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Virtual Public Meeting on Patient-Focused Drug
Development for Vitiligo

Docket No. FDA-2020-N-0255-0054

Moderated by Robyn Bent

Monday, March 8, 2021

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Remote Proceeding

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A P Hollands E A R A N C E S

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Robyn Bent, RN, Office of the Center Director

Kendall Marcus, MD, Division of Dermatology and
Dentistry

Theresa Mullin, PhD, Office of the Center Director

Brenda Carr, MD, Division of Dermatology and Dentistry

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P R O C E E D I N G S

1
2 MS. BENT: Good morning. Thank you all
3 for joining us today for our Patient-Focused Drug
4 Development meeting for vitiligo. I'm Robyn Bent, the
5 director of Patient-Focused Drug Development within
6 the Center for Drug Evaluation and Research at FDA.
7 I'll serve as the meeting facilitator for today's
8 meeting.

9 We have a full agenda planned for the
10 meeting today. We'll start with opening remarks from
11 Dr. Kendall Marcus, director of the Division of
12 Dermatology and Dental here in the Center for Drug
13 Evaluation and Research at FDA. After Dr. Marcus's
14 opening remarks, we'll hear from Dr. Theresa Mullin,
15 associate director for Strategic Initiatives, who will
16 talk about FDA's patient-focused drug development
17 efforts. We'll then spend some time hearing from Dr.
18 Brenda Carr, also from the Division of Dermatology and
19 Dental, who will provide with a background on vitiligo
20 just to set the stage for the meeting. And then we'll
21 move on to our discussion with individuals are living

1 with vitiligo and their loved ones and advocates.

2 We'll have two sessions. Our first
3 session will focus on the health effects and daily
4 impacts of vitiligo that matter most to individuals.
5 Our second session will focus on your thoughts about
6 current approaches to managing vitiligo. I'll better
7 explain the meeting format and the processes right
8 before we get to our first panel session.

9 Before we begin, though, I'd like to go
10 over just a few logistics and housekeeping points.
11 This meeting is taking place in the fully virtual
12 setting and is focused on hearing from people who have
13 personal experiences with vitiligo. Throughout the
14 day, we'll have polling questions. You'll be able to
15 access the polling questions using a cell phone or any
16 type of computer or tablet. We'll talk a bit more
17 about that in a few minutes. In addition to the
18 polling questions, you'll have the opportunity to
19 share your experiences by either using the chat
20 feature in the bottom right corner of the meeting
21 screen or by calling the phone number that we'll be

1 putting on the screen throughout the meeting.

2 This meeting is being webcast, and the
3 webcast is being recorded. Both the webcast and
4 transcripts of today's meeting will be archived on our
5 website.

6 With that, it is my pleasure to
7 introduce Dr. Kendall Marcus, who will be providing
8 opening remarks. I'd like to invite Dr. Marcus to now
9 turn on her video and unmute to share her opening
10 remarks. Thank you.

11 DR. MARCUS: Morning. Can you hear me?

12 MS. BENT: Yes, I can.

13 DR. MARCUS: Thank you. Good morning
14 and welcome to this Patient-Focused Drug Development
15 meeting on vitiligo. I'm Dr. Kendall Marcus, and I'm
16 the director of the Division of Dermatology and
17 Dentistry in the Office of New Drugs at the Food and
18 Drug Administration. Our division reviews drugs for
19 the prevention and treatment of dermatologic
20 conditions including vitiligo. This is a very
21 important meeting, and we're looking forward to

1 hearing from patients, your loved ones, caregivers
2 about how they think about vitiligo and what is
3 important to them about potential treatments.

4 We're excited to have so many people
5 joining us today with broad representation not only
6 from patients and caregivers but also from advocates,
7 from drug companies, and from academia. It's
8 encouraging to see this high level of interest from a
9 broad range of stakeholders in drug development for
10 vitiligo.

11 I'm now going to spend a few minutes
12 explaining the role of FDA and of drug companies in
13 the development of new drugs in order that people here
14 today understand where the FDA fits into the process.
15 FDA protects and promotes public health by regulating
16 drug development and research done by drug companies
17 and other researchers. Drug companies are the ones
18 who conduct studies of new drugs for medical
19 conditions like vitiligo.

20 When they're finished conducting their
21 studies, they submit marketing applications to the FDA

1 to ask for permission to sell those drugs in the
2 United States. It's our job to review the drug
3 company's study plans and then to review their
4 marketing applications to make sure that the possible
5 benefits of a drug outweigh its possible risks. If we
6 think the company has done a good job, shown that the
7 drug works, and described the possible side effects,
8 and that the benefit risk assessment is favorable,
9 then we let them sell the drug in the US. This is how
10 FDA regulates drug companies.

11 One final point that is important to
12 understand is that FDA cannot direct or order drug
13 companies to develop drugs for specific medical
14 conditions. So where to patients fit into this
15 process? We want to hear from you today to help us
16 understand how patients view benefits and risks of
17 possible new treatments for vitiligo. Today's meeting
18 is about listening to you and your loved ones about
19 how vitiligo impacts your life and what you value in a
20 potential new treatment. I understand that not every
21 person with vitiligo wants treatment. We're

1 interested in hearing everyone's perspective, but we
2 would also like to hear from patients who are
3 interested in treatments because of the impact that
4 vitiligo has had on their lives. Thank you.

5 MS. BENT: Thank you, Dr. Marcus.
6 Thank you and your office for working so hard on this
7 meeting, especially given how busy I know everyone has
8 been. And now, I'd like to invite Dr. Theresa Mullin
9 to unmute, turn on her camera, and provide us with a
10 little background on the FDA Patient-Focused Drug
11 Development program and patient-focused meetings. Dr.
12 Mullin?

13 DR. MULLIN: Thank you, Robyn. Hi.
14 I'm Theresa Mullin, the associate center director for
15 Strategic Initiatives in the FDA Center for Drugs.
16 I'll give you a little bit of background on this
17 Patient-Focused Drug Development, for which is now a
18 program, and what we try to accomplish with this
19 effort. And so next slide please.

20 So what is Patient-Focused Drug
21 Development? We define this to be a systematic

1 approach to help ensure that the patients'
2 experiences, their perspectives, their needs, and
3 priorities are captured and meaningfully incorporated
4 into drug development programs into our evaluation.
5 And next slide please. And so Patient-Focused Drug
6 Development meetings give us an opportunity for more
7 systematic collection and listening to patients'
8 perspectives and on the severity of their condition
9 and of the impact of their condition on their daily
10 life and their experiences with the available
11 treatment options.

12 We've learned over the course of this
13 effort that we've had underway for about eight years
14 now that patients are uniquely positioned to inform
15 our understanding of the clinical context for review
16 and our regulatory decision making. And before the
17 Patient-Focused Drug Development initiative, we had
18 fairly limited ways to try to hear from patients. So
19 the available mechanisms were generally in the context
20 of specific application and a particular matter to do
21 with that, and we would have limited participation of

1 patient representatives, who because it was about a
2 specific application had to undergo a fair amount of
3 screening for conflict of interest. And so that
4 really limited our ability to hear from the broader
5 community. So these Patient-Focused Drug Development
6 meetings give us a way to really reach out to a wider
7 range of people who have a condition to hear their
8 view and what they've been experiencing.

9 Next slide please. And so Patient-
10 Focused Drug Development meetings are not only for FDA
11 but also other stakeholders are given the opportunity
12 to hear the patient's voice. And so I know that in
13 the meeting today, we have a really great
14 participation. We're really happy about the
15 participation from patients and caregivers. We also
16 know that there are industry parties on the call who
17 may be interested in developing drugs to treat
18 vitiligo as well as healthcare professionals, academic
19 researchers, and others. And so it's a chance to just
20 for a wide range of stakeholders, if you will, to hear
21 patients' perspectives on this.

1 We began this back in 2012, and based
2 on frankly patients coming and talking to people when
3 they were in the middle of user fee negotiations about
4 wanting more participation and more of an opportunity
5 to inform FDA and others about what they were going
6 through. And so in 2013 to 2017, we really launched
7 this effort. And at that time, FDA conducted 24 of
8 these meetings in different disease areas. By about
9 2016, though, patient groups were coming to us and
10 saying, "Look. It's great that you're doing this, but
11 our disease might not be among the number that you're
12 able to do. Why don't you expand it?" So we expanded
13 this to have an externally led patient-focused
14 component to the program now.

15 And that's really allowed us to expand
16 much more in our ability to hear what the patient's
17 perspective is on their condition and the available
18 treatments. And at this stage, we're actually
19 developing guidance documents to try to help inform,
20 collecting this information in a way that makes it
21 maximally useful in drug development and for FDA

1 decision making. And so that's another piece of what
2 we have underway now.

3 Next slide please. So this slide just
4 kind of shows you the snapshot of the different
5 disease areas. I hope you can see it. The font is
6 kind of tiny, but I think we'll have these slides.
7 They'll probably be on our website later so you can
8 see it. But it's basically a very wide range of
9 disease areas that FDA has used, and in addition to
10 those, as I mentioned, we've now had over 40
11 externally led meetings that FDA's had the opportunity
12 for our clinicians to just go another step to attend
13 and listen. These are meetings that are organized and
14 conducted by patient organizations. And we've tried
15 to support them in their efforts. So well over 60,
16 almost 70 meetings to date in different disease areas.
17 So it's been really fantastic.

18 Next slide please. So as Dr. Marcus
19 was just explaining a little while ago, FDA's role is
20 not one of conducting the trials or developing the
21 drugs. But as part of our mission to protect and

1 promote public health, we do include this monitoring
2 and evaluation of the safety and effectiveness of new
3 drugs and marketed drugs. We play a critical role in
4 development, although we don't conduct the development
5 activities. We don't develop them or conduct the
6 trials. But our review divisions like Dr. Marcus's
7 division and others really conduct oversight
8 throughout the development process and are able to
9 advise companies to have a stronger development
10 program, one that's more protective of patients and
11 makes better use of the time that patients spend back
12 in trials, and then that final stage of reviewing the
13 submitted application and then following drugs once
14 they're on the market to make sure they continue to be
15 safe and effective. So that's the kind of role that
16 FDA plays throughout this. And you can see where
17 there are opportunities all along the way for patients
18 to inform FDA and others about what matters to them in
19 terms of benefits and risks.

20 Next slide please. So this slide gives
21 you an overview. These patient-focused meetings have

1 a town hall style to them. In this case, we're going
2 to have a virtual town hall. And it begins as we are
3 now with this overview. And next, you'll hear from
4 Dr. Carr about the clinical background and currently
5 available treatments. And following that kind of
6 stage setting, we move into that first session that
7 Captain Bent described, which is an opportunity to
8 hear more about the symptoms and daily impacts of the
9 condition on the patients who are living with it and
10 maybe their families as well.

11 And we've launched that with a panel.
12 Hopefully, providing a diverse range of perspectives
13 on patients or maybe caregivers who are living with
14 the person who has the condition or living with the
15 condition. And we see that as kind of a launchpad for
16 the discussion that follows, pulling in the wider
17 range of people who have the disease who are
18 participating in the meeting.

19 And that session is followed by a
20 session on current treatment options. Similar format.
21 We begin with a panel discussion representing

1 hopefully a range of experiences with different
2 treatment opts that may be available. And that, we
3 hope serves as a way to launch the broader discussion
4 and hear from the broader community participating in
5 our meeting about their experiences with available
6 treatments.

7 Next slide please. I mean, each of
8 these meetings is tailored to the questions for the
9 particular condition that we're hearing about. And we
10 encourage other participants in addition to patients
11 and caregivers: advocates, researchers, drug
12 developers, healthcare providers, and even government
13 officials. But our focus is on hearing directly from
14 patients and their caregivers. And so we're going to
15 ask everybody else to remain silent and in listening
16 mode, so that we can really have this be a platform
17 for hearing directly from patients and caregivers and
18 maximize our opportunity today for that.

19 And then, after the meeting, we have a
20 docket that we keep open, an electronic docket, where
21 people can submit additional information that they may

1 think of later. It will be open for a while after the
2 meeting. Some number of days after the meeting. And
3 with the information that we hear today and receive
4 today and that comes in through docket, we create a
5 voice of the patient report to try to capture and
6 faithfully reflect what we've heard from you all
7 today.

8 And finally, the last slide -- next
9 slide please -- provides you just the resources that
10 you can avail yourselves to at any time. The report
11 that we will produce will be on this webpage. You can
12 get to this webpage by Googling, or whatever other
13 search engine you might want to use, Patient-Focused
14 Drug Development. And it'll take to you to this
15 landing page where you can see the guidance we have in
16 development, other programs, and all about these
17 patient-focused meeting, including the externally led
18 and other resources. And with that, we really look
19 forward to hearing from you today and thank you. And
20 I'll end. Thank you.

21 MS. BENT: Thank you so much, Dr.

1 Mullin. I think it's clear from the number of people
2 participating in the meeting today that Patient-
3 Focused Drug Development and these PFDD meetings
4 really play an important part in incorporating the
5 patient voice into medical product development
6 process.

7 And so now I would like to ask Dr.
8 Brenda Carr to unmute and turn on her video to begin
9 her presentation that will provide us with an overview
10 of vitiligo. Dr. Carr?

11 DR. CARR: Morning. I'm Brenda Carr.
12 I'm a medical officer in the Division of Dermatology
13 and Dentistry. And I'll be providing an overview of
14 vitiligo. Next slide please. Here's an outline of my
15 talk. I'll begin with the introduction, a few words
16 on epidemiology, then clinical features, treatment,
17 and the impact of vitiligo. Next slide please.

18 Vitiligo is a chronic acquired disorder
19 of pigment loss. Characteristic lesions are white
20 patches with sharp margins. Vitiligo results from
21 destruction of melanocytes, and the pathogenesis is

1 not entirely understood. There are number proposed
2 theories as to the cause of the melanocyte
3 destruction, the prevailing theory of -- autoimmunity.
4 Next slide please.

5 The prevalence of vitiligo is estimated
6 to be at 1 percent of the worldwide population.
7 Nearly 50 percent of patients have onset before the
8 age of 20 years, and onset in children younger than 12
9 years of age is common. Vitiligo affects males and
10 females equally. Next slide please.

11 There are two major types of vitiligo.
12 The non-segmental type is the most common form and
13 presents bilaterally, symmetrically, generally, and is
14 unpredictable in its course, which may be
15 characterized by progression and appearance of flares.
16 There are several subtypes of non-segmental vitiligo,
17 including localized acrofacial, generalized, and
18 universal. Segmental vitiligo generally presents
19 unilaterally and is stable in its course. Initially,
20 it may progress rapidly but ultimately stabilizes.
21 Hair in affected areas may be depigmented, and

1 vitiligo may involve the mucosa. Next slide please.

2 This picture depicts a patient with
3 acrofacial vitiligo, which generally involves the
4 head, hands, and feet. This particular variant is
5 sometimes referred to as lip tip vitiligo because it
6 involves the lips and the tips of the digits. Next
7 side please.

8 This patient has generalized vitiligo,
9 and you can see the widespread dissemination of
10 disease on both of the sides of trunk and the upper
11 extremities. Next slide please. This is another
12 patient with generalized vitiligo, and this patient
13 has prominent involvement of the face as well as the
14 trunk and extremities. Next slide please.

15 This is a patient with universal
16 vitiligo. And you can see the trunk is nearly
17 completely depigmented with small islands of pigmented
18 skin present. Next slide please.

19 And finally, we have a patient with
20 segmental vitiligo, which is involving one side of the
21 face. And you can see that some of the hairs in the

1 affected areas are depigmented. Next slide please.

2 There are no FDA-approved products with
3 vitiligo repigmentation as an indication. The only
4 FDA-approved therapy with the vitiligo indication is
5 monobenzone cream, which is no longer marketed, and
6 it's indicated for final depigmentation in extensive
7 vitiligo, so for removal of remaining pigment in
8 widespread disease. Next slide please.

9 Topical therapies include
10 corticosteroids as the first line treatment and used
11 in several strengths and in different regimens.
12 Calcineurin inhibitors may be the choice for areas
13 that are vulnerable to atrophy, such as the face. And
14 they may be used along with corticosteroids on
15 alternate days with those steroids. Vitamin D analogs
16 are less often used because the efficacy may be
17 limited. Next slide please.

18 Phototherapy is administered using
19 either light in the ultraviolet B wavelength or the
20 ultraviolet A wavelengths. There are two categories
21 of UVB therapy. Narrowband UVB treatment is

1 phototherapy treatment of choice because of its
2 efficacy and its good safety profile. Targeted UVB
3 therapy may be administered using monochromatic
4 excimer light via lasers or lamps. Psoralen with UVA
5 light, photochemotherapy or PUVA, was the first form
6 of phototherapy. And the Psoralen may be applied
7 topically to individual lesions or orally if the
8 disease is more widely disseminated. Current
9 practices favor the use of narrowband UVB because of
10 the safety profile of PUVA, which includes
11 phototoxicity, GI distress, and increased risk of skin
12 cancer. Next slide please.

13 Systemically, corticosteroids may be
14 used to stabilize rapidly progressive disease. And
15 they're most commonly used via the oral route but may
16 be administered via other routes. There's limited
17 information on the use of other immunosuppressants,
18 such as methotrexate, cyclosporine, Cyclophosphamide.
19 Next slide please.

20 Broadly, surgical therapies involve the
21 transplantation of melanocytes from pigmented regions

1 to the vitiliginous lesions with the hope being that
2 the melanocytes will proliferate and populate the
3 vitiliginous areas. Tissue grafts are accomplished by
4 several methods. The punch technique involves
5 obtaining the graft via biopsy techniques. In the
6 suction blister method, the graft is obtained from a
7 blister that's been created in the donor region.
8 Cellular grafts may be used for wider spread lesions.
9 These techniques are more complicated and expensive
10 and involve the use of suspensions that contain
11 keratinocytes and melanocytes. Next slide please.

12 Camouflage techniques include the use
13 of coverup makeup, which is applied daily; tattooing,
14 which carries a risk of infection, mismatch, or poor
15 matching of the tattoo pigment with the native skin
16 color. And the vitiliginous lesions may progress
17 beyond the borders of the tattoos. Self-tanning
18 products are waterproof creams that may provide
19 coverage for several days. Next slide please. A
20 possible adjunctive role for vitamins, minerals, and
21 botanicals has been explored. Next slide please.

1 Vitiligo may significantly impact
2 patients' psychosocial wellness. Some patients have
3 reported feelings of disempowerment and loss of self-
4 esteem, a profound diminution in the quality of life.
5 Others have reported feelings of worry, anger, shame,
6 and depression with impairment of social life. It is
7 important to note that these sentiments don't
8 characterize all patients with vitiligo as some
9 patients are very accepting of the condition.
10 Economic impact may include costs associated with
11 medical office visits and cost of supplies, such as
12 makeup. Next slide please.

13 So we're aware of unmet medical needs
14 experienced by patients who have vitiligo. We're
15 conducting this public meeting to hear comments about
16 the impact of vitiligo on patients, caregivers, and
17 family members. I want to thank you for taking the
18 time to join us to share your experiences and your
19 unique perspectives. Thank you.

20 MS. BENT: Thank you, Dr. Carr. I
21 think that this is really helpful for us to have this

1 presentation to set the stage for what we're about to
2 hear from our panelists and meeting attendees who have
3 lived experiences with vitiligo.

4 Moving on, I'd like to share with you a
5 bit more about how this meeting will proceed. I'd
6 like to start by saying. It's really been truly an
7 honor to work with the panelists that you'll meet in
8 just a moment as we prepared for today's meeting. And
9 thank you to Drs. Marcus, Mullin, and Carr for the
10 really helpful presentations that give us some context
11 to think about as the next part of this meeting. That
12 is really yours. So if you're new to the area of what
13 FDA does and what patient-focused medical product
14 development is, then I hope we just gave you a little
15 bit of a background on that and especially on some of
16 the key terms and words that will we'll using today.

17 Before we kick off this next part of
18 the meeting where those of you with lived experiences
19 with vitiligo are the center of this show, I just want
20 to share a little bit of information, kind of an
21 orientation, to help you understand the meeting

1 structure and why we set it up this way because it's
2 very intentional. Those of you who are viewing,
3 representing yourselves, or loved ones with lived
4 experiences with vitiligo, you are the experts. And
5 the expertise that you have is what we're all here
6 today to hear.

7 We've kind of flipped the script on the
8 type of meetings that most of us go to where you have
9 a lot of medical professionals giving presentations
10 and having discussions while you listen. Today, we've
11 reversed that. We've heard some opening remarks from
12 some experts in their field, but you're the ones who
13 are the expert in your field. You're the ones who
14 know what vitiligo is like to live with. So our goal
15 today, as we start this discussion portion of our
16 meeting, is to really foster an open dialogue on
17 personal experiences and perspectives on vitiligo.

18 Our two main topics for discussion are
19 health effects and daily impacts of vitiligo, followed
20 by current approaches to treatment. We'll kick off
21 each session with a panel of individuals with

1 vitiligo. There are five panelists for the first
2 topic. After the panelists, we'll introduce our three
3 discussion starters, and we'll broaden the dialogue to
4 include other individuals and family members who are
5 joining us on the webcast. Anyone who's watching the
6 meeting who identifies as a person with vitiligo or a
7 family member or loved one is welcome to participate.
8 Aside from the panelists and our discussion starters,
9 we don't have anyone else identified to speak. So we
10 need you to share your experiences for this meeting to
11 be successful.

12 The purpose is to build on the
13 experiences shared by the panel. I'll ask a number of
14 follow-up questions. Throughout the day, polling will
15 be done via computer or cell phone. And as I
16 mentioned previously, we're taking comments from
17 online through the meeting chat feature and via
18 telephone. So if you've got something to add, this is
19 your opportunity to build on the information shared by
20 the panel in discussion starters.

21 And I really hope that you feel the

1 importance of your participation in the meeting today.
2 To have your experiences and priorities heard not only
3 by the FDA but by representatives from medical product
4 developers, researchers, and clinicians about vitiligo
5 and what you'd like to see happen to help those with
6 vitiligo. So please take this opportunity, and we
7 hope this will be your invitation to participate with
8 us in the discussion.

9 We encourage you to call via phone to
10 share your comments. When speaking, you may remain
11 anonymous. I mean, you don't have to give us your
12 names. You may state your names if you want. But
13 what we really care about is your experience.

14 And we you call in, there's a couple of
15 things that will help us. One is if you stay on the
16 topic that we're discussing. Whatever topic we're
17 talking about. If we're talking about symptoms, if
18 we're talking about daily impact, to try and think
19 about what topic is and stay as close to that topic as
20 possible. It's also helpful if you can keep your
21 points to maybe just one or two things, so that we can

1 go to as many people who want to speak as possible.

