PUBLIC MEETING ON PATIENT-FOCUSED DRUG DEVELOPMENT FOR PSORIASIS

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Reported by: Nate Riveness,
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PROCEEDINGS

DR. EGGERS: Everyone has taken their seats so let's get started. Good morning, everyone. My name is Sara Eggers and I'm at the Center for Drug Evaluation and Research in the office of Strategic Programs. I'll be serving as the facilitator today. We have a very busy day and a very robust crowd today. This is wonderful to see. We are excited.

You have forced us to move from our typical round tables with white table cloth style of meeting to more of an auditorium style because there are so many of you here today. We also have a lot of folks on the webcast so I want to say to you welcome. We are happy that you are here.

We are experiencing sometimes some technical issues this morning so please be patient. If you have technical issues we are working at that. We know about those issues so just be patient. We might not be able to see comments if you send them into us or questions immediately. There might be a delay. So please be patient with us. I think it's because there's such a large crowd on the web today.

I'm going to go through a few logistical and housekeeping things and then we will turn it over to -- for real welcoming remarks. We have a full agenda today. First, we're going to spend some time in the morning setting the context for our discussion. Our discussion, the bulk of it, of this five-hour discussion is listening from patients.

But we have a few things we need to say first from FDA point of view on the program that we're running. The patient-focused drug development, the background on psoriasis and the therapeutic options, and then I'll come back and give an overview of the discussion format so you'll know how the day is going to look.

We have two primary topics today, one that we discuss in the morning on the disease symptoms and daily impacts that matter most to you as patients. After lunch we will have your prospectives on current approaches to treatment and a number of things to discuss there.

As I mentioned before, there is lunch. There is a kiosk. We have basic lunch and snack options for sale and we recommend highly that you pre-order your lunch in advance if you haven't already done so. After -- following discussion topic two we'll have some open public comment remarks which gives a chance for patients but also others, industry or other stakeholders who are here who want to present a comment today, and then we'll close with some closing remarks.

I also want to -- I'll say that later. Never mind. So before we get into that, a few things. The meeting will be -- it'll be on the webcast and it will be recorded and transcribed and put up on our public meeting web page.

The restrooms are located behind the kiosk so if you go out toward the kiosk, keep going towards the wall behind it and take a right and you'll find them. Sorry, it's a bit of a walk. And I'm going to look to my colleagues to see if there's anything I'm missing in terms of logistics to say. Okay, good.

So let's go through and do some introductions. We have our table of FDA colleagues up here. I'm going to ask just each of you to say your name and your role.

DR. BEITZ: Good morning. My name is Julie Beitz. I’m the director of the Office of Drug Evaluation Three.

DR. MARCUS: Good morning. I’m Kendall Marcus, the director of the Division of Dermatology and Dental Products at the Food and Drug Administration.

DR. LINDSTROM: Hello. My name is Jill Lindstrom. I’m the deputy director of the Division of Dermatology and Dental Products.

DR. KO: Good morning. I’m Hansan Ko. I’m a medical officer in the Division of Dermatology and Dental Products.

DR. LIEDTKA: Hi, I’m Jane Liedtka also a medical officer for DDDP.

DR. EPPS: Good morning. I’m Roselyn Epps. I’m a medical officer in the Division of Dermatology and Dental Products.

DR. CHOUDHRY: Good morning. I’m Yasmin Choudhry. I’m a medical officer and a reviewer from the Clinical Outcome Assessment staff.

DR. MULLIN: Hi. I'm Theresa Mullin and I direct the Office of Strategic Programs in the Center for Drugs.

DR. EGGERS: And we have a number of other colleagues here who are here to help today. I don't know if your mics are on. If you can just say your names.

MR. THOMPSON: Graham Thompson.

MS. ANGELASANI (ph): Megan Angelasani.

MS. VIDA (ph): Pagida (ph) Vida from the Office of Strategic Programs.

DR. EGGERS: And we have others. Juan Deserra (ph) and others who are floating around, so if you have any questions come to one of us up here or me and we will answer those questions. And with that, I'm going to turn it over to Kendall Marcus to give some opening remarks.

DR. MARCUS: Top of the morning to you and a warm St. Patty's day welcome to our Patient-Focused Drug Development for Psoriasis. I -- once again, I'm Dr. Kendall Marcus. I'm the director of the Division of Dermatology and Dental Products here at the FDA. Our Division reviews drugs for prevention and treatment of dermatologic and dental conditions including psoriasis.

We're happy to see so many patients and patient advocates here today in the audience and I understand that we have many more joining us via web. I want to personally thank all of you for being part of our meeting and sharing your experiences with us. We're really excited to have this opportunity to engage directly with you and to learn about the symptoms that matter most to you, as well as the impact that psoriasis has on your daily lives and what factors that you take into account when selecting a treatment.

In our discussion today we'll be focusing on various types of psoriasis, primarily focusing on skin symptoms. Dr. Jane Liedtka from our division will provide a bit more background on psoriasis and currently available therapies in a few minutes.

We understand that psoriasis is a serious condition with physical, emotional, and social impacts, and that there is an unmet medical need for patients.

It's our responsibility to ensure that the benefits of the drug outweigh its risks. And having this kind of dialogue is extremely valuable for us because hearing what patients care about can help us lead the way in figuring out how to best facilitate drug development for psoriasis and how patients understand the benefits and risks of treatments.

We'd like to hear from you today -- what we hear from you today can help us understand how to better develop end points to measure the aspects of psoriasis that are important to you. I know we also have representation here today from industry, academia, and other government partners.

While FDA plays a critical role in drug development, we are just one part of the process and it's great to see a high level of interest from those of you who also play an important role in the drug development process.

Once again, we're all here today to hear the voice of the patient and I just want to thank you again for your participation. We're grateful to each and every one of you for being here to share your personal stories, experiences, and perspectives. We look forward to incorporating what we learn today into the agency’s thinking and understanding of how patients view benefits and risks of psoriasis treatments.

I’ll now turn the podium over to Theresa Mullin who’s -- who will be providing background on the FDA’s Patient-Focused Drug Development efforts.

MS. MULLIN: Thank you and good morning. So as Dr. Marcus was saying, our -- one of our major jobs is to assess whether the benefits outweigh the risks and when we evaluate new drugs, and so this initiative, and I’m telling you about the Patient-Focused Drug Development initiative because this meeting is -- has been set up as one of the set that we are doing under this initiative that’s part of the reauthorization of -- the 2012 reauthorization of the Prescription Drug User Fee Act. And we realized in our assessment of benefits risk that, you know, the patient’s voice is quite critical.

The patient is the one who’s going to

experience the benefits and the risks that there are -- associated with the drug and we didn't have a good systematic way established for getting that kind of input we have.

Patient representative programs where we involve maybe an individual patient representing that community and that's a very valuable role and a very valuable voice to have but we -- we realized we weren't getting the broader input from the community experiencing the disease and that we really would benefit from that.

And so this initiative is to sort of pilot test this approach so that we're able to get a more comprehensive input on the patient's experience with the condition and then how -- how well the available treatments are working.

It helps us not only in assessment of a new drug application but even in thinking and giving us insights across the development program process throughout the development phase of the drug, and even in the post-market phase trying to continue to assess benefit versus risk.

And so the Patient-Focused Drug Development was an initiative set up under the fifth authorization of the Prescription Drug User Fee Act. We committed in 2012 to conduct at least 20 such meetings in different disease areas and this would -- and see what we could learn from this trying to get a more systematic input from patients in different disease areas.

So in 2012, we put out an announcement and we put forth a set of possible diseases and asked for public comment. We got over 4,500 comments on that list and we evaluated the comments that we received, came up with an initial set of diseases for the first three years and then last year we went through a process to identify the final set and we’re -- we’ve identified 24 diseases that we’re covering through this initiative over the five-year authorization.

And here you see the diseases that we have held meetings around to date. Today’s meeting on psoriasis and we have another one scheduled so far on June 10 for neuropathic pain associated with peripheral neuropathy, and as you can see we have others that we’ll be scheduling beyond that in the future. And this is just the initial set, as we said.

We have other spinoff efforts that as we learn and hear and try to figure out how to build on our learnings from the Patient-Focused initiative. From the meeting today, and the input that you provide us in the room, and from what we hear in the webcast from participants and comments we receive from the webcast, and from what we get submitted to the docket.

We have an electronic docket set up that’ll be open for some time after this meeting to allow you or people on the -- who are joining us by webcast or others, to send in additional information, thoughts, other information you think would be useful for us to incorporate or have related to psoriasis. And we’ll take that information and analyze it, and produce a report.

We call these reports the Voice of the Patient report. These are available on our website, the one’s that we’ve produced so far on those meetings that I showed you the list for earlier. And we try to summarize what hear -- we hear from the patients in this meeting and from the docket and so on, and the unique views we may hear beyond that from the webcast. We find that these reports -- and we try to make these reports very accurately describe what you tell us in the words that the patients and the community and caregivers are using to describe your experience and reflect that in the report.

And we find that these reports are providing not only a useful reference for our reviewers, but sponsors are able to use them to see if they're development program is being responsive to the kinds of things that are being described in these meetings and we've also been told by patients that they find this a very valuable resource for -- and just seeing what others experience has been with their disease.

And we think the long-term impact of this program is going to be -- we're going to continue to evolve other methodology that we can use to try to go even further to incorporate the patient's perspective in a kind of rigorous way so that we're able to have that be available to us, have the resulting data that's collected from that be available as additional evidence that can be used in regulatory decision making. That's our ultimate goal.

So with that, I'm going to turn it over to Dr. Liedtka who is going to talk about overview of psoriasis and available treatments. Thanks.

DR. LIEDTKA: Good morning. My name is Jane Liedtka and I'm a dermatologist and a medical officer for the FDA and today I'm going to give you a brief overview of psoriasis.

We're going to start by talking about the epidemiology and a little bit about the clinical presentation. Then we're going to discuss options for treatment and finally get into a brief discussion of the impact of psoriasis on patients who have this condition.

Psoriasis is a chronic common inflammatory multisystem disease that predominantly affects the skin and the joints. It affects about two to three percent of the U.S. population. Here is a typical presentation of plaque psoriasis.

This gentleman has fairly extensive red, scaly plaques. These can be itchy or sore. Joint involvement occurs in addition, in about a third of patients with psoriatic arthritis. This is a typical plaque on the knee. You can see the thick, scaly what we call micaceous or silvery scale.

And here’s a gentleman with more extensive disease with plaques distributed over his trunk. I want to thank the National Psoriasis Foundation for loaning me these clinical slides.

When it comes to treatment options, most of the time we start with topical corticosteroids. These have been around for a long time. They vary in their strength and the choice of product is determined by the location that it’s going to be applied. We tend to use the milder topical steroids on the face or the fold areas where the skin is thin and more delicate because of concerns about long-term side effects of skin thinning or atrophy.

In addition to topical corticosteroids we have topical retinoids and then there are also vitamin D analogs. There are products that combine these different components as well. When topical products are not enough or when there’s a contraindication to their use, phototherapy is another option.

Phototherapy can either be UVB, which can be delivered as narrow band or broad band or PUVA. PUVA is a combination of oral psoralen that's taken and then UVA light is delivered. PUVA's not used as commonly anymore for psoriasis because of concerns about toxicity. Both the acute toxicity in the short-term to the skin and the eye and also the longer term risks of increased skin malignancies, including melanoma.

When psoriasis is more extensive or fails to respond to these other treatments, systemic agents are often used. These can be divided into the traditional agents and the biologics. The traditional agents include methotrexate, which is a folic acid inhibitor, and that's been around for a long time. We've been using methotrexate for over 40 years. Acitretin which is a retinoid was approved in 1996. Cyclosporine, a T-cell inhibitor, which is more commonly known as a treatment for patients who've transplants, was approved in 1997.

And then finally in 2014, we approved

Apremilast, a PDE-4 inhibitor. The biologics have been a major change and a major improvement in the possible treatment for more severe psoriasis. The first biologic approved was Etanercept which is a tumor necrosis factor alpha inhibitor which was approved in 2004. This was followed shortly by Infliximab in 2006, another TNF inhibitor. And then Adalimumab in 2008, another TNF inhibitor.

In 2009, a new class of biologics came on to the market with Ustekinumab which is an IL-12, IL-23 inhibitor. And then finally, just last year, we approved Secukinumab, an IL-17 inhibitor, in 2015. Despite the advances made with the addition of biologics to our treatment armamentarium there's still a large impact of psoriasis on the quality of life for patients who have this condition.

There are social, psychological, and economic impacts. The impacts for patients with severe psoriasis is comparable to that observed in other chronic conditions such as diabetes and depression. The National Psoriasis Foundation conducted a survey between 2003 and 2011. There were

811 respondents. This survey was published in JAMA in 2013.

More than sixty percent of patients who responded to the survey noted that the psoriasis impacted their self-esteem and their emotional well-being. More than two-thirds admitted to avoiding social activities including dating and intimacy because of their psoriasis. And over half of patients stated that they are untreated or undertreated, the two main reasons being fear of side effects and cost or perceived cost of therapy.

We at the FDA are aware of the unmet medical needs experienced by patients who have psoriasis. We're conducting this public meeting to hear comments about the impact from patients, caregivers, and family members. We thank you for taking the time and making the trip to share your comments with us today.

MS. CHOUDHRY: So in my presentation today, I will briefly tell you how we utilize the information from these Patient-Focused Drug Development meetings and how we aim to incorporate patient input into clinical study endpoints.

So before I start the presentation, I would like to give you a quick introduction to my team, the Clinical Outcome Assessment staff. So we are basically consultants to the Review Divisions and we provide advice to the Review Divisions regarding clinical outcome assessments which include physician questionnaires and most importantly, patient questionnaires as well.

So we review these questionnaires to ensure that they are measuring the symptoms and impacts that are most important to patients and that these questionnaires are also measuring these concepts in an accurate and reliable manner. So the views expressed here in this presentation are mine and they do not reflect the agency's so you may be wondering -- it's not moving up. Yes. Okay. Thank you.

This one, okay. All right. Thank you. So you may be wondering how is the information from these Patient-Focused Drug Development meetings used by us and we have these meetings but where do we go from here. And how do we take this valuable information and generate clinically relevant patient-focused endpoints to place in clinical studies. So I hope in the next few slides I will be able to answer some of these questions.

So one of the main advantages in having these meetings is that it gives all stakeholders an opportunity to listen to the patient's voice. So we at FDA find that it very useful to hear the patient's experience but to clearly to hear what is important from the patient's perspectives and how they describe their symptoms and impacts in their own words.

We also hope that the drug sponsors are getting some ideas to incorporate into their questionnaires. The information from these meetings also helps us inform how we at FDA review patient questionnaires and drug applications.

Now while these meetings provide initial patient input, we also strongly recommend that the drug sponsors engage with additional patients in focus groups or one-on-one patient interviews. This is also referred to as qualitative research.

The goal of the qualitative research is to confirm that the questionnaires include important and relevant information and to ensure that the questionnaires are clear and understandable to patients.

Now another advantage of these meetings is that it helps us to think about clinical study endpoints. So what is an endpoint? Let me give you an example of an endpoint. In the case, for example -- in the case of a patient questionnaire the study endpoint would be how the patient's -- the questionnaire's score is going to be measured and analyzed in the clinical study.

Now, you may know that the question -- the questionnaires have several questions -- or may have several questions and items, each one of those is scored -- is given a score. So at the end the questionnaire's score is measured in the clinical trials and analyzed.

So, for example, if patients are reporting that the most important treatment benefit to them is symptom improvement, then the study endpoint could possibly be change in the questionnaire's score during the clinical study. Now, which would measure the amount of symptom improvement. So one key consideration here is that there are many, many things that may be important to patients that are discussed during these meetings and/or patient interviews. However, you need to keep in mind that not all of these things lend themselves to being measured in clinical studies for drug approval as they may not be impacted directly by the treatment itself and making it difficult to interpret the results at the end.

Now here at the FDA we focus on efficacy and safety mainly. So, for example, financial well-being may be an important concept to patients but maybe minimally or may not at all be impacted by treatment in a clinical study setting. So we encourage drug sponsors to consider selecting those concepts which are very important to the patients, as well as that -- those can be measured in the perspective of the treatment effect as their key study endpoints.

Now other important concepts may be measured, they can be measured which are unrelated to treatment but they can be used for exploratory purposes, not as key endpoints. So at the FDA, as you know, we have to uphold laws and regulations. Now within these regulations there are regulatory standards for assessments, which require that the methods of assessments should be well defined and reliable. And we do not want to include statements in the product labeling at the end that may be false or misleading. So we also recommend that the sponsors conduct the appropriate quantitative research or statistical testing to show that the questionnaire is well-defined and reliable.

Now additionally, this research can provide an estimate of what a meaningful change or improvement is on the questionnaire for which we believe patient involvement is extremely important. So we have two pathways to provide advice to those who are interested in using patient questionnaires are other clinical outcome assessments and clinical trials.

One is within an individual drug development program like through the investigational new drug applications and the other one is through our drug development requalification program and through this program when we review an instrument or a questionnaire and we qualify the instrument, or the questionnaire, that questionnaire is available -- can be available for broader use in multiple drug development programs. And we -- under this program actually, we work with many stakeholders including consortia, patient groups, individual academic researchers, and drug developers and -- to address unmet public health needs.

So the key takeaways from this presentation would be that these meetings, the Patient-Focused Drug Development meetings, are the starting point for developing and using patient-focused outcome measures and endpoints. The outcomes of these meetings will support and guide FDA's assessment and clinical benefit in drug reviews. And patient's input ultimately helps determine what is measured to provide evidence of treatment benefit, how best to measure, and what matters most to patients, and what amount of change is meaningful to patients. Thank you.

DR. EGGERS: Thank you very much, Yasmin. So you've gotten now a background on why we're here, on the basic -- just make sure -- you're on the same about psoriasis and its treatments and also you just heard from Yasmin and Theresa about how this input really helps both the benefit risk assessments that guide the regulatory decision-making, as well as very specific things such as how the input we hear will help to inform the work that we and others do on translating these -- what matters most to you into things that can help measure or understand benefit of a treatment.

With that now we're ready to move into the real star of the show which is to hear from you, the patients and patient representatives in the audience. I'm just going to give a bit of background on what we will be doing today.

This is, as Theresa mentioned, is our 18th meeting and they all run a very similar format to this. Never quite with this size of group so you've put us to the challenge. We are excited about that challenge. We'll just see how the day goes with this. Okay.

As I mentioned there were two topics and we're going to try our best to keep those topics really on topic as much as we can throughout the morning and the afternoon. And Topic One is really on the symptoms that matter most to you, what's life like, which symptoms have the most impact, how do they affect your ability to do specific activities, how do they change from the best days to the worst days, and how do they change over time.

And what we hear here today really we're looking for the specific things that kind of go beyond that general background that we provided this morning to say, how really does itching affect you daily? How really does the amount of skin coverage affect you daily and in what ways? So we'll be getting into the details with that.

And in the afternoon we'll go and look at the approaches to treatment, how -- what are you doing to treat your psoriasis from the treatments that were mentioned today but there are other things that you are doing we know. And how well are those treatments -- treating those symptoms that you told us were more significant to you. What are the biggest downsides of those treatments? What would you look for in an ideal treatment both in terms of what symptoms they would better address and what downsides you would love to do away with.

And then another really important discussion today is what factors you consider with your healthcare provider when selecting a course of treatment. How this will work for each of those topics is that we're first going to call up a panel of patients, and I'm going to ask now that our panel one, Topic One panel discussants to make their way to the front here.

We have five patients today who have submitted comments in advance and we thought would be representative across the experiences to really set a foundation for a facilitated discussion that we will get into. They're -- they reflect the range of experiences with psoriasis and what we'll do after we hear these five comments is move into a facilitative discussion involving you in the audience and you on the web to really build on what we've heard in the comments this morning.

