow. When the skin started to

1 heal, it would itch constantly, and the dead skin
2 would peel off of my head.

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

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

21 In my experience, all these treatments I tried
22 had the same downsides. The medication did not

1 prevent new hair loss from developing. It become
2 ineffective after a while and was at least very
3 uncomfortable, but the majority was very super
4 painful.

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

12 I did not seek any treatment for 11 years.
13 But recently through a friend, a mutual friend
14 that I have on Facebook, and I start sending her
15 some pictures and asking her what she was doing,
16 and I learned about the Xeljanz. I'm being on the
17 treatment with Xeljanz with Dr. King for 4 months,
18 and for the first time, I have hope again that I
19 will have my hair back. I've never been with not
20 wig in front of anybody that I did not know, but
21 I'm very happy, and I want to share with everybody
22 in the community. I see 6 percent of my hair is

1 growing, my brows are coming back, under the
2 tattoo that now is kind of out of place.

3 (Laughter.)

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

8 (Applause.)

9 MS. CHALASANI: Thank you.

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

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

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

9 Thank you for the opportunity.

10 (Applause.)

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

17 One thing that Andrea said that really
18 resonated with me was that -- and I'm going to
19 have to paraphrase here, and feel free to jump in
20 on your mic -- was that you said managing alopecia
21 is like managing weather, you can't, so you can
22 only work around it? Is that -- prepare for it,

1 yes, exactly. How many of you feel like that in
2 the room?

3 (Show of hands.)

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

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

11 So first, for the pediatric and young adults,
12 have you ever used any of the following drug
13 therapies or medical devices to treat your
14 alopecia areata? So currently or in the past.
15 And please feel free to check all that apply. A,
16 Topical corticosteroids; B, Injectable
17 corticosteroids; C, oral corticosteroids; D, Other
18 topical treatments, such as minoxidil, Rogaine,
19 anthralin, immunotherapy, such diphencyprone/DPCP;
20 E, Immunomodulatory therapies, such as Xeljanz or
21 Jakafi; F, Light treatment, such as laser or
22 phototherapy; G, Other prescription medicine, such

1 as psychiatric or pain medication; H, Other drug
2 therapies or medical devices not mentioned; and,
3 I, I am not using any drug therapies or medical
4 devices.

5 (Using clickers.)

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

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

20 Okay. So let's take a look at these results.
21 We have 89 percent topical corticosteroids,
22 followed by 63 percent for other topical

1 treatments. Following topical, we just have a
2 very nice range of approaches that have been tried
3 in the room. H, 41 percent for other drugs
4 therapies or medical devices. So after the adults
5 have a chance to take this question as well, we'll
6 definitely come back, and I'm interested in
7 hearing what those other drug therapies or medical
8 devices may be.

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

14 (Using clickers.)

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

1 Large-Group Facilitated Discussion: Topic 2

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

17 JULIA: Hi. My name is Julia, and I was
18 diagnosed with patchy alopecia probably about 5
19 years ago. And I used topical, injectable, and
20 other topical treatments, such as Rogaine,
21 probably for about 2 years. And then one day I
22 just said I'm doing anything else, this is it, I'm

1 not doing another injection. And at that point, I
2 started --

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

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

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

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

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

22 (Applause.)

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

3 RUTH: Hi. My name is Ruth. And I have a
4 10-year-old daughter, Bailey, right here. My
5 daughter was diagnosed with alopecia areata right
6 before her third birthday. It was terrifying. I
7 had hoped that it was ringworm. Of course, took
8 her to the dermatologist, who first prescribed
9 topical steroids and the Protopic. We were on it
10 for 3 months. No effect at all. As a matter of
11 fact, her hair continued to fall out.

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

1 shampoo.

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

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

19 The effects have not been as severe as what
20 many have probably read about, blistering and pus.
21 I think I've just learned how to use it and to
22 toggle it. I've become the DNCB expert. But it

1 would be nice for my daughter to have some form of
2 therapy where the hair will just stay and that she
3 doesn't have to scratch her head for every day of
4 her life. So that's been our experience with
5 DNCB.

6 (Applause.)

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

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

19 (Heads nodding.)

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

1 (Heads nodding.)