2 In addition, for transparency, we
3 request that at the time of your first comment that
4 you disclose if you're affiliated with an organization
5 that has an interest related to vitiligo or if you
6 have a significant financial interest in vitiligo drug
7 development. If you're submitting comments via the
8 webcast, you can provide whatever name you'd like.
9 Don't worry about us being overwhelmed by comments.
10 We can handle them. We'll try to summarize them as
11 much as possible. We'll do our best to share the
12 comments we receive via the web platform. If we're
13 not able to read all the comments out loud today, your
14 comments will be incorporated into our final meeting
15 summary report called The Voice of the Patient report.

16 And as Dr. Mullin mentioned earlier, we
17 also have a public docket for this meeting that will
18 be open until May 10. We encourage you to share your
19 experiences and expand on what we discuss here today
20 through the public docket. The comments will be
21 incorporated into our summary report as well. Anyone

1 is welcome to comment through the docket, whether
2 you're joining us via the web or you know someone who
3 wasn't able to participate today but you think they
4 have something to contribute. Please encourage them
5 to submit their comments.

6 You'll find the link on the slide here,
7 and we'll also e-mail this link to everyone after the
8 meeting who registered via the event website. You can
9 submit your comments as anonymous. And I want you to
10 keep in mind that if you submit your comments to the
11 public docket, the word public is there for a reason.
12 This will go to the website. So please, again, think
13 about how much personal information you want to share
14 because we don't need your personal information. We
15 care about what your experience is. So please keep
16 that in mind. You can just say anonymous or leave
17 that part empty when they ask what your name is.

18 So one thing that is very exciting
19 about our meeting today is that we have had more than
20 a thousand people register to participate in the
21 meeting. Of the people registered, actually, I think

1 it's probably about 700 of you are either people with
2 vitiligo or loved ones, patient representatives. So
3 now this is wonderful, and we're incredibly grateful
4 for the support of the vitiligo community for this
5 meeting.

6 But we also realize that there may not
7 be enough time for everybody who wants to share their
8 experience today to share their experience. So we're
9 going to open a crowdsourcing website. Now this is a
10 pilot program, and we're hoping that this will offer
11 an opportunity or an additional way for people to
12 share their experiences and interact with FDA. Our
13 plan is to open the site later this week and to keep
14 it open for approximately two weeks. As with the
15 comments that are submitted to the public docket,
16 you're able to participate anonymously.

17 We're still putting the finishing
18 touches on the site. So for those of you who are
19 registered for the meeting, please keep an eye out for
20 an e-mail announcing the availability of the site.
21 And for those of you who are viewing without

1 registering, we will share the meeting information or
2 the crowdsourcing information to our meeting website.
3 Information shared through the crowdsourcing site will
4 also be incorporated into the meeting summary report,
5 The Voice of the Patient report.

6 Moving on, there are a few ground rules
7 for our discussion today. We are here, first and
8 foremost, to listen to those with vitiligo and their
9 loved ones. We'll try to accommodate everyone who
10 wants to speak. We're happy to see a number of those
11 who represent research and medical product development
12 registered for this meeting. We believe that the
13 input we hear today will be important for you as well.
14 We just hope that you are able to stay in listening
15 mode.

16 And FDA staff really is here to listen
17 as well. We know that you may have questions about
18 drug development or drug review. If you have specific
19 questions, we encourage to share them via e-mail with
20 our FDA staff. Our contact information is on the
21 meeting website. We'll get back to you with more

1 information following the meeting.

2 As has been described, our discussion
3 today is focused first on the health effects of
4 vitiligo and daily impacts and then the approaches to
5 managing those health effects. Our discussions may
6 touch upon scientific treatments. However, the
7 discussion of any specific treatments should be done
8 in a way that helps us to understand the broader
9 issues, such as what health effects are being
10 addressed and how that is meaningful to individuals
11 with vitiligo.

12 Our discussion is going to focus,
13 again, on health effects and treatments. We know that
14 this is a very complicated issue. There are many
15 concerns and many questions you have and thing that
16 you have to think about living with vitiligo and
17 getting the support that you need. Those are all
18 important. Today, we hope to focus on the topics that
19 FDA needs the most input on, so that we can best
20 fulfill our role in medical product development and
21 decision making. And we certainly understand and

1 respect that not everyone who has been diagnosed with
2 vitiligo chooses to treat their vitiligo. But our
3 conversation today, because we're the FDA, is going to
4 focus a little bit on treatment and what matters to
5 patients as far as treatment.

6 So while you take in the information on
7 this slide that outlines how to actively participate
8 in the meeting, I'm going to take this opportunity to
9 ask my FDA colleagues on the FDA panel to turn on
10 their video and introduce themselves because I want
11 you to see that we do have a lot of people.
12 Unfortunately, the virtual setting keeps you from
13 seeing them sitting on a panel the way they would
14 usually in our face-to-face meetings. But this gives
15 you the opportunity to see that we do have a number of
16 people here. So let me start with Dr. Marcus.

17 DR. MARCUS: Hi, everybody. Welcome.

18 MS. BENT: Thank you. Dr. Targum?

19 DR. TARGUM: Hey, everybody. Good
20 morning. Welcome.

21 MS. BENT: Dr. Trajkovic?

1 DR. TRAJKOVIC: Good morning. My name
2 is Snezana Trajkovic. I'm a clinical team leader at
3 the Division of Dermatology and Dentistry in the
4 Center of Drug Research.

5 MS. BENT: Thank you. Dr. Carr?

6 DR. CARR: Good morning and, again,
7 welcome.

8 MS. BENT: Thank you. Dr. Reyes?

9 DR. REYES: Hi. Good morning,
10 everyone. I work in Drug Safety Surveillance at the
11 Center of Drugs. I'm excited to hear about everyone's
12 experiences today.

13 MS. BENT: Thank you. Dr. Marquart?

14 DR. MARQUART: Good morning, everyone.
15 I'm Laura Marquart. I'm a dermatologist, and I work
16 in the Center for Devices in Radiologic Health. So we
17 look at the devices that would be used for vitiligo.
18 Thank you.

19 MS. BENT: Thank you. Dr. Chung?

20 DR. CHUNG: Everyone, I'm Yujin Chung,
21 reviewer from the Division of Clinical Outcome

1 Assessment. We're under Center for Drug Evaluation
2 Research.

3 MS. BENT: Thank you. And Dr.
4 Imperato?

5 DR. IMPERATO: Morning, everyone. I'm
6 a physician in the Center for Biologics Evaluation and
7 Research. I'm very much looking forward to hearing
8 the lived experiences with vitiligo.

9 MS. BENT: Great. Thank you. And last
10 but not least, Dr. Mullin?

11 DR. MULLIN: Hello. Good to join you
12 again. Theresa Mullin associate director for
13 Strategic Initiatives in the Center for Drugs. Thank
14 you.

15 MS. BENT: Thank you. You're all
16 welcome to turn off your video now if you would like.
17 So thank you. From time to time during the meeting,
18 we'll turn back to our FDA panelists to see if they
19 have any questions or if they have any follow-up or
20 clarifying questions for anything that we just heard.
21 I'd also like to take this moment to introduce my

1 colleague Shannon Cole, who will be keeping an eye out
2 for comments that come through the internet. She'll
3 be sharing those comments throughout the meeting.

4 Good morning, Shannon.

5 MS. COLE: Good morning.

6 MS. BENT: Shannon will also be
7 coordinating with our other colleague Lena Murduke,
8 who you'll be speaking to if you call in to provide
9 comments via phone. And we'll have some polling
10 questions today. And we're using a third-party
11 application called Mentimeter to run our polling.
12 Polling on Mentimeter's site menti.com is anonymous
13 and can be done via cell phone or on your laptop or
14 tablet. Please note that we're not tracking
15 individual people's answers. We'll only see the
16 responses grouped by option. You can access the
17 Mentimeter poll in two ways. You can use your cell
18 phone camera to view the QR Code on this slide, which
19 will take you to the survey, or you can go to
20 [www.menti](http://www.menti.com), M-E-N-T-I, .com. And use the digital code
21 on this slide to enter the survey.

1 So with that, let's begin a polling
2 question. So please get your cell phones or computers
3 ready. Okay. So for Question One, we're starting
4 with some basic demographic questions so that you can
5 get familiar with the polling platform. And the first
6 question is pretty straight forward. It is where do
7 you live. I'm sorry. I'm not seeing the demographic
8 question on the screen. Thank you. Okay.

9 Where do you live? You have two
10 options because we're very DC centric right now.
11 Option number one is within the Washington, DC
12 metropolitan area, including Virginia and Maryland
13 suburbs. Option number two is outside of the
14 Washington, DC metropolitan area.

15 And so while you're completing the
16 polling questions, I'm going to share with you one of
17 the challenges of the virtual setting. So there is a
18 little bit of a lag time between when we speak here on
19 the backend of the meeting and when it's broadcast to
20 the meeting participants. And so that lag time can be
21 20 to 30 seconds. So you'll see that as the answers

1 for the polling kind of trickle in.

2 For some of the questions, you will
3 have one answer, or you may be able to select one
4 answer. For others, you may be able to select
5 multiple answers. These polling questions are really
6 meant to be a discussion aid for today. They are not
7 meant to be in any way a scientific survey.

8 So okay. Great. So it looks like
9 right now, everything is working. I don't think that
10 we're having any challenges with the application. And
11 I think that, as you can see, and this is truly
12 exciting to us and one of the benefits of the virtual
13 meeting setting, is that we have just a small
14 percentage of people who are answering from the DC
15 metropolitan area. And we certainly have been able to
16 reach a much larger group of people through the
17 virtual setting. As you can see, there's 88 or 87
18 percent of people are outside of the DC area. And
19 that is always great for us to see.

20 So now let's move onto the next
21 question. And that is have you ever been diagnosed as

1 having vitiligo. And so there you have two answers:
2 yes or no. I'll just give it a few more seconds. The
3 answers kind of come in.

4 All right. Great. So from this point
5 on, we're going to ask that polling questions be
6 answered only by individuals with vitiligo or someone
7 who is answering on behalf of a loved one with
8 vitiligo. And so moving onto the next question. That
9 would be what is your age. Remember, if you're
10 answering for a loved one, please answer with their
11 age. And the options that you have are younger than
12 eight years old, eight to seventeen years old,
13 eighteen to twenty-nine years old, thirty to thirty-
14 nine years old, forty to forty-nine years old, fifty
15 to fifty-nine years old, and sixty years and older.

16 Great. This is great. It looks like
17 we have a really good representation across kind of
18 all the age ranges. And so that's wonderful. I think
19 one of our goals in this meeting really is to hear
20 from as broad a group of people, a diverse a group of
21 people as we can hear from. And so this is very

1 exciting to see the distribution. So thank you all
2 for that.

3 Let's move on briefly to the next
4 question, which is do you identify as male, female, or
5 other. Wonderful. Okay. So we're seeing that we
6 have a few more women participating in the meeting
7 than men. But it does seem like we have a pretty good
8 representation of both men and women. It doesn't look
9 like we have people who identify as other who are
10 participating in the polling but, hopefully, are
11 participating in the meeting.

12 Let's move onto our next question,
13 which is where is your vitiligo located. And for this
14 one, you can select all that apply. And so the
15 options that we have are scalp, face and/or neck,
16 hands and/or feet, trunk, arms and/or legs, skin
17 folds, such as the underarm area, genitals, such as
18 the groin, or other areas not mentioned.

19 All right. Great. And so it does seem
20 like we're seeing people who have experiences with
21 vitiligo in all areas of the body. So that will be

1 helpful for us as we speak to kind of lived
2 experiences with vitiligo to get different
3 perspectives from people who have vitiligo impacting
4 different areas. And so my thanks to everyone.

5 Before we move onto our panel
6 discussion, we have just one more question. And that
7 one kind of goes back to one of the presentations that
8 one of the things that Brenda talked about during her
9 presentation or Dr. Carr talked about during her
10 presentation. What pattern does your vitiligo appear
11 in? Focal, where it's depigmentation is limited to a
12 few spots in one area of the body. Segmental, loss of
13 skin color occurs on only one side of your body.
14 Generalized, pigment loss is widespread across many
15 parts of your body. Other or I'm not sure.

16 Okay. So it looks like we have a large
17 representation of people who have generalized
18 vitiligo. We also have a number of people with
19 segmental, a few with focal or other, and people who
20 maybe don't know or don't want to talk about exactly
21 which one it is or perhaps more than one. So okay.

1 Thank you all. We certainly have a range of people
2 participating today, and that's great. It's really
3 exactly what we hoped for.

4 So with that, let's start with our
5 first panel now. So as we mentioned, topic one will
6 focus on the health effects and daily impacts of
7 vitiligo. And we have five panelists who will start
8 off the session by sharing their experiences. In
9 about 30 minutes when our panelists are done sharing
10 their experiences, we'll move to the interactive
11 portion of the meeting by asking about your
12 experiences. And if there's something that you hear
13 from our panelists that really resonates with you or
14 you want to share a bit of your own experience, please
15 consider sharing your comments via the web or closer
16 to the end of the 30-minute period. Maybe around
17 11:15 Eastern time. Maybe a little bit later. You
18 want to give us call at 1-800-527-1401 to share your
19 experiences. You should also know that if you call in
20 and are placed on hold, the hold music will not be
21 music. It will be this meeting. So you won't miss

1 out on hearing from our panelists if you call in to
2 speak.

3 Now we're going to turn the meeting
4 over to our panelists. And I'd like to start by
5 inviting Sharon to share her experiences with
6 vitiligo. So Sharon, if you would like to turn on
7 your camera and unmute, we would be grateful, and we
8 look forward to hearing from you. Thank you.

9 MS. KING: Thank you so much, Robyn.
10 Good morning, everyone. My name is Sharon King. I'm
11 the founder of the Litty Ligo Outreach and Advocacy
12 Network. I'm here to share my experience.

13 So imagine yourself in the sixth grade.
14 Now imagine yourself going to a new school in a new
15 town with a condition that you can't explain to your
16 peers. I was emotionally overwhelmed. I was a little
17 devastated when I first got diagnosed when I was 12.
18 You know I'm very dark skinned. My father's from
19 Panama. My mother is from New Jersey. And I used to
20 live in a predominantly white town, and I got
21 tormented for my skin, my features, my hair, my lips,

1 everything. So when I -- you know? -- got diagnosed
2 in 1999, my 12-year-old mind, I really thought that
3 vitiligo was my own fault for wishing to be white.
4 You know? It's really jarring when you are -- you
5 know? -- around people that you want to call your
6 friends, and they literally just make you feel
7 unwanted, not just -- you know? -- for any other
8 reason than what your skin looks like.

9 So when we went to the dermatologist,
10 we didn't really have a lot of options. The options
11 were cream, the lightbox. But the lightbox wasn't
12 something that interested me because the side effects
13 scared me frankly. So I opted out. And the
14 dermatologist didn't really have any other information
15 outside of that.

16 So as time passed, I just kind of coped
17 with my vitiligo. You know? My surroundings were
18 much more important to me. You know? Like I said, I
19 moved from a predominantly white town to an
20 underserved, very diverse neighborhood. Nothing like
21 I'd ever experienced. So there was a lot of things

1 going on. There was violence. There was death.
2 There was a lot of things that were regular that I had
3 to worry about. So for me, I minimized my feelings
4 for my vitiligo.

5 Depigmenting. Like I've literally gone
6 from having vitiligo on 70 percent of my face to not
7 having any at all like you guys can see now. And that
8 was hard. It's happened about three or four times.
9 But the last couple of times, I was luckily in a place
10 of acceptance. So you know? It was different. But
11 you know? It does still scare me that at any time my
12 skin can decide that -- you know? -- my pigment can
13 go. And it does scare me.

14 When I was younger, personal
15 relationships were very, very hard. You know? I'm
16 already this 12-year-old girl trying to -- you
17 know? -- navigate my own feelings with my skin. Then
18 -- you know? -- I have to deal with the questions, the
19 stares, people asking me all these things that I don't
20 know the answer to and that I'm not ready to answer
21 frankly. You know? I was literally crippled by

1 anxiety. Like I didn't want to laughed at just for
2 literally sitting there. You know? I wasn't warned
3 about that. The reactions and stuff. And my teachers
4 were just as unprepared. I actually had a teacher
5 that had focal vitiligo, but he never acknowledged it.
6 So I was like, "Well, maybe I shouldn't either." And
7 so I didn't. And whenever those things came up,
8 whenever -- you know? -- questions about my skin or
9 things came up, I found myself in verbal altercations,
10 physical altercations because it was maddening. It's
11 so frustrating where -- you know? -- there's this
12 person. I'm like, "He won't talk to me but okay." So
13 it was hard. You know?

14 Luckily -- -- you know? -- my mom kept
15 me active. When we moved to this new neighborhood,
16 she was -- you know? -- very aware that -- you know? -
17 - I got to stay active to stay out of these streets.
18 So you know? I settled on basketball. Love
19 basketball to this day. And I found -- you know? --
20 my tribe. I found my people, my support system. And
21 I found my voice.

1 And speaking of my support system, I
2 found a really good friend. And I tell him I'm going
3 to tell this story whenever I have the chance. So
4 Christopher J. Brookins [ph] was the most -- well, not
5 the most -- but one of the most popular boys in
6 school. He was tall -- you know? -- played
7 basketball, and all the ladies loved him. And then
8 one day we were in class. It was sixth grade. We
9 were in class, and -- you know? -- some kids were
10 making fun of me. And I'm -- you know? -- kind of a
11 shell of myself at this point, and he stands up. He
12 goes, "You know? Sharon's going to grow up, and she's
13 going to realize she's beautiful. And she's not going
14 to pay any you guys any mind."

15 And even though, I didn't feel that way
16 at the time, it was a turning point for me. I decided
17 like, "You know what? I may not feel this way, but
18 I'm going to fake it until I do." So you know? I've
19 always had this kind of confident presentation, which
20 it was true but it wasn't. I wasn't truly confident
21 until honestly about four or five years ago. So

1 that's a 20-year battle.

2 At home, I was very supported. My
3 father, my sister, my grandmother, all live with
4 vitiligo. So you know? People understood in my
5 household. So I didn't have to deal with the things I
6 dealt with outside of that. My son. When my son was
7 eight years old, we had a conversation because -- you
8 know? -- I saw his face one day coming out of school.
9 You know? I asked him like, "Do your friends ask you
10 about my skin?" And he said, "Yeah." You know?
11 Eventually, he was kind of reluctant, and eventually,
12 he was like, "You know? They ask me if you got
13 burned, and it makes me upset." And you know? I had
14 to explain it to him and explain what vitiligo was.
15 And eventually, with that education, he became an
16 advocate. He was able to put together the words and
17 to really articulate how it makes him feel when people
18 make fun of his mom's skin.

19 I really, really hope that this gave
20 you a little bit of insight into how it is to live
21 with vitiligo. So even though, I personally don't

1 want treatment. There are so many people out here
2 that do, that want it, that need it. And everyone
3 deserves to heal in their own way. So thank you so
4 much for having me.

5 MS. BENT: Thanks so much, Sharon. And
6 thanks for being the first one to speak. But most
7 importantly, thanks for sharing your experiences.

8 We're now going to move onto Tonja
9 who's going to share her experience. You've already
10 turned on your camera. Perfect. And unmute. Thank
11 you so much. And please go ahead.

12 MS. JOHNSON: Good morning. My name is
13 Tonja Johnson. I was diagnosed with vitiligo in 2013
14 at the age of 43. The impact of losing so much color
15 so quickly really bothered me for a while and caused
16 me to go into deep depression and seriously
17 contemplate suicide. I literally wanted to die. So I
18 wouldn't have to deal with this awful disease that had
19 taken over my beautiful black skin.

20 Losing over 85 percent of my color has
21 had me wondering who I am and asking myself, "Where's

1 the beautiful dark-skinned woman I used to know?" I
2 often feel like I'm losing the very thing that
3 identifies me as a black woman. So am I really losing
4 my identity as a black woman or the skin that
5 identifies as a black woman? Unfortunately, many may
6 say it's just skin, but for me, it goes much deeper
7 than just skin color. I'm learning the fact that
8 although I'm losing the skin color that identifies me
9 as black but not the characteristics that I value as a
10 black woman.

11 Working in public helped throughout a
12 global pandemic, and seeing firsthand experiences of
13 other people dealing with COVID as well as myself
14 being diagnosed with COVID was very stressful and
15 caused my spots to become wider and new spots to
16 appear on my legs. There are still so many unknowns
17 to COVID-19 that I still wonder about the future
18 impacts that it will have for those of us living with
19 vitiligo.

20 Although I've lost a significant amount
21 of color, I have gained much more. Vitiligo's impact

1 on my growth and self-confidence becoming stronger, I
2 have learned how to ground myself, become resilient,
3 and focus on loving my new skin color. There's a
4 newfound love for who I am today and a level of
5 confidence that I did not have before my diagnosis.

6 I embrace my vitiligo and founded
7 Beautifully Unblemished vitiligo support group here in
8 the State of Florida. I am passionately empowering
9 individuals to focus on body image, building their
10 self-esteem, and loving the skin that they're in. I
11 share my journey today because I now stand in the
12 strength of family, friends, and even strangers who
13 offer their love, support, and encouragement. I live
14 a happy, beautiful, and exciting life with vitiligo,
15 and I wear it with great poise and grace. Thank you.

16 MS. BENT: Thank you so much, Tonja. I
17 suspect that many of the experiences that mentioned
18 are going to resonate with a lot of the meeting
19 participants, and we'll touch more on some of these
20 topics during our panel discussion.

21 So now I'd like to turn it over to Mark

1 who is going to share his experiences. Mark, please
2 go ahead.

3 MR. BRAXTON: Greetings and thank you
4 for the opportunity to share my story. I have some
5 things written down, but I can also speak from my
6 mind. But I don't want to do that because I'll go on
7 forever.

8 But my journey with vitiligo started in
9 my 20s, and now I'm almost 50. A couple of years shy
10 from 50. And I struggled with it until 2019 when I
11 decided to no longer let vitiligo take me on its
12 journey. It had to live life with me. So my mindset
13 has changed on how I view my vitiligo.

14 But here's pretty much my story and how
15 it affected me. It started as a small spot on my
16 hand, and it was really tiny. But then, it started to
17 spread all over my body over the years: my hands,
18 arms, arm pits, torso, back, chest, legs, feet,
19 thighs, around my mouth, and genital area. Vitiligo
20 forced me into self-isolation, extreme introversion,
21 and at times fully closed me off to the world. That

1 was a choice I made because of having my vitiligo.