I have to take a moment to say that you as a collective group, those of you who sent in your comments, they were amazing and you made our job very difficult. I want to put a shout out. Even if you weren't identified as a panelist, it's so important that we get those comments in advance because it really helps us tailor our -- what we talk about today. You've given us a really good sense of what we might be talking about. So if you've sent in comments, thank you, and I think you can submit those -- I think National Psoriasis Foundation has offered if you send your comments that you sent to us to them, they will submit those to the public docket for you and they will be included in our record.

Okay. So in the facilitative discussion we have a lot of people and we know you all want to speak. We're going to ask that you raise your hand if you want to respond to one of the questions. I'll be posing questions, my colleagues up here will be posing questions. We're going to be building on what we hear from the panel. So if you raise your hand, we'll come to you with microphones. We've got three mic runners out there. They'll come to you. Please state your first name before answering and please try to stay on whatever topic that we're on as best as you can. We know you won't be able to say everything you want to say, that's why we have the docket. I'll get to that in a second.

We also will utilize polling questions today. We find that this is also very important because it gives us -- it gives everyone a chance to comment and provide input through those polling questions. It's not a scientific survey. Please do not treat it as such. It's really to aid our discussion.

We have clickers that we'll be handing out now and it's -- we'll practice on a few easy questions to get started. But you'll just -- when the polling question comes up, you'll just select the answer choice that best matches your experience or your perspective. We're going to ask in this meeting since we have so many patients that we keep the clicker responses and the polling question responses to patients or the parent of a patient if you're here for a child or a teenager and speaking on their behalf, or if you’re here on someone else’s behalf.

The web participants, you are very important and I hear that we have fixed the technical issues so we should be able to collect your comments in real time better now. Again, still if you have technical issues please write to us and we will try to address those as best we can. You will also on the web have a chance to answer the polling questions and you’ll have a chance to type in your responses.

Please feel free, if you hear something -- what the most significant symptoms are, for example, type in your responses. We will be -- one, we collect all that information. It will be part of our input that goes into our report, but we’ll also try to report back.

We also will occasionally go to the phones once or twice for each session to give you another opportunity to contribute but I will say, with so many people on the web, you know, we won’t be able to go to too many people on the phone but it is important. We will try to get to a few of you. You can send us your comments through the public docket. We know many of you already have and we thank you.

You can continue to do so until May 17th, even if you've already submitted a comment so far. We'll take multiples. We don't care. We read through all of them. This is your chance to share your experience more fully than maybe you had a chance to today as part of the discussion or there may be things that we can't delve into in depth. You can expand upon those thoughts in the docket comment.

If you're on the web, same thing. You can do the docket. Or if you know that there are folks that you think should be contributing their voice and they weren't here in the meeting today or on the web, please encourage them to do so.

I think National Psoriasis Foundation has made it easy to do that through their website. They can correct me at the break if I'm wrong about that. It's -- you can go to this website that's here on the screen and there's just a comment now button. If you have any trouble doing so, we have a website patient focus at fda.hss.gov.

We also have other resources. Besides our office of Strategic Programs, which is coordinating the meeting today, we rely heavily on our colleagues in the FDA’s office of Health and Constituent Affairs. They can answer questions. They help organize the patient representative programs. If you have questions about that, please reach out to them.

And in the Center for Drugs and Evaluation and Research we have a professional affairs [inaudible] engagement group and Christopher Melton, if -- are you here in the audience. Yes. Okay. So he’s your guy. You can go to him if you have any questions as well as any of us. And they really facilitate broader communication and collaboration between FDA Cedar and the -- and patient and healthcare professional stakeholders.

Okay. There are a few ground rules that we want to make sure that we go over because this dialogue is very important and we want to make sure that we have it as effective, efficient, and respectful as possible.

We encourage patients, all of you to contribute to the dialogue. Caregivers and advocates are welcome too, but our primary focus -- oh, caregivers, if you're speaking for a pediatric -- a child or a teenager, please speak up. We really hope to hear from you. Our colleagues here at FDA are primarily here to listen. They won't be able to answer perhaps all the questions that you may have in your mind today. Send us a note afterwards or come find us and we can direct you to the right folks if you do have a question. But they will be here to help.

Ask the more detailed questions as you see fit. Our discussion is really trying to focus on the symptoms and the treatments. We know there's a lot that is important to you regarding your overall life with psoriasis including healthcare, access issues, et cetera. We can't delve into all of those today.

We're really focusing on the things that are within FDA's jurisdiction and what we can really think about and do something about. So we won't be able to focus those comments, but please use the docket to express your thoughts on those as well, and we do read them and they will be incorporated somehow. We also -

- when we talk about treatments, we're not here necessarily to talk about specific -- extol benefits of specific treatment or the downsides of other treatments.

What we're really looking is that higher -- that more common ground about treatments in general, what they're generally working well, addressing, and what they're general downsides are. We must remember that the views today are personal opinions. Respect for one another is paramount and we -- that's really preaching to the choir, you know that.

One thing I'll mention, the open public comment period is available if you want to comment on other topics. The -- we had a very strong showing for the open public comment and we have -- I believe it's full as of this point, so you were able -- folks were able to register to present an open comment at that time. It is full.

We won't be able to take any more open public comments but, again, the docket serves the same purpose, so please send us your comments that way. And also let us know how the meeting went today. How

-- and even before the meeting. What kind of preparatory materials you got in advance and how well -- helpful that was for you. There will be evaluations forms at the registration table.

Okay. So with that, we're going to start with a few polling questions, so if you have a clicker -- does anyone need one? If you could raise your hand if you're a patient or a parent or other caregiver. Everyone has them? Great. Great.

Okay. So we're going to start out with hopefully an easy one. Where do you live? And you'll click A on your clicker. Go ahead and get your glasses out, if you don't have them. But click A on your clicker if you live within the Washington DC metro area and B if you came from outside of the area today.

Okay. So most of you came from outside. We think -- well, we think anyone who travels the Belt Way on a daily basis. That's -- it's a feat to get here. But particular the folks that have traveled here today, you are demonstrating that this is meaningful to you and we appreciate that. Have you ever been diagnosed as having psoriasis? A for yes, B for no.

Okay. So, yes. We ask patients to -- we knew this but I'm -- it gives us a sense of how many folks are responding to this, so. That was a real easy question. Okay. Have you ever been diagnosed with psoriatic arthritis? A for yes or B for no. And why don't we give it just a little bit more time because we have so many folks.

Okay. All right. So over half of you here today are psoriatic arthritis. Okay. And on the web, do we have --

DR.CHALASANI: We have very similar. We have 61 percent on the web of -- we have 160 people on the web so 60 percent of them also been diagnosed with that.

DR. EGGERS: Great. Thank you, web folks, for attending. Our discussion today as was mentioned will be focusing primarily on the dermal aspects. We do have a question that will help you give us a sense of how they relate in terms of importance for you at the end, but we will be focusing primarily on the skin symptoms. But this is very helpful to know how many of you here have psoriatic arthritis.

Okay. Your age, please. A younger than 18, B 18 to 29, C 30 to 39, D if you're 40 to 49, E 50 to 59, F if you're 60 or better. Okay. We have a more than -- okay so we have a surprising spike at 50 to 59. Okay. Well that's -- I don't know what we make of that but.

All right. Let me see the pediatrics. Okay. We have only a few pediatric patients. We'll be coming to you directly and calling on you to speak some throughout the day. On the web, do we have -- particularly the pediatric the --

MS. ANGELASANI: We actually don't have any pediatric patients or participants on the web as of now but otherwise we have it pretty evenly distributed.

DR. EGGERS: Okay. Great. The review division identified pediatric as being something that they would like to hear perspectives on, both in terms of symptoms that matter most and treatments that -- treatment experiences so if you know folks out there who are the parents of or who are kids and teens that have psoriasis, please encourage them to submit their comments to the docket. Do you identify as A male or B female? Okay. We have more females here, about two-thirds, but a nice mix.

What is the length of time since your psoriasis diagnosis? A if it was less than five years ago, B if it was five to ten years ago, C tent to 20 years ago, D more than 20 years ago, or if you're not sure, put E. Okay. So a lot of you have been living with this for a long time. All right. The majority of you have -- most of you here have said more than 20 years ago. It might be correlated a bit with the age distribution here. So we will want to hear equally from the folk -- from those of you in the room who were diagnosed more recently, the less than five years ago. We might come to you with specific questions.

Okay. So now they get a little more complicated questions. What type of psoriasis do you have and you can check all that apply. Plaque push A, gut ache push B, C inverse, D pustular, E erythrodermic, F other, and G if you're not sure.

Again, all that apply. Okay. Okay. So the majority of you have plaque, in addition to other aspects likely and then a range beyond that. Okay. And on the web?

MS. ANGELASANI: We have 90 percent with plaque and the other ones are evenly distributed, 30 percent inverse, 30 percent pustular.

DR. EGGERS: And then can you go back to the question on length of time since diagnosis?

MS. ANGELASANI: Sure. It was actually very similar to what we had seen in the room.

DR. EGGERS: Great. Thanks.

MS. ANGELASANI: Majority were more than 20 years ago.

DR. EGGERS: Okay. Where is your psoriasis located. Check all that apply again. A scalp, B face, C hands or feet, D nails, E trunk, arms or legs, F skin folds, G genital area, H other skin areas that were not mentioned. Okay. There -- it's -- we can talk about a lot of things today. So we will try to address all of these aspects and all of these locations, but we might have to pick and choose a little bit so thank you. And on the web?

MS. ANGELASANI: Very similar actually. Seventy-eight percent indicated trunk, arms, and legs, and then the second most was scalp and nails.

DR. EGGERS: Okay. Very similar. Great. I think that is the last polling question. We will be revisiting the pulling questions for each of the discussion topics so keep those clickers handy. We just ask, you know, please don't take them home as a souvenir is all. You know, some people want to I guess. We don't know how they disappear but they do sometimes. So let's get into the Topic 1 discussion.

Again, we want to thank you Diane, Ellen, Marie, John, and Christina for joining us today. We have asked them to prepare some comments. They're going to go through and just read them. If you have any -- to my FDA colleagues, if you have any clarifying questions after each, just let me know and we can do that. Just click your red button before you start speaking and if I need to, I'll bring the mic up to you closer. So we'll start with Diane. Thank you very much.

MS. TALBERT: Good morning, everybody. First, I want to thank the FDA for allowing me to speak today. This is such a honor that I will always remember. I remember a time in my life when I didn't even want to say the word psoriasis but look at me now.

My name is Diane Talbert and being a woman of color I've had many challenges with psoriasis for the past 53 years. I would like to tell you some of how being African American and having psoriasis has affected my life.

I was diagnosed with psoriasis at the age of 5 and quarantined when I tried to attend public school in 1963. I didn't know what this meant or understood what was going on at the time but I knew I was different.

What's been especially challenging in my lifelong struggle with psoriasis has been the general lack of information, as well as the medical community lacking the knowledge when it comes to psoriasis of people of color. When I was a teenager I used to go the library to justify the picture of someone who looked like me. I spent countless hours just looking for one photo.

After months and months of searching, I found nothing. I believe I was alone in this world and there was no one like me with psoriasis. I did find some photos of Caucasian people with psoriasis but theirs didn’t look like mine. My psoriasis was very dark and very thick.

Caucasians had red or pink patches of thickened skin that was covered with white as scales just like the articles that described what psoriasis looked like. This was not me.

As a child, this was extremely confusing because I didn’t have that. So for the next 40 years of my life I went on a journey to find out what I had and how to get rid of it. One of the things that has changed for me over my life is not being able to run, walk fast, or jump rope because I have to take drugs for pain.

There was a point in my life when my husband had to help me do everything from walking to taking a bath, going to bathroom, cleaning the house, and cooking. I had to take a brief period off from work because of pain.

I had a doctor who wanted to put me on full disability at the age of 40 because of my psoriasis but I refused to take that route. I knew I wanted to help others, as well as help myself and for people to know they were not alone in this journey.

The one thing that bothers me the most for having psoriasis is the intense itching and the pain that will cause me so much discomfort. I have a hard time sleeping, walking, shopping, bathing, and working. There have been numerous jobs that I have applied for but the minute people would see my psoriasis they would shy away.

There were certain jobs that I could go to but going to the doctor two or three times a week I couldn't take those jobs. When I did find a job that I liked back in the day, I would wear two or three pantyhose to cover up my psoriasis or I would wear a long-sleeved shirt, undershirt, tie a rubber band around the wrist because so many flakes would fall out.

I would try not to drink anything during the day because if I went to the restroom flakes would be everywhere and I'd have to be on my hands and knees to clean the flakes up. I just -- I would feel very self-conscious about my appearance and never wanted to go out in public.

My life did change about the age of 46. Before that I had to hold onto something to walk. I would scratch holes in my skin. I would cry in my sleep because of pain. Years ago someone told me, well, you know you're different, Diane. You need to see a doctor like you. They were talking about a black doctor. So I did that. I found a black doctor. But unfortunately I still didn't get the results that I wanted.

I still 70 to 80 percent covered in psoriasis with no relief in sight. So I went searching again for a doctor. I did find a good doctor. He is Caucasian and has been my dermatologist for over 15 years now.

What I did learn from this experience that when it comes to finding a good doctor, color has nothing to do with it. One of the things that worries me the most about having psoriasis is that one day it will come back with a vengeance and never go away or my treatment will just stop working.

I'm thinking by the time I'm 80 if they don't find a cure and I get sick, who's going to take care of me. I just wanted to say if there was ever a time to have psoriasis, it would be now. There are so many great treatment options out here. Again, I want to thank the FDA for conducting this meeting and making me a part of it. Thank you.

DR. EGGERS: Thank you very much, Diane. Great. Now we'll go to Ellen.

ELLEN: Good morning and thank you for allowing me to tell my story. I'm going to take a slightly different path with my story because the impact on my life has been somewhat different. I want to go through how it changed over time first so that rest will be relevant.

As a child, I had moderate skin disease. No one was, back then, able to diagnose what it was except that I had patches of itchy, raised skin and that it was prevalent throughout my body. But then when I became a teenager and hormones kicked in, for whatever reason it seemed to go into remission. I didn't have any impact externally from psoriasis until I reached adulthood.

And then as a young adult it started coming out more in inverse areas, in the navel, in folds of my body, etcetera, but it wasn't that impactful on my social life at that time, thankfully because I became newly married, had children, so it was a good time for me then.

But as an adult I went through a very stressful period for about three months where all of a sudden my body exploded. My scalp was covered and -- with thick plaque to the point where if I combed my hair it would come off in sheets and pus would ooze out of my scalp.

I had it in saucer-size patches of plaque over my legs and my arms, throughout my torso. Again, the back of my neck, behind my ears, but the inverse psoriasis was the worst because it not only impacted the folds of my body but it impacted up inside my anus, throughout my genitals, and that was a very difficult time.

I am controlled today and fairly clear, I'd say about 80 percent clear, so I'm thankful for that. But what I want to talk about is and focus on are the symptoms and the impact it's had on my life. The first one is the constant mind-blowing itch and I say mind-blowing because it never goes away.

Whether there's external plaque or not, the itch prevails. And what it does is when I'm presenting, if I have a task at hand it will sometimes take the focus off of what I'm doing because I start thinking about the itch and my need to scratch it. Inverse psoriasis.

I don't know how many people have it but that has played a major role in the impact on my life. When I flared in my mid adulthood it was so bad that my husband was afraid to touch me. It hurt if I had intercourse and it hurt him in other ways seeing me that way. So it had a major impact on the intimacy and my life and my marriage.

Thankfully I'm married to a guy who just loves me for what I am. But that was -- that's the major one. And in the folds of the body it tends to crack and bleed, and the problem there is that the skin is so -- is thinner and when it cracks it doesn't heal really well and it hurts. It hurts to sit. It hurts to move. So that's a difficult aspect of it. The flaking. The constant flaking like Diane mentioned.

Similar to Diane, we spent a lot of time vacuuming around my house and vacuuming my car out. The embarrassment in my office, knowing that the cleaning people were coming in and were going to find this snow on the floor of my office that they were going to be cleaning up and wondering, what does this woman have. So -- I am in a blue -- white collar world in the blue suit, navy blue suit, black suit. I give presentations to Fortune 1000 companies all the time. I'm in board rooms with CEO's, CFO's, chairmen, and the embarrassment of walking into the room with flakes all over the back of my -- on my shoulders and my back and then having them see the scales on my forehead and on my ears would draw attention away from what I was saying to them that was -- I thought more important.

And my employer, not my current employer, but my past employer, when I was flared the most, would ask me to please try to deliver from the furthest end of the boardroom so they couldn't see it. And a couple of times it went so far as to not invite me into the room and give my presentation to somebody else to give it. It had a major impact.

I was anxious all the time, became depressed, and threw me into counseling so that I could get through life in general, especially with my career. Many social aspects, besides not being able to do many sports, exercise, etcetera, because of the cracking and bleeding, people don't understand it. Even today with all the televised psoriasis advertisements, they still feel like there's something you have that they're going to catch. So to go into a pool or a hot tub, people get out right away and they take their children out. That's very embarrassing.

As a child I wouldn't be asked to play with a group because moms didn't want their children to play with me because they might catch it. That has been prevalent -- and it continues today. Just a month ago I got into a hot tub and some people got out. So why am I doing this? I put myself out there with intimacy issues, et cetera? My grandchildren. I now have grandchildren who are living with the disease same as I did.

I have two boys, two grandsons who were diagnosed very early and they're now 19 and 21 but they played sports. And they were set back from their peers all the time or left out of some of the more social aspects of being on the team. I have a granddaughter who was diagnosed at age two. She's now eight and she's a major speaker at our walks in Boston. She gets out there and talks about it and she's not embarrassed by it. She's got it all over her body but she is out there to tell you, I don't like the itch, I want it to go away, and I want you to find a cure.

So it's very upsetting to know that I'm not able to help them. And I hear them come in the house and they cry when they're excluded from something.

And I don’t want them to have to go through what I went through.

What worries me most about having psoriasis, I also have psoriatic arthritis, is the potential for the severe adverse side effects of a treatment and the comorbidities that exist in the psoriasis population. Heart disease. Cancer is a possibility. Death remote happens. So that’s what scares me. And thank you for having me today.

DR. EGGERS: Thank you very much, Ellen. Thank you. And now we have Marie.

MS. GRIFFITHS: Thank you for having me today. My name is Marie Griffiths. I’m 27 years old. I was first diagnosed with guttate psoriasis when I was 15, although my mom thinks I may have had minor symptoms early in life that no one seemed to put together.

I will say it’s hard enough having a very visible disease that you wear every day but it was a very difficult transition for me navigating a new psoriasis diagnosis and adolescence at the same time. One of the hardest parts of being a pediatric patient was knowing how to advocate for myself.

My strongest physical symptoms at the time I was diagnosed were redness and the itchiness. I looked like I was covered in red polka dots everywhere, absolutely everywhere. And I had trouble explaining to the dermatologist that I saw that the itch was stronger than my self-control not to scratch it so then I ended up with complications like bleeding skin and open sores.

My dermatologists were focused on the symptoms like what it looked like and trying to help me look that way. And at the time they seemed fairly minor. In retrospect, those were some of my worst days in terms of both physical and emotional pain from psoriasis.

The emotional symptoms were worse. High school is not really the best time to add in a layer of lacking self-confidence. On top of everything else, I was embarrassed about how my skin looked. It was all over my arms, my legs, my scalp, and it felt like everyone was staring at me, and some of them were. I had a girl in my class ask me how I managed to get scabies. So it's hard to forget that.

But then and now I can say that on my best days I pretend I don't even have psoriasis. I forget it's there. And on my worst days I spend my day trying to forget I have psoriasis because it's always there. At only one point in the past ten to twelve years I've had clear skin. All but the most very stubborn of last patches it were gone and it was great. But then my symptoms flared back the second I started scaling back on the treatment, which you have to do for certain treatments. You can't keep them up at that rate.