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

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

16 Go ahead.

17 MEGHA: So I did something called ayurvedic
18 treatment. It's an Indian treatment. I spent
19 over a month in India inside a hospital. And so
20 what it did was like they gave me medicine and I
21 was like on a strict diet. I wasn't allowed to
22 get exposed to the sun. I had to stay in the

1 hospital. And like it was a really -- they had
2 like different things where you had to be massaged
3 in oils and stuff that was supposed to help like
4 circulate things in your body. And then they had
5 a lot of different things. But like all-in-all it
6 was like -- it was really hard because I was only
7 9 years old when I went through it, and I barely
8 could eat anything. I couldn't go outside. And I
9 couldn't -- I literally couldn't do anything. I
10 was -- and the medicine was like so bad, I
11 couldn't even eat it. Like there were days where
12 they said you can't eat anything until like
13 literally the end of the day.

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

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

22 One other -- well, the medical devices. We

1 didn't really hear any comments thus far about
2 folks who have tried light treatments, such as
3 laser or phototherapy. Has anyone in the audience
4 tried this treatment and willing to share an
5 experience perhaps? Okay, perfect.

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

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

10 GURU: Well, I can talk about light also
11 because we've tried that, too. My name is Guru.
12 I'm from Dallas, Texas. I have a 7-year-old,
13 8-year-old daughter now, Mia (ph). She got
14 alopecia when she was 2 years old. And, like
15 Megha, we're also from India.

16 And as a 2-year-old and someone from India,
17 anytime anybody sees, especially folks, current
18 parents or other relatives, sees a child with no
19 hair or hair falling off, everybody has got some
20 kind of advice, some kind of oil that they have
21 used, and they want to treat them with diet or
22 with homeopathy or, you know, they know one doctor

1 in this particular city in India who has treated
2 this in the past successfully, and so on. So for
3 the first 1, 2 years when she had this condition,
4 we've gone through a series of different things
5 that we wanted to try. Ayurveda was one. It
6 wasn't as -- I'm sorry, Megha, for what you had to
7 go through, but it wasn't as much as what she
8 mentioned, but there was some kind of oils that we
9 tried, some oral medicines. And then homeopathy
10 was another thing that we tried for maybe 2, 3
11 months. We didn't see any results.

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

19 Yeah, so I would say -- and probably many
20 parents might relate to this -- as a parent who is
21 exposed to this for the first time, you hear a lot
22 of different things, and you want to try and fix

1 this. As a parent, I felt, both my wife and I,
2 very helpless that we're not able to do something
3 to our daughter, whose hair just was falling off
4 every day for a period of 1 year. So we went
5 through a lot of different things that we tried.
6 And we now for the last 4 years or 5 years are not
7 doing any drug therapies. We do some other
8 things, and we can talk about --

9 MS. CHALASANI: Sure.

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

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

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

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

1 months, it did.

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

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

17 So I did try everything over a 5-year period
18 as scientifically and as accurately as I could,
19 eliminating things, focusing just on what we
20 thought his trigger was. We're really no longer
21 interested in what his trigger is or was. Is it
22 stress? Again, is it a lack of a vitamin? Was

1 there some traumatic event? We don't know, and at
2 this point we don't really care, we just have a
3 little boy who's singing again on stage because
4 he's got hair. Thanks.

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

11 UNIDENTIFIED: Not a bit.

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

17 UNIDENTIFIED: I can lead this.

18 MS. CHALASANI: Okay.

19 UNIDENTIFIED: It's really important, I
20 believe, a child at 3 or 4 cannot, but a child at
21 12 who is trying to build his identity is. I
22 also, before I get down to -- I want to say that

1 my son, Charlie, knows that he may not be on the
2 Xeljanz forever. He does understand that there
3 are risks involved. But if it gives him time to
4 build from the inside out his confidence, he's
5 willing to do it.

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

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

22 We did do the Rogaine when the hair was back

1 in. So we had stopped the injections, but we
2 thought almost prophylactically to use the
3 Rogaine. Did it work? I don't think so.

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

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

11 UNIDENTIFIED: Sure.

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

14 KATIE: Hi. My name is Katie. I'm 35. I
15 live in D.C. I originally got alopecia areata in
16 my mid to late twenties, where I lost my eyebrows
17 and my eyelashes. The dermatologist -- I did the
18 injections in my eyebrows, which helped them grow
19 in patches, and at that point, I was using makeup
20 to fill in my eyebrows, and it just kind of got
21 annoying when there are just patches and I kind of
22 had to fill it in, and it made it more obvious

1 than just with no hair and the makeup. I've since
2 gotten the microblading and love it. I highly
3 recommend if you can afford it.