2 It stopped me wearing shorts, going to
3 the pool, beach, social gatherings, festivals, even my
4 college homecoming, which I really enjoyed. But I was
5 ashamed to be in front of my colleagues and my close
6 friends and my fraternity brothers. I didn't want
7 them to see me like this because this is not how they
8 knew me. And besides removing my pigmentation in
9 various areas, vitiligo made me extremely insecure
10 about my body. I battled with low self-esteem,
11 depression, low self-image. And I had to cope with
12 the daily anxiety attacks when moving out into society
13 or into social settings outside of work.

14 It also created challenges when
15 engaging in intimate settings because I wasn't secure
16 with my body, and I was afraid for others to see what
17 I looked like. And you know? One thing I would
18 always hear and I'd never like, people would say it
19 doesn't bother me. And I understand that. It doesn't
20 bother you because you're not the one living with the
21 condition. And you have to take into consideration

1 the person that was living with vitiligo and how it
2 affects them internally.

3 But the current pandemic that we're
4 living in right now brought on additional stress. I
5 notice small spots appearing on my legs and some on my
6 hands. And then they started to merge together. So
7 now those small spots are large spots on my body.

8 And I want -- I guess -- everyone to
9 understand that vitiligo is not just a condition that
10 removes the pigmentation on the surface of the skin.
11 It affects you physically, emotionally, spiritually,
12 and psychologically. It creates challenges in social
13 circles, families, friendships, personal
14 relationships, and in the professional setting.
15 Vitiligo is more than what you see on the outside.
16 Vitiligo is what you can't see that's happening in the
17 inside, and that's what causes the most damage for
18 someone like me in living with my vitiligo.

19 And thank you for the opportunity to
20 share my brief story.

21 MS. BENT: Thank you so much, Mark.

1 We're now going to hear from Andre. Andre, please go
2 ahead. Welcome.

3 MR. JOACHIM: Okay. Hello, everyone.
4 My name is Andre Joachim. I am 47 years old. I've
5 been living with vitiligo about 29 years now. I
6 worked as a youth and family therapist before I came
7 into my professional. I'll take you back on a journey
8 with me before I was diagnosed and when it first
9 started happening.

10 Just imagine you're walking down the
11 street. And then you look, and people are staring at
12 you. People are gawking at you. People are -- you
13 know? -- mouthing words like, "Oh my God. What's
14 wrong with you?" Calling you a monster. Children are
15 running from you. That was a typical day in my life.

16 I remember going to my child's soccer
17 game and his football games, and kids would stare.
18 And he would be afraid to even walk with me, hold
19 hands with me because of so many stares. I know when
20 I first got diagnosed there was not a lot of awareness
21 on vitiligo. Fast forward to now. A lot of people

1 know about vitiligo because of certain celebrities and
2 everything. But it still makes it very hard because
3 there's a lot of the public who's very unaware of
4 things that go on with vitiligo.

5 I remember before I came into my
6 profession and trying to get a job. I say very low-
7 level skill jobs where -- you know? -- you might be
8 working at McDonald's, Burger King, Taco Bell. Very
9 entry level jobs. Well, when I went into get
10 interviews and everything, I would do great
11 interviews, but everyone wanted to focus on my
12 vitiligo. When I'd tell them it's an autoimmune
13 disease, they would be stuck on that word disease.

14 So like sometimes my friend would be
15 like, "You're a shoe in for the job. You should get
16 it. They need people desperately." And then after
17 the interview, one of my friends told me like, "The
18 reason why you didn't get hired was because they were
19 scared that you would run off customers. They were
20 scared that customers would not come back because they
21 think you have this disease that will be given to them

1 or passed onto them." You know? That was very
2 disheartening and heartbreaking to me.

3 And so instead of focusing on that, I
4 went to school where I said, "You know what? I'm
5 going to find a job where people won't focus on so
6 much on my skin issues or how I look." So I became a
7 therapist and everything. I've been working with
8 youth and family, but also I decided to devote my time
9 to the vitiligo community.

10 And you know? I see that we all go
11 through these different stages of like grief and loss.
12 Losing our identity in the process of losing our skin
13 color. And you know? We go through sadness. We go
14 through depression. We go through anger. We go
15 through denial. We go through bargaining. And some
16 of us get to a place of acceptance. I'm at a place of
17 acceptance.

18 And I do like rocking the skin I'm in,
19 but I'm a human. And I go through the same emotions
20 that everyone goes through. So there are days that I
21 wake up, and I have trouble just looking in the

1 mirror. There are people that I know that I've talked
2 to in the community that also have had trouble. And I
3 went through my share of suicide ideation, and I see
4 other people experience that now. And as therapist
5 and as a person in general in the public, you
6 understand that suicide ideation and suicide is a very
7 huge topic in America today or across the world.

8 So I think focusing on issues to help
9 individuals with vitiligo is very important. And you
10 know? While it may not present so much as an issue to
11 people who accept it, there's a large majority who
12 have issues. You know? Some things I can't do that I
13 want to do is go out into the sun. I want to be able
14 to go on the beach and do all these I did. You know?
15 Travel without any problems and without the sun
16 burning me severely and everything. But that's an
17 issue that I have to deal with. And I think that's
18 definitely something that a lot of people can relate
19 to having vitiligo. You know?

20 And so as far as my thoughts and
21 everything, I'd say as a community, as everyone, we

1 should be doing something, anything, we can to help --
2 you know? -- come up with treatment alternatives and
3 solutions to help individuals who have vitiligo
4 because it can be emotionally damaging. It can be
5 physically limiting.

6 So in the grand scheme of things, I
7 think that -- you know? -- all of us have had these
8 experiences as Sharon, Tonja, as Mr. Braxton had
9 pointed out. So you know? With that, I thank you for
10 hearing me out and hearing me speak. And thank you
11 very much.

12 MS. BENT: Thank you so much, Andre.
13 That was a really, really very thoughtful
14 presentation. We really appreciate you taking your
15 time to kind of share it with us.

16 As our final panelist for this session,
17 we're going to hear from Jackie who is going to share
18 her experiences. So let me invite Jackie to turn on
19 her camera, unmute. And please, Jackie, go right
20 ahead.

21 MS. GARDNER: Thank you. Good morning

1 to everybody. So I guess what's left for me to
2 discuss on the impact is the input from a 30-year
3 veteran. I was diagnosed with vitiligo in 1989 during
4 my third pregnancy. And it has ebbed and waned over
5 the years, but it sounds like not unlike a lot of
6 other panelists. It's really snowballed over the past
7 12 to 18 months. Even after 30 years, I don't leave
8 the house or answer the door or even go to the mailbox
9 in daylight without covering the vitiligo on my face.

10 Corrective cosmetics have been both my
11 saving grace and the bane of my existence. The daily
12 process is very tedious and time consuming. It can
13 take anywhere from 30 to 45 minutes in the morning.
14 There are multiple layers of products that take
15 various times to dry and set. And the base coat is
16 always a DHA sunless tanner product that takes
17 anywhere from eight to twelve hours to develop, which
18 of course takes advanced planning. And the flipside
19 is removing it all at the end of the day. DHA is only
20 good for a couple of days before it starts turning
21 very orange. So it has to be exfoliated and reapplied

1 at night in order to be redeveloped by morning.

2 This particular coping mechanism has
3 created challenges, not only for me but for my family,
4 such as having overnight guests in our home. I'm not
5 comfortable coming out of the room in the morning
6 unless I've applied my full makeup, and I won't remove
7 it until the last person is in bed at night. This has
8 also precluded overnight traveling with friends in
9 situations that might require sharing a bathroom. I'm
10 just not comfortable with that situation.

11 And I've also developed some very
12 difficult side effects, such as intense burning and
13 itching. Mostly on the areas that are depigmenting
14 but not always. I mean, my skin just itches. But I
15 awaken at night with burning and itching. And I'm
16 scratching, and I'm rubbing. And the more I scratch
17 or rub or even touch sometimes, the worse it gets. It
18 just feels like cactus needles stuck in my skin. And
19 many times, the only thing that will help is just to
20 get up and get ice packs. After that, it'll usually
21 resolve within an hour or so.

1 And I've also developed a very intense
2 heat intolerance. Making it difficult to participate
3 in any outdoor activities in temperatures over 70
4 degrees. Some of these and other side effects that
5 I've experienced are the result of the comorbidities
6 that I've developed. I have Hashimoto's thyroiditis,
7 metabolic syndrome, adrenal insufficiency, chronic
8 fatigue syndrome, Raynaud's phenomenon, and I'm pre-
9 diabetic.

10 Of all of these, I would say that
11 chronic fatigue's had the greatest impact on my life.
12 I could literally sleep 24 hours a day and never feel
13 rested. I have to just almost throw myself out of bed
14 in the morning. My endocrinologist once told me she
15 didn't know how I was standing in front of her with
16 the flatline cortisol levels that she was looking at
17 in my labs. So for me, getting up at six o'clock in
18 the morning is somewhat like trying to fight through
19 general anesthesia.

20 And that's what I have. Thank you for
21 the opportunity to share my perspective.

1 MS. BENT: Thank you so much, Jackie.
2 And wow. There is a lot to unpack from all of these
3 experiences. And we really need to thank Sharon,
4 Tonja, Mark, Andre, and Jackie for sharing their
5 experiences. And they did it to really help move the
6 field of vitiligo forward. So thank you for that.

7 So how many of you have heard your or
8 your loved one's own experiences reflected in the
9 comments shared by at least one of the speakers today?

10 So in a virtual setting, it isn't
11 really possible for me to see you nodding or
12 applauding the way we usually see in our PFDD
13 meetings. So we're going to use some polling
14 questions to get some feedback from all of you who are
15 joining us online.

16 But before we move to the polling, I'd
17 like to add just another plug for sharing your
18 experiences with us. If you have thoughts to share
19 related to the discussion questions on the screen,
20 please submit them via the web or over the phone. For
21 those of you who'd like to call in or submit comments

1 to be shared, as a reminder, here is how to do it.

2 Okay. So moving onto polling. And
3 we'll leave this screen up for just another minute so
4 that if those of you who want to access the QR code or
5 be reminded of how to access through the website,
6 we'll give you just another minute to look at the
7 polling question information on the bottom of this
8 slide. All right. So just as reminder, polling is
9 still limited to participants who either have lived
10 experiences with vitiligo either as someone with
11 vitiligo or as a family member or a loved one.

12 Okay. So while we're waiting for those
13 of you watching to call in to share some of your
14 experiences, I'm going to turn to my FDA colleagues to
15 see if they have any follow-up questions at this point
16 for our panelists.

17 Okay. Let me turn briefly to Shannon.
18 Shannon, have we received any comments through the
19 online portal before we move onto polling and then to
20 our discussion starters?

21 MS. COLE: Yes. Thanks, Robyn. We

1 have received several comments through the webcast
2 chat. And several participants are kind of echoing
3 these sentiments of the panelists and saying that what
4 the panelists have shared really resonates with them.
5 But others are also mentioning that they too
6 experience comorbidities with their vitiligo, such as
7 diabetes and Hashimoto's thyroiditis.

8 Another commenter noted that it's much
9 more than just the emotional and mental health effects
10 of vitiligo. They suffer from always burning in the
11 sun without the protection of the darkened skin, and
12 they have to slather in sunscreen or stay in the shade.
13 And sometimes even sunscreen doesn't help to stop
14 getting sunburnt. This individual also noted that
15 having to explain to every new romantic partner that
16 their skin looks different under their clothes is
17 definitely a challenge for them as well.

18 We also have another commentor who has
19 shared their experience with their child who has been
20 very cheerful and fun-loving and loves going to
21 school. But when their child was diagnosed with

1 vitiligo about a year ago, it has definitely kind of
2 changed their personality and outlook on life. And
3 they wanted to bring awareness to body shaming in
4 schools and the vulnerabilities that children have
5 with that.

6 MS. BENT: Great. Great. Thank you.
7 That's really, really helpful. To those of you who
8 are sharing your comments and your experiences, please
9 keep doing that. We are looking at them, and they
10 will be included in our meeting summary.

11 So at this point, we're going to turn
12 back to polling questions for a brief moment. And our
13 first polling question is what aspects of your
14 vitiligo are most bothersome to you. And for this one
15 you can choose up to three areas. And the options
16 that we have -- I'll just wait for a moment. There we
17 go. The options that we have are patterns of
18 depigmentation, amount, or extent of depigmentation;
19 location of depigmentation; loss of hair color, such
20 as hair on the scalp, eyelashes, eyebrows, or beard;
21 sun sensitivity, which I think Shannon just touched

1 on, such as sun or temperature or sweat; and other
2 effects not mentioned.

3 All right. So it looks like the amount
4 or extent of depigmentation and the location of
5 depigmentation are particularly bothersome to people.
6 But it also looks like the skin sensitivity, such as
7 sun, temperature, or sweat is also a large concern.
8 And that seems to be consistent kind of with what
9 we've heard from our panelists. So thank you all for
10 providing feedback to that.

11 Moving on maybe to our next question.
12 And this is similar but a little bit different. What
13 do you find to be the most bothersome impacts of
14 vitiligo on your daily life? And so these you can
15 also choose up to three answers. These are a little
16 bit more about the impact on the daily life as opposed
17 to specifically the vitiligo itself. And the options
18 are time or cost of daily maintenance; refraining from
19 activities, such as school, work, sports, and social
20 activities; self-consciousness or embarrassment;
21 bullying or discrimination; impacts on relationships

1 with family and friends; impact on sexual intimacy; or
2 emotional or psychological impacts, such as anxiety,
3 fear, or depression; or other impacts not mentioned.
4 And of course, we understand that there is, obviously,
5 some crossover. None of these happen just alone.

6 And I realize that for most of you, if
7 it's as small for you as it is on mine, it's a little
8 bit challenging. It looks like the self-consciousness
9 or embarrassment is at about 27 percent and emotional
10 or psychological impacts is kind of that mustard
11 yellow on the right at 25 percent. And then
12 refraining from activities, such as school, work,
13 sports, and social activities is the 18 percent
14 mustard yellow on the left. And so it does look like
15 -- you know? -- we are seeing a lot of impacts from
16 vitiligo.

17 And so while we're waiting for
18 additional responses to these polling questions, I'm
19 going to take this opportunity to introduce our
20 discussion starters. And at this point, I'd like to
21 invite our discussion starters, Alicia, Paul, and Olle

1 -- I'm so sorry -- to turn on their cameras for brief
2 introductions. Alicia, if you'd just like to take a
3 moment to introduce yourself just very briefly?

4 MS. ROUFS: Hi. I'm Alicia Roufs from
5 Minnesota, and I am a lifer with vitiligo at 43 years.

6 MS. BENT: Thank you. Olle?

7 MR. WINST: Yes. Hello. My name is
8 Olle.

9 MS. BENT: Olle. Sorry.

10 MR. WINST: I'm 18 years old, and I'm
11 from Sweden actually. And I have had vitiligo for as
12 long as I can remember.

13 MS. BENT: Thank you. And Paul? Paul,
14 you're muted. There you go.

15 MR. MONTERO: Hello. I'm Paul Montero.
16 I'm from Holland from the Netherlands, and I am the
17 chair of the Dutch Vitiligo Organization. I'm also a
18 board member of the Vipoc, the Vitiligo International
19 Patient Organization Committee. And I have vitiligo
20 as a youngster of 12 years, but when I became older in
21 2008 until 2012, I became totally white. So I

1 transformed from Indonesian roots to a total white
2 man. I have vitiligo universalis.

3 MS. BENT: Thank you so much. So
4 looking back, I really appreciate you joining us. And
5 I'd also like to invite our panelists from session one
6 to be ready to kind of turn on your cameras to
7 participate as discussions permit. But I will say
8 that it sounds like we have a good number of callers
9 on the line. So we will be turning to those callers
10 as well.

11 So to start out, it looks like there
12 are a number of ways, looking back at the polling
13 questions, that vitiligo impacts people's lives. And
14 so maybe I can start here with Alicia maybe if you
15 want to tell us a little bit more about how vitiligo
16 has impacted your life, Alicia?

17 MS. ROUFS: Thank you. As I said, I'm
18 a lifer with vitiligo. So I've gone through the
19 childhood all the to adulthood with vitiligo. And as
20 a child, it was very difficult especially being from a
21 small town with no one else with vitiligo having

1 anyone to turn to is very isolating and hard.
2 Bullying was definitely a factor. I was called spot.
3 That was kind of my nickname for people unfortunately,
4 and it definitely was a hard thing to grow up with.

5 Being an adult with it, I'm probably
6 about 85 percent depigmented. And so now dealing with
7 vitiligo as an adult is more of the limitations of
8 being able to be outside, going to the beach without
9 wearing head-to-toe UV clothing or sunscreen, baseball
10 games for my son is difficult. So it's the hard part
11 of dealing with it. You know? Growing up with the
12 psychological issues, developing who I was because of
13 that, and now being an adult and dealing with just the
14 day-to-day life of vitiligo and also having other
15 autoimmune diseases too besides vitiligo. So that's
16 kind of my background with having to deal with
17 vitiligo in my life.

18 MS. BENT: Great. Well, not great.
19 But thank you so much for sharing your experience.
20 That's very helpful for us to hear. Before I turn to
21 our other discussion starters or panelists, I think we

1 have someone on the line. Do we have Cindy on the
2 line? Can we put Cindy on? Cindy?

3 CALLER CINDY: Yes.

4 MS. BENT: Hi. This is Robyn. You're
5 on the line to talk about your experiences with
6 vitiligo. If you want to share one or two things for
7 a minute or two, we'd really appreciate it.

8 CALLER CINDY: Yes, ma'am. I developed
9 vitiligo when I was 20 years old. Up until that
10 point, I had done local modeling and that kind of
11 stuff. And my disease started on my face. So you can
12 imagine the psychological side of that that I went
13 from being somebody that was photographed and out in
14 front of people to having the changes of skin color.
15 And it provided a lot of depression and psychological
16 issues to the point where I wouldn't want to
17 participate or go out and limited my involvement in
18 things.

19 And then I met a man, and I got
20 married. And he had no issues with that, and we have
21 children. The main part of that is I'm a third-

1 generation person with vitiligo. And while my home
2 was very supportive, I want something to happen in
3 some sort of development that my children won't have
4 to go through the name calling and the mean things
5 that people say and the hurtful things, such as the
6 staring and all of that. And while I tried to be
7 supportive and strong for my kids to make it fun --
8 when my daughter was little, I used to let her play
9 connect the dots on my legs just to have some fun with
10 it. And she used to love that. She thought it was
11 cool.

12 But I'd like to see something that this
13 is a generation that we turn it around and change
14 that, help to educate society on it, and give a little
15 more empowerment to those of us who are dealing with
16 the loss of pigment that we can feel more comfortable
17 and not feel like outcasts and be stuck in our homes
18 and that kind of thing.

19 MS. BENT: Thank you. Thank you. I
20 think that's a point we've heard raised by several
21 people today. And it's certainly very important.

1 Thank you so much.

2 I think we have one more caller on the
3 line right now. Rochelle [ph]? Maybe you can put
4 Rochelle through, and then we'll turn back to our
5 panelists to see if they have anything to add.

6 Rochelle, are you on the line?

7 Okay. I don't hear Rochelle. So let
8 me then turn back to our panelists. Actually, let me
9 ask Dr. Marcus. I think she has a clarifying question
10 that she would like to ask. So go ahead, Dr. Marcus.

11 DR. MARCUS: Thank you. Thanks, Robyn.
12 And thanks to everybody who's shared so far. It's
13 really been helpful to hear about all of the
14 challenges that people go through. There are physical
15 challenges, psychological challenges, and even career
16 challenges as we've heard from some people.

17 We've also heard from people that the
18 challenges bring about a good deal of strength and
19 resilience although everybody has a very unique path
20 it sounds like in terms of when and how they get to
21 that point of acceptance of strength and resilience.

1 And I've also heard that it's very difficult,
2 particularly for children in experiencing bullying and
3 isolation.

4 And so my question is, when would
5 people consider taking a treatment that may be very
6 effective but may also have some potentially
7 significant side effects associated with it? From
8 listening to everybody today from my perspective as a
9 regulator -- you know? -- I'm trying to understand
10 when people would consider taking a treatment because
11 of the impacts that it's having on their lives versus
12 trying to push through and come to a place of
13 acceptance.

14 MS. BENT: Great. And so let me see.
15 I don't know if there's anyone who'd specifically like
16 to speak to that. Olle, did you want to speak to
17 that? Would you be interested in speaking to that,
18 maybe we should turn to Paul? Do you have a
19 preference?

20 MR. MONTERO: Yes.

21 MS. BENT: Okay.

1 MR. MONTERO: Sorry?

2 MS. BENT: Go ahead, Paul.

3 MR. MONTERO: Before, I was an
4 entrepreneur in healthcare and successful entrepreneur
5 in healthcare. And in fact, I was born about the fact
6 that people weren't always doing in discussion with my
7 clients in the hospital. They're looking at my hands
8 not looking what I'm was trying to explain to them.
9 So my communication was just focused on my hands and
10 not on what I was telling in fact. And that was
11 bothering me. And at that one moment, I started to
12 try some therapy, UVB, et cetera, et cetera.

13 But the most important thing I think
14 when I lost my color was that I transformed -- I told
15 you -- in a period of four years into a white person.
16 But I've lost also my genetic properties. I was proud
17 of my color. I was proud of my Indonesian color. And
18 I changed from a skin type five into a skin type one.
19 So I told you I was so proud of my Indonesian roots,
20 of my Indonesian skin. And I was successful.

21 And I'm proud that a man with

1 Indonesian roots could be a successful business man,
2 in fact, in Holland. You know? Indonesia is a colony
3 of Holland. So that's the reason I was proud that I
4 became a successful business man. And because of the
5 vitiligo I was worried that I wasn't -- yeah -- I know
6 -- I was proud to be a successful business man --

7 MS. BENT: Right. It sounds like kind
8 of that loss of identity, loss of kind of --

9 MR. MONTERO: Yes.

10 MS. BENT: -- cultural identity has
11 been something that has really impacted a lot our
12 panelists. I think, Mark, you had your hand raised.
13 Did you want to speak to Dr. Marcus's question?

14 MR. BRAXTON: I do. And I don't want
15 to speak on behalf of everyone with vitiligo. But I
16 run a podcast, and I talk to many individuals with
17 vitiligo. And when it comes to treatment, it works
18 for some, and it doesn't work for others. And I think
19 that's the challenge that we have when we look at
20 getting a treatment. How successful will it be to
21 cure my vitiligo?