And there were a few weeks where I felt normal and I looked normal and it's hard for me to remember that now it's been so long. Due to a recent pregnancy I was completely off treatment for several months and I was very surprised that my psoriasis didn't immediately get worse. I'm very glad that I managed well the whole time I was pregnant because that would've been just another heap on top of it all.

But now that I've had my baby it's coming back. The soreness of my skin, the redness, the flaking has gotten out of control. It’s a running joke with my husband and family that I leave a piece of me wherever I go, except it’s not a joke. Right? So it’s embarrassing to get up from a chair when I’m at a meeting at work and realize there’s this pile of skin flakes next to me that I didn’t even realize. I was absent mindedly rubbing on my elbow and there you go. It’s all over the floor at work.

My Swiffer is my best friend at home because I have hardwood floors and I’m sick of seeing myself all over them. It’s too dangerous to wear black shirts because my scalp peels without me even realizing it. Most days I creatively drape my hair across my forehead and bobby pin it in place to hide parts of my forehead.

It can be a self-defeating cycle because the thicker the scales get on my skin, the more they itch, and the more they itch, the more I am likely to scratch them, and the more I scratch them, the more they start to crack, and then more come back and it keeps going and going and going.

I teach elementary school and I’ve chosen the pat response. It’s just a skin thing I have to answer all of the questions that my students ask me but that doesn’t actually stop them from asking more questions about it. Sorry. Oh, no, no, Page Two. My hands are shaking. Sorry.

I’ve noticed triggers to my psoriasis symptoms. Some of them are in my control and some of them are not in my control. The weather changes wreak havoc, especially when it gets colder and dryer, and all of a sudden everything aches everywhere.

If I get sunburned and with freckles and a red-haired mother, I do that frequently on accident. Everything aches that much more and it takes that much longer for my skin to heal from the sunburn just to going back to what it looked like before the sunburn, which wasn’t that great to begin with.

I like to exercise for fun, mostly jogging and like Zumba classes where I wear very long pants but sweat is a trigger because every time I get sweat on my skin starts itching more. And when it starts itching more the cycle continues. I start scratching and it becomes very red.

I see a difference in the redness of my skin if I drink more than one beer. But with an infant at home it's not like I have time to drink more than one beer anyway. But that is a trigger. At this point in my life my biggest issues are the constant itching and the ugly patches of the dry, flaking skin. I've given up all hope of having normal-looking elbows in this life.

I feel like I cope better with the emotional symptoms now like I used to not want to wear short sleeves. I've spent so much time dealing with them that now it's just a little bit easier to get through the day. I've decided that my comfort is way more important than what the world may look at me and see.

But my biggest symptom right now is not for me. It's a fear that my daughter is going to go through the same disease and struggle the same way I have and I guess that fear is just another emotional part of psoriasis I now have to deal with. Thank you.

DR. EGGERS: Thank you very much, Marie. And John, please.

MR. LATELLA: Good morning. I'd first like to thank the FDA Division of Dermatology and Dental Products for letting me exercise my voice as a patient and sometimes as an inpatient patient. I'm John Latella. I'm a 74-year-old United States Navy veteran.

I was diagnosed with psoriasis in 1964 while I was on active duty and psoriatic arthritis in 1976 when I was a civilian. The symptoms of psoriasis that have been most significant impact in my life are the scaling, the bleeding, and the burning sensations from this disease.

Well, let me explain about scaling first. Recently I made a calculation about exfoliating of my scale. I multiplied the number of days in 41 years, added a few for leap year, times one-quarter of an ounce which is kind of a mean average that I used. A scale lost daily and divided it by 16 ounces. That's the number of ounces in a pound. And I obtained a total of 230 pounds of scale lost over the last 41 years. I've got scale from Poland to Hawaii.

I sometime mimic the Pig Pen in a Charlie Brown commercial as I walked across the room. Before

I began the biologic treatment in nine -- 11 years ago. If I may I'd like to put it a perspective. For many years 80 percent of the surface area of my body was involved with psoriasis, plaque psoriasis, and scaling. The impact was great as for most of my work life I traveled and would wake up with a pile of scales on the bed.

Now, I had one of two options. Clean them up or let the maid do it. Well, I chose the latter. In the beginning I would simply scrape the scales from the bed into the trashcan, however, as time went by I had to purchase a small electric vacuum cleaner and I don't mean a dust buster. I mean the one you plug into the wall. I had to carry it with me and I would clean the bed and I'd clean the floor because I was too embarrassed to leave myself behind.

At home we had to vacuum daily and we resorted to purchasing a robotic vacuum cleaner so that we could both get ready for work faster while it was vacuuming. Another concern with scaling was the situation when we were working on retreats. Even if I wore vinyl gloves I was not allowed to work in the kitchen and was relegated to washing pots in hot water, which did more harm than good to my already involved skin.

I didn’t get to achieve sainthood either. In 1933 or 19 -- yeah, 19 -- whoa. In 1993, I was in the hospital for the treatment of erythrodermic psoriasis and I was using a PIC line to take antibiotics every four lines -- four hours. The PIC line accidentally dislodged and it had to be reinserted. So the first nurse came in and she attempted to reinsert the needle and all I heard was, oh, no. The needle bent. So she tried for the second time and she said, oops. The needle bent again. They’re only allowed two tries. The second nurse came in and fortunately she didn’t have the same trouble and they reinserted the PIC line.

Heavy scaling in the areas of my body that bent or moved, my knees, my elbows, my shoulders. These areas would sometimes crack and bleed if the scaling became too thick, which it often did. I tell one story that I was -- I’m a wood worker. I have these tools that scrape wood. I got so frustrated one day I took one of these tools and tried to scrape off the scale. Probably the dumbest thing I did because it started to bleed afterwards and it made it even worse. I don't recommend it.

While the cracking -- bending became the intense burning sensation it was very, very difficult to mitigate. Now I'm going to try to explain to you what I mean by burning.

If you would imagine you're on vacation in Aruba, very close to the equator and you decide to go out on the beach and you didn't put enough sunscreen on. And you sat out there for too long and guess what you got. You got a sunburn. And you know what it feels like afterwards? Your skin -- like your skin is on fire.

Well, that's the sensation that I live with most of my life. This burning sensation. I suffer from palmer psoriasis and experience the similar condition. The cracking, the fissuring, and bleeding of my palms so severe that I could put my hand down on a plain white piece of paper, press it down, lift it up, I'd have a perfect implant of my hand -- imprint of my hand on the paper in blood. It was painful to use a pencil or a pen and virtually impossible to type. And we didn't have computers in those days by the way. I'd like -- I would have to work cotton gloves under latex gloves just to be able to sleep at night. And those were the dark days. It would seemingly drive you out of your mind -- or me out of my mind looking for relief that always seemed elusive.

And I can't begin to estimate the amount of pounds of petroleum products that I have used to soften or exfoliate the psoriatic scales on my body. And I don't even have stock in that companies either. I should've bought it early. I was once asked to leave a public pool in our town because I might infect somebody with the stuff that I had on my body.

In spite of my trying to educate the lifeguard, I was not allowed back in. And I can tell you, since that time in the 1980's I have never gone to a public pool again. I didn't want the embarrassment ever, ever again. I've always built a pool in my own backyard. Intimacy between my wife and I suffered.

Even though we had three daughters, scales tend to become very sharp and rough rubbing against an extremely soft skin. I was able to prepare my skin, reduce the scaling, before intimacy but within a few days the scales were all back. Even after taking a shower I would have to clean the drain of the shower so the darn water would go down.

I've been married for 52 years. My wife does not have psoriasis so I always have a good reason why it is not contagious. My psoriasis is pretty much in remission today due to the -- with the biologic use. However, I've also instituted some lifestyle changes.

I went from a high body weight of 263 pounds to 205 pounds and I've maintained that weight for five years. I ceased smoking in 1979 shortly -- three years after I was diagnosed with psoriatic arthritis which probably was my best salvation.

I ceased alcohol consumption completely in 2000 when I was going on a medicine that had high vitamin A content and I tried to maintain a healthy regimen of eating and exercising on a weekly basis.

When I retired in 2007, my wife and I agreed that we would exercise every three days, Monday, Wednesday, and Friday. It's been a -- a great way for me to keep my body in movement.

I've always considered myself to be a strong person. However, even with that strength, psoriasis has had a physical, emotional, and mental impact in my life. One thing that I know is I can never let my guard down, my psoriasis is with me for life unless a cure is found. Thank you for your attention and concern.

DR. EGGERS: Thank you very much, John. And finally we have Christina.

MS. TOM: Good morning, everyone. And I would like to thank the FDA for giving this wonderful opportunity to hear our voice. My name is Christina Tom. I am 51 years old. I was diagnosed with plaque psoriasis at the age of 5 after a bout of strep throat.

At that time, my parents didn't know what I had and growing up in New York and trying to find a dermatologist was really tough. And the one person who told my father what I have was a little old lady by the name of Susie who was a pharmacist's daughter in the Lower East Side of New York because she's seen psoriasis through her life through immigrants that came through her brother's pharmacy. So she knew what it was. It wasn't even a dermatologist.

And she told my father, you need to take your daughter to see a dermatologist. Psoriasis is my life and what I'm about to share is my life experience in having it.

The three most -- there's three significant symptoms that I recall have -- with psoriasis is the red and thickening lesions. Even wearing tights during the summer month you can still see the outline of my lesions. And even wearing three pairs of panty hose in nude you can still see the traces of the lesion, even with covering it with Dermablend. That's how bad it was. Scaling and flaking.

I can attest to everyone with their vacuuming -- vacuum stories where wherever I go I left a trail and I could still recall the time my sister would pull out the vacuum cleaner to vacuum behind me.

And it was quite insulting at first but, you know, it's the (inaudible). Cracking and bleeding. That was my worse fear. Every time I would move I would bleed. Even my knees, my joints, or just sitting in a chair and getting up.

And when I first entered the workforce after college, the dry cleaners became my best friend. Every week bringing clothes. They had to remove the blood stains on sometimes just the flakes off the shoulder.

As far as specific activities, during grammar in high school I was very conscientious in participating in sporting activities. I had to wear uniforms that would expose my psoriasis. And I became very conscientious with my skin flaking, bleeding, or cracking during activity.

There was one incident I do recall and I will share with you that I never shared with my parents. And when I was in the fifth grade I was in the back of the class and I was just scratching my head. And then my teacher called me down to the nurse's office and in front of four other students, she took two tongue depressors and she went through my scalp thinking I had lice. And I told her, no, it's not. It's psoriasis. I was so humiliated and (inaudible) violated that I never told my parents what happened.

Growing up with psoriasis and then having it throughout my adulthood, one of the most difficult decisions I had to make was my desire not to have any children. I clearly recall the difficulties my parents had to face to find doctors and treatment to help my psoriasis. I'm sorry I'm crying. And my parent's dedication and love in a effort to protect me from people questioning the lesions on my skin and their love to give me a very normal childhood.

There was one conversation I had with my gynecologist before I went on biologics was to harvest my eggs. They said, Christina, you had an opportunity. And I said to her, I want to so much. I can't take the burden. I know there's treatment out there but what if my child has it and how can I treat myself and my child and (inaudible) just unfair. Adoption was an option but I said, I don't think I will have the stamina and the strength to do it. And I can't just depend on my family all the time and they will support me, but it's my choice and I decided no children.

On my best days with my psoriasis I'm relieved when I can wear clothes that I don't have to cover my psoriasis. And on my worst days there are times when I am embarrassed to leave the house when I'm unable to wash off the treatment residue from my hair and body.

At times I had to spend a lot of time in the morning and even to wake up early to know that because the pain is too time consuming and I just opted to stay home. Even it was painful to get dressed because of the lesions in my knees and my elbows. Because of the result of my skin cracking and bleeding means another pair of stockings, another pair of undergarment.

My symptoms have changed over the years. During my childhood 80 percent of my body was covered with psoriasis including my scalp and I'd have to say, I still have a memory. I have a bald spot here from a section I always picked. I did go through remission once and then the psoriasis returned in a vengeance.

Treatment also plays a factor with my psoriasis and its symptoms. After years of topical ointments, occlusion, and light therapy I know longer responded to the most conservative form of treatment. When I found success with systemic and biologic treatments I not only have clear skin but I developed symptoms of IBS, which is irritable bowel syndrome, uveitis, and psoriatic arthritis.

Also as a precaution I do undergo routine gynecological exams to ensure that I am clear of any abnormal pap smears. There was a time when my lesions was getting better but I was getting a lot of abnormal pap smears and because I'm on a biologic I have to take extra precaution of that.

I have to say today my condition is well managed due to my current treatment protocol and lifestyle changes, and I have a great medical team. Though I am living a very productive life every day, I still have worries that my current treatment will stop working. I worry about how I will react to new treatments it's accessibility and affordability. Thank you for your time.

DR. EGGERS: Thank you Christine -- and Christina and thank you to all of them. Another round of applause, please, for what we know is courage. And we hope that you heard your own stories reflected in this. Can I have a show of hands to see how many -- that you heard -- that your symptoms and what matters to you and your impacts were reflected in at least one person's. Great, yeah.

We probably -- there are probably differing experiences out here and we'll try to get to all of that as much as we can. So now we're going to move into -- to build on what we've heard from Diane and Ellen, Marie and John, and Christina.

We're going to start with some polling questions that will help set the stage for our discussion and we have on up so get those clickers out. Of all the non-joint symptoms you've experienced because of psoriasis which do you consider to have the most significant impact on your daily life? And you can choose up to three.

A if it’s flaking or scaling, B itching, C skin rash, D skin tightness, E dry, cracked skin that may bleed, F pain or soreness, G burning or stinging, H thickened, spotted, pitted, or ridged nails, and if there’s something else please indicate that through I. Does anyone else still need a clicker? Raise your hand. I think Georgie’s coming through. Okay.

Okay. So flaking and scaling and itching received the most number but everything has been indicated followed by dry, cracked skin that may bleed, or pain and soreness.

So -- and then we have a couple others and we’ll try to get to those others later. But what we want to do, let’s take a few of these and delve into them a bit more. One thing, I don’t know if there’s a break listed on your agenda until we get to lunch time at 12:30. So please if you have to use the restroom or any -- or get up to stretch your legs, please feel free to do so. We’re a very comfortable atmosphere here today.

Okay. Let’s start with the flaking or scaling, although I might not spend as much time on this. We might go to some others, but because we’ve got a lot of the comments from the panel.

So what I’ll ask is if anyone has an experience that is -- that you would characterize as slightly different from what we’ve heard up here regarding that. We have someone back there. No, we can’t hear you so we’ll turn on the mics. Sometimes it takes a second.

DIANE: How about now?

DR. EGGERS: Yep.

DIANE: The flaking and scaling, you know, a lot of dermatologists will tell you, don’t peel your plaques. I found through the years that it’s almost an internal brain sensory mechanism going on to tell me to release this skin that is trying to form underneath the plaque.

And so I remove the plaque for the new skin to grow and -- but they always tell you don’t remove the plaque. It’s almost impossible not to because there’s something going on inside your body subconsciously that you can’t really be aware of. So that’s a point I wanted to make.

DR. EGGERS: Okay.

DIANE: Is, you know, the dermatologists telling you not to do that.

DR. EGGERS: Thank you very much. And your name, please?

DIANE: Diane.

DR. EGGERS: Diane. Thank you, Diane. That resonates with you this urge to keep going. Someone right here. Oh, okay, then we'll -- any other experiences or perspectives that might be building on this. We have someone right there at the white and then we'll come up here. Yeah.

CLARISSA: One symptom that comes back when the lesions are quite large is your ability to keep your temperature even. Lesions are so big you're either very hot or very cold. It's kind of -- it's --

DR. EGGERS: Okay. I'm seeing head nods in resonation. Okay. I'm getting -- you agree.

CAROL: My doctor tells me to wear a hat in the house sometimes.

DR. EGGERS: Okay. Thanks Carol. And your name was? Your name was? Clarissa. Okay. Thank you. And right here?

MS. BRIDGES: Hi. I'm Alicia Bridges and I wanted to talk about being misdiagnosed. Being African American a lot of times our psoriasis doesn't look like what's in the textbook. So I've had it since I was seven and I've seen over 15 doctors and they will say, oh, well maybe you have a fungus under your skin. They would say, hey, maybe you have a different disease. So it was really difficult. You almost felt like a science project that doctors were working on, honestly.

DR. EGGERS: Thank you very much, Alicia. Thank you. Okay. So are there any questions from -- on flaking and scaling, follow up questions? Okay. I saw one more hand raised so we'll go to this gentleman here and then we'll move on to talk about some of the other symptoms.

DAN: Hi, I'm Dan. One symptom that has always freaked me out quite a bit is because of the flaking and scaling there -- and the opening of skin. I'm pretty sure I went septic when I was traveling overseas and almost died because of it. I had no cuts that were visible except for my psoriasis. But my blood was full of bacteria. And then also in regards to intimacy as well, there's this challenge of STD's, you know. You having open skin all the time.

DR. EGGERS: Yep. Okay.

DAN: You know, it's very scary.

DR. EGGERS: Thank you. Thank you. Has any -- a show of hands, if you feel comfortable doing so, I'll do that throughout the day. Anyone else experienced an infection that they attribute to the open -- the flaking and scaling? Okay. Great. Okay. Let's move on to talk about itching. We heard some very eloquent descriptions of the itching and so I'm wondering if there -- anyone wants to share something that is -- can be the same perspective or a unique perspective to build up here. We have one right here. Summer?

SUMMER: Summer. I actually just got diagnosed about four years ago so I haven't had it very long but I have it on the soles of my feet and I found that that was really tough. And it goes -- kind of coincides with the bleeding. I bled all the time because all the pressure is put on the bottom of my feet. But itching was a real bad problem in those areas. I didn’t have that much flaking but it was like all the skin was completely gone because I use -- and it’s your feet, you know. So I found that itching on the soles of my feet was very, very, very bad.

DR. EGGERS: Okay. Thank you very much, Summer. So, oh my goodness. Lots of hands. We’ll go with Mary and then we’ll come over here to Todd.

MARY: Even after I successfully was able to get rid of all the plaques through PUVA, I still had intense subcutaneous itching and my dermatologist told me that was normal. So I had to go on a special cream in order -- to kind of keep that abated.

DR. EGGERS: Okay. Show of hands. Anyone agree with -- and we heard one from up here. Ellen and I think Marie where the skin can be clearer but you’re still experiencing the itching. Okay. Okay. Thank you. Now we’ll go to Todd, please.

TODD: Yeah. With the itching I’d have to say it keeps you up at night so you have, like, this insomnia and it’s -- obviously you need sleep and it’s an huge impact on anybody's life that's dealing with psoriasis and psoriatic arthritis.

DR. EGGERS: Okay. Thanks. We're going to actually get to an issue about sleep in another polling question later on so we'll follow up on that. Right over there and then we'll take a few more over in this side.

PATRICK: Good morning ladies and gentleman. My name is Patrick. I have psoriatic arthritis but to stay on topic here with psoriasis that I'd started out with before the psoriatic arthritis developed, and believe me, I'm in a lot of pain right now just sitting here. I'm sure most of you with that poll that we just took can identify with that, 60 percent and plus.

With the psoriasis aspect of it, how many of you associate the psoriasis with stress? So when you're stressed out you start to itch, right? So one thing that I've learned over the years is to control your stress and see if that itching will calm down. That will help you tremendously. Take it from someone who's been dealing with this disease for 15 years and a lot of pain. A lot has to do associated with -- I used to motocross. So back injuries, the psoriatic arthritis attacks the areas that I broke bones when I used to motocross. One last thing, Marie, the first one who spoke?

MS. TALBERT: Diane.

PATRICK: I'm sorry, Diane, mentioned something very interesting about the education aspect of blacks not being educated as to psoriasis identification. That just opened up a door for a lot of things that could be discussed later on in the future.