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

14 With the eyebrows, again, I probably went
15 every 4 to 6 weeks to my dermatologist for those.
16 Rogaine I probably took for about -- I used for
17 probably about 6 months, but at that point I think
18 is when the rest of my hair started falling out,
19 and then at that point I think I knew that it was
20 just more work and more emotionally -- more
21 emotional work to have the treatments when I
22 wasn't seeing any results. I don't even think I

1 had any response to the injections in my scalp
2 either.

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

5 MS. CHALASANI: Thank you for sharing that.
6 I'm hearing 6 months and less.

7 KATIE: I just want to make --

8 MS. CHALASANI: Sure.

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

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

1 us already.

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

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

15 MS. CHALASANI: Thank you, Shannon.

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

21 Besides the therapies that we've already
22 mentioned, what else are you doing to manage any

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

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

17 (Using clickers.)

18 MS. CHALASANI: Okay. So 71 percent of you
19 are using temporary cosmetic measures, such as
20 wigs, hats, weaves, or makeup to manage your
21 alopecia. And then we have a nice range for all
22 of the other options as well, 47 percent for

1 dietary and herbal supplements, which we've heard
2 a lot about the diet changes similar to D, in diet
3 modifications. F, we have the complementary and
4 alternative therapies. I think we heard a little
5 bit about the Ayurveda, which I think this falls
6 under this bucket here. Twenty-four percent who
7 are saying that, "I'm not doing or taking any
8 therapies to treat my alopecia." Twenty-six,
9 over-the-counter products. And then 22 percent
10 are the cosmetic procedures.

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

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

19 (Show of hands.)

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

22 UNIDENTIFIED: My daughter, Mia, had alopecia,

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

10 (Laughter.)

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

20 And there are different organizations that
21 give wigs free to kids for, you know, X amount of
22 time. And so she has a wig. She chooses to wear

1 it when she wants to wear it. It's an accessory
2 just like her different glasses, and I love that.

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

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

14 (Laughter.)

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

20 And I just needed to know that as a parent,
21 and it just made me think that, okay, I didn't
22 need to make her take these injections, which we

1 can't stand needles, we are not -- all these
2 injections in her head and everything else, I
3 didn't have to do that, that somebody else would
4 love her as much as we did. So that's why we went
5 this way. Is it making a difference? Probably
6 not, but it is what it is. That's how we're
7 looking at it.

8 MS. CHALASANI: Thank you.

9 I think Rosie and Rosie's mother.

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

17 So at that point, we did the topicals for a
18 year, and then Rosie said, "You know what, Mom? I
19 like being bald. I'm okay with this." She's
20 like, "Are you okay?" And I'm like, "If you're
21 okay, I'm okay." So we're in the 24 percent
22 that's just kind of focusing on her confidence,

1 her inner soul, because that's what's going to
2 carry her through life. Hair, wig, head scarf,
3 therapies. I think as a parent we didn't want to
4 drug her up and give her shots in the head. We
5 just want her to be a good person and feel good
6 about herself and love herself. And she's
7 teaching us about being Rosie and being a happy
8 little girl. And she wants to say something. You
9 know, she's the better talker. So here you go.

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

13 (Laughter.)

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

17 (Laughter.)

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

20 (Laughter and applause.)

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

1 ideal treatment.

2 (Laughter.)

3 MS. CHALASANI: I love chocolate as well.

4 One more comment and then -- okay, yes.

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

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

22 But as you hear these laundry list of

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

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

19 Someone in my city actually suggested that we
20 leave Atlanta, where we've lived our whole lives,
21 and move to Sarasota because they knew somebody
22 who had alopecia, and when they went to Sarasota,

1 alopecia went away. Talk about a non-traditional
2 therapy.

3 (Laughter.)

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

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

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

1 (Applause.)

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

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

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

9 (Laughter.)

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

16 Skipping all of the things that she's tried
17 and have not worked, one of the most interesting
18 things that we're dealing with right now is she
19 met a new dermatologist. He was previously the
20 chief of residency for dermatology at the Mayo
21 Clinic, and somehow he landed in Milwaukee,
22 Wisconsin. And after talking about a couple

1 things, he said, "You know what? I can see that
2 this is expanding and expanding and expanding, and
3 I think that we have to find a way to try and
4 actually stop this."