1 I did the cream. The cream did nothing
2 for me. So I stopped. I know some people that have
3 tried the UV treatment; it did not work for them. And
4 they stopped. So I think when we're looking at
5 treatment, we want something that's going to work for
6 -- I guess -- a majority of the population and not
7 just for some and with minimum side effects. I think
8 that's what scares a lot of people. The side effects
9 could be worse than the actual treatment. So I feel
10 like that's one of the concerns I hear in hearing some
11 of the stories from people that have tried various
12 things. Thank you.

13 MS. BENT: Thank you. So Olle, did you
14 want to add anything here?

15 MR. WINST: About treatment --

16 MS. BENT: And just about your
17 experiences. I know that you're one of our younger
18 panelists for this round.

19 MR. WINST: Yes. Yeah. Just a quick
20 summary. Well, I can weigh being pretty lucky from a
21 young age, because as I said, I have had vitiligo

1 since I can remember. But in the early stages, I only
2 had one spot on my knee, one on my foot, and just
3 behind the eyelashes. And so it covered itself
4 really. But then out of nowhere when I was 15, it
5 just exploded, yeah, over all my hands, down on my
6 face, all over my arms. So I feel that kind of shock
7 still until this day. Now it's been three or four
8 years since all of that came. I'm still pretty
9 shocked because it happened so quickly. So quickly.
10 And I think that's just crazy how it's changed us so
11 quickly.

12 And with that said, I was pretty lucky
13 in the young years because I never got really bullied
14 for it because people didn't really see it. Nowadays,
15 of course, I cover myself up every time I go out. But
16 when I was younger, I don't have really much to say
17 from them stages when I was younger because I was
18 pretty lucky then.

19 MS. BENT: Great. Thank you for
20 sharing that. And I think that's one thing that I
21 heard while kind of talking to our panelists, and I

1 think something that we'll hear maybe a little bit
2 more as we continue our conversation is this kind of
3 the challenge of never knowing what to expect and not
4 knowing if your vitiligo is going to change over time
5 and the impact maybe that that has.

6 Let me take a moment now. We do have a
7 number of people on the line. So let me see if we've
8 been able to get Rochelle on the line. Do we have
9 Rochelle on the line? Hello?

10 MS. BRINKMAN: Sorry. I don't like a
11 lot of jelly.

12 MS. BENT: Hello. Can you hear us?
13 Hello?

14 MS. BRINKMAN: Hello?

15 MS. BENT: Yes. Hi. Is this Rochelle?
16 Hello?

17 MS. BRINKMAN: Hello? This Lavis
18 Brinkman [ph].

19 MS. BENT: Okay. Were you interested
20 in sharing your experiences with vitiligo?

21 MS. BRINKMAN: Oh, sure. I'm sorry. I

1 wasn't prepared. Sure. I don't have vitiligo. My
2 son has it. He was diagnosed at age 12. And it came
3 from being bullied at school. That summer it appeared
4 on his. I didn't even know what it was. My daughter
5 was getting ready to be a flower girl at my niece's
6 wedding. We were tying on his shoes, and I looked
7 down on his knees. And there's these spots. My
8 brother-in-law's a physician. And so when we went to
9 Philadelphia, I asked him, "What are these spots on
10 Derek's [ph] legs?" And he said that it's vitiligo,
11 and I need to get him checked out. And sure enough,
12 it was.

13 It started in his legs, and now he is
14 18. His first year of college. It's on his face.
15 His legs are mostly white. His feet are mostly white.
16 For him, he's adjusted very well. The first thing
17 that I did was to get him around other children that
18 had it. So I was part of a group called ADRS, which
19 was very helpful for him because he was able to talk
20 and share. They were able to communicate and share
21 their stories. And then I got him around adults that

1 had it. Very positive. Like Andre who's on the
2 panel. Just being around adults and how they adjusted
3 well has helped him at this point. It was very scary
4 to see him go to college to be honest because when we
5 changed schools from the one where he was bullied at
6 to another one, his vitiligo had just started. And so
7 it grew with him. So he didn't experience bullying.
8 Going off to college in a different state in a
9 different environment for people who did not know him
10 was very scary for me. He just went with the punches.
11 He has adjusted very well. I have not heard anything
12 about being bullied. He's distant with just everyone
13 else. And so I think is that one of the great things
14 for him.

15 I do know that when he gets in the sun,
16 his skin turns very red. But he's a boy. I cannot
17 convince this boy to put on suntan lotion to save his
18 life. But he doesn't complain. I just know that his
19 skin gets really, really red in the sun. But as far
20 as his attitude at this point, he's adjusted very
21 well. And I think it just has a lot to do with the

1 positive people that I've placed in front of him. And
2 so I'm really glad of that experience.

3 MS. BENT: Great. Thank you so much.
4 I'm glad that he's having a positive experience. It
5 sounds like that was due in part to family support.

6 Let me turn now to Heather. I think we
7 have Heather on the line?

8 CALLER HEATHER: I'm here.

9 MS. BENT: Hi, Heather. Please go
10 ahead and share your thoughts on vitiligo. If you
11 could, maybe touch on the impacts vitiligo has on your
12 daily life, maybe on the best days and the worst days.
13 But if there's something specifically you'd like to
14 speak to, we would be happy to hear that as well.

15 CALLER HEATHER: Okay. A brief
16 history. My mother had full body -- she's Caucasian,
17 but she went completely like albino white. Then she
18 started to take an arthritic medication, which is
19 involved in some of those trials. And she started to
20 repigment, and it was quite a challenge for her to
21 live all that time -- you know? -- turning white, et

1 cetera.

2 But I was born with one white patch
3 that eventually turned into what they call the lip and
4 chip: the elbows, the hands, the face, the eyes, the
5 knees, the vaginal area -- you know? -- the feet. And
6 I tried different medicines. Nothing light related
7 but topical creams. One of them that burned actually
8 my face pretty badly. It didn't work very well.

9 But I'm in the entertainment industry.
10 So I'm in front of the camera. And I've used a
11 mineral based makeup to conceal. Some of the other
12 people were speaking about. It's quite a process, and
13 it does not stay on now that we've got COVID masks, et
14 cetera. It's always rubbing off. And so when I have
15 to deal with a makeup artist, I have to, "Don't touch
16 it. It's going to come off. We're going to have a
17 problem." You know? And it's a quite a challenge.

18 Sunshine. Very athletic. I'm also a
19 dancer. I mean -- you know? -- so I can't go outside
20 that much anymore. Just sort of have a restricted
21 life. I've tried to get on some of the clinical

1 trials because I do believe certainly from that
2 experience with my mother that there is something out
3 there that may actually have benefit for people that
4 are suffering to realize some of their color return.

5 But yes. All the points hit. You
6 know? The social sort of embarrassment. You know? A
7 little bit of fear about doing things with other
8 people. Swimming. You know? Just a lot of that
9 stuff.

10 Did I answer what you asked me to
11 answer? Did I sort of go off?

12 MS. BENT: Yes and no. That is fine.
13 I think you gave us a little of our context and really
14 a better understanding of kind of how it impacts your
15 daily life. I mean, talking about the makeup and
16 things like that. So yes. Thank you very much.

17 So let me turn now back to my panelists
18 and discussion starters and see if there's anything
19 that you would like to add to what we've heard so far,
20 as far as the impacts of vitiligo. Particularly,
21 maybe, how vitiligo impacts your life on the best days

1 or on the worst days. And so maybe, Andre, did you
2 want to speak to this a little bit?

3 MR. JOACHIM: Yes.

4 MS. BENT: Okay. There we go.
5 Perfect.

6 MR. JOACHIM: Yeah. I definitely want
7 to speak to this. I think it's important that we
8 recognize that -- you know? -- a lot of other
9 autoimmune conditions have had like spotlight on them.
10 They say that people with lupus, they experience
11 extreme -- I'd say -- emotional state. And I also,
12 like, just from my interaction with the vitiligo
13 community, I see a lot of these things as well.

14 I think definitely there should be
15 focus on research that really pinpoints how the
16 emotional is connected to individuals with vitiligo.
17 Because from a lot of my conversations and even from
18 myself from my own experience, I see that some of the
19 things that go on in my day-to-day life has an even
20 stronger emotional toll and tie to it depending on
21 what it is. And you know? As a therapist, I have to

1 sit back and have a self-talk and be like, "Well, is
2 this really worth getting this upset over?" and
3 different things like that. I know not everyone has
4 those tools to be able to really look at these things.

5 But I definitely think that there's a
6 huge emotional tie, psychological and emotional
7 effects, that really affect people with vitiligo. And
8 I think that's definitely something that maybe
9 research should definitely focus on as well not just
10 on just say medication or treatment or other
11 alternatives and everything. Really getting a full
12 depth and understanding of what individuals face on a
13 daily basis while dealing with the emotional
14 connections that -- you know? -- may throw off our
15 lives or -- you know? -- affect us in certain ways.

16 MS. BENT: Okay. Thank you. I think
17 that is also a very important point.

18 So now let me turn to the phones for a
19 moment. I'm trying to kind of go back and forth. I
20 think we have Catherine on the line. Catherine?

21 CALLER CATHERINE: Yes. Hello. Can

1 you hear me?

2 MS. BENT: Yes, we can. Thank you.

3 CALLER CATHERINE: I just want to thank
4 you for having me and thank you to the rest of the
5 panelists. It's been really, really eye-opening. I'm
6 a Caucasian woman that developed vitiligo in my mid-
7 20s. I'm now 40. And the impact has been really the
8 majority of my body in a very sadder, taxing way. I'm
9 also a professional woman outward thinking
10 professional job where I cannot hide.

11 And I don't want to reiterate what
12 others have said about the impact on lifestyle and
13 trying to stay out of the sun and how that impacts --
14 you know? -- my day-to-day routine. But I want to
15 really talk about my desire to kind of blend. I think
16 that this has led to blend my skin color. And that's
17 really like through a lot of personal experimentation
18 with this disease as it has progressed. We've all
19 talked about the creams and the lasers and vitamins
20 and everything. But it really brings up, I think,
21 with doctors and people that I've spoken with about it

1 ever since the duration of wanting to blend, of
2 wanting to deal with the different colors that exist
3 on your body, and how that changes.

4 So it's been a lot about acceptance for
5 me as others have already discussed. But I wanted to
6 also just kind of mention and speak directly to the
7 question that one of the regulators asked about
8 treatment. You know? Based on my level of acceptance
9 with my body and how it's changed and how that's
10 affected my life, I still would certainly be willing
11 to take a risk with possible therapies.

12 I understand that regulators do a
13 benefit risk assessment. I'm actually in that
14 industry. But patients do too. And this disease
15 really provides, I think, at least for me, a higher
16 risk tolerance, even though I've gone through waves of
17 acceptance of my body and my skin. So I think that we
18 all are changing all the time. And stress certainly
19 impacts that, but I'm excited about what the FDA is
20 looking at here and taking patients thoughts into
21 account, so that we can look at other options, not

1 only to treat the disease but also the underlying
2 impacts to behavior as well. Thank you so much.

3 MS. BENT: Thank you for taking the
4 time to call in. I'd like to take a moment now to
5 turn to Dr. Chung. If you'd like to turn on your
6 video? I know you have a question. Maybe we'll start
7 with our panelists, and then maybe we can turn to
8 someone on the phone as well.

9 DR. CHUNG: Thanks, Robyn. So I
10 remember Jackie mentioning -- I don't think I heard a
11 lot of other people talk about this before -- that
12 when she's maybe sleeping at night, the affected and
13 unaffected areas of her skin -- I remember -- saying
14 there's severe burning and itching. It doesn't seem
15 to be related to the sun exposure. And I'm just
16 wondering if any other people have experienced that as
17 well -- I'm curious -- because I only remember Jackie
18 talking about it. So yeah.

19 MS. BENT: Okay. So Olle, do you want
20 to speak to this? I see you have your hand up.

21 MR. WINST: Yeah, yeah. Sure. I can

1 only say that any without being out in the sun and
2 having some pain on my vitiligo, I have had a few
3 times not many times. But then, I have maybe like
4 four or five times, but then it has been only on my
5 spots on my hands but not anywhere else on my body.
6 But I've actually had it but not very often. But when
7 I've had it, it has been only on my hands.

8 MS. BENT: The pain and the itching and
9 things like that?

10 MR. WINST: Yeah. Mainly itching. Not
11 necessary pain but more itch.

12 MS. BENT: Okay. Thank you. So let me
13 see. Mark, did you want to add to that at all?

14 MR. BRAXTON: I do briefly. I'm not
15 sure if my camera's on. But I noticed that when my
16 spots are spreading, they start to itch first. You
17 know? And it doesn't matter whether it's the summer.
18 It doesn't matter whether it's winter, spring, fall.
19 You feel that itch, you look, and it starts a new
20 spread. Or a new spot is starting to form. I've
21 never had any pain but definitely the itching.

1 MS. BENT: Great. Thank you so much.
2 Is there anyone else who'd like to add a comment about
3 the itching or pain or anything like that before I
4 turn to our meeting participants who are on the phone?

5 Okay. So let me then turn to our
6 meeting participants on the phone. Maybe we can go to
7 Greg.

8 CALLER GREG: Hello.

9 MS. BENT: Hi, Greg.

10 CALLER GREG: How are you doing?

11 MS. BENT: Hi. Great. Thanks. So we
12 have you in the meeting. So if you could share any of
13 your experiences in the next minute or two, we would
14 very much appreciate that.

15 CALLER GREG: All right. Thanks.
16 Well, thanks, everyone, for doing this. This has been
17 great. You know? I can relate to so much that
18 everyone has been talking about.

19 But you know? The one thing that I
20 wanted to share that I don't think anyone's really
21 mentioned has to do with the social and emotional kind

1 of piece. I'm also 40 years old, and I was diagnosed
2 with vitiligo when I was about seven. And you know?
3 In my teens, I started to develop substance abuse
4 issues. You know? And I definitely looking back on
5 it now and all the work that I've done to overcome my
6 substance abuse issues, I definitely contribute
7 vitiligo to kind of affecting that and being a part of
8 that. You know? Feeling insecure and a lot of anger
9 and everything that a lot of people have expressed
10 regarding vitiligo definitely caused me to abuse drugs
11 and alcohol. And it was just one thing. You know? A
12 number of things contributed to my substance abuse,
13 but I definitely would say vitiligo. So I really
14 wanted to share that now.

15 Also I'm 39 years old now. I've been
16 sober and in recovery for 12 plus years. So I've
17 overcome that, but also, like a lot of other people
18 have shared, I'm fairly comfortable with my vitiligo
19 today. And I think a lot has to do with it. But two
20 things: one is the work that I've done in recovery
21 has helped me with dealing with my vitiligo and also

1 psychotherapy. I've been in psychotherapy for years.
2 And that has definitely helped a great deal. So the
3 gentleman who just spoke earlier about the emotional
4 piece and talking about that. And I think I've been
5 lucky to have a great therapist and people to support
6 me in my vitiligo journey.

7 The other thing, just really quick, I
8 have a 20-month-old daughter. My first child. You
9 know? She started to develop some patchy white spots
10 on her skin. And you know? She was dealing with
11 eczema. And my wife, she's a physician, and she was
12 kind of just like putting it off, like, "I think it's
13 just a side effect of the eczema." You know? But I
14 couldn't stop thinking about it. You know? Worrying
15 that she had vitiligo. I get very emotional. You
16 know? So I just really wanted to express that. I'm
17 lucky. We just went to a dermatologist, and I got
18 confirmation that it's not vitiligo. And I told the
19 dermatologist that was worth the \$25 co-pay. You
20 know? And I would have paid \$500 to hear that from a
21 dermatologist. But that just goes to show you the

1 effect of vitiligo. You know? I worry that my
2 daughter might have it. And so once again, I
3 appreciate you guys doing this, and I really hope
4 positive things come from it. So thank you very much.

5 MS. BENT: Thank you so much for
6 sharing that. And I think we touched earlier on kind
7 of the unknown of vitiligo for yourself, but I can
8 only imagine the challenges it has when it comes to
9 the unknown for your kids and your other loved ones.

10 Before we move onto other people on the
11 phone, let me take this moment to turn to Shannon to
12 share some of the comments that we've received online.
13 And as a reminder, I think it's become clear to us
14 that we're not going to be able to hear from every
15 single person that we want to hear from today just by
16 sheer numbers. And we do appreciate you calling in,
17 but please know that anything that you share with us
18 will be included in the report even if we're not able
19 to get to all the comments online. And we will be
20 opening that crowdsourcing site.

21 But Shannon, please go ahead.

1 MS. COLE: Thanks, Robyn. Yes. As
2 Robyn mentioned, we're receiving many webcast
3 comments. And we can't get to all of them, but they
4 will all be included in the Voice of the Patient
5 report. But we're receiving several comments about
6 itching and skin sensitivity from more than 10 people.

7 And one individual shared that their
8 itching feels like tiny bee stings, and they never
9 know when it will happen. And it goes on for about 30
10 minutes to an hour before it will ease. They've also
11 shared that they have heat sensitivity, and they
12 didn't realize that this could possibly be a side
13 effect of vitiligo. They also shared that they have
14 other autoimmune issues as well.

15 We're also hearing a lot on the webcast
16 about the emotional impacts of vitiligo, such as
17 suicidal ideation, anxiety, depression, embarrassment,
18 feeling ashamed. And people are sharing that it's
19 difficult to go out in the summertime. One individual
20 shared that patients need more tools to address social
21 stigma, personal anxiety, and loneliness, especially

1 for them who grew up in rural towns where there's
2 little understanding and underwhelming amounts of
3 resources. And so they expressed the great need for
4 these resources as well.

5 Another commenter shared that they work
6 as a registered nurse, and their vitiligo has
7 increased significantly with the stress of caring for
8 their COVID patients. And they cannot figure out what
9 is triggering this immune response. They've increased
10 their sensitivity to light, and they must wear
11 polarized sunglasses as well. And they've experienced
12 their skin burning very quickly in the sun, which
13 affects their ability to do yardwork, their ability to
14 exercise, and participate in outdoor activities. And
15 they've stated also increases their risk of secondary
16 infections.

17 MS. BENT: Great. Thanks so much,
18 Shannon. I know that we've had over a hundred
19 comments so far coming in, and so you're doing an
20 amazing job of kind of keeping track of those and
21 sharing them with us. So I really very much

1 appreciate that.

2 So now I'm going to go back briefly to
3 our people on the phone. And not to be confused with
4 the Alicia on our panel, I'm going to go Alicia on the
5 phone.

6 MS. ARCHIBALD: Hi. This is Alisha
7 Archibald. Can you hear me?

8 MS. BENT: Yes, I can.

9 MS. ARCHIBALD: Hi.

10 MS. BENT: Hi.

11 MS. ARCHIBALD: Hello. First of all,
12 thank you to everyone on the panel. This has been
13 great. I'm friends with all of your panelists except
14 for the last one, Jackie.

15 My vitiligo started almost seven years
16 ago. When mine started, I started with just a little
17 small spot on the front of my head, and I was getting
18 ready for work one morning. Let me preface this by
19 saying, only one person in my family that we knew of
20 had vitiligo, and that was my grandmother, my dad's
21 mom. Okay. So when I saw my first spot, it was just

1 a little spot on my forehead. And so I'm getting
2 ready trying to get ready for work, and I thought
3 maybe I burned my face with my curling iron. So I
4 just kind of rubbed it with my finger -- you know? --
5 trying to flick it away. And I rubbed it again, and
6 it was about the size of a dime. And instantly, I
7 knew what it was. I just said, "Oh my God. I know
8 what this is." And so it freaked me out. It scared
9 me.

10 So I just watched it for a few days.
11 And it was amazing to me because I had not noticed it.
12 And it seemed like it just appeared overnight for it
13 to be that size. So in my mind, I'm wondering, "Why
14 didn't it start out smaller?" or, "Why I hadn't I
15 noticed this?" And so, again, that was seven years
16 ago.

17 Well, for like three years past that, I
18 just kept watching it. I saw other small spots
19 starting to develop on my face. That was where I saw
20 it for about three years. And I started to get what
21 they call the butterfly effect, what a lot of vitiligo

1 patients have. Same thing with people with lupus. So
2 there are a lot of questions. I didn't know a lot of
3 people who had it. I had just gone through a really
4 stressful time in my life the year before. I didn't
5 think I was stressed at the time.

6 But when they took my call, they asked
7 me what did I want to discuss, and I said, "Well,
8 gosh, there's so many things." Everything that the
9 panel has discussed I've experienced it. So it's been
10 an array of emotions. But what I told them I wanted
11 to discuss was just the mental effect. I've accepted
12 vitiligo. But what I've found, even in my own
13 vitiligo community, sometimes when you say you've
14 accepted it, still some people are like, "Well, I love
15 mine. I'm rocking mine." And I love mine too, and
16 I've accepted it. And I appreciate Andre. I've met
17 Andre. I've spoken Andre several times. But there
18 are times like he said when I go past the mirror --
19 and I'm going to try not to cry -- but there are times
20 when I go past the mirror, and -- you know? -- there
21 are times when it does affect you psychologically.

1 And I just had that experience last week.

2 When I accepted it and decided I'm
3 going to live with this, I'm not going to wear makeup
4 trying to hide it anymore, that was back in 2019. I
5 was getting ready for a party, and I was putting
6 makeup on. I've never been a person to wear a lot of
7 makeup. And I've always been pretty confident. Had
8 self-confidence. But two weekends in a row, I was
9 getting ready for a party, and I was putting all this
10 makeup on around my eyes trying to cover it up. But I
11 made that decision at the end of 2019 that I was going
12 to accept it. If this is what God has for me, this is
13 how it's going to be. And it was almost like when I
14 accepted it, that's when I really started to lose my
15 pigment.

16 Well, now at this point, pretty much
17 the whole top half of my body has lost pigment. I'm
18 losing pigment on my knees, my legs, my feet. So it
19 is generalized. It's all over my entire body. I'm a
20 professional person.

21 When it really started, when I started

1 to lose color, I was working at a bank as a banker.
2 So I had people in front of me all day long every day.
3 So I had a woman sit in front of me. And sometimes
4 it's hard for them to focus on what we're talking
5 about because they're looking at you and looking at
6 your hand when you're pointing at the documents and
7 saying, "Sign here."

8 So I had a lady walk out of my office,
9 and then she returned back the next day. And she just
10 propped her arm up at my office door and asked me,
11 "I've been meaning to ask you. Did you have some kind
12 of chemical peel? I mean, what happened to your
13 face?" At that point, when she asked me that -- you
14 know? -- I was pretty confident, and that comment
15 didn't bother me then. But it's comments like that.