And the last thing I want to point out too, if you do itch, I know this sounds off the wall, but I take -- I was on three different types of chemotherapies, Enbrel for seven years, Humira for five years, and I just started Stelara which is another form of chemotherapy back on December 23rd. I get really sick. But the lesions that come on my knuckles, for example, and you start to itch, I know -- just like in between your treatments, go to the store and go get an aloe vera plant. Put that -- cut the plant and then just put it on your skin. It'll help soothe that itching. That's all I want to say. Thank you.

DR. EGGERS: Thank you very much. We'll be getting into the range of other sort of non-drug therapies in the afternoon so thank you for teeing that up. Can I ask a question? For those that feel comfortable, I'm going to ask for a show of hands question. How many of you are sitting here right now and you are feeling that you -- and you're itching in some way. You're living with this. Okay. So you are sitting here, you're participating, but you're living with itch.

How about pain? Same show of hands. Okay. You're sitting here and you're in pain. You hide it very well, I have to say. So hats off to you to sit through this meeting with that. Let's take one more comment over here about itching and then we'll move on. And your name?

LARA (ph): My name is Lara. I've had psoriasis since I was eight years old. I'm also a doctor. And what I wanted to mention was itching and concentration. So one of my biggest challenges has been particularly when you're sitting and you're quiet and you're trying to get through something like a test or listening in a lecture. The itch is intense.

And I remember really particularly I sat on a committee in medical school that was reviewing treatment options. Treatment options and talking about their healthcare plan. And somebody made the comment, we really need to cover ADHD medications because you can't concentrate when you have ADHD. But, you know, if you just have a rash that's not as important. Itch is a severe impairment to concentrating.

DR. EGGERS: Thank you. Thank you very much. I saw a lot of -- I think -- clapping. Okay. We'll actually get to this. One thing. Yes, Ellen, go ahead.

ELLEN: With the itch one of the other things that hasn't been mentioned today is that if you do scratch it, a lot of people, myself included, if you break the skin that wasn't broken before adjacent to something or even somewhere else just by scratching, there's the Koebner effect where if you break the skin anywhere when you're scratching, plaque will form --

DR. EGGERS: Yep. Okay.

ELLEN: -- on that -- in that spot.

DR. EGGERS: Okay. All right. All right. Let's take one -- okay. Let's see. I'll let the microphone runners decide who's going to be the last person to talk about itching (inaudible). This is what the docket's for. Please go to the docket and describe this. Okay.

XAVION (ph): My name is Xavion and sometime when I'm hope that my feet itch and sometimes I will get something and rub it but then it hurts and it starts bleeding. Then what I would do is sometime I would tell the doctor. They will take the scales off and then some of it -- it will come off but then my feet hurt so.

DR. EGGERS: Thank you, Xavion. It's Xavion? Okay. Can we have a round of applause for this young gentleman? You are here representing kids who have this disease and I think you might be --

there’s only a few. Can -- show of hands -- if you’re another pediatric or parent, can you just raise your hand? Okay. So we have one parent. So you are a very important voice and we thank you for coming today. Okay. Any questions on itching? Okay. We’ll move on.

We have so much to cover today and I see so many hands and it can get a little overwhelming so please be patient with us. I do want to -- I think we talked about pain, you know, quite a bit throughout. The burning and stinging, it can be hard for those of us who don’t experience these symptoms to know the difference between pain or soreness and burning and stinging. Can anyone explain that in their perspectives? We have this -- Melissa. Okay.

MELISSA: Thank you. I’ve had psoriasis for 22 years. I’m only 24, so it’s been a long time. I can also speak about the pediatric component because that’s what I lived through but the burning and stinging was definitely the worst part of my experience.

As a child it felt like I was trapped in a body that just didn't belong to me. Te pain occurs kind of under your skin and it literally felt like I had been lit on fire, but it never stopped.

So I'd wake up in the middle of the night just screaming and as a toddler tried to rip my skin off every single day because my body was attacking and it was just the most excruciating thing you can imagine. It's different from other kinds of pain because it's not on the surface of your skin. It really feels like it's an internal process going on and to speak to the temperature problem, I was always really hot so we tried to use ice packs to cool my body but it did very little.

DR. EGGERS: Okay.

MELISSA: It's also not the kind of burning that, like a Benadryl would help. It's a very different thing all together.

DR. EGGERS: Okay. One more comment on that over here. Somewhere over here.

MS. WEST: Hello, I'm Sharon West. Just to the burning, I've had psoriasis for 50 plus years. Just the burning, I'm currently on biologic which is controlling my symptoms rather well, but even to this day I'll feel like a burning sensation where I had psoriasis like in my ears. It'll just happen and I'll know that it's -- that psoriasis is just trying, you know, to come on out and it's scary, you know, at that time.

And I just want to make one more comment about the stress. Of course stress is something that doesn't help anybody but just -- I just wanted to make sure that people who are in the FDA understand that a lot of the stigma I've had over the years is, oh, you're causing it, you know. Doctors have even said to my mother, what did you do to her, you know. Like something happened.

This was very terrible as an adolescent growing up feeling this. So that I just wanted to say that we don't want to get to the point where we're blaming the patient. Okay? That it's -- stress happens to everyone and if you have psoriasis it doesn't help but we have to keep remembering that its internal disease and getting -- while a rash is part of it a lot of the years people would say with the itch, oh, just try -- this -- I have this thing that I bought in Sephora (ph). You've got to try it or, you know. So I just wanted to mention that and thank you very much.

DR. EGGERS: That's an important point Sharon. We got a lot of head nods. Can we move -- do you have any questions to follow up on the pain, burning, stinging type things from here? Okay. Yasmin, please, yes.

MS. CHOUDHRY: So the patient here in red that just talked about --

DR. EGGERS: Melissa.

MS. CHOUDHRY: -- the burning, stinging, and pain, so do you -- when you experience the pain do you experience stinging is a separate concept and burning is a separate concept or are you trying to use these terms because they're commonly used terms?

MELISSA: The stinging sensation that I felt usually came from the cracking, the bleeding, and then anytime you'd be touched by say like a cream or therapy I'd have a lot of stinging. The burning is a different sensation. I don't even know that burning is the right word because it's something that I truly cannot describe. It's not like putting your hand near a flame. It's like you're just engulfed in it and the best way I can describe it is say that it really comes from the inside out. A lot of times there's a lot of burning sensation right before the psoriasis erupts so it feels like it's impending under the skin and then will emerge.

MS. CHOUDHRY: Okay. So does it happen that at some occasions you feel more burning and then at some other occasions you feel stinging, or are these overlapping concepts?

MELISSA: Yes. Both depending on the severity and presentation of your psoriasis. It's a disease that is constantly changing. I was covered about 90 percent of my body so for me it's a little bit difficult to separate but I can say that the stinging really did feel like it was more on top of my skin, really where the cuts were, where the cracks were, and the burning definitely felt like it was almost a layer under my skin and it was usually everywhere, where the stinging could be localized.

DR. EGGERS: Thank you, Melissa. I have one follow up question for Melissa, too. If you can get rid of one of those symptoms that you just described, you could clear it --

MELISSA: Absolutely.

DR. EGGERS: -- keep the others, which one?

MELISSA: Absolutely. Of any symptom it would be the burning. I mean I would just rip my skin apart because it just felt like there was like an internal flame that was just -- yeah.

DR. EGGERS: Okay. Great. Thank you so much. To keep moving along, what I'd like to add -- okay, John, and then we'll -- I have another question.

MR. LATELLA: Can I just make one comment on burning. I had a erythrodermic psoriasis. My body -- the skin was peeling off so in order to cool me down, because I felt like I was on fire, they would take me down in physical therapy, lay me on a plywood sheet, and dip me in a whirlpool of cold water just to bring my body temperature down. I did that -- I had to do that for twice a day for seven days in order to -- just to keep me in a stable situation. That's the only way that I can explain the burning. It was like your skin is on fire and you can't put it out even in water.

DR. EGGERS: Okay. Thank you. Thank you again, awesome. Keep nodding your heads if you agree because that gives us a sense even if we can't come to you directly. So I would like to move on -- we've heard a lot of symptoms and I -- this is a chance for the folks on the phone. We can take two or three people on the phone as well, so tee up that. I think we have -- so first of all, let me go to see if there's web comments on the symptoms that we've talked about so far.

MS. ANGELASANI: Sure. So currently we have around 180 participants on the web.

DR. EGGERS: Okay.

MS. ANGELASANI: And many of them have been echoing the comments that we've heard in the room and -- or saying that what we've heard in the room has resonated with them. We had one patient with scalp psoriasis who's wondering if this is the same for other folks in the room, if it feels like you're head is being encased in concrete. And if that causes severe headaches for any of the folks here as well because that’s her situation. And we had one participant who’s described the pain and burning is similar to that of the beginning a cold sore but instead of healing or getting to a point that the burning stops, it just continues.

DR. EGGERS: Okay. Thank you Meghan. Okay. So we have talked a lot -- we’ve had a lot of symptoms through our panel comments and what we’ve talked about today. What I’d like to spend a few minutes on is if there’s a symptom that you would put in our top three or even if you’d put it in your top one or two that you could get rid of, and we haven’t mentioned it today, and you would think it would surprising for us to hear it or for your doctor to hear about this symptom, what would that be? Right there in the white.

THERESA: I’m Theresa. I don’t think this is surprising but I found it -- the most debilitating part of it was the emotional part. And being -- like having to go to the doctor, I need depressants. I can't function anymore. It's horrible. And it's -- don't -- everyone's saying don't be stressed, don't be stressed. You're like, well, that's stressing me out to tell me not to get stressed. So please stop. But I do think the hardest part is -- for me was the emotional aspect of it. And every single morning waking up and seeing more every single day. And then the insane fear that it's all going to come back.

DR. EGGERS: Okay. Great. Thank you so much. And what was your name? I'm sorry.

THERESA: Theresa.

DR. EGGERS: Theresa. Thank you. We'll go to John and then we'll come back here.

JOHN EARLEY: Definitely the psychological and stressful part, I know for myself when I was first diagnosed and started on all the different treatments, I know this is going to sound crazy because when I explain it to people I said, maybe I need to have help but the -- for me what I actually did was I literally emotionally and mentally divided myself into two people.

One was a John Earley that had the psoriasis and went through all the treatments and so forth and the other one was the one that went on with their normal life, did their job, you know went to Disney World with his family, wore shorts, and short-sleeved shirts, just didn't think about if people were staring at him or anything like that because if they were they were looking at the other guy and not me.

And that's literally how I dealt with it and for me was able to get through it because it was the other guy and it wasn't me. All the things that made me sick and not feel good and so forth. It just helped me putting it off on that other person helped me get through it.

DR. EGGERS: Okay.

MR. EARLEY: I know that sounds really crazy but that's what I --

DR. EGGERS: I don't think it's crazy.

MR. EARLEY: -- made a conscious decision that that's how I was going to deal with it.

DR. EGGERS: Thank you very much, John. Well come -- let's see. We'll go --

TERRY: Terry. I would say fatigue because it’s a constant battle. You don’t rest well at night so you get up and you’re already fatigued when you get up and you fight it all day, the symptoms. And you wake up tired and you go to bed tired and that’s just your new reality.

DR. EGGERS: Okay.

TERRY: You never feel happy and good. You know, you play at that sometimes. It’s like having a good day but there’s always just that constant fatigue.

DR. EGGERS: Okay. We’re going to take one comment and then we’re going to -- you are segwaying nicely for us into another question that’s going to get at some of these aspects of fatigue and emotional. So we’ll go here.

UNIDENTIFIED SPEAKER: Coincidentally I actually was going to mention the fatigue as well. I’m a school teacher so I’m working all day with children and I come home. I have two young children of my own and just the guilt that I feel that I can’t be a hundred percent for them when I come home because I’m just so exhausted that sometimes I have to take a nap, you know. It's very emotion -- that's an emotional toll on me as well.

DR. EGGERS: Okay. Thank you. Let's -- before we get into the phone, we'll go to the phone in a second, let's put up another polling question that while we're at the phone you can think about this and you can do your clickers while we're hearing to the phone because this one might take some reflection.

We talked about the skin symptoms and now we have another question that I think is going to broaden the impacts and the effective of psoriasis on your daily life. So the question is, what do you find to be the most bothersome impacts of your psoriatic symptoms on your daily life? And you can choose up to three impacts. On the web you can do this as well on your polling question. A limitations on activities such as work, school, sports, and hobbies; B the ability to concentrate or stay focused, as we heard described earlier; C the ability to fall asleep or stay asleep, as we just heard; D stigma or embarrassment; E social discrimination which is something that goes a little beyond stigma; F impact on sexual intimacy; G impact on relationships are more broadly; H emotional impacts such as that self-esteem and I think you could put the stress in there as well.

And I, if there's another thing that you don't think fits into one of those categories. And while you're thinking about it, let's go and take two phone calls. Do we have any folks on the phone? Oh, we don't have any folks. Okay. All right. So if you're on the web you also can then write in your comments to explain why you chose any of these as well. So I'll give you a few minutes for that.

Okay. The emotional impacts are coming out as the most frequently mentioned with many of you in the room saying that -- and then there's a range where it's a lot of other impacts, limitations, the ability to fall asleep or stay asleep, stigma. The social discrimination being up there as well, too. Would anyone like to explain something that's may be building on what we've heard before to explain one of theirs? Someone that we haven't heard from before. Okay.

MS. ANDREWS: I have an 11-year-old son who has psoriasis and psoriatic arthritis, and one of the biggest emotional impacts on our family was two years ago Dylan (ph) admitted to his dermatologist, who he has a great rapport with, that he had thoughts of suicide.

He was tired of hurting. He was tired of the treatments. Nothing was working for him at the time. He had such discrimination and being made fun of and bullying at school because, ewe, look at the kid with, you know, that stuff on his skin. Somebody else had mentioned being kicked out of a water park. We were kicked out of a water park because I didn't have documentation that my son didn't have a contagious disease. And to tell a child, we have to go because your skin, you know, because of that. So we were lucky that we had such a good relation -- that he had such a good relationship with his doctor and felt comfortable, you know, telling his doctor that but I don't think -- especially when you're thinking of young children, I don't think that doctors and other people are asking these children -- when we go into a doctor's appointment they always ask, physically, how are you feeling?

I think that it needs to be stepped up to, how are you feeling emotionally? What are you going through? Because most people don't think that children as young as Dylan was would have thoughts of suicide but when a person or a family member dies when you're explaining that to your child, you say, they're not hurting anymore. So in a child's mind they're thinking, well, I'm hurting all the time. If I'm not here anymore I won't hurt.

DR. EGGERS: Thank you so much. We had -- Carol had her hand up and then we'll go back there some --

CAROL: Yes, I'd like to say three things real quickly. First of all, as in my childbearing years I was never able to get off of a drug that would have prohibited that long enough. I was bedridden, I was 100 percent Social Security Disability, I was frequently hospitalized.

I was never able to either have or adopt children. And while that may not sound like a daily impact, it is. The second thing that I would lift up is that I was not able to pursue my chosen career because I was not physically able. And the third thing, I was going to lift up -- is that, just briefly, this goes so far beyond the rather off-topic subjects of the other things you get because you have this disease. It just -- it impacts every aspect of your life.

DR. EGGERS: The other conditions you get, the other physical, which we heard Christina talk about. Thank you very much, Carol. Okay. Back there.

ERIC: Is it on?

DR. EGGERS: Yes.

ERIC: Okay. My name is Eric and the point I want to make about the emotional impact is sort of a sense of pessimism that kind of continues to grow over time. So in my case, I've had it for 25 years and as each year goes by, you know, you have two or three or four or five more psoriasis spots and you always have the sense of what's going to happen the following year. How many are you going to have? How much is it going to grow? And in my case up until about a year or plus ago, I had something like 120, 130. I sort of lost count, they're everywhere.

But to end on a positive note, what's really helped me is that I have a home UVB three-panel light box and that's totally dramatically changed my life. So I've gone from like 120 spots to three or four in over the past year. So that has really totally changed my sense of optimism from the other side, which I had for many, many years.

DR. EGGERS: Great. Thank you. So, okay, we'll take a few more. Right here. Sarah, Sarah.

SARAH: So I answered G, impact on relationships, but I looked at this a little differently, not as a relationship to a husband or a boyfriend but this is impact on my friends or hairdresser. You know, fatigue is a really big issue for me and I've had a problem with my friendships because of this.

My energy level goes up and down, and I make plans and I cancel, and I make plans and I cancel. And people get to where they think I'm flaking out. They get offended. And they don't believe me because

I don’t look sick and all of those things. And so I have a real problem with that.

And people just don’t understand and it’s had a really big impact on a lot of my relationships. It’s hard. I have really bad scalp psoriasis. It’s hard to go to the hairdresser and it’s very embarrassing to go in and get things done. I hate it. I hate going in.

So that’s been a big problem and I don’t think that that’s really reflected very well in some of the questions that are being asked. And I think that’s a problem probably a lot of us have and it’s -- so I just wanted to bring that up.

DR. EGGERS: Yeah. We’re getting a lot of head nods so thank you for the clarification. Go ahead, yes.

TONYA: Hi, my name is Tonya and emotional impact is really something for me. I’m sorry for being emotional because unlike some of the women that I’ve met here, I’m not very lucky with a husband. I was recently diagnosed with -- I mean, I was diagnosed with plaque psoriasis in 2007 and of course from the moment it started in my elbows it progressed everywhere from my head -- thank you -- to my toes.

And it -- like everybody else here, when I walk it drops. I mean it's like snowing every day everywhere I go and it doesn't even snow in California. And the one thing that really hurt me the most, and it came from my own husband, he said, why don't you vacuum this. It's getting into my feet. It was very difficult for him to understand what I was going through.

And whenever we would go to social gatherings and her hus -- with his family and when he would see my hand go this way, he would immediately hold my hand and put it down and say, don't scratch. And that was difficult, not having the support. And the itching. The embarrassment of itching is -- it's so much because I have psoriasis also in the genitals and when it starts itching so badly, how do you scratch your genitals, especially in the office? They might think you're doing something sexual and what would they think of you. And could you always go to the restroom to scratch yourself?

I mean -- and when you do you end up, you know, you end up scratching so hard and it would bleed and you would have blood all over your underwear. How do you deal with that? And that's what I've been living on since.

DR. EGGERS: Tonya, I can tell by the head nods that you're not the only one who has experienced this so thank you so much for sharing that.

UNIDENTIFIED SPEAKER: Oh, thank you. So one thing about the psychological impact, I mean there's several. One is that, like, I have 40 percent coverage. A lot of times my doctor or the nurses will say, well, that's not so bad. I've seen much worse.

And, you know, I can't wear shorts. I'm starting not to be able wear long, you know, short-sleeved shirts, and it's kind of devastating. But I would say also that I know exactly when I got psoriasis and it was after, like, four weeks after a cataclysmic life event and research shows that if you're predisposed it will show up about four weeks after, you know, some very, very stressful event. And I had a series of really stressful events and if I described them all, everyone here would start itching. So I'm not going to do that.

But I do know that psychologically when I look down at my skin I'm reminded of those events and later hopefully I'll be able to talk about a clinical trial I was in that actually pretty much cured me but then I -- the drug was halted and I was unable to continue with it and I had a rebound effect. So I'm really, you know, living with, you know, evidence of some of the most miserable events of my life. Sort of anthropomorphisize on my skin.

DR. EGGERS: Yep. Thank you very much. We can take a few more. How about back there? Sarah, if you could get the woman right there and then we'll come up here.

DEIDRE: Hi, I'm Deidre. And getting to some of the stigmas and embarrassments that go along with it, for me one of the things that has become very difficult for me is just going to regular doctor's visits because every time you go into a doctor's visit you're having to re-explain your condition to the doctor. The last visit that I went to I was actually asked to take a AIDS test, which was very embarrassing, very humiliating, and of course -- and I told them I don't have AIDS but I will be more than glad to submit myself to a test.