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

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

16 But, so we started the process to get Xeljanz,
17 and her insurance -- this is kind of where it gets
18 back to the panel -- the insurance company said,
19 "Actually, what we would like you to do is try
20 methotrexate," and the one that starts with an L
21 that I was trying to remember, which is like
22 really dangerous, and because Xeljanz is not

1 approved for alopecia areata, and as you know,
2 nothing is.

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

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

19 Thank you.

20 (Applause.)

21 MS. CHALASANI: Thank you, Chris. Thank you.
22 I think you raised several really important

1 points. I would like to just keep in mind that we
2 do want to focus our conversation on treatments
3 more broadly. This isn't necessarily the most
4 appropriate platform to talk about one specific
5 medical product.

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

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

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

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

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

19 My mom would have to visit these schools each
20 and every single year explaining to these
21 officials why I'm going through this and what she
22 is going through as a parent. And I wish she was

1 here right now. She couldn't make it this
2 weekend, but just to sit here in the gap for so
3 many young people is an honor and a privilege to
4 be able to do something about this because I
5 really want to see our kids happy.

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

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

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

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

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

1 (Applause.)

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

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

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

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

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

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

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

22 (Using clickers.)

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

15 Thank you.

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

21 (Using clickers.)

22 MS. CHALASANI: Okay. Different results,

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

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

19 I think we could easily talk about this for a
20 very long period of time, this question itself,
21 but in the interest of time, I'm going to ask all
22 of you for a favor. Please note this question

1 down. It's very much of interest to us. But then
2 please go to the public docket that we've been
3 talking about throughout the afternoon and tell us
4 a little bit more about why you selected what you
5 did for your most burdensome downsides. I think
6 some of the concepts and topics we've heard so far
7 have hinted at it, but any examples and specific
8 experiences that you can share with us would be
9 really helpful.

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

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

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

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

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

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

20 More common side effects of this therapy may
21 include fatigue, headaches, weight gain, sore
22 throat, and gastrointestinal issues. Rare, but

1 more serious, side effects may include liver
2 problems, cancer, stroke, infertility, or birth
3 defects.

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

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

11 (Show of hands.)

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

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

16 (Laughter.)

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

20 (Applause.)

21 MS. CHALASANI: I think that's helpful, and I
22 think we heard some participants who said it would

1 have to be at least 90 percent I think is what we
2 heard earlier. Okay.

3 A few other comments from folks in the
4 audience?

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

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

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

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

21 UNIDENTIFIED: So this clinical trial is not
22 acceptable.

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

3 (Applause.)

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

7 DANIELLE: (Off microphone.)

8 MS. CHALASANI: Okay.

9 (Laughter.)

10 UNIDENTIFIED: Way to go, Danielle.

11 (Laughter.)

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

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

20 So let me change up the scenario question a
21 little bit. I'm going to change the second
22 sentence of the second paragraph to, "Early

1 research in animals and people show that this
2 treatment may increase hair growth on the scalp by
3 50 percent in some people." Now, what kind of
4 responses? I'm still seeing folks shaking their
5 head no.

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

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

12 (Laughter.)

13 MS. CHALASANI: Okay.

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

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

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

6 UNIDENTIFIED: (Off microphone.)

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

9 (Laughter.)

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

16 MS. SMITH: Hi. My name is Diana Smith. I'm
17 a support contact and a legislative liaison with
18 NAAF. And I got alopecia when I was 5 years old.
19 I think a lot of the resistance here is that you
20 still have to somehow manage yourself 50 percent
21 hair loss. You know, if you get one eyebrow
22 instead of zero, that's still drawing on one in

1 the morning, that still hasn't made a drastic
2 change in your self-management of the disease.
3 And that's not the ultimate goal for me of
4 treatment, and I feel like a lot of people would
5 agree with that. So --

6 (Applause.)

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

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

18 JESSICA: I'm Jessica. I'm from Michigan.
19 I've had alopecia since I was 10 months old. I
20 feel like if I were to do something like this,
21 infertility would not be an option. I would never
22 do anything that would make me not be able to have

1 children in the future. So if that was something
2 that they said, I would 100 percent not do it, no
3 matter how much came back.