16 I had a little girl ask me in my
17 office, "Why is your face so dirty?" So it's some
18 many different things. It does affect you
19 psychologically. So even though, I've accepted it.
20 And then I started my group. I started a group here
21 in Athens, Georgia, simply because my grandmother, she

1 lived with it. But she suffered with it. And I just
2 wanted to --

3 MS. BENT: Thank you so much, Alicia.
4 I'm so sorry to cut you off, but unfortunately, we
5 have a lot of people that we need to hear from today.
6 But your experiences are really valuable, and it's
7 very helpful for us to understand kind of everything
8 that you've gone through. So I hope that you will
9 consider kind of participating also in the
10 crowdsourcing or sharing your experiences through the
11 federal register because it's really important for us
12 to hear this.

13 So let me turn back to the phone and
14 see if we have Rochelle on the line?

15 CALLER ROCHELLE: Yes.

16 MS. BENT: Rochelle?

17 CALLER ROCHELLE: Hello? Yes.

18 MS. BENT: Finally. Success. Right.
19 Sorry for all of the phone glitches.

20 CALLER ROCHELLE: Oh, no worries.

21 MS. BENT: Please go ahead.

1 CALLER ROCHELLE: I just wanted to say
2 that I'm 56. And I've had vitiligo since I was 25.
3 And just like what Alicia was saying in Georgia, it's
4 pretty much the same kind of stories that everyone
5 else has gone through.

6 But just recently, we had a flood, and
7 everything happened to our house. And we just had to
8 have a restoration team come in. And these two guys
9 came in, and they were -- you know? -- looking at the
10 house and everything. So my husband was showing them
11 the carpet and so forth. And then I came in, and they
12 were asking us to sign something. I said, "Well, I
13 can't sign it. Let me call the insurance company."
14 So when my husband went back out there and was talking
15 to one of the guys who was just playing with one of
16 our dogs, and the other guy was gone. And so he said,
17 "Well, hey. Man, where's your partner?" He said,
18 "Oh, he's outside. He doesn't really feel comfortable
19 with you being black and your wife is white."

20 And all these years, I mean, I thought
21 I had it pretty much together. I do run a support

1 group here in Virginia. And you know? I talk to
2 other people, and I'm pretty comfortable in that. But
3 for that moment -- you know? -- it's like I'm not. I
4 mean, but the guy started justifying. He said, "I
5 think they're pretty. A lot of fine black people in
6 the world." So it's like a different kind of racism,
7 and it was just really upsetting. And I couldn't
8 believe. I said, "After all these years, that hurt my
9 feelings," because he didn't want to come in our house
10 because that's what it was.

11 So it seems like that that I've been
12 dealing with and like what other people are saying
13 with the kids. And I have two sons. And when they
14 were younger, and that's what people would say, "Is
15 that your son?" "Yes." "It's him right there?"
16 "Yes." "The one in the red shirt?" "Yes." I said,
17 "The one with the brown face, yes. That's my son."

18 And you know? You're trying not to be
19 so frustrated, so I kind of try to find a little humor
20 in some things to try to help me cope. Not to cover
21 but just to cope. And it seemed to kind of lightened

1 the mood when you could talk to people about it.

2 But I did try that PUVA treatment years
3 ago. And it worked for me, and I had like 75 percent
4 of my body was depigmented. And then it all came back
5 with the PUVA treatment. But then I ran into a
6 problem with my insurance company. And the insurance
7 wouldn't cover it because the coding looked like it
8 was for psoriasis, and when they found out I was
9 taking the treatment, then that's when it all messed
10 up. Then I lost it all again. So that's a struggle
11 to go through that. It's hard on your body. And I
12 don't know if I would do that again. But I just
13 wanted to share that with you.

14 MS. BENT: Yeah. Thank you very much
15 for that. I'd like to turn now to one of our
16 panelists, Alicia. I will tell all of you who are
17 watching online that your stories that we're hearing
18 today are really impactful and really profound. And I
19 think that Alicia just wants to briefly kind of touch
20 on the existence of support groups and things like
21 that. So let me turn to her for just a brief moment.

1 Go ahead, Alicia.

2 MS. ROUFS: Hi, everybody, again. I
3 just wanted to mention the amazing support community
4 our vitiligo community has. And this is something
5 that has been slowly in existence for the last decade
6 or so and really has taken a huge push in the last
7 five to six, seven, eight years. And it really has
8 brought our community together and has brought us here
9 today to the FDA. And that was through the support
10 that we have for each other.

11 And so any of you guys that are
12 watching this that aren't on the panel that are
13 looking for support, there are so many great places to
14 go to. So just check Facebook. Check Google. And
15 check out support communities. And we will reach out
16 to you and bring you guys together. There are great
17 resources for kids now that I never had growing up.
18 Great resources for parents and people struggling day-
19 to-day with vitiligo. So you are not alone in this.
20 We are here for you. Please reach out. And thank you
21 to the FDA for doing this too to bring us all

1 together.

2 MS. BENT: Thanks, Alicia. And when
3 your mentioning of kids, I kind of wanted to maybe to
4 take a moment and circle back a little bit to Dr.
5 Marcus's question, which was really trying to
6 understand as people are, particularly, when you're
7 younger and -- not that it's different as we age. But
8 when you're younger, kids can be a little bit more
9 harsh, I think, than adults sometimes. And so I think
10 what would be helpful for us to understand is would
11 your younger self -- I guess for lack of a better term
12 -- be willing to kind of take a different amount of
13 risk for an effective treatment than somebody's who
14 has been living with vitiligo for a longer period of
15 time and kind of come to a degree of acceptance with
16 it. So let me see if there's anybody who has any
17 thoughts on that before we turn back to people on the
18 phone. Is there anybody that might want to speak to
19 that? And of course, as everybody is aware, we will
20 be kind of getting more into that impacts of treatment
21 in Panel Two this afternoon after what I will call

1 lunch. Depending on where you are, it might be
2 something different. Go ahead, Alicia.

3 MS. ROUFS: Yeah. And I was telling
4 Dr. Marcus this too. I think with the risks of being
5 a child, what was hard for me when we looked into
6 doing treatments was the frequency that we would have
7 to do them in the doctor's office. So light therapy
8 is something that is seen as probably the most
9 effective treatment along with creams, and we had to
10 go to the doctor's office three times a week to do
11 that. And not having it in town, the cost associated
12 with it, and the time spent, I think is what a lot of
13 people just don't do.

14 So as children, when you're running
15 around and you're in all these activities, who has
16 time for that? So I think if it's something that we
17 can have at home that we can do ourselves, yes, there
18 are always risks in any kind of treatment you do. And
19 so knowing those risks and being able to accept those
20 risks if you're going to see results, I think a lot of
21 people would willing to do that. But I think for most

1 of us in the vitiligo community, having it not take so
2 much time and so much money is key.

3 MS. BENT: Thanks. Let me go to Mark
4 now.

5 MR. BRAXTON: Yes, I just wanted to add
6 quickly that when we look at our youth and our
7 students, I think a big component is education. We
8 have to not just teach our children how to accept kids
9 with differences or adults with differences; we have
10 to teach our adults as well. And I think the big
11 difference between our generation and the kids'
12 generation, I feel like our kids are more about
13 inclusion. They support each other. They like to
14 include.

15 But I think in our generation, anyone
16 who looked different, whether it's a condition, skin,
17 whatever, we kind of balked at that. We kind of
18 standoffish, or we treated them differently as other
19 have put it like monster sometimes based on how you
20 look. But I think our youth are at a point where they
21 are more understanding than we think so. And we need

1 to give them credit. They do understand. And also
2 they sometimes teach us as adults how to treat each
3 other, and I think a lot of it starts with our
4 elementary school kids. Teach them there how to
5 accept -- you know? -- our conditions and other
6 conditions.

7 And as they become adults, I think
8 they'll have less issues. But also -- you know? --
9 let's look for ways to provide treatment to our youth
10 for our kids that need it or that want it. And I
11 think a lot of times the want comes from the parents
12 because they want the kids to move about normally like
13 everyone else, or what we consider normal. Thank you.

14 MS. BENT: Thank you. Let me turn
15 briefly to Sharon, and then we're going to go back to
16 the phone lines. Sharon?

17 MS. KING: Thank you. I absolutely
18 think that if there were more options and there was
19 more information in 1999, I would more likely than not
20 explored other ways to treat my vitiligo. But at the
21 time -- you know? -- I just made the basketball team.

1 As Alicia said, we're doing all these activities. And
2 my mother was a big advocate when I said I didn't want
3 to do it. That was just it. You know? And I think
4 that sometimes -- you know? -- like Mark said parents
5 do get caught up in that and not wanting their
6 children to be ostracized and things like that.

7 So I absolutely think if there were
8 better options, more options, options that weren't
9 just medical, I definitely would have engaged more in
10 some type of treatment or some type of support. As
11 Alicia said, there wasn't a lot of information back in
12 those days where you see now everything is inclusive.
13 You see vitiligo everywhere in the mainstream.
14 Everywhere. So you don't feel as alone as you would
15 have -- you know? -- back in our day. So yeah.
16 That's what I got to say.

17 MS. BENT: Thank you. That's helpful,
18 and I think we have made some progress. I think that
19 that's really very encouraging.

20 So let me turn now back to the phones.
21 And I think we have Kathy on the phone? Hello?

1 Hello? Hello? Okay. So maybe we'll put Kathy back
2 on hold for a moment and go to Makayla [ph]?

3 CALLER MIKAEL: Hello. This is Mikael
4 [ph] from Iowa.

5 MS. BENT: Hi. If you could share your
6 experiences with us for just a minute or two, we would
7 really appreciate that.

8 CALLER MIKAEL: Sure. I am 35 years
9 old, and I have had vitiligo since I was two. I have
10 universal vitiligo. So I'm completely depigmented.
11 And I just wanted to say that once you have universal
12 vitiligo, I feel like a lot of dermatologists think
13 that you're fine. And I would like to say that it's
14 not over when you're completely depigmented. Like you
15 still have the effects, for me, childhood. The
16 emotional effects. And then also I worry about my
17 children. I have a son who has vitiligo and thinking
18 about having more children really worries me because I
19 already have one that has vitiligo. And there really
20 aren't many treatments for my son. The ones that he's
21 doing right now are the laser treatments, and he has

1 to go three times a week. And he doesn't like having
2 to do that three times a week as an 11-year-old.

3 So treatments that we could do at home
4 would be awesome, and more options would also be
5 great. And then also the depigmentation of hair is a
6 big thing for me having universal vitiligo. If there
7 were any treatment options for that, that would be
8 wonderful.

9 MS. BENT: Great. Thank you. Let me
10 turn now to Terry on the line. Terry?

11 CALLER PERRY: Hello.

12 MS. BENT: Yes. Hi.

13 CALLER PERRY: Hello. Is this me? I'm
14 Perry actually if that's who you're mentioning?

15 MS. BENT: Yes. Yes. That's who I'm
16 looking for. If you could share your experiences in
17 just a minute?

18 CALLER PERRY: I'm Perry from Philly.
19 The main thing I want to say is it's important for
20 vitiligo sufferers to find the right dermatologist. I
21 didn't at first. Very briefly background. In my 40s,

1 I had a very small spot. Once I got over 60, it
2 exploded. And it exploded literally overnight. One
3 morning I woke up, my forehead was gone. One morning
4 I woke up, I had spots all over my arms.

5 So I went to the dermatologist that I
6 had used for years for relative sort of matters to
7 treat me with creams and never mentioned that there
8 was such a thing as UVB treatment. Never mentioned it
9 for two or three years. I was just treated with the
10 creams. And one day, she said, "Well, you probably
11 would be a candidate for having all the pigment
12 removed from your skin because it's pretty pervasive,
13 and you haven't responded to the creams."

14 Well, I knew I didn't want to do that.
15 So I looked things up on the internet, which
16 unfortunately I'd never done before. I found a
17 dermatologist that had UVB treatments. I went in
18 there, and within five minutes, she said, "Why haven't
19 you been getting UVB treatment?" And I said, "It's
20 never been offered." So I began to have that. And
21 it's still kind of -- but it does provide very gradual

1 results. In my case, it does shrink some of the
2 spots.

3 But I went to a dermatologist, and this
4 was no hole in the wall dermatologist. This was a
5 respected mainline Philadelphia dermatologist who
6 withheld knowledge of a certain type of treatment
7 either because she didn't know about it or couldn't do
8 it. So I just want to stress the point that it's
9 important to -- if you're not happy with your
10 dermatologist, look further. Because I never would
11 have thought to have this.

12 God forbid I'd have cancer, and she'd
13 withheld treatment. So very important. And I want to
14 make sure that all your listeners know that. Don't
15 settle for somebody who doesn't know what they're
16 doing.

17 MS. BENT: Right. I think it's
18 universally important to find a care provider that
19 you're comfortable with. Thank you for that.

20 I know we're going to be wrapping up
21 the session. In fact, we're a few minutes over. Let

1 me get one more person from on the line before we wrap
2 up this session. Would that be Terry? Okay. Hello?

3 CALLER TERRY: Can you hear me?

4 MS. BENT: Yes, I can hear you. Please
5 go ahead. I would ask you just to keep your comments
6 relatively short because we've kind of run over in
7 this session, but we do want to hear what you have to
8 say. So please go ahead.

9 CALLER TERRY: Okay. So my name is
10 Terry. I'm calling from Atlanta, Georgia. I'm going
11 to keep this very brief. This about the FDA and
12 vitiligo. Okay. Basically, FDA knows a lot of
13 information in reference to diseases and everything
14 else. The reality here is that the FDA just needs to
15 pay attention to vitiligo. We know at this point in
16 time there is no really known cure for vitiligo, and
17 I've heard the whole calls all morning. I've heard
18 the calls and the concerns of people. There's only
19 one reality. It's that the FDA is going to cooperate
20 with the vitiligo community in reference to treatment
21 or other things that we need. And it's really just

1 that simple. So FDA, the topic of discussion today is
2 working with the patients. We need your support in
3 every area of treatment at this point. And it's
4 really that simple. FDA, you have enough resources to
5 study vitiligo, and at this point, there is no cure.
6 Research and money will help the situation at this
7 point. And it's really just that simple.

8 MS. BENT: Thanks so much, Terry.
9 Appreciate your comments. So now at this point in the
10 meeting, I'd like invite all of our panelists and
11 discussion starters to just turn on their cameras for
12 a brief moment, just so that we can really say thank
13 you to everybody for the really important, insight,
14 and impactful comments and thoughts they've shared
15 throughout our first session. I can't tell you how
16 much we very much appreciate all of you sharing this
17 information. And I really hope that this will really
18 make others understand what people living with
19 vitiligo are experiencing. I also want to take this
20 opportunity to thank people who have submitted
21 comments and called in. So thank you all. Really

1 appreciate it. And we're going to now take a break
2 until 12:45 Eastern time, where we will come back and
3 kick off session two. So thank you all for taking
4 this time to be with us. And we'll see you at 12:45
5 Eastern. Thanks, everybody.

6 (Off the record.)

7 MS. BENT: Welcome back, everybody. I
8 hope that you had a good break. There might be some
9 noise on the line. So welcome back, everybody. I
10 hope that you had a good break. We have limited time.
11 So we're going to go straight into Topic Two.

12 As we mentioned, Topic Two will focus
13 on current approaches to treatment of vitiligo, your
14 experiences, and your perspectives on that, what you'd
15 like to see in an ideal treatment, if future
16 treatments could be better, how could they be better.
17 And we have five panelists who will start off our
18 discussion by sharing their experiences. Before we
19 launch into our panelists' experiences, I want to let
20 you know that our first question for the open
21 discussion question is going to be: what are you

1 currently doing to treat your vitiligo; how has your
2 treatment regimen changed over time and why; and what
3 symptoms would you like to see most improved or
4 resolved by treatment?

5 So we're now about 30 minutes away from
6 people sharing their answers. But if you're
7 interested in responding to that question, please
8 consider sharing via the internet or by calling the
9 1-800-527-1401 in about 30 minutes. I'd like to
10 welcome our session two panelists and thank them for
11 joining us today. I'm going to start by inviting
12 Jamila to share her experiences with vitiligo.
13 Jamila, if you'd like to turn on your video and
14 unmute?

15 MS. CHOWDURY: Yes. Hi, everyone. My
16 name is Jamila. I'm 18 years old. And I'm here to
17 talk about my experience with vitiligo. The first
18 patches to appear were on my face, specifically around
19 my eyes when I was around eight years old. It was
20 alarming to say the least for something to appear
21 seemingly out of nowhere. It's been around 10 years

1 since my diagnosis. I have tried various methods of
2 treatment and other forms of interventions for my
3 vitiligo, including topical treatments, laser
4 treatment, homeopathic remedies, and makeup.

5 In the beginning stages, I developed
6 patches on my knees, elbows, underarms, and a tiny
7 spot on my neck. Certain areas of my body developed
8 vitiligo later on in life, such as a small spot on my
9 ankle, my chin, behind my ears, and a little patch at
10 the tip of my nose. I have used prescription
11 ointments, such as Protopic, and excimer laser
12 treatment, as soon as I was diagnosed.

13 Applying the ointment was very tedious
14 and not something I did frequently because of the
15 sticky texture. I had a more positive experience with
16 the excimer laser. I would go to the dermatologist
17 weekly to receive treatment on all areas of my body
18 that had vitiligo. The most responsive were around my
19 eyes, my knees, my elbows, my underarms, chin, and
20 neck. The spots around my eyes and neck have
21 disappeared since receiving treatment. The pigment

1 came back in little spots, and occasionally I would
2 experience a bit of burning, irritation, and peeling
3 due to the high heat of the laser treatment.

4 The next time that I would return to
5 receive treatment, the strength of the laser would not
6 be increased to prevent burning. However, other than
7 the rare and mild irritation, my experience with
8 excimer laser was overall positive. It wasn't always
9 convenient to get treatment as my schedule got busier.
10 I wasn't able to commute to the clinic as often.
11 Eventually, my schedule no longer permitted me to get
12 weekly treatment, and today, I no longer receive
13 treatment after being treated on and off since my
14 diagnosis.

15 I'm open to being treated again. And
16 in an ideal treatment, I think it would be best if it
17 was a medication that I could administer on my own at
18 home and is cost effective. I'd be okay with mild
19 side effects if the results are promising. I look
20 forward to future discussion about vitiligo, and I'd
21 like to thank you all for taking the time to listen to

1 my experience and for giving a platform to share our
2 experiences. Also to my fellow panelists, thank you
3 for being brave enough to share your stories.

4 MS. BENT: Thank you so much, Jamila.
5 I'd like to now turn to Priyanka [ph] and Vimla [ph].
6 They are going to share their experiences together as
7 mother and daughter.

8 PANELIST VIMLA: I want to start off by
9 thanking the FDA for giving Priyanka and me this great
10 opportunity to share our perspectives, not only as a
11 patient but also as a caregiver, and join our voices
12 with the rest of the vitiligo community today. It's
13 been a fantastic experience so far.

14 So my 15-year-old daughter Priyanka
15 who's here with me today had her first onset of
16 segmental vitiligo at age 12. The diagnosis was not
17 straightforward, and the treatment options were few,
18 onerous, very expensive, and not easily accessible.
19 Priyanka's treatments over the last three to four
20 years focused mainly on repigmentation, and that
21 included both surgical as well as non-surgical

1 options, which really were topicals, light treatment
2 as well as many punch graft surgeries.

3 The treatments ran a long course and
4 failed to yield optimal clinical results while the
5 vitiligo continued to ravage her body, spreading from
6 her face to the neck, shoulder, arms, and the back. I
7 will say that our journey was a very frustrating one
8 because the rate of progression of a segmental
9 vitiligo was significantly greater than the few specks
10 of repigmentation observed. Overall, the disease and
11 the treatments have resulted in debilitating side
12 effects with a dire impact on her physical, emotional,
13 and psychological health.

14 Priyanka has also needed to gradually
15 shift her treatments as well as treatment regimens due
16 to the lack of immediate response. She actually
17 started with topical creams, such as triamcinolone,
18 every day. And then switched to a combination of
19 tofacitinib in combination with tacrolimus on
20 weekends. She then switched to a combination of
21 topical treatments with light treatment, which last

1 for three years at twice a week frequency.

2 Most recently, since the start of the
3 pandemic, she has started using the handheld DermaPal
4 unit for light treatment. Overall, the side effects
5 of the light treatment were many, ranging from severe
6 skin inflammation, redness, itching, photosensitivity,
7 burning sensation, blistering, and pain. Two weeks
8 ago, she actually had a chance to have a mini punch
9 grafting surgery and experienced residual pain in the
10 grafted areas.

11 Today, we honestly see the FDA's
12 support as well as the medical community's support to
13 universally recognize vitiligo as a medical condition
14 and not a cosmetic condition to spur new treatments
15 for all patients. We also would love to get support
16 on providing more effective oral, topical as well as
17 injectable treatments, advanced surgical options, and
18 improved light therapies that permanently repigment
19 and have limited side effects. There was a panelist
20 who also alluded to this exact point in the morning
21 session. So we'd really love to see advancements in

1 this area. And lastly, I'd say, we'd love support on
2 global scientific research as well as clinical trials
3 with broad patient populations including children.

4 With that, I want to thank you very
5 much again for this great opportunity. And I will now
6 pass on it on to Priyanka, so she could share her
7 patient perspectives. Thank you.

8 PANELIST PRIYANKA: Hello. My name is
9 Priyanka. And I'm here to talk about my vitiligo
10 journey. So my vitiligo journey to date has been a
11 very difficult one, ranging from shock, disbelief, and
12 frustration to education, advocacy, and sharing of my
13 vitiligo experiences with the community.

14 As I have a darker skin tone, my
15 noticeable vitiligo draws the most attention from
16 others with unwanted stares, disgusted looks, and
17 unspoken questions. Returning to school post-
18 treatments was painful with blisters, caked ointments
19 on my skin, a sore face, and extreme discomfort from
20 clothes chaffing against my treated skin. And my
21 recent punch grafting surgery wasn't exactly an easy

1 experience either.

2 I used to swim, bike, skateboard, play
3 the violin at concerts, and manage track and field at
4 my school. But due to my vitiligo and the painful
5 side effects of the treatments, I cannot practice the
6 violin or participate in performances, meetings, or
7 social gatherings as much as I would like. During the
8 pandemic with remote learning, I am always off camera
9 on Zoom to avoid prying questions from my peers. And
10 this impacts interactions in class and hinders my
11 level of learning. I have also been the only kid with
12 vitiligo in my entire elementary, middle, and high
13 school, which makes me feel often very isolated.

14 The impact of vitiligo and the lack of
15 treatments to limit disease progression has burdened
16 me psychologically and emotionally and stigmatized me
17 socially in ways that I cannot adequately explain. At
18 a time in my life when I was ready to explore the
19 world, learn new things, and have fun, vitiligo
20 chipped away at my morale, self-esteem, confidence,
21 and quality of life. I know I'm not alone in this

1 journey and request the FDA to help advance better
2 treatments and cure for this disease. Thank you.