So when it gets to some of these other diseases that are linked to it, I think that the probability that a lot of us continue on and our health conditions worsen is because we don't feel comfortable often going to doctors.

So I think that we need to do more to educate doctors on this disease, not only just those that deal with the skin, but doctors throughout other forms of treatment so that we can make sure that we can help us not get diseases such as diabetes or going in for a colonoscopy and those things because those are real fears and embarrassing stigmas that people with psoriasis live with.

DR. EGGERS: Thank you very much. We'll go one more here and then I have -- right here and then I have a follow up question on something.

MS. GARDNER: Hi, my name is Pantshia Gardner. I have psoriasis on my hands and my feet and the one thing for me that just socially and just embarrassment is, you know, when you meet someone you shake their hand.

And so when I do this professionally you meet people, you shake their hand, and they feel my scales, they feel my skin, and they don't know how to react to it. And you -- I see in their look in their face, just that look of just puzzle and what is on her hands and what's wrong with her.

And I know we have cotton gloves that we can wear and everything but that just draws more attention to that area. And as psoriasis patients, we just sometimes want to be invisible and, you know, just be normal.

And so with wearing gloves it just draws more attention to it, but if I don't wear gloves they feel the skin and, you know, socially, of course, you know, you greet people with a handshake and I find that very difficult for myself just being out there and even attending church service on the weekend where you greet each other and, you know, sometimes it just kind of holds me back from going to do that too. And so that's how it impacts me personally.

DR. EGGERS: So I'm hearing there's a very clear distinction between what could be sort of overt stigma and embarrassment, and just the everyday people don't know how to react even if they don't mean anything by it and can I ask a question?

How many of you find -- which one do you find to be more challenging in your day? The sort of overt kind of stigma, raise your hand, or -- then I'll go to this sort of what Pantshia is talking about where it's this dealing with people -- people don't mean anything by it, they just don't know how to react. So the -- sort of the overt, you find that to be more of your issue? Okay. Or the more -- the softer stuff where it's just, I don't know how people are going to react to me? That's very informative. Thank you.

I want to have a follow -- let me ask one follow up question before it loses -- before I lose my train of thought on this one. When we were talking -- when we were discussing the limitations on activities in our group and trying to (inaudible), one thing we talked about were the difference between physical limitations, so something that's physically keeping you able from doing your work or were you thinking more of, I'll say social limitations like we heard from Ellen and others here.

So how many of you when you chose, A, limitations on activities, were you thinking of physical pain or cracked or something? Okay. Can you put your hands up? Okay. And how many of you when you answered that you were thinking primarily of some sort of social aspect or social limitation? So about half and half. Can I have someone who picked the physical limitation on an activity to explain what they were -- why they answered as such? Right here.

JODY: My name is Jody. Part of it is inconsistency. If you join a team you can play this week but you can't play next week.

DR. EGGERS: Okay.

JODY: So you really let them down so you try to do things on your own and that's boring and you don't do it anymore. So that's my big problem.

DR. EGGERS: Thanks. And we have one in the back right there.

NICKY: Hi, my name is Nicky. My son is Xavion. He’s eight. The physical limitation for him is at school. He can’t participate in PE because he has psoriasis on his feet and hands. So if he has to run, his feet cracks. If he has to do pushups he can’t because his hands are cracked. He can’t play sports due to his feet because he can’t wear the shoes because his feet are swollen from the psoriasis.

DR. EGGERS: Thank you very much. And while I have you, I’m going to ask -- so this is -- we’re going to jump a topic because I -- you have the pediatric perspective right now in front of you. When you hear today is there one thing that comes to your mind that you’d say is the biggest difference between what Xavion is experiencing now, like a symptom he’s experiencing, that might be different than how the adults are talking about this here today.

NICKY: For Xavion, the symptoms for him would be the scaling --

MS. EGGER: Scaling. Okay.

NICKY: -- as well as the kids bullying him.

They don’t want to shake his hand. He’s come to the conclusion where he’ll just tell them that he glued his hands together and he snatched them apart and that’s why his hands are white and scaly. So he makes up his own way to deal with the bullying but I think for him that’s the most.

DR. EGGERS: Okay.

NICKY: I mean he does do the scratching only at home. I don’t think that he does it in school. But he does do it at home a lot to where he tries to get the skin to come off. So right now he’s okay.

DR. EGGERS: So it sounds like he’s dealing with very adult issues because it sounds like what he’s dealing with is what the --

NICKY: Yeah.

DR. EGGERS: -- you adults are saying as well. Can I go -- with that parent, there was a parent here. Would you -- if something comes to mind as being like the biggest difference between what your child is experiencing, different than what you hear from the adults here in the room.

UNIDENTIFIED SPEAKER: I have children of many different ages so I've watched pediatric issues change over a generation. I think that the world is a kinder place now. I know that elementary school is really touch and junior high can be too but with the right kind of education going into the schools, and I've been a part of doing that and so have my children, it -- they're really much more receptive so that's a big change that's happened in the last ten to 15 years.

DR. EGGERS: Okay.

UNIDENTIFIED SPEAKER: And probably the physical limitations I would agree. Not being able to do the things that other kids can do and participate in sports and activities and other things that just make you feel like a normal kid. I had a kid who wanted to be on a swim team. Oh, knees are all swollen, can't go. I got a kid who wants to play soccer. Oh, dear, you know, arthritis and the skin are just going to prohibit that. Not that they were being excluded for, you know, their appearance, but just because of the physical limitations that were apparent.

DR. EGGERS: Okay. Thank you very much. On the web, are we getting any comments on the bothersome impacts?

MS. ANGELASANI: Yes. We had one that I think really summarized what we've been hearing is that one other impact is just the sheer amount of time that it took and takes to manage the disease daily itself. It's just a cumbersome impact as well.

DR. EGGERS: Yep. A time burden. Okay. Thank you.

MS. ANGELASANI: And then many of the other ones have been echoed in the room already.

DR. EGGERS: Okay. Great. So we -- before -- we're going to come back and keep going. Let me ask any -- if there's any specific questions that you have that have come to mind here. Kendall.

DR. MARCUS: People have talked about physical barriers to activities and social barriers to activities, and people have also talked about the emotional impact on the disease, but I'm interested in knowing specifically in terms of emotional impact on activities, and I think Christina you mentioned this when you talked. And correct me if I'm wrong but you talked about not going to work because you could not bring yourself to do the self-care it sounds like that you needed to do in order to be able to go to work. And I would like to know how many people have missed days from work and days from school simply because they emotionally are not up to doing what it takes to attend work or school.

DR. EGGERS: Okay. That's the majority of you.

DR. MARCUS: And then I would like to ask how many people have sought treatment for depression or anxiety that have resulted from all of the other impacts of the disease.

DR. EGGERS: Thank you. Okay. Thank you. Okay, we -- I was going to try to get into the topic of flares, so a time when symptoms are really exacerbating but I think we've covered that a lot, we've heard it a lot. So I'm going to just open up the floor. I know a lot of you have been wanting to say, you know -- to talk about it so you can talk about any of the topics that we have been talking about. I'll just ask to build on what someone else has said. So we have -- over there.

PATRICK: Thank you so much again. Thank you FDA also because about six months ago I was talking to my wife about support groups and this is awesome that I can come here and relate to someone that his going through something that I'm going through. The pain, the flares, the psoriasis, the itching, the embarrassment. I can go on and on -- we can go on and on on this.

One thing I do want to note, in 1995 I was diagnosed with psoriasis and it wasn't until 2002 I was diagnosed with psoriatic arthritis. Those seven years -- for those who have not done it yet, I highly recommend if you're only diagnosed with the psoriasis aspect of it, go to a rheumatologist to get a special blood platelet test to see if you have psoriatic arthritis because if you're suffering in pain that much from psoriasis, you may have the psoriatic arthritis aspect of the disease.

DR. EGGERS: Let me ask --

PATRICK: Hang on just a moment, please. This is really important because I won't be able to stay here the second half because I'm in a lot of pain right now. And one thing also, in the morning times -- and I've missed a lot of work to the point where I had to retire but I'm fortunate to do it.

But in the morning times, I don't know how many people can empathize but I walk, you know, like Ozzie Osbourne like he's drunk to go to the bathroom. If you can understand that and deal with that and think you just have psoriasis, go check to get -- to see if you've got psoriatic arthritis. It's critical. Because that way you can get on the type of chemotherapies that it's either helping the people on the panel or helping someone as myself.

I've got a lot of psoriatic arthritis so it's going to take time with this new drug, with the Stelara, and, you know, to jump in that hot shower and to get that relief because you kind of feel like the tin man from the Wizard of Oz and that hot water helps you kind of get your body moving together and to get you -- your day started. And it's been a really difficult road. I have to say this since she’s not in the room -- oh, there she is in the back.

My wife has been unbelievable support for me and you have your spouse and I know some of you are single here and I really feel for you if you’re suffering this alone because if it wasn’t for my wife I wouldn’t be sitting here because six months I was suicidal. I want the pain to go away. I want the pain to go away.

I’ve been dealing with this every single day. I am on the strongest narcotics. I’ve got two narcotics. You hear that? Those are pain pills? And this has really hit me at home right now and I really -- you guys are my heroes. Up here in the panel, you’re my heroes. You guys have really opened my eyes today because I thought I was the only bloody person suffering from this.

You get doctors that are looking at you, like, you know. They think you’re crazy. When you have to over and over and justify. Look, this is a very painful process that we’re going through. You’ve got to help me out. I’m in pain management. I’ve been on Percocet for five years. I'm on Oxycontin for a year next month. It's going to be one year. When does it stop?

You've got people on pain medicines and now you've got the CDC coming out, there's no empathy coming out when they're not seeing the true patient of what is really the root problem. Sure, we've got a systemic problem with addiction, but we got to open up our minds so the people, the true legitimacy of people, the patients here in this room now. What was it when you guys started the meeting this morning? You were, like, surprised. Like all these people came out. So it's what, three, 400 people right now? Watch. The next meeting I hope there's 800 people. And I hope the next meeting there's 1,600 people and it goes and goes and goes because it's going to take education and it's going to take time for this message to get out. And I hope today, right here, I hope people start talking. Thank you so much.

DR. EGGERS: Thank you, Patrick. So I'm going to ask a follow up question to Patrick. I mean, it's hard to follow that with a follow up question but

I have one. We -- so that the focus was not on the arthritic components of psoriasis but overwhelming -- most -- over half of you mentioned here and on the web that you have that. So I'm going to ask just one question, if you could do a show of hands.

For those of you who live with both the skin aspects and the arthritis aspects, which one is the more significant to you on a day to day basis? If it's your skin aspects, if you could raise your hand. Okay. Or your arthritic aspects? Okay. And that's made a point here today, so thank you very much for that.

So we'll go -- we're going to try to go to folks that have not mentioned as much so we'll go back there and then we'll come here. Right there with (inaudible), right there, gentleman, and then we'll come up here.

MR. REDDING: My name is Pete Redding and one of the things I'd like to talk about or hear about today are the comorbidities. At my age I'm much more concerned about the shortness of life and I understand statistically that those of us who have psoriatic arthritis live about five years less or shorter life span. I don't think that's going to happen in my case because I'm pretty far along. But it is something that I think we need to know about and something we need to study very closely because it's just connected and all these other diseases that are now recognized as invasive to people who have psoriatic arthritis, I think that's something we need to be studying.

DR. EGGERS: Thank you very much. And right here. It'll come. Just give it a second.

ALEXANDRA: My name is Alexandra. I've had psoriasis since I was 14 years old. I've had it now for over 35 years. I think it's important and I don't know if the FDA has an educational component for clinicians, but at 14 I was told by my dermatologist, a professor at Albert Einstein, said to me, it's just psoriasis. It was not just psoriasis. It impacted the ability for my physicians to diagnose psoriatic arthritis early on. So if that could be heard. Thank you.

DR. EGGERS: Thank you. We have one right here and then -- let's go right here Pugita (ph), first. Right here, raising your hand. Suzanne.

SUZANNE: And when we were talking about the emotional, one of the big components for me the emotional was to be alone. I can’t believe I’m crying. Anyway, friends would just -- oh, here, try this lotion. You put the lotion on it and it’s like pouring gasoline on a burning fire. You’re absolutely in excruciating pain and here they thought they were being helpful to you. Who could understand the flaking and you’re not even realizing you’re talking and all of a sudden you realize it. Oh, my God, I’m scratching. And you look down and you see -- you just created, like they said, the snow fall and you’re starting to bleed and the people are, oh, my God, you know.

And they’re embarrassed and they don’t know what to do. And there’s no one to talk to. Last night at the dinner table we’re sitting there and we’re talking about it and then all of a sudden we’re laughing about it. We’re laughing about, oh, my gosh, you know, to get a new pair of sheets, you know, that has no blood stain and no stains from all the lotions and everything. And to find that kind of -- you know, you can say is the dark humor but to able to find the other parts that you have lived through and to be able to share them and to know that you're not alone.

I think that's a huge component. I think that's what this is starting today and that's why I am here and my daughter is here, is we're here to -- we want to start a support group in our city in St. Louis and I think the more that we get together and talk about it, the emotional part can be handled a lot better.

DR. EGGERS: Right. Thank you very much. Before -- Roselyn had a question and was very patient so I -- and then I forgot, so please go ahead.

MS. EPPS: That's all right. Thank you. Actually I had a couple of questions but it's okay. For those people who have children in the schools currently or recently, I was wondering whether or not you were able to have any kind of treatment in the schools or if the doctors facilitated that or a school nurse or teacher, if there was someone to assist children in schools? I think Xavion is our representative today. Okay.

DR. EGGERS: Hang on one second. One second. They're very temperamental microphones here. Very.

NICKY: The nurse will actually give him Vaseline to put in his hands which burns and I tried to let him know that you should not do anything without my permission because I don't know if it's going to flare it up even more. He's got it on his hands so -- on his nails and the bottom of his hands but they don't do any -- the schools don't do anything and I'm not sure if they're allowed to do even if the doctors give them permission because they don't know what's going to happen after they place it on their hands.

DR. EGGERS: Okay. Is there a different perspective, a different experience? Right here we have --

UNIDENTIFIED SPEAKER: So our school will let him have pain medicine. If he's having pain they'll administer that. And I'm -- we are allowed to keep one non-prescription lotion in the office so if his hands or if one of his spots is feeling extra dry or hurting him a little bit more and he needs some, you know, some moisturizer or whatever, he can go down to the office and they'll let him put like a Lubriderm or, you know, something like that on him. But that's it. Which it doesn't do anything, you know, it's really more of his peace of mind almost.

If something's on it it's not as itchy. And I have been called in the past. We are lucky that we live close to the school. There has been times where he has -- and this was, you know, -- it's a huge flare for his where he has run into the office in tears and said, you need to call my mom. You need to get -- I need my prescription. And I've had to go in and -- they had to, like, sequester us in this room. They didn't want anything to even be shown that -- where somebody could walk by and see it. Which for him also was a little bit of an embarrassment, you know. It was almost like he was doing something wrong because he needed his medicine.

DR. EGGERS: Okay.

MS. EPPS: Thank you. The second question I had briefly regarding psoriasis of people of color that was brought up and introduced. Can you briefly comment on the pigmentation changes that come with psoriasis? Not only -- whether it's from the disease or the treatment.

MS. TALBERT: Well, for me because I was diagnosed in 1963, and back then they didn't know much about psoriasis, so I grew up in a Caucasian town where there weren't any black dermatologists so they told me at the time they didn't know -- they thought it was a fungus. So they sent me to another town and the doctor said, oh yeah, she has psoriasis.

Like I said, back in the day they didn't know what it was and then when they -- they started to just give me, like -- I had psoriasis on 90 percent of my body and they gave me a little tubes of medicine to put on it. And then over the years when I go to doctors, they would say, you don't have psoriasis. I've had eight biopsies to prove that I have psoriasis because some doctors have even said, people of color don't get psoriasis. So I've had to get these biopsies over the years and, you know -- like, my psoriasis doesn't look like everybody else's. It's thick and it's dark. It's not white scaly, so it's been a challenge.

DR. EGGERS: Okay. I don't think we have time -- we're going to have to wrap up but I saw some head nods so I think that there is a resonance with that. So I think we -- we're going to have to go into lunch but before we do that, are there any final web comments? No.

Okay. So I know everyone had their hand raised and didn't always get it answered but I just want to, first of all, thank you as participants for being very respectful of our conversation today and moving it forward and appreciating that there's a lot of folks who want to talk. So thank you very much. I expect great things for Topic Two in the afternoon. If you have any questions, find one of us during lunch and please enjoy your lunch and we'll be back here at 1:30. Thanks a lot.

(Lunch Recess)

DR. EGGERS: Okay. I think we're ready to begin the afternoon portion. Oh, everyone got very quiet. Thank you. What a productive morning that we've had and I've heard from our colleagues up her that they've really gotten a lot of useful information in the morning and we're excited to continue the discussion into our topic on treatment approaches and your perspectives on that.

As I mentioned, this topic is now delving into how you approach the management of psoriasis day to day, including the treatments that you're on with a particular focus on what are they addressing well, what they're not addressing well, what they're downsides are. And then we'll get into things about looking for an ideal treatment.

So we're going to ask a question later today about if you could have one benefit -- a couple benefits that are most meaningful for you out of a treatment, that a treatment could address, what would that be? We'll have a polling question to get that kicked off. And then we'll wrap it up by looking at the decision-making process that you go through, and it sounds like you have to go through quite often, to determine whether a treatment is the right treatment for you, whether you want to embark upon a new treatment. So we'll get into that as well.

But first we have some panel discussants to kick it off just like we did. The first panel was wonderful at doing that. It really, I think, set the stage nicely for us to build on in the after -- in this facilitative discussion so we're asking the panel here, Caleb, Sarah, Amy, Paisha, and John to do the same thing. So we'll start with Caleb and we'll just go through.

MR. SEXTON: Hi everyone. My name's Caleb Sexton. First and foremost, I want to thank you guys for being awesome and for letting us have this be here today. But a second point too, I think the gentleman who had the psoriatic arthritis who left, I have never been in a room with folks like me, like you guys, before and had this opportunity.

And I'd like to say that I think the most strongest group of people I've ever met in my life is sitting in those chairs. All right there. So thank you so much for what you're doing and thank you guys so much for letter us have the chance to talk. I was first diagnosed in 2007.

I was about 19, 20, going into my second year of college. A small town in Mississippi at the time and I was very lucky, very fortunate enough to find a dermatologist who immediately picked it out. I had never really had any symptoms of psoriasis prior and it came on like a light switch where I went from zero to 80, 85 percent coverage in about three months.

And of course, you know, talking about the treatments, I was very lucky that basically he decided to pull all the bags of the trick. I was put on the systemic chemo drugs, biologics, UV therapy, steroids, every kit and caboodle you could imagine all at the same time.

And of course, you know, the -- side effects of that right are pretty intense. A lot of sickness, a lot of missed days of school. Kind of debilitating. But ultimately it took about two years for that to get clear and ever since the -- I was on oractiva (ph) which got pulled from the market. I have been pretty consistent on the biologics and steroids. Of course I've had the opportunity to now cycle through I guess about three, four of them. So there have been changes, you know.

From my experience, my journey has been that the biologics have really helped. You know, it’s really cleared me up for, you know, for at least 70 percent of the time. I’ve had flare ups here and there but they’ve really helped the skin challenges, the problems at bay. It never stops the itch, it never stops the cracking or the bleeding, you know.

All of the things that were talked about earlier but for me it’s really been a huge benefit and a huge value add to go through and at least relatively be able to lead a normal life, you know. I would like to say that I think that one of the biggest problems has been the downsides, you know. When we talk about the side effects and the fear and what that could mean, but also to the excessive costs and trying to figure that out. I know -- I single handedly bankrupted my family in college, my mom and them trying to help pay for my healthcare.