4 (Applause.)

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

7 I think we have some hands back here.

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

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

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

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

9 (Applause.)

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

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

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

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

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

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

19 Successful therapy for different diseases and
20 conditions often build on themselves, and the
21 first success is not necessarily a complete
22 success in terms of getting a drug that is, you

1 know, 100 percent effective by whatever definition
2 of "effective" that is used. And it's never 100
3 percent safe. You know, when I started working at
4 FDA, I stopped using the term "safe and effective"
5 and started using "risk and benefit."

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

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

18 And so with that in mind, I hear all of the
19 reaction, I hear the immediate pushback to the
20 scenarios that we're giving you, but these are the
21 types of decisions we have to make if that's the
22 product -- you know, if the development program

1 doesn't deliver that 100 percent. And you really
2 have to start somewhere. You all clearly know,
3 you all painfully know, that there are no approved
4 treatments.

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

11 (Applause.)

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

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

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

14 DR. MARCUS: Right.

15 KATIE: So it was a huge win for me.

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

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

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

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

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

17 MS. CHALASANI: Thank you.

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

20 MR. REINHART (ph): Hi. My name is Ed
21 Reinhart. I'm the proud father of Katie. I
22 apologize. Kendall, thank you so much for those

1 comments. We're part of the Dr. King fan club.
2 Xeljanz changed our lives. And what I would
3 encourage you -- and we came all the way from
4 Yakima, Washington, to let the FDA know that --
5 Xeljanz is an FDA-approved drug, but it treats
6 pain.

7 And what I would let you know that alopecia is
8 also painful. And I would really encourage you to
9 open it up. Because right now our insurance
10 company doesn't cover Xeljanz, so I have to go to
11 Canada. Where right now if I went in the United
12 States, it's \$4,000 for 60 tablets, I go to
13 Canada, and it's \$1,000. The same drug, from
14 Pfizer, but we found a way, and it's a miracle
15 drug. And you're right, it's not going to work
16 for everybody, but we also have blood exams every
17 3, 4 months to keep track of it. But it's a
18 start.

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

1 difference to us. Thank you.

2 (Applause.)

3 MS. CHALASANI: Thank you, Ed.

4 Kendall.

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

14 MS. CHALASANI: Thank you, Kendall.

15 I think we have --

16 MS. CUNNINGHAM: Again, I'm Samantha, from
17 Detroit. For me personally, I would be willing to
18 -- when I look at all the things that my parents
19 have paid for that are not approved by the FDA,
20 with unknown side effects, with, you know, witch
21 doctors coming out of the blue, you know, with
22 diagnoses and ways to cure alopecia, and all the

1 different things that we've gone through, that to
2 know, to at least know, what the possible side
3 effects are, to know that I can go and have blood
4 work done, and that they can tell me if I'm
5 starting to have gastrointestinal issues or that
6 if I'm starting to have liver issues, and then I
7 can choose to end the treatment, is a win for me.

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

14 MS. CHALASANI: Thank you, Samantha.

15 We are cutting it really close on time right
16 now, and we do have to move forward with our Open
17 Public Comment session portion of the afternoon.
18 I just want to make another plug-in for the public
19 docket. You've seen the questions, change the
20 scenario, and send it back to us. Anything that
21 you can expand on, elaborate on, provide us more
22 insight into your daily life and your experience

1 would be very informative and insightful for us
2 here at the FDA.

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

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

11 Open Public Comment

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

14 (Chorus of noes.)

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

17 So this is the portion of our program where,
18 particularly if you signed up, actually we have 16
19 people have signed up. We want to make sure we
20 get you out on time, and so that we can wrap up
21 the meeting. So we're going to ask everyone to
22 please stick to 2 minutes, and I will have to stop

1 you. Hopefully, if you're a self-advocate or a
2 parent in the room, and what you have said is
3 resonating with what others have said, you can
4 strike yourself off of this and that will make
5 sure that everyone gets their time.

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

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

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

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

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

7 DR. EGGERS: Yeah. Is Ember here?

8 (No audible response.)