3 MS. BENT: Thank you so much both,
4 Priyanka and Vimla. We're now going to turn to Lee to
5 share his experiences. Lee, if you'd like to turn on
6 your video and unmute?

7 MR. THOMAS: Okay. Can everybody hear
8 me?

9 MS. BENT: Yes.

10 MR. THOMAS: Okay. I'll try to keep my
11 comments brief because I can talk a lot. So let me
12 start off by saying my name is Lee Thomas. I've had
13 vitiligo most of my adult life. That's almost 30
14 years. I've had pigment come back in about 80 percent
15 of my body and then go again, which is something that
16 I really was not expecting. I've also spent most of
17 my adult life in the public eye. I'm an anchor
18 reporter, and I wrote a book about my disease, about
19 my struggle, and I got the opportunity to tour the
20 world sharing my story, which was honestly quite
21 difficult but necessary I felt.

1 And I'll share a quick story. I was on
2 a plane. I was next to a guy. He seemed like he was
3 doing very well. We had a good conversation. The
4 plane's getting ready to land. And the guy says to
5 me, "No offense. But are you a black guy? Because if
6 you're no longer black, then what are you?" So I'll
7 answer that question and ask it again. I'm a black
8 man who's had many attempts at trying to stay black
9 honestly. And I tried everything. Everything that I
10 could afford, I tried. I tried steroids. I tried
11 inhibitors. I tried PUVA. I tried laser, excimer
12 laser. I tried every light treatment that was
13 suggested to me by whatever doctor I could get in
14 front of until I found the best doctor that I could
15 find.

16 For one year of my life, I would do the
17 morning show here in my city. I would take off my
18 makeup. I would drive to the hospital, stand in front
19 of a light completely naked, three times a week for
20 about one minute, and then I'd have to put my makeup
21 back on, go back to work, and finish my reports for

1 the day. I would squeeze it right in between the
2 morning show and the noon show. It was very
3 difficult. It was unsustainable. It was not
4 affordable. And I could not do it. I tried every
5 treatment that our country had to offer.

6 Now I stopped 10 years ago. But after
7 the book, I found myself in Russia on a panel with
8 government officials, with doctors, with drug
9 companies. And that made me very hopeful. That was a
10 decade ago. It seemed like doctors weren't sharing
11 their information a decade ago, but they are now
12 thanks to Vitiligo Research Foundation, Global
13 Vitiligo Foundation. I love those places.

14 But the best treatment I found was in
15 Germany. It gave me 80 percent of my pigment back. I
16 want to show everybody what that looked like. It gave
17 me a lot of my pigment back. This is me. My face was
18 about 60/40 there. I had to wear makeup to be on TV
19 to do my thing. But it was the most successful thing
20 I found. Dr. Schallreuter is her name. But as you
21 can tell, it has gone again. And I don't know what

1 it's going to do. Summertime, sometimes it gets
2 better.

3 I'll leave you guys with this. One
4 question stood out on the survey I was sent. It was
5 about a particular body part. I'll read the question.
6 "Is there a particular body area affected by vitiligo,
7 such as face, body, that you would prioritize for
8 treatment?" And that question made me laugh because
9 it's like picking your favorite kid. But I get it for
10 clinical purposes. I understand. And my answer is I
11 would love to have my face back. I was born a black
12 child. I'd like to die a black man. I don't know if
13 that's ever going to be possible for me.

14 But it's important for me to represent
15 people with vitiligo. Hopefully in my lifetime,
16 they'll be an affordable treatment that everybody can
17 have in our country. So I guess, I will end by saying
18 I believe in this process. I believe in the FDA, the
19 doctors, the many support groups, including the one
20 that I'm a part of. Be Strong. All of the support
21 groups.

1 And if there's a drug that in
2 development or a treatment that's in development, I'll
3 leave everyone with this question. And the question
4 is quite simple. It is. What are you? And to me,
5 this entire group, this entire process, is what are
6 we. And hopefully, we can be the beginning of the
7 answer.

8 So thank you for giving me the time,
9 FDA and everybody else. I appreciate it.

10 MS. BENT: Okay. Thanks so much, Lee.
11 Really appreciate that. We're now going to turn to
12 Carrie and Bella to hear their experiences. Go ahead,
13 Carrie and Bella, whenever you're ready.

14 MS. C. GUARINO: Thank you so much for
15 giving us the opportunity to speak on behalf of myself
16 and Bella and the many teens impacted by vitiligo.
17 Bella's also a member of a teen support group called
18 Purple Patch Teen, a part of VITFriends. That's had a
19 huge impact on her recently and helped her so much.
20 And I just want to share that a lot of what Bella's
21 going to be talking today is representative amongst

1 the group as well.

2 But I thought I'd give an overview of
3 Bella's journey with vitiligo and then turn it over to
4 her to talk more specifically about the treatments and
5 her experiences with them. So Bella was diagnosed
6 with vitiligo just shy of her 13th birthday. I
7 remember doing her hair and noticing some white spots
8 behind her neck. At first, we thought it was tinea
9 versicolor, which is often confused with vitiligo.
10 And it was confirmed that she did have vitiligo. Over
11 the course of about a year, her spots traveled from
12 her neck to other parts of her body, including her
13 knees, her chest, her back, her armpits on both sides,
14 and eventually her face.

15 And she started out taking or using
16 tacrolimus monotherapy as prescribed by her
17 dermatologist. And she was using it on all of the
18 different spots for over a year and had very little
19 effect. And when the vitiligo ended up traveling to
20 her face, we sought some different treatment from a
21 specialist, and he prescribed more aggressive therapy

1 that included combination phototherapy with some other
2 creams. And I just want to emphasize before I turn it
3 over to Bella that the process has been quite
4 laborious. It's been extremely challenging. It's
5 been lengthy. Just the treatments. The process of
6 it. Burdensome. Just emotionally and financially.

7 Bella has had treatment success as you
8 can see her face. I did send in some pictures. I'm
9 sure they'll be on the presentation at some point
10 later. But her face has repigmented, but it's taken a
11 lot to get there. And we just wanted to emphasize,
12 again, that the journey's not been easy. So I'm going
13 to turn it over to Bella to take you through the
14 treatments starting out with her experience with
15 tacrolimus.

16 MS. B. GUARINO: Hi, everyone. I'm
17 Bella. I'm 16, and I'm glad I'm able to share my
18 vitiligo journey with you guys. So as my mom said,
19 first, I was prescribed the tacrolimus ointment. And
20 I used that twice per day, and it really wasn't very
21 effective either. I was on it for about a year, and I

1 saw really very few results. And there were a lot of
2 other side effects as well. The ointment was very
3 greasy, and it often made me break out a little bit,
4 which I wasn't expecting. And there were like red
5 bumps, and it really wasn't a nice ointment to use.

6 So after about a year on that ointment,
7 my doctors prescribed me with another topical steroid
8 to use in addition to tacrolimus. So I used both of
9 those together twice per day. And we also started
10 phototherapy in addition to those two ointments. We
11 used phototherapy three times per week, and I'm very
12 fortunate. I do have a phototherapy unit at my house.
13 My parents and I thought it would just be more
14 efficient than having to drive to the dermatologist
15 three times per week for like two minutes in a light
16 box.

17 So the phototherapy I'm going to talk
18 about for a little bit because I thought it was really
19 important and a big role in my vitiligo journey. So
20 phototherapy really helped. It's supposed to make
21 your vitiligo spots a little bit pink so that they can

1 repigment. But there were a few other side effects
2 that you have to be aware of when you're going through
3 a phototherapy unit. One of them is that you have to
4 wear protective eye goggles. And an issue that came
5 up for me was that I did have a vitiligo spot on my
6 eyelid. So we had to weigh the risk benefits of going
7 in wearing goggles versus not wearing goggles. So we
8 actually decided not to wear goggles.

9 My doctor actually suggested I put a
10 pillowcase on my face midway half in because another
11 thing we were coming across was that my face was
12 getting very, very red. And it was very sensitive to
13 the light. And my vitiligo spots weren't really
14 getting the things that they needed in order to
15 repigment. So we were kind of shocked by him saying
16 that I should put a pillowcase on my head.

17 MS. C. GUARINO: Yeah. There were
18 barriers to treatment, and different things we had to
19 play with.

20 MS. B. GUARINO: Right. Yeah. So I
21 think that we just had to play around with a little

1 bit to see how long I needed to be in there without my
2 face burning and the with the other spots getting
3 pink. But it did really make a big difference in my
4 journey.

5 The most recent medication that I've
6 been on right now is ruxolitinib. It's a topical
7 cream. I just started it a few months ago. I think
8 it's really the most effective aside from the
9 phototherapy right now. The issue is that it's
10 extremely expensive. Like the small tube that we have
11 is \$350. So you really have to prioritize how you use
12 it.

13 MS. C. GUARINO: Right. Bella's doctor
14 had -- I think two weeks into the treatment, she had
15 used up the little bottle or the little tube, and at
16 that point, we called the doctor. And he said you
17 really just need to choose which spots you want to use
18 it on because we can't be refilling the prescription
19 every two weeks.

20 So Bella's given you kind of a glimpse
21 of her journey. And obviously, there's so much more

1 that's gone into it over the last three years. She's
2 16 now. She has had success. However, it's not come
3 without a lot of challenges on a daily basis, and just
4 a lot big -- in terms of time commitment, creams, side
5 effects, emotionally, physically. You know? Just so
6 much has gone into it.

7 And I think one of the things that she
8 and I talk about Bella's relied so much on the
9 phototherapy unit to keep her vitiligo at bay. The
10 concern that I have and that we talk about moving
11 forward is you can't take a phototherapy unit with you
12 to college. And she'll be going off to college in a
13 couple of years. And so we have some anxiety related
14 to the challenges that go along with treatment when
15 Bella leaves our house.

16 So anyway, thank you so much for the
17 time you've given us to speak today and hearing
18 Bella's story. And we hope that the FDA and that
19 companies can come up with further treatments that'll
20 simplify the whole process.

21 MS. BENT: Thank you so much, Carrie

1 and Bella, for sharing your experiences. And your
2 story having to choose which spots to put the ointment
3 on or the creams on kind of harkens back to what we
4 said about having to choose your favorite child as far
5 as choosing the spots. So I think that that is
6 probably a theme that we're going to hear quite a bit
7 today.

8 So moving on. Stephen [ph], I see that
9 you have turned on your camera, and you're unmuted.
10 So if you wouldn't mind sharing your experiences, I
11 would really, really appreciate that. Thank you.

12 MR. TAYLOR: Thank you. My name is
13 Steve Taylor, and I am a 61-year-old retired Afro-
14 American with vitiligo. Since being diagnosed in
15 1982, I tried various forms of treatments. For
16 example, I tried different light treatments, different
17 topical medications, and off label products to name a
18 few. When my dermatologist first diagnosed me with
19 vitiligo, the initial outbreak was in the hands and
20 elbow area. And he pretty much said in so many words
21 there is no cure or treatment for this disease. I

1 said no problem. I accepted it as fact. Moved on
2 with my life. I pursued professional counseling,
3 support from my wife. And I made pact with myself.
4 As long as I don't break out in the face area, I'll
5 deal with it.

6 Well -- virtual connectivity
7 interruption -- break out on the face. And because of
8 that, I sought after a second opinion. Now this
9 dermatologist was more knowledgeable than the previous
10 one because he prescribed a Protopic medication for me
11 to apply on my face. Now I didn't apply it apply
12 below the neck because the spread of vitiligo was too
13 large of an area to treat. And for the most part, the
14 ointment did prevent the face part of the application
15 from getting worse.

16 The following year, my dermatologist
17 mentioned to me about a new photochemical light
18 treatment called PUVA was now available. I was
19 excited. I said, "Yeah. Sign me up." So for the
20 next six months, I traveled three days a week, a two-
21 hour roundtrip visit to the University Hospital in Ann

1 Arbor, Michigan. I go into this full light treatment
2 process, ranging from 15 seconds to 20 minutes at
3 most. And that's all the treatment I had.

4 Now about two months into the treatment
5 process, the stress kicked in. Time, travel, gas,
6 leaving work early, unforeseen circumstances. And did
7 I mention that this was a stressful period in my life?
8 However, halfway through the treatment process, I
9 began to repigment, especially around the face. That
10 was the shot in the arm I needed to stay focused and
11 true to the course.

12 Now at the end of the six months, my
13 dermatologist and I did a risk benefit assessment.
14 And I decided to discontinue treatment because the
15 risk outweighed the benefits. That is to say the
16 potential side effects, premature aging of the skin,
17 skin irritation, skin cancer, cataract, not to mention
18 the continued stress of moving forward with the next
19 phase of the PUVA process -- and just a side note, I
20 did try UVB light treatment but to no avail.

21 So in summary, I am 98 percent void of

1 color. And I am no longer taking any treatments. And
2 why? I'm still dealing with the emotional stress of
3 the loss of my color. My identity. And I do not want
4 to go through this process again unless there is a
5 cure and not a treatment. In conclusion, I'd like to
6 thank the Food and Drug Administration, all of the
7 dermatologists, all of the researchers, all of the
8 pharmaceutical companies, and all of the vitiligo
9 support groups worldwide working unitedly for the
10 cure. Thank you.

11 MS. BENT: Thank you so much, Steve.
12 Really, really appreciate that. So once again, these
13 are some really compelling and diverse experiences.
14 And I thank our panelists, Jamila, Priyanka, Vimla,
15 Lee, Carrie, Bella, and Steve, for sharing them.

16 I'm now going to take this opportunity
17 to introduce our discussion starters. So at this
18 point, I would like to invite Jay, Beverly, and Mary
19 to turn on their cameras. As with the discussion
20 starters for Panel One, these great people have agreed
21 to kick off our discussion by answering some of our

1 questions. I'd also encourage if our panelists have
2 thoughts that they might want to share, we'd be happy
3 to hear them as well, although we are planning on
4 going to some of the people that we have waiting on
5 the phone as well.

6 So as I mentioned before, these are our
7 discussion questions for Session One. And our first
8 discussion question is, "What are you currently doing
9 to treat your vitiligo? How has your treatment
10 regimen changed over time and why? What symptoms
11 would you like to see most improved or resolved by
12 treatment?" So I'm wondering maybe if I could turn to
13 Jay. Jay, would you be willing to kind of take a
14 first answer at the question of, "What are you
15 currently doing to treat your vitiligo? How has that
16 changed over time? What symptoms would you like to
17 see most improved?"

18 MR. HAMPTON: Yes. Thanks for the
19 panel, and the FDA for giving this opportunity to me.

20 MS. BENT: Thanks, Jay.

21 MR. HAMPTON: I mean, I've been doing

1 treatments since I was -- what? -- 15. I'm 34 right
2 now. And currently, as I'm talking you, I'm not doing
3 any type of treatment at all. Yeah, back when I was
4 22, my dermatologist sat me in his office, and he
5 essentially said -- like I'm sure other people that
6 take treatment as well -- he said, "Jay, there's
7 really nothing else I can do for you." And that was
8 like a shot in the gut for me because I was really
9 gung-ho on this whole experience.

10 But with me, though, I did take the
11 PUVA and the light treatment. I'm from Baltimore. I
12 don't know if you know anything about John Hopkins
13 Hospital and University. Very research hospital. My
14 dermatologist was from there. They do a whole lot of
15 types of experimental treatments for me. And one of
16 the ones that proved very effective was the suction
17 therapy. They took this this suction machine and
18 placed it on my forearms. And they sucked up the stem
19 cells in hopes that they'd take the stem cells and
20 implant them in my face. And then when my skin would
21 heal, I would use light treatment, and that would

1 spread pigment on my face. So what you see my face
2 now, my whole face had vitiligo on my scalp, back of
3 my neck. And it's come back.

4 But I will say that sticks out the most
5 when I was taking that PUVA treatment. I had to take
6 three horse pills. I'd go three times a week. And if
7 didn't have nothing on my stomach, it was like death
8 taking those pills. Very, very nauseating. Very
9 uncomfortable. And I was a teenager at the time. You
10 know? So you always have crackers because sometimes I
11 wasn't able to eat nothing when I had to take those
12 pills, but I'd stroll up on time for my appointment.

13 So that's basically what was my
14 experience with it. But to be honest with you, with
15 the light treatment in my mind, I'm thinking, "Okay.
16 There's UVA light and UVB light." And sometimes when
17 work I out and I go to the gym, I go to the tanning
18 salon. You know? And I know the light that that is.
19 But in my mind, I'm thinking it's doing something
20 because it's darkening my skin pigment-wise. It's a
21 proven fact of somewhat because my skin gets darker,

1 and it kind of contrasts my light spots. So I don't
2 know if that's bringing it back. I don't know if
3 that's my mind. But I'm just trying to find different
4 things I can do in the interval.

5 MS. BENT: Great. Thank you. That's
6 really helpful to hear. Let me take a pause now from
7 talking to our panelists and turn briefly to the
8 phone. Let's go to Line 2, Kay from Maryland.

9 CALLER KAY: Hello.

10 MS. BENT: Hello, Kay.

11 CALLER KAY: Hello. Can you hear me?

12 MS. BENT: Yes, we can hear you.

13 CALLER KAY: Okay. Thank you. Thank
14 you for this opportunity. So my story's no different
15 from other people, but age 48, I saw white spots on my
16 hands in September 2019. Not long ago. Soon after
17 that, I was diagnosed with vitiligo. And vitiligo is
18 spreading fast all over my body. Now I look like I
19 almost lost more than 75 percent of my color.

20 So one thing I want to mention here
21 first is the first dermatologist told me, "Oh, you

1 have vitiligo. It's just nothing. It's a cosmetic
2 problem." He just dismissed all my concerns. And
3 that really painful because it was really affecting
4 already the psychology. The most difficult issue I
5 have now is the itchiness. It can itch me anytime,
6 mostly on my back, in between my legs. It's very
7 irritating. When I take a shower, it's feels better.
8 And that's one problem I have besides the
9 psychological impact. I've tried everything. I used
10 multiple creams, light therapy. I used to have the
11 light treatment three times a week. I tried it about
12 six months. Nothing changed. I tried oral steroids.
13 I tried topical steroids. I tried everything. And at
14 the end now, I decided, especially with COVID, I don't
15 want to deal with this. I have other things. I try
16 to forget, but still, it's in my head. I am doing
17 nothing treatment-wise because I gave up. We don't
18 have anything further -- because it seems like nobody
19 can see there to begin with that this is a problem.
20 They think it's cosmetic, but it's more for me. I am
21 lifelong colored person. I feel like I lost my

1 identity. I'm sorry. It's very difficult to be so
2 emotional.

3 MS. BENT: It's okay. We understand.
4 These are emotional topics.

5 CALLER KAY: Yeah. Yeah. Sorry.
6 After I tried everything, I decided that I don't want
7 to have any more problems. I already have enough
8 problems. So let me just deal with the psychology. I
9 used to start seeing a psychologist. There's no drug
10 for this monster. Just ripped my confidence, my
11 coloring, my identity. I really wish they'll be
12 something else for me. I am 50 years old now. For
13 the young kids, we need somebody to understand and
14 consider this as it is a problem. And I -- for my --
15 this is like disparity. It's one with a disparity.
16 It's mostly affects colored people, and it's more
17 visible on colored people. Hasn't been considered as
18 a problem. And I want the FDA to consider how much
19 the impact of vitiligo on our mental health. For 49
20 years, healthy person being now, I don't want to go
21 outside. I don't want to see my face in the mirror.

1 And thank you for the opportunity and sorry to be
2 emotional. Thank you.

3 MS. BENT: No. Thank you, Kay. And I
4 think that we've heard from a number of people the
5 challenge that vitiligo adds to their identity. And
6 it certainly seems to be very, very impactful.

7 So let me pause for a moment and turn
8 to Shannon to see if we have any comments from people
9 online. Shannon, do we have comments?

10 MS. COLE: Yes. Thank you, Robyn. We
11 have several comments from webcast participants,
12 mainly, talking about their current treatments.

13 One said that they are currently using
14 tacrolimus and excimer therapies. Another one said
15 that they are seeing improvements from the excimer
16 laser therapy. Another participant stated that
17 they're using fluocinonide, Elidel, and UVB light
18 therapy. And after five months of sticking to a
19 strict regimen of using the UVB light and creams,
20 they've noticed about 75 percent repigmentation.
21 Another participant has used topical ointments and

1 stated that they even tried a liquid medication that's
2 not prescribed in the United States. But it did help
3 for them to gain back some of that pigmentation, but
4 they stated that it's been difficult to continue that
5 medication since it's not available in the US.

6 We also have some participants who have
7 used PUVA, and it was effective. But they stated that
8 they needed a break from it because of the side
9 effects and the treatment regimen. And we also had
10 one more who has used NUVB and tacrolimus vitamins and
11 stated that their face is most responsive to the NUVB
12 and tacrolimus. And their hands and ankles are
13 virtually impossible to treat with the available
14 methods that they have tried.

15 MS. BENT: Thank you so much, Shannon.
16 So we're going to now move onto some polling questions
17 to get feedback from all of you who are joining us
18 online. Polling remains limited to participants who
19 have lived experiences with vitiligo. If we can go to
20 the polling question, this is just to kind of start
21 the discussion.

1 Polling question -- I guess technically
2 it's number nine, but I don't feel like it is. Have
3 you ever used any of the following medical products?
4 And this would include drug therapies or medical
5 devices or interventions to treat your vitiligo. And
6 the first option is topical medications for
7 repigmentation, such as corticosteroids or
8 immunomodulators, which would include Protopic or
9 Elidel. Oral medications, again, such as prednisone
10 or other steroids or other immunomodulators. Light
11 therapy, such as laser, phototherapy, or PUVA.
12 Surgery, including grafting, melanocyte transplants,
13 or micro-pigmentation. Topical medications for
14 depigmentation, such as benoquin. Other medical
15 products or interventions not mentioned. Or are you
16 not using any medical products or interventions. And
17 this not using any medical products or interventions
18 would be never used medical products or interventions.
19 So all right. Looking at the results,
20 and again, there is a bit of a delay between when we
21 ask the question and when it kind of makes it out to

1 the frontend for people to respond to the question,
2 but it does look like we're seeing a large use of
3 topical medications as well as light treatments. The
4 first blue block is topical medications. The green
5 block that's showing at about 31 percent are the light
6 treatments, and the final 9 percent at the end kind of
7 the far right or 8 percent -- it's changing as I speak
8 -- is not using medical products or interventions and
9 never used medical products or interventions.

10 So while we're waiting for these
11 polling questions, I wonder if we can start with one
12 of our discussion starters. Beverly, I wonder if you
13 would be willing to speak to us a little bit about
14 what kind of treatments you've tried and what aspects
15 they addressed and what aspects they didn't address
16 and maybe how your experiences with them have changed
17 over time?