Since then, you know, we have gotten out of that and that’s been good but I knew going forward that, you know, you kind of have two options with this disease. One, you get to the point of accepting that it’s -- until we figure out a cure and that there’s never anything that’s going to disappear. You’re going to have to accept it. And you either let the disease control you or you control it as best you can. Use it as a way to become an advocate, to reach out and be a champion. So that’s all I got. Thank you, guys.

DR. EGGERS: Thank you very much, John. Thank you. Before Sarah gets on I’ve gotten the wink from Pujita that I am supposed to mention a few things before, and I apologize to interrupt this to mention these things.

One is that we have -- we put the public comment sheet back out there. If -- we had a lot of patients sign up for public comment. If you feel that you have -- that what your comment would have been -- has been expressed through our dialogue today, we would encourage you to consider whether you still want to make a public comment. If not, it might let some of the others who don’t have as much of a chance to speak today, give a public comment.

So we would then say you could go back out and look to see if there's some names crossed off, if we could add a few more names to the list. It doesn't mean that we can get to everyone. We will try our best. Please be appreciative of that and respectful of it. If you don't get to do the public comment today, if you didn't make the list, the docket is there. So I just wanted to make that point.

And also the evaluation forms. I had mentioned that we would be handing them out, they're actually -- there's so many of you here today we're going to leave them in the back. Please fill them out. It's very important to us.

And finally, we had one of our colleagues come up and mentioned skin tightness that we didn't really cover that today. So we might not get to that in the course of the discussion, but -- so this is a homework assignment for those of you that indicated skin tightness was one of your top three symptoms. If you could just jot a little something and submit it.

The National Psoriasis Foundation has a way, you know -- has something easy on their website to do that. Just send us what that’s like and why you consider that to be most important, because we didn’t cover it. With that, I am sorry Sarah to interrupt that and thank you Caleb. And now we’ll move on to Sarah.

MS. TRUMAN: Hi. Thank you so much for having me here today. My name is Sarah Truman. I was diagnosed with psoriasis about 20-something years ago when I was 18 and psoriatic arthritis about 12 years ago. But it’s very prevalent in my family.

My mother, my grandmother, my great-grandfather, a couple of cousins, and a couple of aunts also have it. So it’s very, very prevalent in my family. So it’s a very complex disease. As most of us know it’s not just psoriasis. For me I also have some comorbidities as well.

I’m also, as I mentioned, diagnosed with psoriatic arthritis. I have Fibromyalgia due to my disease I also have hepatitis and my disease has attacked my liver. I’m having problems with my eyes. I have hypothyroid. I have asthma. I have to take allergy pills every day because when I stress out now I break out in welts. That's something new for me.

I have migraines. I have numerous side effects from the medications I take. Insomnia because of the pain. For me, I also live with chronic fatigue, chronic pain. So what does that mean?

So for me a typical day on my medications is a pill about a half hour before breakfast, nine pills with breakfast, two with lunch, six or seven with dinner, checking into a hospital once a month for four hours or so to get my biologic. And that's a good day.

If I'm having bad days, so flares, more pain, more problems, more headaches I have to take extra medications for that. So it's a constant balance for me. I feel like I'm tied to my pill box all the time. And I pack them everywhere. So that's -- my purse is full of them, my backpack at work. It's a very much a pain and I'm young to have to deal with that. And it's changed quite a bit over time, you know.

I started with the -- I guess the weaker drugs, the things that were the least impactful to my immune system and that had the least side effects and moved up the scale. And they did that so I didn’t have to deal with the least amount of side effects and the drugs that would work the best for me without moving into some of those that had more powerful side effects. Unfortunately, none of those worked for me.

So I’m now getting ready to start my fourth biologic. I’ve also become immune to most of them after about 12 or 18 months so they don’t work for me. I’ve done things like split the Enbrel up and take it, you know, I think twice a week. For the Remicade I started at eight weeks, moved to six weeks. I’m on four weeks now. They’ve upped the doses as much as they can get.

The Remicade’s only working for two weeks and I stretch that as long as I possibly could because I know there’s only a finite amount of choices that I have for biologics at this time. The worst thing about all the medication changes has been like going through the loading doses. Sometimes you have to go through eight or 12 weeks of loading doses and then you have to wait another eight or 12 weeks to see if they work, so switching all these medications sometimes to find out if anything works, sometimes you're at, you know, five or six months.

And then you have to try something else again. And then try something else and it's very frustrating to go through, you know, or your skin's broke out when -- I guess I didn't say that to begin with. When I had my initial onset I was completely covered, probably more than 90 percent of my body. My hair fell out.

It was all over my face, my body, my genitals. It was everywhere. It was horrible. I didn't want to leave my house. I had to seek treatment for depression. I didn't want to leave my house. It was the worst thing I ever went through. The biologics have helped more than anything. I'm very thankful to have them. I wish we had more than those that are on the market to choose from.

The other thing that has helped, you know, I've been through the exercises, meditation, and diet. Meditation doesn't do much for me. Exercise, it's very hard to exercise when you're so tired that you can't even want to get out of bed. It's all you can do to go to work.

Your energy level is like a bank account and sleeping is like your deposits. So you have to really plan. So, for instance, I knew I was coming here this week. I was on Capitol Hill yesterday. I'm here today. I have a couple things to do tomorrow. I had to plan for that and for the last week I really had to not do anything and just do nothing but go to work and come home and sleep and rest for that knowing that I had to save all my energy for these couple of days. And that's how I live my life and it's very frustrating to do that.

And, you know, my -- as I said, my body becomes immune to things so that's also very frustrating. The one thing that I did notice in diet is I had to quit drinking all alcohol and that made a really big difference for me. Beer and whiskey and the hard alcohol, those types of things, are the very worst. Wine is the least impactful I guess. It can take me two hours to get out of bed if I have any type of alcohol in the mornings and it also is a big trigger for my skin and for the arthritis. So not to mention the mix with the medications isn’t good, but it really makes a big difference for me.

As far as the downsides for me, I mean obviously other than being tied to the pill bottle, just to take the Remicade, for instance, I have to take one afternoon off every four weeks and spend about three or four hours in the hospital to get my infusion.

The treatment itself takes about two and a half hours, however, the infusion clinic cannot order my bag until I’m on site because of the cost of the medication and the chance that something might happen between me calling and saying I’m going to show up and me actually being there. So sometimes it can take an hour and a half for the pharmacy on the Hill to mix my bag and bring it to the infusion clinic. So I’m up there, I’m waiting.

I had to take the day off of work. They bring it to me and then I’m there for another two and a half hours. I schedule my infusions on Fridays on purpose because it -- of the fatigue. I'm tired anyway but to actually receive the Remicade really wears me out. I fall asleep during my infusions every time and I sleep through the whole weekend until Monday when I'm ready to go to work. So that's really a downside for me.

It's also really hard on my personal life. I have three children and a grandson. It's hard to spend time with them. It's hard to spend time with my husband when he's, you know, ready to go on the weekends and I have to stay in bed. So that's been very frustrating, very hard.

Some of the things I would look for in an ideal situation would be -- I don't want something that lowers my whole immune system. We treat it like we treat cancer. It's -- you know, radiation and chemotherapy treat the whole body instead of the target and we're doing the same thing with this disease. We lower the entire immune system instead of just treating the thing that's wrong. And that's very frustrating to me.

I also want something that puts me in a

hundred percent remission. No matter what, I have not been able to get rid of the scalp and the face, and that's very hard. I manage a very large department for a big global corporation. I deal with a lot of executives and I don't like to wear makeup. Makeup is an irritant for me. Anything I put on the skin is and I constantly have like red spots on my forehead or my face or my scalp and it's very hard to deal with that.

So no matter all the biologics I've taken it doesn't get rid of the itch and it doesn't get rid of the burning.

DR. EGGERS: Any final comments, Sarah? I need to --

MS. TRUMAN: Wrap me up? Is that you're saying?

DR. EGGERS: No. No.

MS. TRUMAN: Okay. Something that would be more meaningful I guess is less side effects, potential for the liver, and mouth sores, and the immune system. Some other factors to take into account when selecting treatment is -- I always weigh the side effects and are they worth how I am and so --

how many bad days am I going to get in a month versus how many good days, and my bad days would be the flares or the pain versus how many days am I going to feel well, and that's ultimately what I have to choose to go with.

And as far as the information on the potential benefits of these treatment factors make my decision is -- you know, another thing is how much time goes into the administration of the medication and how much time it takes me to get the medication. And part of that is how much it helps my joint pain because I have the psoriatic arthritis as well.

Another thing I have to take into consideration, and I think Christina touched on this lightly when she talked about having children is, one of my sons is very adamant about adopting children because he does not want to have any to pass this on to his children because of what he's watched me go through and that's very heartbreaking as a parent to hear that he has made that decision and will not change it because he absolutely does not want to have a child and have them go through anything I've gone through because it means that much to him and has hurt him so badly to have to watch me. So that's very painful to know.

And things that I do to assess the treatments versus the side effects I guess. I do have my blood tests done every four weeks. I see a liver specialist. I have ultrasounds on my kidneys, my heart, my liver. I have liver biopsies done. And I do have confirmed liver damage, although that was from the disease, not the medication.

I have kidney infections every year that I have to deal with as a fact of life. I guess in wrapping up I really do not want to pass this down my genetic line and I would like to see something that would, I don't know, remove that somehow. I don't know how to do that. And I really want to see an autoimmune suppressant that doesn't suppress everything in my whole body. So …

DR. EGGERS: Thank you very much, Sarah. Thank you. Now we have Amy.

MR. VASQUEZ: Good afternoon. My name is Amy Vasquez. I'm married, 45 years old, and I have one child. I was diagnosed with psoriasis at the age of eight.

At that time, which was in the ‘70s, I was given ointments and cold tar baths which did nothing for the psoriasis that I have. I have severe plaque psoriasis and it covers about 90 percent of my body. There was nothing that I did not try. Ointments, lotions, topicals, phototherapy, summers at the beach baking in the sun, diets, herbs, acupuncture. You name it, I’ve done it.

I gave up hope because the treatments were always the same. Until my dermatologist suggested I try biologics. I decided to give biologics a try and it was like anything else, after a while they stopped working. I was on one biologic and it only worked for about three months. And while on another biologic it only lasted for about two years.

My psoriasis would start to come back. I would be about 60 to 80 percent covered by the time they stopped working. I am now on Stelara and prescribed topical ointments. I also try to eat healthy and exercise. Right now my regimen is working great. I no longer itch as much. No more scales. No more redness. I still have some stubborn spots. My condition is getting better. I go to the dermatologist's office to get the shot and blood work, which I'm not too crazy about.

I get frustrated because I have to take time off from work to go to the doctor's office to get the shot and then again, who wants to get stuck with a needle to get their blood drawn. I would like something long term, a long-term medication that would not lose its effectiveness.

I would also like a medication where I wouldn't have to go to the doctor's office to get blood work, a medication with no scary side effects. Ideally, a medication that could give me total clearance.

When I look at a medication, I look at how effective it will be, then I look at the side effects of the medication can potentially give me, and finally I look at the ease of taking the medication. For example, is it every two weeks or is it every 12 weeks. I don't mind the headaches, the nausea, the injection site pain. All of that is nothing compared to having clear skin. I think about the serious side effects every day. That's always on my mind. But I can't live a single day knowing that there is some type of relief out there and that I'm too scared to at least give it a try. Clearance and relief from this dreadful disease is most important for me because then I can live a normal life. Thank you.

DR. EGGERS: Thank you very much, Amy. And now we have Pashia (ph).

MS. GARDNER: Good afternoon everyone. My name is Pashia Gardner. I'm 36 years old, a branding consultant, a wife, and a mother of five children. I was diagnosed with psoriasis at age 23.

My psoriasis is located on my hands and feet, the hardest areas to clear according to my dermatologist. I'm currently using methotrexate and Humira to help treat my symptoms. When I first was diagnosed I was strictly using topical steroid ointments because my psoriasis only affected a quarter of my left palm.

But within three years it spreads to my

right palm and both the soles of my feet, in turn effecting my fingernails and toenails significantly. At that time, steroid topicals were not working to address these areas because it was too widespread. After consulting with my dermatologist I shifted to exclusively using Enbrel.

After three months on Enbrel with no positive results, my doctor added UV therapy to the regimen. This combination worked. My skin cleared up on and my nails grew back normally. Every change in medication has been due to a lack of response to the therapy.

The best results were initially observed with the Enbrel/UV therapy combination but this was abandoned during my third and fourth pregnancies between 2008 and 2011. Not because of adverse effects of the treatment, but because my psoriasis cleared up significantly during my pregnancies.

However, this combination was retried without success in 2012. Right now my psoriasis is uncontrolled with my current combination drug treatment. This regimen hasn’t helped with clearing my skin or with the inflammation.

According to published studies, this combination therapy showed great results in alleviating symptoms. But I haven't seen any changes in my condition thus far. I have been on this regimen for four months with no change.

My dermatologist recently recommended a different biologic and I am in the process of getting it approved through my insurance company. The downside of my current treatment is the monthly blood draws to check liver function and the cost associated with both the medication and the blood tests. Psychologically it affects me because I'm always anticipating adverse side effects that may be irreversible.

The ideal -- I believe the ideal treatment for me is something that completely clears my skin and restores my fingernails and toenails. The factors that I take into account when making my decision about a course of treatment include the response rate of others to the medication, whether it's a biologic or chemical drug, side effects of the drug, doctor's recommendation, and most importantly the cost associated with the medication.

When it comes to weighing the potential benefits versus the less common but serious risks associated with the treatments, I usually take into account the history of how well other patients responded to the treatment and the success rate of the medication.

Quality of life comes into play when making the decision to engage in a treatment with the less common but serious risks because now I'm dealing with other possible health issues. Unless a treatment is prescribed to be long-term, I'm not opposed to trying it on a short-term basis to see how my body responds to it.

If my psoriasis responds favorably to the treatment and it's something I should consider sticking with indefinitely to clear up my psoriasis, then I need to re-evaluate at that time the benefits and the risks of a long-term regimen. Thank you.

DR. EGGERS: Thank you very much, Pashia. And we have John.

MR. EARLY: Hi. Good afternoon. My name is John Earley. I am 62 years old and I'm an architect from Arlington, Texas, and the proud dad of a newly married daughter. Thanks to the FDA for providing this venue inviting us to this gathering.

I have had plaque psoriasis since the early '80s. In that time I have been through about every treatment available. In 1983, I moved to Texas from Maryland and found an excellent dermatologist who guided me through treatments from creams to light treatments to drugs and finally to what I am on now, which is a biologic drug called Humira.

My journey to this point was not an easy one. My wife was always concerned about the side effects of the treatments. If she felt the treatments were getting to me, she would not hesitate to say something. The treatments would work for a time and then the psoriasis would come back.

Going through the treatments caused me to miss work and in some cases disastrous side effects, especially when taking cyclosporine. My blood pressure would sky rocket and my head would hurt constantly. The end was a trip to the emergency room, the doctors thinking I was having a stroke.

After this and a short time on methotrexate, which just made me feel bad, my dermatologist told me there was nothing else that was FDA approved for treatment. I remember that day well. What was I going to do? How bad would my psoriasis get without treatment? What qualify of life would I have? How would I be able to do my job which requires a lot of interaction with other people?

And the next second after all this was going through my mind, my dermatologist, who I trust, started explaining to me about biologic drugs which target a specific operation in your body which causes psoriasis. He said they were starting a research study for a new one and would I be interested in participating.

The consent and waiver forms listed all these bad things that could happen to you. However, my wife and I decided there was no choice to participate in the clinical trial, the alternative was worse. Four weeks of no treatments due to the requirements of the clinical trial and 12 weeks on a placebo was not very pleasant.

My psoriasis spread like wild fire with constant burning and itching. My wife said my legs looked like mince meat. After the 12 weeks, they told me I would get the drug. Within 60 days after receiving the drug I was almost clear.

That was over 11 years ago and I have been pretty clear ever since, almost to the point I feel I have been cured. I took some photos of myself before I started on the biologic and get them out to look at them to remind me that I am not cured but both my wife and myself consider it a miracle.

I still get a patch once in a while but with over-the-counter cream it goes away. I have not experienced the side effects they say you can have and I don’t feel my immune system has been compromised. I have to give bloodwork every 12 weeks and a TB test every year.

I have to keep the drug refrigerated until I am ready to inject which is once every two weeks. The most time it takes in the injection process is to let the syringe get to room temperature I learned early and painfully not to inject with a cold serine. My biggest fear now is that it will stop working.

I have met people in my journey as a volunteer with the National Psoriasis Foundation that this drug did not help him or it worked for a while and then stop working, just like these people had said and/or that they had side effects.

I also know people that it has helped like me. I know that the drug is doing something to my body and think about the long term effects because I've been on the drug for so long. But using this drug for me has been a blessing.

The cost has been offset by (inaudible) and I am grateful for that. Although, finding the right insurance is a challenge each year because of the insurance companies treat specialty drugs. In conclusion, the most important things I have learned from over the past 30 years of having plaque psoriasis is be educated. Education, education, education. Not only for yourself but your family as well.

Find a good dermatologist, someone who has empathy but tells you like it is, and be involved. This is a disease of heredity and genetics, if not for yourself, for future generations. Thank you.

DR. EGGERS: Thank you again for the panelists. It is. It can -- It's so helpful to hear your stories that we can then build on to hear it. And we heard about those of you who are well controlled, the fortunate well-controlled and those who are not as well controlled and who suffer who have very, very complex regimens.

You all have complex regimens but to more a less degree. Will you agree, do you agree that we've identified folks that have really run a gamut of experiences that reflect you? Okay. Good. Lots of head nods there. So -- So, good you've done. You've done exactly what we were hoping to set the context. The second portion of the afternoon will look very similar to the first.

We're going to go through and talk about each one of these. We're going to start with some, a polling question. So, anyone need a clicker before we get into that polling question? Okay.

(Break)

DR. EGGERS: And I'll take this time to say welcome back to the folks on the web. We are reading your comments, and getting them in, and we appreciate your participation. I think we can go to the polling question.

We'll, we'll give you guys the -- guys and ladies who haven't had a clicker, a chance to answer. But it's, it's a complicated question. I won't read the drug names, because I would embarrass myself. So I'm just going to read through the top choices here.

Have you ever used any of the following medical products -- and by that we mean drug therapies, or medical devices, I believe prescribed that would come from a doctor's orders -- to help treat your psoriasis? We have another question that we'll ask a few other types of treatments. Okay, so A topical treatments; B oral or injected medications; C another prescription medication such as a pain medication, phototherapy, another medical like prescribed medical product, drug or device not mentioned?

And if you're not using any sort of prescription medical products choose F please. I'll give you some time. Choose all that apply. I have a feeling we may not be surprised by the answers that we're going to see, so.

Okay. Yes there is a lot of -- a lot of medical product usage here. Almost all of you having -- currently using, or have tried topical treatments, three quarters of you in the room with the oral, injected, and then phototherapy. Many of you have tried phototherapy. We have -- we'll have a question on that later. And some of you are not using any medical products. We might come back, and ask you some questions too about that as well. On the web?

MS. ANGELASANI: Very similar. We have all the folks that responded said that they use topical treatments, and then after that phototherapy was the most frequently used.

DR. EGGERS: After the topical.

MS. ANGELASANI: After topical.

DR. EGGERS: Then it was phototherapy, and then was …

MS. ANGELASANI: After that was -- actually phototherapy and oral, or injected medications are tied right now for second place.

DR. EGGERS: Okay, all right. Well, let's start with the oral or injected medications. We heard I think several different examples mentioned of different types of, of different products. So I think instead of going through step -- product by product we'll keep it general.