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

11 MR. YEAGLEY: Okay. My name is Jonathan
12 Yeagley. I'm from Berwyn, Pennsylvania. Mr.
13 Reinhart, who -- we're all big fans of Dr. King.
14 My son got alopecia in 7th grade. In March of
15 2016, we found Dr. King. He started us on
16 Xeljanz. By Christmas of that year, he was able
17 to take off his hairpiece. We went through all
18 the topicals, the injections, and, you know, we
19 couldn't be more happy with the effect that
20 Xeljanz has had on us. I'm amazed that they
21 haven't gone through -- I don't know if it's in
22 trial now or it hasn't progressed any further.

1 But Mr. Reinhart hooked me up with a doctor in
2 Canada who wrote a prescription for us. I travel
3 7 hours, I drive 7 hours to Buffalo, cross a
4 bridge, go half a mile to a Walmart to buy the
5 drug. It costs me \$1,250 a month as opposed to
6 \$3,900 a month at our local drug store. That's
7 \$15,000 a year versus \$47,000 a year in the United
8 States, which I think is just outrageous.

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

18 DR. EGGERS: Thank you. Thank you.

19 JONATHAN: Hello. I'm Jonathan as well. In
20 2nd grade, I was first diagnosed with alopecia,
21 and then it slowly grew back a little bit, but by
22 6th or 7th grade, I had to wear a hairpiece. And

1 until last semester -- I'm 19 years old, I'm a
2 sophomore in college, and last semester was the
3 first time I could finally go without my
4 hairpiece. So I went all through high school, all
5 through 7th and 8th grade with my hairpiece. And
6 as many of you people know, it's just awful.
7 People look at you like all the time. Like I'm
8 still paranoid that people are constantly looking
9 at me.

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

18 I thought it would change right away, but it's
19 slow progress, and I sort of feel guilty that I'm
20 one of the few people in here able to have this
21 drug. And I really wish it would be affordable
22 for everyone because I know what you guys are

1 going through. And I feel that one day there is
2 going to be a solution, just hang in there.

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

5 (Applause.)

6 DR. EGGERS: Thank you, Jonathan.

7 Ember. Ember, would you like to say
8 something?

9 UNIDENTIFIED: This is Ember. She's 12 years
10 old. She's had it about 3 years. And I have to
11 say the hardest part is trying to get the wigs.

12 (Becomes emotional.) The insurance will not cover
13 it unless it is hair loss due to chemotherapy.

14 And all the wigs for kids and everything, you can
15 only get one a year. She's a child. She plays
16 volleyball. It's a pain in the butt. But we're
17 making the best.

18 And do you want to say anything?

19 (No audible response.)

20 UNIDENTIFIED: No? Okay. You're good.

21 (Applause.)

22 DR. EGGERS: Thank you, Ember. And if I can

1 point out, Ember and her family have been here --

2 UNIDENTIFIED: Hello?

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

9 (Laughter and applause.)

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

12 DR. SIERRA: Yeah. How are you going? I work
13 for LEO Pharma. I am here not only to represent
14 LEO, but also I have alopecia. I had it since
15 2005. Shaved my head in 2006. And it's been
16 moving around ever since. Lost an eyebrow, and
17 the fingernails are starting.

18 I think it's a real privilege to be here and
19 be talking about alopecia. I know at least in
20 Leo, used a lot of time to push for looking at not
21 only the other skin indications we're looking at,
22 but also alopecia. We have a JAK inhibitor that's

1 in development, and we're looking at potentially
2 systemic antibodies and biologics that could be
3 used in treatment.

4 We've been associated with the NAAF since
5 2014. And I'm not really -- I mean, I'm in a
6 position now where my hair doesn't really bother
7 me, but the stories that I've heard today from
8 these young people and adults really moves me.
9 And I know that you've probably been as moved as
10 much. And I think that it's really necessary that
11 we, as the pharmaceutical industry, and also the
12 FDA, look at how we can bring treatments to really
13 support and help these families moving forward.

14 Thank you.

15 (Applause.)

16 DR. EGGERS: Thank you, Michael.

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

19 CALLIE: Hi. I'm Callie. I'm a terrible
20 speaker and I'm really nervous, so I apologize in
21 advance. I lost all my hair by the age of 3. I
22 started wearing my first wig in 1st grade. I went

1 through years of kids tearing off my wigs and my
2 hats. By the age of 15, I was so severely
3 depressed that I attempted suicide. Luckily, it
4 wasn't successful. I still struggle daily with
5 anxiety and depression.

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

14 (Applause.)