18 MS. SMITH: Yes. Thank you so much for
19 having me and this discussion with the FDA.

20 When I was first diagnosed with
21 vitiligo in 2015 at the age of 67, I was immediately

1 given the Protopic. I was also given the photo light
2 treatment where I went three times a week in a full
3 body chamber for photo light. I did that for about
4 two and a half years. And I really didn't see a lot
5 of progress in either one of those treatments, even
6 though the dermatologist took photos and kind of said,
7 "I see a little more pigmentation here and a little
8 bit more here." But I don't know. My vitiligo just
9 progressed and was so aggressive. I didn't see any
10 progress at all period.

11 So after about two and a half years of
12 going three times a week for the photo light therapy
13 and using the creams, my medical started not to cover
14 the visits because they said it was cosmetic. So I
15 wasn't able to pay for those three times a week
16 treatments on my own. So I kind of discontinued the
17 treatments. But for me personally, I didn't see any
18 effect of the photo light or the creams. So I just
19 stopped using all of them and just let the vitiligo
20 progress as it would normally do.

21 So right now after about six years of

1 vitiligo, I'm just about 85 percent covered with
2 vitiligo. So I do hope for the children who are on
3 the panel, the young people, that we can find some
4 kind of cure or a more effective treatment, so they
5 wouldn't have to live their whole lives with vitiligo.
6 I'm very fortunate to only have had vitiligo for six
7 years. I'm 73 years old right now. And I have not
8 had any problems with my vitiligo at all period. I am
9 fortunate to be in a great group with Lee Thomas and
10 Stephen, Be Strong support community. Folks are very,
11 very helpful in all aspects of vitiligo. So we really
12 need treatments that are more effective than what we
13 have already.

14 MS. BENT: Thank you so much, Beverly.
15 Let me now turn to maybe the phone. Line 2, Kay, to
16 maybe speak to thoughts about treatment and what you
17 look for in an effective treatment. Sorry. Line 3,
18 Anna. Hi, Anna.

19 CALLER ANNA: Hello. Hi. I'm glad to
20 be here. Thank you for doing this. It's exciting. I
21 am here today. I have had vitiligo for over 40 years.

1 I've tried millions of treatments from all over the
2 place. And my daughter also now has it. She's had it
3 for about 11 years. And our most successful treatment
4 is with the German treatment, the pseudocatalase, in
5 Germany and Jordan. The Dead Sea trip. And we put my
6 daughter pretty much in remission. Ever since our
7 first trip there, hers was never spread. It's never
8 gone away completely, but it's never spread. And
9 mine, I've never been able to get it to stop
10 spreading. I consider it a form of art. It's
11 movement.

12 But I would like to bring up to this
13 discussion is here in the US, I've felt a big
14 resistance with the dermatologists against wanting to
15 treat. I've had a few tell me they don't want to do
16 it. They don't want to treat because the people get
17 frustrated because there's no cure and they spend
18 money. And then all the sudden, it spreads again, and
19 they just rather not deal with it. So I know from
20 many support groups I belong to that people set an
21 appointment and come back extremely disappointed

1 because the dermatologists don't understand that I'd
2 rather have less vitiligo than more vitiligo. And I
3 want to keep treating.

4 And the access to the narrowband UVB,
5 which in my personal opinion is one of the best
6 treatments out there, needs to be affordable. In
7 Europe, there's no big restriction on it. You can
8 order one, and the simple handheld unit is \$150. Here
9 in the US, you have to battle the company. You have
10 to have prescription from a doctor. You have to pay
11 at least \$350 or more because they keep getting a
12 little bit more modern, and every year the price goes
13 up. So I think these are real concerns. You know?
14 The UVB works very well.

15 The other good about the UVB that I've
16 noticed is if you do 15 seconds each side of your
17 vitiligo spots every day, you can go out in the sun
18 and not be so terribly sunburned. Like if I'm not
19 doing the UVB treatments and I start going out in the
20 sun, I immediately get sunburned. But if I take every
21 morning and just do a minute in front of it, I do like

1 15 seconds each side, and I do it every day, I can go
2 outside. I don't need to be plastering myself five
3 times a day in sun lotion. I just put it on if I'm
4 going to be on an extended stay out there. So I think
5 things need to be expressed.

6 MS. BENT: Yes. No. Thank you very
7 much. Really appreciate your thoughts on that. Let
8 me turn to Joe on, I believe, Line 5.

9 CALLER JOE: Hello?

10 MS. BENT: Hi. Hi, Joe. Thank you for
11 calling. I wonder if you would share with us kind of
12 some of the thoughts you have about treatments and
13 maybe what an effective treatment would look like for
14 you?

15 CALLER JOE: I just want to say thanks
16 for everybody taking the time and looking into this.
17 I've had vitiligo since I've been a baby, and I'm 55
18 now. My mother, when I was a teen, found treatment as
19 in just a vitamin treatment. And was taking a vitamin
20 regimen. First, starting with liquid and then going
21 to just the pill form. I've gotten rid of probably

1 over 65, 70 percent of my vitiligo.

2 And then later in life, I slowed down.

3 Did not take the vitamins anymore, and it started to

4 come back. And now I'm back on the vitamin regimen.

5 And I've got some vitiligo on my face, and I see it

6 starting to fill in on my beard as well as around my

7 eyes and my arms as well again. So I'm back on the

8 vitamin regimen not under any doctor treatment plan or

9 anything like that. Just based off of what my mother

10 has looked up. And that seemed to do wonders for me.

11 Not knowing if anybody's looked into a vitamin

12 treatment or doses of how much vitamin would help with

13 treatment at all or not.

14 MS. BENT: Okay. Thank you. And that

15 actually kind of leads us right into our next polling

16 question that we're going to go to, which is a

17 question about besides the medical products or

18 interventions mentioned previously, what are you doing

19 currently to manage your vitiligo.

20 And the options that we have, and I

21 will read them to you because they are very small on

1 the screen. A, temporary cosmetic procedures, such as
2 makeup or sunscreen, et cetera; b, dietary and herbal
3 supplements -- and you can choose all that apply -- c,
4 diet modifications, such as limiting alcohol
5 consumption, a keto diet, a Paleo diet, vegan diet, et
6 cetera; d, over-the-counter products; e, complementary
7 or alternative therapies; f, counseling or
8 psychological treatment; g, other therapies not
9 mentioned; and h, not doing any treatment.

10 Okay. And again, since it's
11 particularly challenging, I think, to see the answers,
12 I will read them to you once we get a few more
13 seconds. So it looks like the blue line is temporary
14 cosmetic procedures, such as makeup or sunscreen. The
15 first blue. The second, the 19 percent is dietary or
16 herbal supplements. Then we have diet modifications.
17 The pink is over-the-counter products. The purple is
18 complementary or alternative therapies. F is
19 counseling. G is other therapies not mentioned. And
20 H, the large green at the far end is I'm not taking
21 any therapies or treatments.

1 So let me turn briefly now back to our
2 panelists and see if we have anybody who's kind of
3 using some non-drug therapies. Anyone who's using
4 non-drug therapies, why you decided to use them, and
5 how is your experience?

6 Mary, I don't know if you want to speak
7 to this? Is that okay? Great. If you wouldn't mind
8 speaking to that. I believe you're muted. Perfect.
9 Now you're not.

10 PANELIST MARY: Hello, everybody. This
11 is Mary. I'm in France right now. I'm originally
12 from Turkey. My vitiligo appeared with a tiny dot on
13 my finger when I was 21 years old. Now I'm 39, and
14 almost half of my skin area is now depigmented.

15 At the beginning, I tried a topical
16 cortisone without much success. Three years later, I
17 tried an unconventional therapy from a pharmacist that
18 had trained himself with different non-conventional
19 approaches. So he proposed a therapy combining some
20 steam bathing with a lot of creams that we had to
21 apply before going out into the sun or under the

1 steamer as well as some herbs and spices that we had
2 to consume orally. And it had really great results.
3 I could repigment all of my face within a month's
4 time.

5 It was really amazing, but the protocol
6 was so much time consuming that it wasn't compatible
7 with any other occupation during the day. I mean, you
8 had to leave anything else aside and just focus on the
9 treatment. So I just felt that the vitiligo could
10 relapse at any time, and I thought I couldn't spend
11 all of my life treating myself and not doing anything
12 else. I gave up. I gave up after two months of
13 therapy. And I decided to stop treating myself, but
14 it was more easily said than done.

15 Two years ago, so rather recently, I
16 decided to change my diet mainly. I removed all
17 cereals and dairy products from my diet. And combined
18 with exposure to sun, my vitiligo started to repigment
19 very quickly. But it's impossible to maintain regular
20 exposure to sun given the winter, the kids, the
21 professional life, and so on. So I still continue to

1 diet. And I see repigmentation at times when I can
2 expose myself to sun for a few days in a row, but I'm
3 not any more deliberately looking for the opportunity.

4 And what I could say for an ideal
5 therapy for me, I mean, most of the other proposals
6 for therapy, I filtered them -- I could say.
7 Depending on my mood at that time, how I saw my
8 vitiligo, if I convinced that it could actually be
9 treated or not, and now I'm convinced that treatment
10 for vitiligo cannot be convincing if it's simply
11 targeting the skin unless the manifestation of
12 vitiligo itself is very localized and specific. For
13 my case or for cases of expanded vitiligo like mine,
14 it's clear to me that vitiligo is only the symptom of
15 other deregulations, either physiological or
16 psychological if not both.

17 So in an ideal treatment, I would
18 certainly look for a comprehensive approach looking
19 for the root causes and addressing them and combining
20 multiple strategies that do not necessarily fit within
21 one drug if needed. Treatment proposals from the

1 Eastern medicines, from radical or traditional Chinese
2 medicine are, for instance, very interesting. They do
3 not propose one single drug. But I do not the
4 expertise myself to judge on their merits as such.

5 MS. BENT: Thank you.

6 PANELIST MARY: If I could?

7 MS. BENT: Yes, please.

8 PANELIST MARY: And other than any
9 treatment approach to vitiligo itself, it's very
10 important to systematic proposals to psychological
11 health because, I mean, everybody talked about it.
12 This could be one of the reasons of the onset of the
13 vitiligo, but even if it's not the reason, it has
14 certainly effects on our psychology. So in any case,
15 I think psychological help is essential for patients
16 suffering from vitiligo. Thank you.

17 MS. BENT: Thank you. Beverly, did you
18 want to add something briefly before we go to somebody
19 on the phone?

20 MS. SMITH: Were you speaking to me?

21 MS. BENT: Yeah. Sorry. I thought you

1 had your camera on. So I wondered if you wanted to
2 add something briefly?

3 MS. SMITH: No. No. Okay.

4 MS. BENT: Okay. Great. All right.

5 Thank you. So let me then turn to Savannah on Line 6?

6 CALLER SAVANNAH: Hello.

7 MS. BENT: Hi, Savannah.

8 CALLER SAVANNAH: Hi. Hi, everyone.

9 My name is Savannah, and I want to start by thanking
10 you all for sharing your experiences and to the FDA
11 for hosting this meeting.

12 I was diagnosed with segmental vitiligo
13 when I was around 16, following the appearance of a
14 halo nevus on my back. I'm now 22, and no one else in
15 my family has or had vitiligo. It was very stagnant
16 for a while, only spreading on the right side of my
17 back and chest. But it's changed a lot over time.
18 And one of the biggest things I've noticed is the
19 correlation between stress in my life and the spread
20 of vitiligo.

21 But in terms of treatments, I've tried

1 topical treatments, such as Protopic, Elidel, and
2 others, which are -- for quite a while. But a lot of
3 these creams stain absolutely everything, which makes
4 it challenging to keep up the treatment: sheets,
5 pillows, clothes, towels, et cetera. And I know many
6 people cannot afford to constantly replace these
7 items. So it's either treatment or stained
8 belongings. So my hope is that drug developers will
9 keep this in mind.

10 And in terms of accessibility, most
11 topical treatments that I've tried are not covered by
12 medical insurance for the purpose of treating
13 vitiligo. So hopefully conversations such as these
14 will allow us to make progress on this, so that
15 vitiligans of all socioeconomic statuses can obtain
16 treatment.

17 I believe it's very important to have
18 these conversations. So awareness can be brought to
19 vitiligo as something that is more than an aesthetic
20 inconvenience, but rather a condition that truly does
21 affect people's every day lives all over the world

1 like we've heard today whether that manifests itself
2 physically, psychologically, socially, and more. So I
3 really appreciate all of you for hosting this meeting
4 today. Thank you so much.

5 MS. BENT: Great. Thank you so much
6 for your thoughts on that.

7 Let us move now to one more polling
8 question, which is about the medical products or
9 interventions. What are the most burdensome impacts
10 of the treatment? And so the question is, for the
11 medical products or interventions you use, what do you
12 consider to be the most burdensome impacts. And you
13 can choose up to three answers. The first one is how
14 the medication is administered, such as topical cream
15 or an injection; change in the pigmentation of the
16 skin, such as color or pattern; the treatment only
17 provides minimal benefit; the treatment is effective
18 only for a short-term; bothersome side effects of the
19 treatment; concerns about serious risks of the
20 treatment; uncertainty about the long-term effects of
21 the treatment; difficulty in accessing treatment, such

1 as insurance or physician referral; and other negative
2 impacts not mentioned.

3 And I think that we've kind of already
4 touched on this quite a bit with our panelists and the
5 people on the phones. But I think it's helpful just
6 to kind of continue the discussion to really
7 understand the impacts that a broader portion of
8 people participating in the meeting are experiencing.
9 So it looks like pretty much all of these impacts are
10 burdensome and impactful to people. So I think that
11 this really speaks to what we've heard already.

12 So thank you for that. I think as the
13 polling results are coming in, I would like to really
14 kind of ask you a little bit more about efficacy and
15 safety. So efficacy and safety are important for any
16 treatment. So when you think about a treatment for
17 vitiligo, does it matter to you whether the product
18 might improve your most bothersome symptom or whether
19 it would have some bothersome side effects? I guess,
20 what we're kind of asking is, would you consider
21 improvement in -- sorry. I kind of lost my train my

1 thought midway through there. But as far as when
2 you're considering the benefits of a treatment and the
3 risks of a treatment, how do you make a decision about
4 what you would consider accepting as far as risks when
5 you're thinking about a treatment?

6 I realize some of the people that we
7 have on the line may have called in for different
8 purposes. But for those of you waiting on the line,
9 I'm going to turn to you in a moment to see if you
10 have any thoughts on that.

11 Jay, it seems like maybe you might have
12 a thought on that if you wouldn't mind kind of sharing
13 that thought with us?

14 MR. HAMPTON: Yeah. Sure. It's just
15 mainly just with how resourceful the treatment is and
16 how often, where you can purchase it at, and also
17 costs with it as well. I was very fortunate that a
18 lot of my treatments were given to me for research
19 purposes. Of course, that was way back in the early
20 2000s. I know everybody's not as fortunate to have
21 received that right now. So that's the main thing.

1 And also just with a lot of the side
2 effects with it can be very burdensome. And just
3 having a voice with talking to your dermatologist
4 that's an advocate for you. Provide an advocacy for
5 these types of treatments for vitiligo. Just to keep
6 somebody who's trying or starting new treatment to
7 sustain it -- you know? -- so to speak and have
8 support with it. That's all.

9 MS. BENT: Thanks, Jay. Stephen, did
10 you want to say something?

11 MR. TAYLOR: Yes -- -- virtual
12 connectivity interruption -- it's a major factor --

13 MS. BENT: Stephen, I'm having a little
14 trouble with your audio. I don't know if others are
15 as well. Okay.

16 MR. TAYLOR: Can you hear me now?

17 MS. BENT: Yes.

18 MR. TAYLOR: Okay. I was just thinking
19 about something. Stress is a key factor for vitiligo
20 and its spread. When I was taking treatment, the
21 stress of taking the treatment: the drive, the waiting

1 in line, and coming back, the three days a week, the
2 six months of treatment, and then any future
3 treatments from other light treatments. I think that
4 caused my vitiligo to regress even though I was making
5 progress because I was stressing during the treatment
6 process.

7 MS. BENT: That is an interesting
8 thought. I think Mary touched on that kind of earlier
9 as well. So no. Thank you.

10 So now let me turn to Netta [ph] on
11 Line 8 to hear from some of our phone line callers.
12 Netta?

13 CALLER NETTA: Netta. Hi.

14 MS. BENT: Netta. Sorry.

15 CALLER NETTA: No, it's totally fine.
16 So I'm 29, about to be 30. And so in two months, I
17 would have had vitiligo for 20 years, which is a scary
18 number. My God. But I got it when I was 10. It was
19 like a little spot on my chin. And the thing is we
20 went to my primary care doctor, which was the worst
21 idea because then it spread to my chin and then my

1 neck. And that's all where I have it.

2 And I started with UVB light. And like
3 everybody was sharing, which I really appreciate, I
4 would go three times a week after school, and my
5 childhood was very intense because I would go after
6 school. And I'd come back to school or go to theater.
7 So it was very, very time consuming. And then I
8 switched to UVA. And we thought we could snap it with
9 UVB first because it was narrowband, more precise.
10 And then UVA, we knew the risks. Did it anyway.

11 And then after a while, then we did
12 excimer. So then I would go to Stanford three times a
13 week. And then when I went to college, that's where
14 it stopped because I went to Orange County. And UC
15 Irvine had it, but then when I called the medical
16 board, I remember whoever was on the line said, "Oh,
17 it's a cosmetic thing." And that really pissed me off
18 because then I said, "Okay. Whoever's on that line
19 doesn't know. Isn't educated about it." And I
20 thought to myself, "I couldn't get anywhere." So then
21 I haven't had treatment.

1 But then my dad, he bought me that
2 portable kit from Daavlin, and I feel so bad because I
3 haven't used it as well. And I feel like it was a
4 waste of money because I still have it with me. But
5 the way it's designed, I can't cover with a sheet.
6 And even with the light treatment, I would do the
7 goggles, the cream on the face, the towels, everything
8 going in. And so I still have that, and I'm curious
9 if anyone else had Daavlin or know how to use it.

10 But then right now, I do Protopic, and
11 I also bought this vegetarian tablet called Recouleur.
12 So it's supports reappearance of color in gray hair
13 and depigmented skin. So I thought it can't hurt.
14 Gave that to my holistic nutritionist that tested on
15 me. A little Eastern medicine thing. And he said it
16 was fine.

17 And what's curious is I went to my
18 dermatologist last year. A new one. I live in LA
19 now. And what was interesting was that I think I want
20 to tell everyone that whoever's your dermatologist,
21 make sure they're empathetic and compassionate and

1 care about vitiligo because the way she spoke to me
2 was like she didn't care. You know? We all talked
3 about the psychological, the emotional, all of that.
4 I mean, to have your doctor not really care. I always
5 ask this, "Are there any updates?" And she said,
6 "Well, you've had it for almost 20 years. So I guess
7 it's pretty old now." And hearing everybody say how
8 long they've had it, I'm like, "That can't be an
9 answer." Like I still feel like the body can do
10 something. Heal itself. That was very disheartening
11 to hear, and I'm not going to her again.

12 And I'm also an actor and a singer.
13 And I go on set. And this is for the cosmetic
14 portion, that I feel like there should be a makeup
15 line for makeup artists who work in TV and films -- if
16 this could be a conversation down the road one day --
17 where there's a makeup line that the ingredients are
18 specifically for entertainment people with vitiligo
19 because we've worked hard to maintain our vitiligo
20 health. And so I don't want to Dr. Big use makeup
21 products that I don't know what the ingredients are

1 made of.

2 MS. BENT: Great. Thank you so much,
3 Netta. We really appreciate your thoughts.
4 Unfortunately, we're going to need to move on now to
5 Kelly on Line 7. Kelly? Kelly?

6 CALLER KELLY: Hello.

7 MS. BENT: Hi.

8 CALLER KELLY: Hi. Sorry for the jump.
9 Hi. Yes. I am so sorry. I was listening. What was
10 the question I'm being asked to respond to?

11 MS. BENT: So I think that it would be
12 really helpful for us to understand kind of from a
13 benefit risk standpoint what would an effective
14 treatment look like to you and what kind of side
15 effects would you be willing to tolerate for an
16 effective treatment.

17 CALLER KELLY: Okay. Okay. I can help
18 you with that.

19 MS. BENT: If you have something else
20 that you'd like to speak to, please feel free just in
21 kind of a minute or two.

1 CALLER KELLY: Okay. No. I can
2 address what you asked, and I think put my two cents
3 in at the same time. I've had vitiligo for 23 years
4 since I was 12. I'm currently 34. I'm an African
5 American woman with vitiligo. And so my experience
6 with it has been prepubescent all the way until
7 womanhood.

8 And I feel that the treatment that is
9 most needed right now is more research into the use of
10 the cream benoquin, the treatment of monobenzene, for
11 people of color earlier intersections of having
12 vitiligo. What I find is that most dermatologists do
13 not want to give people of color benoquin before
14 they're 50 percent covered with vitiligo. But what
15 happens in order for us to get to that point, because
16 it's an autoimmune condition, everyone depigments at
17 their own rate, and they're not taking into
18 consideration the sociopsychological effects of
19 walking around with two pigments.

20 And as a person of color that has this
21 for over 20 years now, I've had the hardest time

1 maintaining work because of my social experiences in
2 the workplace. And it's been emotionally debilitating
3 because I just want to take care of myself. But
4 because of the way that current treatments are with
5 vitiligo, they're focusing more on trying to help
6 people repigment successfully instead of depigment
7 successfully. And I think we need to rework that idea
8 because we know that monobenzone works.

9 And I feel like helping people adjust
10 to the changes in their appearance is going to happen
11 either way. When Michael Jackson died, he still had
12 benoquin on his bedside. So there's certain emotional
13 understandings that I feel we can help the vitiligo
14 people reach through psychotherapy and through
15 training psychotherapists to deal with vitiligo
16 patients and other patients with autoimmune conditions
17 for that matter. Where I'm at personally is I finally
18 have monobenzone, but I'm 34. And I'm underemployed
19 because of everything that I've been through with
20 vitiligo. And if they would have just given me the
21 cream when I asked for it when I was 21 and in

1 undergrad and seeing dermatologists at Howard
2 University who specialized in vitiligo, but no they
3 wanted to do all these treatments on me to try to help
4 me repigment. And that wasn't what I was interested
5 in as a patient.