Again, what we're -- and mention, you can mention, which product you're on. But what we're really looking for is to clean out -- if a product works for you, what is it addressing well? If it doesn't work for you, what is it not addressing well? And then maybe we'll get to the downsides later.

So let's first focus on treatments that are working well for people, and what we want to hear is what they're working well for. So I see hand right here, and then we can go -- if you can state your name.

SUMMER: Okay. I'm Summer. I spoke earlier. But currently I'm on Remicade. And hearing

Sarah's story was exactly like mine. I actually drive a six-hour round-trip to get my infusions every six weeks.

I failed every other biologic. So Remicade is my last option, and has cleared my psoriasis, so I'm very thankful for that. I had it on the soles of my feet and the palms of my hands as I said earlier. But the psoriatic arthritis, which is, you know, it's not under control at all. So clearing one, but not the other.

And like I said I drive three hours there. Have to wait two hours, because they don't want to make sure I show up, because it's a very expensive medication. Sit there for four hours, and then three hours back home. And so that, and then three days after, you know, I'm sleeping most of the time.

DR. EGGERS: Yeah, okay. All right, thank you very much Summer. We'll go back there.

MS. ANDREWS: Renee Andrews. My son is the one that's 11, and he is currently on methotrexate injections, and Remicade infusions off label, because they're not approved on label. And we're at a point right now where they're working for the most part, but we're getting, you know, slight patches. And what scares me is we tried and failed a lot of the other biologics.

I don't know where we go from here, because there's not -- right now there's no approved on label that he can take. And it's -- and it's an expensive drug. So we're hoping for in the future that we have more choices if he does start rebounding, and the Remicade and methotrexate don't work for him anymore that we're hoping that in the future we have more options.

DR. EGGERS: Okay. So while we're there -- so let's stay with this, and we'll come back. Other kids or teens do you have a -- or parents of those do you have a similar experience on any of those products, or different experience, any experience on those products? Okay. We'll come back here, and then we'll go over here.

UNIDENTIFIED SPEAKER: We were on methotrexate and Enbrel. The methotrexate I find it gives little relief. The Enbrel did nothing at all.

So right now we’re back on methotrexate. He’s been approved (inaudible) so we’re going to see how that does for him.

DR. EGGERS: Okay. Thank you very much. And back here.

PJ: Yeah, my name is PJ. When my number three daughter was diagnosed as a teenager with both psoriatic arthritis and skin disease biologics have been around for a while for adults. But providers were extremely hesitant to prescribe biologics for anyone under the age of 18 regardless of the fact that there was a clear presentation of psoriatic arthritis, and a strong family history of early psoriatic arthritis onset going back multiple generations.

It was a real fight to finally get them to accept the idea that a clinical diagnosis of PA at the age of 17 would actually indicate the use of a entanercept, or another TNFA medication. Because it was either going to work within a fairly short period of time, or it was simply not going to.

It was a real fight that went on for a year and a half. Today she’s found out as time has gone by that actually another TNF inhibitor is more effective for her. But it allowed her to complete her education, to go to college and be successful, and today she's pursing a professional career in nursing. But all of those things would have been extremely difficult if not impossible without the intervention of disease modifying biologic medications available at a younger age.

DR. EGGERS: Thank you, PJ. Okay. We might come back. We recognize that this -- there's a lot of adults in the room, and we're hearing a lot of adult perspectives on, and experiences with the treatments. But we did want to specifically ask about the pediatric.

And as you go and encourage parents, or kids, or teens to talk about their experiences, please encourage them to write to the docket. It's very important for us to hear that. Okay. Let's go back to just any product, and if it's working well what it's addressing. Diane.

Diane: Okay. I take a biologic that totally clears me. But to get to that point during the usual method of getting approvals you have to start with the less costly or the most costly, and see what works for you.

What we haven't touched upon is the difference in people. Some people, TNF inhibitors do not work at all. Only the IL-12/23, or IL-17 work for them. I'm one of those people, but unfortunately the lesser expensive biologics that are out there are the ones that have been around a long time, and those are all the TNF blockers.

So it took about three years of my body fighting the disease, which can lead to comorbidities, because your body internally is fighting the disease. Puts pressure on your heart and everything else. It took a couple years to get to the point where I could take one that would clear me.

DR. EGGERS: Okay. Thank you.

TODD: Thank you. I'm on a medication that's working great for me for both the skin and joints. And that medication is Cosentyx. I also use Taclonex as a topical. So I'll keep it short.

DR. EGGERS: When you say it's working great for you let me follow up on something we were mentioning this morning, because I asked in the room if you're sitting here with -- maybe with clearing of skin clearance, but you're still sitting with either itching, or pain. When you say it's working great for you do you mean all of those aspects, or particular aspects that would be bothersome to you?

TODD: Well, I have minor pain in my joints compared to before. And my skin is I would have to say 99 percent clear, except for inverse psoriasis, which I use you know, my Taclonex on, and some other non-steroidal creams on.

DR. EGGERS: Great. It's really helpful when you say it works well to be -- to be concrete, and what's really working well, and what kind of change you're seeing, so thank you Todd. Okay, I think right here in the blue.

Sarah: Sarah.

DR. EGGERS: Oh. Oh. And then we'll go back there.

AMANDA: I wanted to speak -- I don't actually have psoriasis. My mom does. And I wanted to say something after hearing everyone else talk, so you can hear what is -- you deal with it in your family.

My mom has -- the TNF doesn't work for her. When you plan vacations you have to plan around what her psoriasis look like, because she may not want to go into a pool, or wear shorts. So you don't do Florida in the summer, because then you're just going to sweat, because she'll wear pants.

My daughter got eczema, and has extreme sensitive skin, and the first fear was she has psoriasis. And anytime a spot comes out that's the first thing you go to because you have a family member that has it.

The pain she feels from the cracks and the arthritis that stop her from doing things especially in the winter. And we live in Georgia, so it's not as cold. The heart disease, that's found in psoriasis patients. And last year she had a scare, where she had to go on heart medicines, because she might have had a stroke. She is not even 60 yet, and to think that you could die from something else because of this is extremely fearful.

She -- when she had pregnancy, which I think is something I think you should consider when women. A couple people here last night at the reception said when they were pregnant their psoriasis cleared up. Unfortunately for men you don't go through that, but if women if in -- during pregnancy have their psoriasis clear there's got to be something that they're producing to help clear that, that you might want to explore, look more into that may help more women broader across the board.

Also, why to say that, because of the medication she takes she has to pay $4500.00 every quarter, which some of it is paid back by the insurance companies, but she's on Kaiser. So you're stuck with one dermatologist, and one sort of medication, and that really, you know, halters any help, because the prescriptions are so expensive.

On top of that I wanted to thank all of you here, and the people I met last night. I'm truly in awe and impressed with all of you that you talk about this, because there are so many people that have it.

And now when I see someone I can automatically tell with a patch of that's psoriasis. And it just -- I'm really proud of all y'all. This has to be extremely scary for everyone to go through, so thanks.

DR. EGGERS: We agree. Thank you Amanda.

So let's take a few more -- we're going to meaty and important issues have been raised. Let's try to focus on specific aspects of the condition that are being addressed in our next few questions. Because we have time -- we have things that go into the decision making, like the cost factors, and the access factors. We have a polling question for that. So I'll ask for right now just to focus more on those issues. Do we have other folks? Okay. Yes, back there Diane.

DIANE: Yeah, I just wanted to ask -- well, I wanted to ask one question, and make one statement. My question was I'd be curious to find out how many people -- I'm participating in a double blind study right now on medications, and because I needed medication very badly and fortunately was able to get it on the study.

But I was curious to see how many other people were involved in double blind studies, or involved in the psoriasis research studies with the medications. And also my statement was, is anything done in the avenue of gene therapy?

DR. EGGERS: Well, I -- let's take the first question I think is a very, would be a very informative we were going to ask it later, but you bring up -- it's a good ask it now. You can -- a show of hands if you have participated in a clinical trial? Okay. So a nice active bunch. Thank you for participating in clinical trials. If we have time we'll come back, and explore that a bit further.

As far -- I'm not sure if we can address all the questions about what things are looking at. I'll look to my colleagues about the gene therapy. Yeah. We won't be able -- yeah. Yeah. We don't have the right experts here to address that, but it's a -- the question you raised is noted. So. Okay. So, all right.

UNIDENTIFIED SPEAKER: I for a while before being in a study today I was only using topical treatments. And among all that was prescribed to me it was Clobetasol and Clobex spray that worked for me, cleared up the redness, the plaque, and it minimized the itching.

I’m in a clinical trial now for Cosentyx. And I’ve just received my third injection, and on my second injection I -- there’s a very, very significant change, because the plaque has gone down. The redness has gone down significantly too. The itching is still there, but it’s not as severe. I mean, if you guys have been looking at me I’ve been scratching myself from time to time. But it’s the first biologic that I have ever tried, and it seems to work.

DR. EGGERS: Okay. Thank you very much. I’ll take a, a few more. Okay.

MS. TYSON: I’m Terry Tyson. I live in Atlanta. I’ve had the disease for 41 years, so I’ve had all of these treatments over various periods of time. But I’ve been on Enbrel the longest now. I’ve been on Enbrel for since before it was approved by the FDA. So I think that’s been 16 or 17 years now. That has worked beautifully for me.

I guess my concern over time would be that we do more to stimulate and promote the development of drugs and treatments that are going to attack the systemic nature of an autoimmune disease. I'm less concerned at this age I'm at now than -- you know, topical treatments are great, and we all need those, but what we really need are treatments and modalities that are going to attack the comorbid nature of the disease, and help prolong life span, and do other systemic things to deal with the really long-term nature of the disease.

I think one of the things we haven't -- we've heard a little bit of today, but not enough of, so I hope next time where there's a convening like this we hear more about is just that -- the very nature of the disease itself, and what does the nature of the disease then demand in terms of treatments and investments.

DR. EGGERS: Thank you very much. One more, and then we'll go to a web summary.

Lillian: Hi. My name is Lillian, and I've had psoriasis for 56 years. So of course I have tried everything as well, but currently I'm on Remicade and methotrexate. And the only things that have ever worked for me -- I was on methotrexate for like 20 years, and it worked -- it kept me about 80 percent clear.

And then the biologics came along, and my doctor thought I'd been on methotrexate way too long. So I went to Enbrel for three years, which did absolutely nothing, put me in a bad, bad flare, and it took me another three years to recover from that. And currently I'm on Remicade, which was working phenomenally up until last October when I started breaking out again. So I've added methotrexate back in rather than trying another biologic.

So the combination of methotrexate, and Remicade keep me about 95 percent clear. But the itching, the few little spots I have, which I'm grateful for the few little spots I have, I still itch like crazy on those spots.

DR. EGGERS: Okay. Can I ask -- so let's build up on this a more general question. When you're talking about your treatments are cleaning, or achieving skin clearance can you have a show of hands even if you're pretty happy with your treatment is it still leaving the itching? Is it still leaving any pain? Okay. That's very helpful. Can we -- what are we hearing on the web Megan?

MS. ANGELASANI: Sure. Many of -- similar stories. We had one participant who was on a biologic and then developed a rare near-fatal lung infection active histoplasmosis. And so because of that she wasn't allowed to take any amino suppressive therapy to control the progression after that. And so that's definitely affected her, because she doesn't have any options because of that.

And then other than that a lot of people have reiterated how they are living with symptoms, which are side effects of the drugs and so forth.

DR. EGGERS: So you're living with symptoms that are side effects of the drug. Let's take just a few minutes to highlight of the side effects you're facing just and, and -- so we can get as many as we can. We'll keep it kind of brief. What are the biggest side effects that are most bothersome to you?

We've heard other downsides, but now let's focus on side effects.

UNIDENTIFIED SPEAKER: It's not currently bothersome to me. But I tried Enbrel. It cleared my skin, gave me near a fatal respiratory infection. I was in the hospital for 10 days.

DR. EGGERS: Okay. Okay. Others. Oh yeah. I don't think we have any -- no mics on this side, so okay. One second we'll go here for (inaudible).

DIEDRA: All right. I -- about two or three years ago I could barely get out of the bed and walk. In fact I went to this doctor, and was basically told that I was probably need knee replacements at some point. At that time -- I do have both. I have psoriasis, and psoriatic arthritis.

At that time the psoriasis part of my disease was very well under control. It was very mild. I took Enbrel, and the Enbrel was almost like a miracle drug as far as joints. I could walk; I could move. It was as if I didn't need a knee replacement, or anything. I could function very normally.

The bad side effect that I'm still coping with though is that the skin condition worsened. So I went from having a very mild form of the disease to a very severe form of the disease. So now trying to get something that will manage that has been the problem that I face.

DR. EGGERS: Okay. Thank you. So we had Caleb here. Oh, Kendall. Let's let Kendall ask a follow-up question.

DR. MARCUS: Yes, I'm curious how often that happens for people who have both psoriasis and psoriatic arthritis that the treatment seems to be unlinked, or that the successful treatment of one can lead to an exacerbation of the other. So if you wanted to do that polling style.

DR. EGGERS: Yeah. Yeah. Sure. Oh, so following up on --- and what was your name again?

DIEDRA: Diedra.

DR. EGGERS: Diedra. Following up on what Diedra say how many -- it address-- let's take first that it addresses the psoriatic arthritis but inflames the dermal aspects of it. Raise your hand please. Okay. I've been asked to count out the number of hand raises for the web. So about five of you. Web folks it's only going to be an approximation because I can't count that fast.

And then so the other way around, you found something that really has worked well for you dermal symptoms. But has either worsened, or not at all -- let's say worsened your psoriatic arthritis. Okay. We have about 10 I'd say here.

Okay. What about just it addresses your skin aspects but does absolutely nothing, but it doesn't worsen your arthritis. Okay. Okay. All right. Thank you. So we had Caleb here.

CALEB: Yeah. I just wanted to echo the statement a minute ago. You know, for me I think the biologics work really great on the visible aspect. But it's all of the invisible things that go on that's related to this disease that it doesn't get addressed, like the fatigue, the itch, the burning. You know, all of that, it doesn't get taken away. And I think being able to figure out how to address that is paramount to being able to like lead a normal life.

DR. EGGERS: Okay. Thank you, Caleb. We're going to actually have I think a polling question that will help tease out what would be meaningful for you. Jane, do you have a question?

JANE: Yes. Several people have brought up the fact that the skin clears, but the burning, or the itch is still there, and I wanted to clarify. Is it still there in the places where you still have a little bit of psoriasis left, or is it still everywhere?

DR. EGGERS: Okay. So how about in just specific areas is it still there? Okay, we have about ten -- five to ten. And how about it's still everywhere this underlying as was mentioned before -- Melissa -- as Melissa mentioned, where it's still sort of all body. Okay. About five, so about half. So, thank you, Jane. Okay. I want to make sure we get to the other therapies too.

One that we wanted to ask a bout was phototherapy. We have about 40 percent of you in the room. So that's approximately 30 folks in the room, and several on the web. Can you describe any comments on how that's working for you, and whether you are using your own, as we heard from a gentlemen, one that's in your own home, or one that -- or if you're going to the clinic for that? Okay. We'll start with John.

MR. LATELLA: This is John again. In 1970 I built my own light box.

DR. EGGERS: Okay. You can also mention if you built one. Okay. We'll put that in.

MR. LATELLA: The reason I did it, because when I went to a dermatologist, she said the only thing available was a light, a single light. He says the problem was if you expose one side of your body, then you expose the other side of your body you have danger of burning yourself.

So I said let me think about this, and I built a superman box, what I call it. It looked like a telephone booth, lined it with aluminum foil, put two bulbs in each corner with a 45 degree angle, put an industrial timer on it, and would use that to go in there daily to try and clear my psoriasis.

It did work on my upper torso. But unfortunately I had bronchitis, within 24 hours it was all back.

After that, several years later I went to PUVA, and as explained by some of the people on the panel, they didn't tell me what the side effects might be down the road 15 years. And since that time I've had nine biopsies, and at least four operations to receive to remove basal carcinoma. But I still have to be checked by a dermatologist every time I go there.

I think if people had in home light boxes they would be more used than if you have to travel. I used to have to travel an hour to take PUVA. And the first exposures were like 20 seconds. And I'd have to travel another hour to work. I get up at 5 o'clock in the morning to do this. And I had to do it three days a week. I did it because I was hoping it would work.

DR. EGGERS: Thank you John. One more comment on the phototherapy. Yes.

MELISSA: I actually don't use phototherapy. I'm in a study. And since phototherapy does help -- I don't want to skew the study. Anyways, I have a brother that's -- that does phototherapy. And he's a vet, and because of that -- and a college student now he doesn't qualify for a lot of -- or insurance-wise for medications. So he does do phototherapy five days a week, and it does help. But if he goes two days without doing it it's all right back again. So it's -- it works for him if he does it every single day five days a week at least.

DR. EGGERS: Okay. And other folks, does this resonate with you about the temporal aspect. Okay. We're having a lot of head nods for that. So thank you for that point. Okay. We'll take one more on phototherapy, and then we'll have to move onto other types of treatments.

MS. TYSON: Terry Tyson again. So one thing I'll say about phototherapy having had it for many, many years -- when there were no other therapies available that's what we did, right? And so I've had skin cancer twice removed as a result probably of that. But who really knows, right, what causes these things.

The one thing I will say about phototherapy, and I'll just reiterate what I said before is that if we solve the external manifestation of the disease with phototherapy how do we know that the internal manifestation of the disease is really being resolved?

So my concern again is that if we allow insurers to support these external therapies without requiring the internal therapies that would benefit all of us are we really doing a service to people with the disease.

MS. EGGES: Thank you. Okay. Feel free to clap anytime, anytime. And that -- the webcast folks can then hear that you're clapping.

So the prescription medications, we didn't specify which ones. So can I -- if you feel comfortable just a show of hands how many of you are a pain medication? Are there any types of specific pain medications you'd want to get a show of hands for? Just pain in general? Okay. Well, how about -- can we ask about for anxiety or depression? Okay. Were there others -- just briefly, any others that -- so not one of those two that you said for an other prescription medication? Okay. Right here.

UNIDENTIFIED SPEAKER: Sleeping pills. I've been taking a sleeping pill since I took prednisone eight years ago. One. Three weeks on prednisone, and I've been on sleeping pills for eight years because of it.

DR. EGGERS: Okay. All right. Thank you. So let's put -- a show of hands. So something for -- to help with sleep of any kind. Okay. So a handful of you, about 10 of you, or so. Any other prescription medications to address things that you attribute to psoriasis? Yeah.

UNIDENTIFIED SPEAKER: A lot of us who have been around for a long time have been using prescription antihistamines. The most popular one that was -- is usually prescribed in dermatology inpatient clinics is hydroxyzine. The brand name is atarax. Generally speaking most patients would start at five or ten milligrams. And it helps to calm down the itch quite a bit. But a side effect is that it makes people very, very sleepy.

It is true that if you take it consistently for several days eventually that sleepiness will subside to some extent. The problem with it is that the longer that you take this medication as a maintenance medication to control itch especially for instance if you go to sleep people scratch in their sleep. They don't even know it. So they may be able to control it during the day, but you wake up in the morning, and you're covered with a bloody mess, because you tore off the gloves that you were wearing to try to protect your body.

So by over time that dose needs to increase. So at this point somebody like myself who's been treating this for over 40 years, you know, I'm at about 50 milligrams of atarax on a daily basis as a maintenance dose just to keep myself being able to concentrate, and function and pay attention without being fully distracted by that particular symptom.

DR. EGGERS: Thank you very much. Can I ask if there's any specific -- before we move onto the question, anymore about specific medical products or prescription therapies that you'd want to ask about, or aspects? Okay. Yes. Kendall, please.

DR. MARCUS: One of the choices is other medical products not mentioned. And, you know, I think we’ve heard about the prescription medications and I the hydroxyzine falls into the category. But I’m curious if people could mention specific others that haven’t been listed there.

DR. EGGERS: Okay. We’ll come back.