15 UNIDENTIFIED: I'm also nervous. I'm Callie's
16 dad. You know, this has been a long journey of
17 treatments that didn't work. People talked about
18 witch doctor I don't even call them treatments.
19 And I think this is where the FDA can really come
20 in, where we recognize that you can't recommend
21 drugs or you can't -- I think one of the things
22 that's really important is to possibly sort of

1 influence the pharmaceutical community to do
2 research, JAK inhibition works. There's an
3 opportunity for expanding upon the work that's
4 been done by Pfizer. And I think the opportunity
5 for doctors like Dr. King to promote these types
6 of things and move forward to sort of stimulate
7 this research I think is real instrumental for
8 what the FDA can possibly do.

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

16 We understood last night from Dr. Christiano
17 (ph) that there's actually work being done with
18 NIH funding some of this sort of stuff, so I think
19 this is something where the FDA can come in and
20 sort of stimulate this opportunity to do more
21 research in this area of things that actually
22 work. Because we've seen all the things that

1 don't work, from tar ointments on the scalp to, I
2 mean, just unbelievable things that you can't even
3 imagine are not even scientific, and it's just
4 like, "Are you kidding me?" And as a parent, you
5 just shake your head, you just can't understand
6 it. But thank you for the opportunity.

7 (Applause.)

8 DR. EGGERS: Thank you very much.

9 We have Dory Kranz. Dory? Dory Kranz? Dory
10 Kranz?

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

19 I'm also a board member of the National Health
20 Council, which is the united patient voice for
21 more than 133 million Americans living with
22 chronic disease or disability. And on behalf of

1 both organizations, I thank you, the FDA, for
2 recognizing the importance of bringing the voice
3 of the patient into your benefit-risk process for
4 new treatments. It's heartening and we are really
5 grateful for the whole PFDD initiative.

6 (Applause.)

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

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

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

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

22 And one specific example, we are grateful to

1 be working with the FDA as well as patients,
2 industry partners, key opinion leaders, and
3 treatment -- health economics outcomes research
4 experts on the development of a patient-reported
5 outcome instrument that this meeting will inform
6 as well as many other things to demonstrate the
7 patient benefit to payers so that treatments are
8 covered by insurance and accessible and affordable
9 for everyone who needs them.

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

12 (Applause.)

13 DR. EGGERS: Thank you very much, Dory.

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

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

1 (Applause.)

2 DR. EGGERS: Thank you.

3 Mason?

4 Abby is up next.

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

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

19 (Applause.)

20 DR. EGGERS: Thank you.

21 We have Abby.

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

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

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

16 And another thing I wanted to touch on was
17 like the wig costs. So the medicine is super
18 expensive. I may be willing to take it if I knew
19 that maybe 90 percent of my hair would grow back.
20 But I also -- I have chosen to wear wigs, I did it
21 from the age of 6 to 19, but now I work abroad in
22 international development, and I interact with a

1 lot of people, and so I've chosen to, but the wigs
2 are around \$4,000 to \$5,000, and you have to get a
3 new one -- I mean, you don't have to, but every 2
4 to 3 years. There are less expensive wigs, but
5 these are like regular hair wigs, I mean, human
6 hair wigs, so, you know, you can do anything with
7 them that you want, whereas with synthetic, you
8 can't do as much. So that's something. They're
9 not covered by insurance for the most part. And
10 I'm really fortunate that I can afford that, but I
11 know that so many people aren't.

12 So I just wanted to add that. Thanks.

13 (Applause.)

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

15 We have Sally Alterman. Sally Alterman?

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

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

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

17 (Applause.)

18 DR. EGGERS: Thank you.

19 We have Sarah Seward? Or Seward, sorry.

20 MS. SEWARD: Hi. I'm Sarah Seward. I am a
21 legislative liaison with NAAF. I think the
22 biggest thing -- (becomes emotional) -- sorry,

1 it's going to happen -- I think the biggest today
2 that -- I thought that I was in a much better
3 place than I am. Today ripped off a Band-aid that
4 I thought I was dealing with -- I thought I had a
5 grasp on this unpredictable disease. I was
6 diagnosed when I was 21. I lost all my hair in 2
7 weeks. I am grower and I'm a shedder, so I lose
8 in patches -- I'm so sorry.