6 So I want more research done for people
7 of color for monobenzene treatment and for
8 psychological therapy. I'm understand that vitiligo
9 affects everyone that has it, and I'm not putting down
10 any other racial ethnicity -- vitiligo. But what I'm
11 expressing is that because it's harder to cover in
12 darker pigmented people, it just becomes an issue of
13 marginalization and social stratification. Therefore,
14 you're going to have more psychological problems, and
15 monobenzene works. It takes away the color. It's a
16 painful process to lose your color with vitiligo
17 anyway.

18 I've had a dermatologist tell me he
19 didn't want to give me monobenzene because he wasn't
20 sure if I could handle being white. And so there's a
21 huge problem in the medical community with racial

1 biases and treatment of vitiligo patients. And that
2 was my two cents.

3 But research on monobenzene, how it
4 affects the immune system but also the autonomic
5 nervous system would be great. Because the truth is
6 we can manage wearing sunblock for the rest of our
7 lives, but going through multi-pigmented in the all
8 different areas of your live, it's just emotionally
9 exhausting. And I know that's across the board with
10 all patients that suffer with vitiligo understand
11 that. And the subconsciousness, you think someone can
12 see a spot that they can't even see. Like, it's just
13 you know? So more research --

14 MS. BENT: Right. Thank you. And I
15 think that is an important point. And I think we have
16 heard a number of times today that there is identity
17 kind of tied to the pigmentation and the
18 depigmentation. And it is very impactful to people.
19 So I think you've raised some very good points. Thank
20 you for that.

21 Let me turn now to our FDA panelists,

1 particularly, Dr. Marcus to see if you had any
2 questions or clarifying questions that you had for our
3 panelists or our callers please.

4 DR. MARCUS: Sure. Thank you, Robyn.
5 And I just want to say that I completely respect the
6 caller's perspective that depigmentation is sometimes
7 the preferred goal for patients. But focusing on
8 repigmentation, I'd like to ask people today, in the
9 context of how well a product works, do you all have
10 ideas about what a clinically -- in FDA speak we like
11 to talk about clinically meaningful improvements.

12 And in terms of addressing diseases and
13 providing effective treatments, progress is often made
14 in small stepwise fashion, where initially products
15 provide modest efficacy. Scientists and drug
16 companies build on what has been learned from the
17 first products that are developed, and subsequently,
18 oftentimes, although not always, new products will
19 have more efficacy.

20 In that context in this area where
21 there is still a significant unmet medical need, if as

1 a patient you were going to take a treatment, is there
2 some minimal level of improvement or repigmentation
3 that would be meaningful to you? So would any level
4 of repigmentation for those who have lost the majority
5 of their pigment, would that be meaningful to you?
6 Would it be meaningful if you regained half of your
7 pigment? If that's the best that you could do, would
8 you be satisfied with that as being better than no
9 treatment? I'd just like to hear about that level of
10 improvement that patients would accept from any
11 treatment. Thank you.

12 MS. BENT: Okay. Let me start by
13 turning to Beverly, and then we'll go to Mary.

14 MS. SMITH: Yes. To answer that
15 question, I think both Lee and Stephen spoke to the
16 area if we had choose an area, and that would be our
17 face. I know when I was diagnosed, I said, "Well,
18 just please don't let it come to my face." And it
19 took it about two and a half years before it got to my
20 face. So if there were some treatment that could
21 bring the pigment back in our face areas, would be

1 very helpful because that's where people see you. And
2 they can hear you, what you're saying, if they can see
3 a normal face when you're trying to advocate or talk
4 about something important. Educate people on
5 vitiligo. That's we do now. We're all advocates. So
6 that would be an area that I think that we would all
7 be happy if we can get the pigmentation back into our
8 faces.

9 MS. BENT: Thanks, Beverly. And let me
10 just ask a quick follow-up question. So when Dr.
11 Marcus was talking about maybe like 50 percent
12 pigmentation back or when you think about getting the
13 pigmentation back, can you speak about what would be a
14 success? Would it be kind of like half the
15 pigmentation back, or are you thinking kind of
16 complete? I mean, obviously, complete would be
17 wonderful. But would 50 percent be something?

18 MS. SMITH: To me or someone else?

19 MS. BENT: You. Just really quick at
20 the end of your comments.

21 MS. SMITH: I think 50 percent would

1 not -- for the facial area, if we can get more than
2 the 50 percent, you can do other with makeup. But I
3 decided not to wear makeup at all period. But in the
4 facial area, it can be wearing makeup can do the other
5 part of it, and it wouldn't look so much like you
6 wearing makeup, which many people do. I don't anymore
7 at all period. But I think more than 50 percent area
8 in the face would be helpful.

9 MS. BENT: Great. Thank you. Now let
10 me turn to Mary and then Stephen and then Vimla and
11 Priyanka. And then we'll go back to the phones.

12 PANELIST MARY: Yes. To me, also the
13 face is very important. I think we will all agree
14 about this. And also, I mean, face and the
15 continuity, somewhat the neck and the neckline,
16 because, I mean, where we end the makeup somewhere,
17 there's a greater gap of color between the makeup and
18 not makeup part.

19 But I think in efficacy of the
20 treatment is not only about how much recovery of
21 pigment it allows, but it's also about how long this

1 recovery will last. Because most of the treatments do
2 bring improvement, I mean, not every treatment can
3 work with everybody. But there are some treatments
4 that will work with some people. But even in these
5 cases, when we stop the treatment, it will all come
6 back somehow slower or quicker. So it's also very
7 important. I mean, the efficacy question for me is
8 also the lasting effect of the treatment if possible.

9 MS. BENT: That's helpful too. Thank
10 you. Stephen?

11 MR. TAYLOR: I'm going to underscore
12 what she said at the end. I was thinking the same
13 thing too. I want a qualifier in there. Because
14 every time I had improvements and stopped taking
15 treatments, I have lost what I'd gained. I don't need
16 to go through an emotional rollercoaster ride. So I
17 want a hundred percent guarantee. Okay? I know
18 that's asking for a lot. From my experience, I just
19 don't want to lose what I have gained because I've
20 gone through this process so many times.

21 And so I've got to rephrase the

1 question as a qualifier. If we can guarantee a high
2 percentage of efficacy and it is going to stay that
3 way, then we'll have that conversation.

4 MS. BENT: Very good. Thank you. And
5 now let me turn to Vimla and Priyanka.

6 PANELIST VIMLA: Thank you for that
7 question. I just wanted emphasize that we definitely
8 want a high percentage. So typically, in the 80 to
9 100 percent, mainly because there's also a pattern of
10 progression of the vitiligo. So your baseline
11 assessment is constantly changing, which is why you
12 want a very high degree of repigmentation and
13 permanent repigmentation at very high numbers far
14 greater than 50 percent just because the spread and
15 the rate of spread is much higher than the rate of
16 repigmentation. So that is why you want to hit it
17 even before it spreads. So I would say a pretty high
18 number. Like 80 to 100 percent.

19 Priyanka, do you want to add anything?

20 PANELIST PRIYANKA: In addition to what
21 some other panelists mentioned earlier, I think

1 location is really important. So I would much rather
2 prefer that results rise on my face as opposed to
3 other parts of my body just because those are the most
4 visual areas and those are the areas that people tend
5 to judge. That's all.

6 MS. BENT: Great. Thank you very much.
7 Now let me turn to Betty on Line 8.

8 CALLER BETTY: Good afternoon. I just
9 kind of wanted to answer the question the doctor was
10 proposing as far as what would you consider success.
11 I have had vitiligo for 45 years, and I have it like
12 over 75 percent of my body, mostly my face is
13 impacted. I would say in order to gauge that, you
14 would probably do a demographic and ask people of
15 different groups how much do they have over their
16 entire body. And then kind of give them a timeline as
17 to the treatment. You know? In six months, if you
18 could get 25 percent back, would that be successful to
19 you? You know? In 12 months, if you could get 50
20 percent back, would that be something you would
21 interested in doing? Not everyone is interested in

1 getting the repigmentation treatment. So that will be
2 something that will be helpful to people with
3 vitiligo. So I would say to do something in that
4 regard to kind of assess what the needs are.

5 MS. BENT: Great. Thank you, Betty.
6 Really appreciate that. Let me turn now briefly to
7 Shannon to see if we have any comments from people
8 online regarding this question.

9 MS. COLE: Thanks, Robyn. We've
10 received several comments online about clinically
11 meaningful treatment benefits. And they're all kind
12 of differing based on the individual's experience.

13 But one individual said that they would
14 love to regain even half of their pigment as long as
15 the effects and the process were not too arduous. And
16 on the other hand, some had expressed that they are
17 looking for all or nothing in a treatment and that
18 consistency is very important in terms of that unknown
19 factor of possibly losing pigmentation in the future.

20 Another commenter stated that they're
21 now 43 years into their journey with vitiligo, and

1 they are not interested in small improvement
2 treatment. But 50 percent or higher would be very
3 beneficial, especially if the treatment was easy. If
4 it was a cream that they have to use twenty hours a
5 day, seven days a week, then the 50 percent would not
6 be worth it to them.

7 Another individual expressed that they
8 have universal vitiligo and a hundred percent natural
9 skin depigmentation. So they would only consider a
10 treatment that repigments, at least, 80 percent of
11 their skin. And they would also consider a higher
12 risk treatment if it was effective at putting their
13 vitiligo into remission for a longer period of time.
14 They would also love to see a treatment for the
15 repigmentation of their hair.

16 And a few other commenters also
17 mentioned that their face is probably their first
18 priority in terms of treatment and seeking that
19 repigmentation.

20 MS. BENT: Okay. Thanks, Shannon.
21 Let's move on now. Actually, we have a hypothetical

1 scenario that kind of touches on this, and we'll kind
2 of give us a good idea of what people throughout our
3 webcast are thinking about this.

4 So if we can move on to Hypothetical 1,
5 which is a new skin cream. Okay. So I am going to
6 read the hypothetical scenario to you. So imagine
7 that a new topical cream, not a steroid, indicated to
8 treat vitiligo has recently been approved by the FDA.
9 Your doctor believes that you or your loved one may be
10 a good candidate for this medication. The topical
11 cream needs to be applied once a day. Research in
12 animals and people show that this treatment may
13 improve pigmentation by up to 50 percent. Some common
14 side effects for this therapy may include redness and
15 irritation at the application site, mild acne, and
16 burning. Rarer but more serious side effects may
17 include fever, pain during swallowing, insomnia,
18 nausea, and increased heart rate. What first thoughts
19 come to your mind as you hear this scenario? What
20 questions would you ask your doctor about this
21 treatment?

1 And so our question to you first is
2 given the risks and benefits, would you be interested
3 in taking this medication? And the options are yes,
4 no, or maybe. Okay. And it looks like we're pretty
5 split about that with 43 percent of people saying yes,
6 about 25 to 30 percent saying no, and 30 saying maybe.
7 So this is helpful for us to hear. It would also be
8 helpful for us to know kind of what degree of risks
9 are you willing to accept for an effective treatment:
10 risks such as immunosuppression or potential other
11 challenges as we look at that.

12 So while we're waiting for the results
13 to kind of stabilize, let me turn to just a few more
14 people that we have on the phone. And let me see.
15 I'm sorry. I've lost my list of people on the phone.
16 Do we still have Masooma on Line 10?

17 CALLER MASOOMA: Yes. I am still on
18 the line. Can you hear me?

19 MS. BENT: Great. Thank you so much
20 for your patience and for holding. So I wonder if you
21 would be willing to speak a little bit to the thoughts

1 about treatment and effective treatments and what
2 would that look like and side effects you'd be willing
3 to kind of deal with. But if you had something else
4 you'd like to speak to, we'd be happy to hear that in
5 the next minute or two.

6 CALLER MASOOMA: Yes. Thank you so
7 much, again, for the opportunity to voice our opinions
8 to both the FDA and the organizers of this meeting and
9 all of the patients with vitiligo that have already
10 shared their stories.

11 I wanted to touch on a few different
12 points. In terms of the clinical outcomes and looking
13 at optional therapies for future, I think going back
14 to the 50 percent option of repigmentation. Again, I
15 think this can vary quite a bit. Again, I would agree
16 with the rest of the speakers that who already spoken
17 before, the face is very important. So I think 50
18 percent is not acceptable to me. I really would like
19 that area to be higher.

20 And of course, the other issue is that
21 repigmentation pattern. For somebody's who has lost a

1 lot of pigment already, regaining 50 percent might
2 make them actually look perhaps worse in terms of
3 their own opinion versus being more uniform in color.
4 So I think that's a consideration.

5 The other thing is the duration of
6 pigment gains and how long the effect will last as
7 well should be consider because, again, we're kind of
8 tethering back and forth between having repigmentation
9 and then losing it again. And I think bringing sort
10 of the cause of vitiligo and perhaps autoimmunity in
11 general becomes very important in this regard because
12 the issue is that we're always playing catchup with
13 the condition. So I think really putting more
14 research and understanding into the causes of the
15 disease, I think, can help in that regard. Because
16 we're not just repigmenting, we're also slowing the
17 progression or perhaps even halting additional
18 slayers.

19 The other thing I want to mention also
20 is that considering some of the other options that are
21 already in development that are being looked at

1 vitiligo, they carry significant side effects, such as
2 immunosuppression, that you've already mentioned. So
3 if I have a risk of a very severe infection down the
4 road or perhaps even cancer, that really makes me
5 rethink, "Does my immune system need to be suppressed
6 via an oral medication versus a topical?" So I would
7 be more open to a topical medication if that is very
8 effective. But again, if the oral treatment had a
9 very favorable benefit risk profile, I would
10 definitely consider that as well. But I think, again,
11 some of these need to be looked at more long-term in
12 terms of the side effects as well because we don't
13 want to just be addressing that now and having some
14 major other issues down the road.

15 One other thing I want to implore the
16 FDA to do also is in terms of looking at this from a
17 holistic perspective, many of us have already
18 mentioned that vitiligo carries vast and varied
19 negative consequences for many of us, including
20 physical, psychological, emotional, et cetera. So I
21 think, again, this may be the first step, but really

1 bringing together some of the other regulatory
2 agencies or government agencies including
3 academicians, researchers, et cetera, and
4 pharmaceutical companies to look at this and provide
5 more answers in what really may be effective in
6 stopping the progression of the disease not just
7 looking at treatment options once it's already
8 developed. And again, we're playing catchup. So
9 thank you, again, for the opportunity to comment.

10 MS. BENT: Thank you so much. That was
11 really very insightful comments. I appreciate those.
12 Let me turn to Denise on Line 5.

13 CALLER DENISE: Hi. Can you hear me
14 okay?

15 MS. BENT: Yes, ma'am.

16 CALLER DENISE: I'm Denise from
17 Indianapolis, Indiana. And I'm the president of
18 Fearfully and Wonderfully Made IDC Vitiligo Community.
19 But I was diagnosed 16 years ago. In fact, I was 50
20 when I first had my first spot, went to four different
21 doctors, and got four different skin biopsies, and

1 finally got the right diagnosis. I was misdiagnosed
2 first.

3 But I just want to say really fast that
4 I agree with everything, especially the last lady in
5 front of me what she just said about this. She was
6 spot on. But I wanted to bring up a couple of things
7 that in my group that I've had people share with me
8 that haven't been shared yet. One, a person who had
9 vitiligo in my group, her vitiligo and stopping her
10 makeup was the straw that broke the camel's back. And
11 she got a divorce. And then another person in my
12 vitiligo group, she needs to write a book. But
13 because of her, I now carry a doctor's statement in my
14 car because of the political climate today with the
15 police thing and things like that. I don't want to be
16 stopped, and somebody look at my license and look at
17 my picture on my license, which does not look like my
18 face anymore, and get arrested because they think I'm
19 trying to be somebody that I'm not.

20 So those are all things that are just
21 really so important. And why, like Perry said, we

1 really need you guys to really pay attention. And I'm
2 so thankful for this avenue and the fact that you're
3 doing this right now. So thank you so much for
4 letting me get on and letting me share this. Okay?
5 And I'm going to still be boots on the ground in
6 Indiana spreading awareness about vitiligo.

7 MS. BENT: Great. Thanks so much,
8 Denise. Really appreciate your call.

9 So it looks like we're coming up on the
10 end of the meeting. Let me turn back to our
11 panelists. I don't know if we have anybody who wants
12 to share any final thoughts. Lee Thomas, I know you
13 had raised your hand a bit earlier, and I hadn't been
14 able to get to you. Did you have any final thoughts
15 that you wanted to share with us before we kind of
16 wrap up the meeting?

17 MR. THOMAS: I'm trying to unmute
18 myself.

19 MS. BENT: You're unmuted. Your video
20 is not on, which is fine. We can still hear you.

21 MR. THOMAS: Okay. All right. There

1 is it. You guys allowed me to start my video. Thank
2 you. The only thing I want to say is I heard -- I
3 think it was -- Vita [ph] from California or Vetta
4 [ph] from California -- she asked about makeup. And I
5 have to put makeup on every day. So I found a couple
6 of products that actually work. And one of them is
7 Cover FX. It was made for rosacea to cover rosacea,
8 but it has the pigment in the makeup. Actually, works
9 pretty good.

10 The last thing I'll say is I just
11 really appreciate this. I really do. I've traveled
12 around, and this is the first time I'm sitting on a
13 panel with people from the FDA or I'm part of a panel
14 with people from the FDA. So I'm very encouraged by
15 this day. And it's been emotional, and it's been
16 insightful. And I just want to say thank you, Robyn,
17 and thank you to the people from the FDA for letting
18 me be a part of it. And I'm anxious to see what
19 happens next.

20 MS. BENT: Thanks so much. Let me go
21 to Mary and then Jay for final comments before we turn

1 it over to Dr. Marcus for closing remarks. Mary?

2 PANELIST MARY: You can hear me better
3 now. Thank you for this meeting. It was very
4 enlightening to hear the other vitiligo patients'
5 experiences. I really would like to underline the
6 importance for me, at least, to work on the root
7 causes of vitiligo because now we are all focusing on
8 symptomatic treatments because that's what we are
9 interested in. I mean, we try to look better. We try
10 to feel self-confident about the way we look. Of
11 course, this is understandable. But I think we do
12 have to look at the root causes and try to find the
13 treatments that are going to heal the root causes
14 because the skin is just manifesting something that's
15 probably going wrong somewhere else. So I really
16 would like to see more research on the root causes of
17 vitiligo. Thank you.

18 MS. BENT: Thank you. And Jay?

19 MR. HAMPTON: Yes. Lastly, just to put
20 on there, I know some of that wasn't discussed and I
21 know that worked for me is the last-ditch type of

1 treatment, all of us that's watching this, is
2 acceptance. You know? Once we accept who we are and
3 love who we are, that gives us a driving force to keep
4 going on. And the support that we have with this type
5 of FDA panel and all this through Facebook that wasn't
6 around when I first came on eons ago has helped me a
7 whole lot. So whether we get a treatment or a cure or
8 not, just knowing I'm not in this battle by myself --
9 to at least be grateful I'm waking up and keep going
10 on. I can share experiences in strength and hope and
11 my depression and all that stuff with people, my
12 support group, and know that I'm not talking by
13 myself. So I thank you all again. Much love.

14 MS. BENT: Thanks, Jay. I can't think
15 of a better way to kind of end the panel session. So
16 thank you all for an amazing meeting. Your sharing
17 today has really provided us with valuable insights.
18 And again, if we weren't able to get to your comments
19 today, that doesn't mean they're not valuable. We do
20 really want to hear them. So please consider sharing
21 them to the federal register, and we will also include

1 them in the Voice of the Patient report.

2 In addition, as a reminder, we will be
3 launching the crowdsourcing website later on this week
4 hopefully. And so we'll share that information when
5 that is launched with you, so that you can continue to
6 share your experiences with us. And those who are not
7 watching this in real time but who are watching this
8 as a recording, hopefully, you'll be watching it
9 within the next week or so and will also be able to
10 participate in the crowdsourcing.

11 With that, I'd like to turn the mic
12 over to Dr. Marcus, again, from the Center for Drug
13 Evaluation and Research here who will provide us with
14 closing remarks. Dr. Marcus?

15 DR. MARCUS: Thank you. Thank you,
16 everybody, for participating in this meeting today and
17 for sharing your stories, experiences, and
18 perspectives. Usually, I like to provide a broad
19 overview of what I've heard, and we've heard so much
20 today that's it's challenging for me to put it all
21 together.

1 I think that anybody listening today
2 would understand the tremendous impact that vitiligo
3 has on people's lives. I don't think that there's any
4 denying that it can result in the loss of even one's
5 identity, what you see when you look in the mirror.
6 It impacts the way that others interact with you. And
7 we heard in some cases that people were unable to get
8 employment, that they are avoided, that they're
9 bullied.

10 And what's particularly difficult to
11 hear about that is that at the same time for some of
12 you, you have difficulty having your disease taken
13 seriously by physicians who view it largely as a
14 cosmetic condition and are reluctant to treat because
15 they believe that your expectations will not be met
16 and that it will be an exercise in frustration. I'm
17 really sorry to hear that for all the people who have
18 experienced that.

19 We've also heard from you about
20 treatments and the impacts that some of the treatments
21 can have on your lives. Making it impossible to do

1 other activities, such as work or care for yourself in
2 other ways. That's certainly not the kind of
3 treatment burden that anybody wants to have. We also
4 heard about the wish to have cures as well as
5 prevention of progression of disease. I want to make
6 sure that you all understand that you were heard
7 today. And that you understand that this kind of
8 dialogue is important, not just for us, but also for
9 the drug companies, the researchers, and other medical
10 product developers who are also here today.

11 So again, I just want to let you know
12 we're all listening to what you have to say. And I
13 hope that the information you provided to us today
14 helps to advance the science and development of new
15 treatments for those who would like to have them.
16 Thank you very much.

17 MS. BENT: Thank you, Dr. Marcus.

18 Thank you, everybody. Have a wonderful day. Goodbye.

19 (Whereupon, the meeting concluded at
20 2:26 p.m.)

21

1 CERTIFICATE OF NOTARY PUBLIC

2 I, Carl Hellandsjo, the officer before whom
3 the foregoing proceedings were taken, do hereby
4 certify that any witness(es) in the foregoing
5 proceedings, prior to testifying, were duly sworn;
6 that the proceedings were recorded by me and
7 thereafter reduced to typewriting by a qualified
8 transcriptionist; that said digital audio recording of
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10 best of my knowledge, skills, and ability; that I am
11 neither counsel for, related to, nor employed by any
12 of the parties to the action in which this was taken;
13 and, further, that I am not a relative or employee of
14 any counsel or attorney employed by the parties
15 hereto, nor financially or otherwise interested in the
16 outcome of this action.

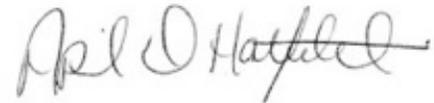


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18 Carl Hellandsjo
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20 District of Columbia
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