9 DR. EGGERS: No, it's okay.

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

20 Alopecia changed my life in the sense that
21 when I was first diagnosed, I was a hairdresser,
22 and I changed my complete career because I was

1 told that I needed to wear a wig to work in order
2 for my clients to trust me. I went through a deep
3 depression. I didn't know who I was. I didn't
4 feel like a woman anymore. I had it taken away
5 from me, and I let it be taken away from me.

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

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

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

5 (Applause.)

6 DR. EGGERS: Lori Jacobi?

7 MS. JACOBI: Right here.

8 DR. EGGERS: Okay. Hi.

9 UNIDENTIFIED: Lori, not Dory.

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

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

20 Within 3 months, all of the hair on my body
21 was gone, and my life had changed forever. I
22 eventually lost that job, and it didn't ever dawn

1 on me that it was probably due to my appearance,
2 but in retrospect, that was probably what was
3 going on with that.

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

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

21 Also, over the past couple months, I've become
22 a substitute teacher in my retired life, and it's

1 great to be able to go into a school with my cap
2 on, or if I get too hot, I can take my cap off,
3 and the kids go, "What happened to your hair?" and
4 I go, "I don't know. It just fell out." And they
5 go, "Oh, okay," and they go on with their life.

6 (Laughter.)

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

11 (Applause.)

12 DR. EGGERS: Thank you.

13 Karen and Marianne? Karen and Marianne?

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

17 My son was diagnosed when he was 16. He is
18 now 24. He did lose everything, but now it's
19 almost all regrown. It's about 90 percent
20 regrown. So I guess what I would say, to add to
21 what's already been said, is just that for those
22 who have the patchiness, if there's any type of

1 treatment that could help fill in, you know, the
2 remaining spots that would be safe, that's the
3 main thing I wanted to say, is I think my son
4 wouldn't opt for anything that's risky to the
5 immune system, but if there was some type of drug
6 that could come out that was very, very safe
7 because he wouldn't want to risk all the side
8 effects.

9 DR. EGGERS: Thank you so much.

10 UNIDENTIFIED: Thank you.

11 (Applause.)

12 DR. EGGERS: And then I have Cheryl.

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

17 My daughter is 24, diagnosed at 14. She's in
18 Florida. I wish she could be here with us. She's
19 safe. But she has alopecia universalis. It
20 started like pretty much everybody else's, a lot
21 of it just fell out, and she had alopecia
22 universalis at 16. The torture, the stuff she's

1 been through, and all the kids that -- just nasty.
2 It's more than any child should ever have to go
3 through.

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

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

20 At this point, she's going to be 25, and when
21 she gets to 26, she's going to have to start
22 paying for it. And if it's not something that a

1 child can afford or a lot of other people can
2 afford, what is the point? Because if it's not
3 covered, those are things that are very important
4 to us as well as the effectiveness and the fact
5 that it doesn't cause problems from an autoimmune
6 standpoint, are there other issues?

7 I appreciate it, and thanks for everything
8 today.

9 (Applause.)

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

12 Okay. Hi, Cheryl.

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

17 Guys at the FDA, I would just implore you to
18 research and find an acceptable treatment that
19 doesn't have all the side effects, and also
20 something that's going to be covered, because a
21 lot of us don't have the money to pay for \$3,500 a
22 month for a medication that might not even work

1 for everyone. I mean, I'm not going to put out
2 that money if I don't know it's going to work.

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

4 (Applause).

5 DR. EGGERS: Thank you, Cheryl.

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

11 DR. OUSSOVA: Wow, what a meeting.

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

15 DR. OUSSOVA: Sure.

16 GURU: So I'm Guru again. My daughter is 8.
17 She had alopecia when she was 2. I heard a lot of
18 parents talk today, and I don't want to repeat
19 what they said, I can relate to everything. And I
20 also heard a lot of excitement and some life-
21 changing stories from young adults and adolescents
22 about JAK inhibitors, and it's great that that's

1 in development, but I really hope I'm not in the
2 minority here.

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

13 That's all. Thank you.

14 (Applause.)

15 DR. OUSSOVA: Thank you.

16 Closing Remarks

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

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

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

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

22 And I would like to assure you that all your

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

10 (Appause.)

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

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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
State of Maryland

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CERTIFICATE OF TRANSCRIBER

I, DEBORAH ARBOGAST, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.



SEPTEMBER 25, 2017

DEBORAH ARBOGAST

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