DR. MARCUS: I don’t know if that -- yeah. Phototherapy is up there, so I guess I’m a loss as to what the other medical products are.

UNIDENTIFIED SPEAKER: It’ll come on.

MS. EGGES: It’ll come on. They are really temperamental today. This is more than usual. Oh. There we go.

UNIDENTIFIED SPEAKER: Yes. Okay. I think the correct name is occlusion. And what that was they basically put like tar all over me, then they put me in pajamas. Then they wet the pajamas. Then they put me in a plastic suit, and I would sit in that for eight hours, and then I would do light treatment.

This was back like high school, college. And I would do that treatment for -- what is it? Okay. That’s the name of it yes. So I would do that for like four weeks at a time on like my winter break for school. So that's another medical treatment that I use.

DR. EGGERS: Okay. We have back there. We'll go to.

UNIDENTIFIED SPEAKER: There's two things that I've tried before. I had a similar thing that I did with my scalp with peanut oil of some sort. And it was like a couple hours. Not as long. And then I found like moisturizer really helped specifically with your urea, and lanolin, or something like that.

DR. EGGERS: Okay.

UNIDENTIFIED SPEAKER: But it's very temperamental which ones.

DR. EGGERS: Okay. We have lots. Okay, go ahead

JODI: Is it -- is it on. This is Jodi. What about other stuff? Like I go through so many band-aids that at any point in time I have probably 30 of them on me because of bleeding, and covering, things like that. Post op boots that I wear that help when it flares on my feet. Gloves. Everywhere I go there's a glove for me to put on. So I'm always buying stuff like that. And that helps a lot.

DR. EGGERS: Okay. I think the next polling question is going to get at these things. So let's see. Let's take three more. We're going to go right here, and then here, and then and then Pagida.

PAGIDA: It's okay. I tried the eczema laser, and what I found with that is the people that actually gave that laser, the laser, didn't really know anything about it. And I went for -- I have severe foot psoriasis, and it basically doesn't work for that. And like they had no idea what it really worked, if it did or it didn't. So it was a failed therapy for me.

DR. EGGERS: Okay. We'll go to Tammy and then we'll go to Pashia. And then we're -- I think the next point -- I can't speak without the mic. So, go ahead Tammy.

TAMMY: I also had the eczema laser for three time a week for three months with -- on my scalp with no change.

PASHIA: Now, someone mentioned prednisone. And I was on prednisone for something else other than psoriasis. But what I found that it totally cleared up my psoriasis. My nails grew back, and my toenails grew back. And the inflammation and the scaling, all of that cleared up when I was on prednisone.

Now is there -- I know prednisone is like a great drug, but you can't be on it long term, and the side effects are crazy. But is there something, you know, that could be developed, or is in the making, or along the lines of prednisone what the ingredients are because there's something in prednisone that works. And just to kind of pinpoint that would be great. Thank you.

MS EGGERS: I think you've raised a very interesting question that we won't be able to address today. But it is noted that there is a desire for something that could address symptoms is that way. So thank you, Pagida. Let's move to the polling question. Next one. I'm sorry. We have so much to -- so much to cover today, and we would love to have everyone be able to get all of their comments in.

So I'll put another plug out for the docket. It is really important. Follow up on these specific medications especially the prescription ones. Just tell us your experiences please. But besides your drug therapies what else are you doing to manage any symptoms that you experience because of your psoriasis. And you can check all that apply.

A, Dietary and herbal supplements; B, diet modifications; C, over-the-counter products; D, complimentary or alternative therapies. Some other therapies that have not been mentioned yet, or if you're not doing, or taking any of these sort of not -- other than drug therapies to treat your symptoms. You can do current and past. Okay. All right.

So the most here is the over-the-counter products. I think we heard about some of those, the coal tar, the Epsom, the complimentary alternative therapies, some large number of other therapies. And some of you have mentioned the dietary modifications that were mentioned before. I think Diane over lunch she mentioned MSG and sugar as being something that she has to avoid.

We not might have -- oh, I can tell you we don't have a lot of time to cover into every one of these. But is there something in particular from this list that you'd like to explore? I would personally -- just without going into too much detail what are the complimentary therapies since over a quarter of you have said those. Just what are they, and briefly are the working, or not working generally? Okay, back there. First, we'll go here to Diane.

DIANE: I had a statement about the -- it wasn't on the complimentary although it may be complimentary. But another therapy that I have done, I used to go up to a lake in New Hampshire every year. And when my psoriasis got very bad I would go up and soak in the lake every day. And it wasn't necessarily Epsom salt, but it was the minerals in the water, it cleared me significantly when I did that on a daily basis.

DR. EGGERS: Thank you very much. Okay. We'll come over here.

MS. PRATT: Okay. My name is Jennifer Pratt. And I had gone to a doctor and got -- well, first the first question, the complimentary, or alternative therapies. Right now, I'm doing acupuncture, which helps a little bit, not necessarily with like any skin psoriasis, but with pain. So but I don't know that I like super encourage that. I don't know.

Anyway, I'm not sure yet if that's effective. But seven years ago I was sick of trying to figure out why I was in so much pain, and how to help my psoriasis. So I did a cleanse, and at the end of the -- so for three weeks I didn't eat. All I eat was fruits and vegetables, and a supplement. And my pain went away, and my psoriasis started clearing up, and I didn't itch anymore.

So after those three weeks I added -- I was like okay well I guess I'll just eat normal food again. So I added wheat back in, and then it hurt my stomach so I left out the wheat. And then the next day ate a lot of corn. And my psoriasis, like my skin itched almost immediately.

So for the last seven years I haven't been eating corn. And almost all my psoriasis is gone. Like I have one little patch that's barely like came back. So anyway corn is a big thing, and that's a reason why I’m nervous to take any sort of medications because most medications have some sort of corn as filler in them. And so I’m nervous that I took -- I also have psoriatic arthritis, and so I’m nervous that if I took some sort of medicine to help that it would make my psoriasis come back.

DR. EGGERS: Thank you very much. Let’s go to Clarissa.

CLARISSA: Oh yes. Thank you. I’m looking at alternative therapies, and I have found that consistently salt therapy works. The Epsom salts -- this lady was talking about that -- it works particularly well if a person is really itchy, or they’re hurting really bad to soak in a tub with about four cups of Epsom salt. And then in conjunction with the phototherapy. It works great. It works great.

DR. EGGERS: Okay. Thank you. We can have one more, and then we’re going to -- we have a couple other topic to address. So we’ll go right here. You had your hand up next. I forgot your name.

DAN: I’m Dan.

DR. EGGERS: Dan, thank you.

DAN: So summers are like the good time for me. The salt water, and direct sunlight. And my uncle also he lives overseas in Israel and he goes to the Dead Sea, which is also a heavy dead salt. And one thing that I wanted to mention also, and disclosure I work for this company as well. There's a company called PatientsLikeMe that does data collection. And also, like I've heard a lot of people talking today about emotional support, and peer support, and it's a global support group, so, I'm glad you mentioned it.

DR. EGGERS: Okay. Thank you, Dan. Okay to wrap up on the -- on the other drug therapies let me ask a show of hands questions that will give us a sense of your overall feeling about these other therapies.

So how many of you with a show of hands -- and on the web you can voice in as well -- how many of you would say that collectively your non-drug therapies, or life style changes give you as much, or more overall benefit as any medication? If you could raise your hand. Okay.

How many of you -- so I'm sorry. We have about five. Yeah, I think five. How many of you raise your hands please if you would say that you're doing one of these non-drug therapies and that they're important, but they can't match the benefit of the medications that you've tried. Okay.

We ask this type of question for the other disease -- the other conditions and we get very varying responses. So it's important to ask this question. All experiences are different, this different areas. Okay, so can I have a, a summary, any comments on the web about these non-drug therapies?

MS. ANGELASANI: Sure. We did hear from several participants that they go to the Dead Sea for weeks at a time. One person said she went for four weeks, and it kept her symptom free for six months. Other things mentioned include nutrition, controlling dairy and grains, mineral baths, juice from hot pepper leaves, Vicks Vaporub, turmeric vinegar tablets, Vitamin D. And then going back to the previous with prescription treatments we also heard that cosentyx helped clear this person's psoriasis. Otezla was another one that we had heard. Vectical, or Vectical, and --

DR. EGGERS: Oh, we won't make you say what their names are. If I don't say it, you don't have to say it.

MS. ANGELASANI: And Clobetasol.

DR. EGGERS: Thank you. Thank you. This resonates with one point that was made earlier today in the morning about the -- I personally appreciate when you how -- when you try these things, and you hear about them working for people with psoriasis how you have to balance that with all the other things that people are telling you to try. I'm sure that is very difficult to try to balance and manage all of that.

Okay. We're going to move off and talk now about the kind of summarize -- move into some more global things. And I have a show of hands question for you to help with that. And so on the web please us ping us with your show of hands through the comments. So when you think about all your therapies together and where you are today, how many of you share John's perspective, and I think a few others on the panel that you still battle your condition.

You still, you know, you still deal with it, but you feel that you are managing it -- that it's pretty well managed, or you're managing it the best that you can expect. Show of hands if you agree with that. Okay. We have about 25 folks, roughly half of you. And so I'm going to ask the other side of this. If you can please raise your hand if you feel your condition is not in control or getting progressively worst that you're getting very little relief where you are today. Okay, the other half of you.

So we have half and half. And I think we've heard throughout the discussion what's symptoms are addressed well. We heard Sarah talk about, and others found that resonating about what they were addressing and not well.

So what I want to focus on is if you haven't heard a particular symptom already yet mentioned that you wish -- one of those skin related symptoms that you wish was better managed in your treatment. What would that -- what is that? And on the phone if there's anyone who wants to contribute to this over the phone we'll ask you to focus on symptoms that are not well managed that you wish could be better managed. Would anyone like to address this? Okay. We'll start with Sarah.

SARAH: Yeah. I didn't bring this up very well earlier, but I think symptoms in the groin are not very well managed either. You know, they give you some topical thing that you put on your face, but it's painful. It's hard to put on. It's hard to administer, and what they give you really doesn't work.

DR. EGGERS: Okay. Thank you very much. Go over here.

UNIDENTIFIED SPEAKER: Sometimes another issue is compliance. Like for example I had scalp psoriasis, and they give you shampoo, or items to put in your hair. Well, I don't wash my hair every day. So sometimes compliance is an issue with different medicines.

DR. EGGERS: Okay, thanks. Right here.

UNIDENTIFIED SPEAKER: I would just add that male symptoms are very poorly addressed.

DR. EGGERS: Okay. Okay. We got a lot of head nods to that one. Okay, a couple more. Back there.

UNIDENTIFIED SPEAKER: The cracking and the bleeding on the feet. I mean, with stepping of course they're going to crack, but we don't have anything to soften, or to control the bleeding throughout the day. So like you have the bloody socks, or --

DR. EGGERS: Okay. We'll take Summer, then John, and then Theresa. Thank you.

SUMMER: Can you hear me?

DR. EGGERS: Yeah.

SUMMER: To go off what she said a little bit, since I have it on the soles of me the swelling, and so when my feet would swell from the arthritis the psoriasis would crack and bleed so, you know, the swelling in places where you have psoriasis when you have the arthritis that's a really big problem.

DR. EGGERS: Thank you very much Summer. And then John.

MR. LATELLA: This is a subset of psoriatic arthritis, is (inaudible), which is inflammation of the tissue at the skeleton. I don't think that's being very well addressed. I know it's rare. But people that have it are really suffering.

DR. EGGERS: Okay. Thank you John. And then Theresa.

THERESA: I was going to go back with the groin thing that I'm on a phenomenal biologic. It instantly started clearing up. You haven't approved it yet, but I like it. But the only issue I have it's still in -- on my lady parts situation. And nothing -- like a topical will work for a little bit. But it's something that almost has to be applied every day, and it is the tightening skin thing is the biggest issue with it. And so it does often, like crack and bleed. But a lot of the other topicals also are too strong there.

DR. EGGERS: Okay. Thank you very much. Do we have any folks on the phone? Okay. And if you're on the web you can just keep sending in those comments. Okay. Then we can take one more. Oh no, no wait for the mic. It's for the webcast to hear.

JENNIFER: I'm Jennifer. I don't think that the scalp is very well addressed. I feel like the scalp is a completely separate entity from the body, and that a lot of times when the body clears the scalp remains as problematic as it was from the beginning.

DR. EGGERS: Okay. A lot of head nods on that. Yes. Okay. So now any questions before we move on about symptoms, about being better -- address that you want to follow up on anything you've heard so far. Hansam (sic). And turn your mic on please.

HANSAM: I'm curious about that question earlier from Pagida on prednisone. That's a corticosteroid. And it has been for quite a while that topical corticosteroids were also used under occlusion. It seems that that's not much use these days. I would like to know how many people using topical --

DR. EGGERS: Topical corticosteroid.

HANSAM: -- under occlusion.

DR. EGGERS: A topical corticosteriod for what?

HANSAM: Under occlusion.

DR. EGGERS: Okay. You guys --

UNIDENTIFIED SPEAKER: We used to tell people to put saran wrap around. So if that sounds familiar it's when you put your steroid on then you wrap yourself with saran wrap.

DR. EGGERS: Okay, thanks. A show of hands if -- okay, so we have a dozen or so answering that question. Thank you so much, Hansam. Okay. Oh, yeah.

Okay. So let's move onto the next polling question, which ties into this a little bit. We're going to start to get into what symptoms could be addressed that would be most meaningful to you when you're looking at a treatment if you could say this is what I'm really looking to get out of a treatment.

This is the polling question that will help us get to that discussion. So when considering a new treatment for psoriasis, which of the following benefits would you consider to be the most meaningful. And here you can choose up to three. A, reduced scaling or flaking; B, reduced itching; C, reduced redness and inflammation; D, reduction in the number of plaques, E reduction in the number of pustules; F, reduced pain or soreness; G, reduced burning or stinging, or something other. And this would be in a treatment that addresses skin related aspects of psoriasis. Give it a few more minutes.

Okay. So let's see. We have the most being the reduced scaling or flaking, the reduced itching. It just goes down the line except for E and the reduction in the number of pustules, and then H would be other. For those of you that's other what -- what is it? What is your other? Okay. Sarah did one. Did someone else do another?

UNIDENTIFIED SPEAKER: Fatigue.

UNIDENTIFIED SPEAKER: Fatigue. Okay. Great. Another other. Diane back there.

DIANE: My other is, you know, the saying the heartbreak of psoriasis I passed it down to one of my children that I would like to see eliminated.

UNIDENTIFIED SPEAKER: Okay. Very fair point. On the web.

MS. ANGELASANI: We are seeing that they'd like to see reduction in fatigue, reduced side effects. One person said that, “It’s only meaningful if you’re able to treat all of it.” So she said, “I wouldn’t consider reducing itching to be a meaningful improvement if my skin was still flaking off. Or I wouldn’t consider a less time consuming treatment if it came at the cost of potentially severe side effects.”

DR. EGGERS: Okay. Okay. Thank you. And that is another very fair point. Then this web commenter is not going to be necessarily happy with the next question, which is the same question, but now we’re forcing you to choose the most -- what benefit you would most -- what’s one benefit that you consider to be the most meaningful if it could be addressed?

Reduced scaling or flaking, reduced itching; C reduced redness and inflammation; D, reduction in the number of plaques; E, reduction in the number of pustules; F, reduced pain or soreness; G, reduced burning or stinging; or H, something else, other.

I’m hearing a few grumbles in the participants. Maybe we’ll take that as a sign that this maybe a very hard question to pose. But you're bearing with us. Most of you have clicked on the clicker. Okay. Well, it's -- this tells us that as we force you to choose one there is a lot of variation within this group here.

With nothing overwhelming they've got the scaling, the flaking, and the itching. I think those have consistently throughout our conversation been the two that we've heard the most about today. So that's consistent. But we also have the reduction in the number of plaque, and the reduction of reduced pain, or soreness. And on the web.

MS. ANGELASANI: We have 30 percent of the folks who say reduced redness and inflammation. And then 25 percent say reduced scaling, or flaking, and 25 percent for reduction in the number of plaques.

DR. EGGERS: Okay, great. Anything here that you want to follow up on any of those? Okay. All right, well I think we'll take the web commenters point that it's hard to probably isolate any one thing. But this has been very helpful to us to kind of get a sense of what types of benefits are -- where you might put priorities if you had to -- if we had to make you put priorities on some things.

Okay. Let's move on. We have a scenario question. So this is a question, and I'll read this through in a second. But let me set it up for a minute. We're very interested in understanding, and we've heard some today about this, about how you approach these treatment decisions. As we saw you are facing these decisions over, and over, and over again.

And so we want to know what goes through your mind as you faced with a new treatment decision. So we have a scenario, and we're going to ask what first comes to mind, or what questions you might have about that.

This scenario is this. Imagine that a new injectable medication is indicated to treat moderate to severe psoriasis has recently been approved by FDA. And your doctor believes that you may be a good candidate for this medication.

In the clinical trials that were conducted the medication was shown to achieve at least 75 percent clearance of skin lesions in approximately one half of the adults who were treated with this product within three months' time.

Okay. The common side effects of the medication include fatigue, headaches, weight gain, swelling, sore throat, diarrhea, and upper respiratory tract infection. And the drug is also believed to cause rare but serious side effects such as liver problems, cancer, stroke, infertility, or birth defects.

So the question -- we threw a doozy at you. So the question is not -- it's just what first come to mind, or what first question would you be asking your doctor about this medication if this is all the information you were given?

UNIDENTIFIED SPEAKER: I would go right in the order you have that there because I'm in a situation that I've tried everything. So the word new is the only thing I see up there, because I have a new treatment. Then 75 percent I'm like 50 percent of them. A 50/50 chance that's a lot better than the other ones I've had and then the last one is, oh well. I have no choice.

DR. EGGERS: Let’s let Julie here.

JULIE: I would ask if any of my doctor’s other patients have tried it, and what their experience was and if I could talk with them.

DR. EGGERS: Someone. Okay. And the then put you over there and then we’ll come here -- up here.

UNIDENTIFIED SPEAKER: Of course, I would probably ask about the most serious side effects first. I would probably ask the number of people in that study that had those problems.

DR. EGGERS: Okay.

UNIDENTIFIED SPEAKER: Oh, I would ask how rare is rare. Because I’m not sure I’d agree numerically.

DR. EGGERS: Okay. Thank you. So we’ll go -- we’ll go with Carol, and then we’ll go to Sarah.

CAROL: This touches on a pet peeve of mine. I never feel like I have enough information. If 75 percent of half of the people cleared how’d the other half do?

DR. EGGERS: Okay. So what was the overall response rate across the population, not just those who we say responded well. Okay, we'll go to Sarah, and then we'll go to John. And then we'll come up here.

SARAH: I always ask how it will interfere, or interact with all my other medications.

DR. EGGERS: Okay, great. John.

JOHN: Oh. One of the first questions I would ask if this was kind of like what I'm taking now is specifically what percentage of the people that were in the clinical trial got the different side effects. In other words was it 25 percent, or was it 2 percent?

DR. EGGERS: And when you say the side effects do you mean those more common?

JOHN: All of them.

DR. EGGERS: All of them.

JOHN: All of them. I would want specific percentage information of the population of the clinical trial and percentage wise that actually got those side effects.

DR. EGGERS: John can I ask you how would you factor that into your decision?

JOHN: That would be pretty high. I think that, you know, I mean, you know, this is what -- this kind of brings back memories, because this the kind of language that was in -- other than there was a thing that might kill you know, when I was in a clinical trial.

But when you sign the waiver these were kind of the same -- exact same things that were presented to me, but, you know, again it's specifically I would want the -- it would definitely -- for me it would -- the percentage-wise, because if it's a small percent, you know, then you can at least analyze the risk. Now, if it's a high percentage I mean you may analyze the risk, and you still may take it depending on your current -- like everybody else here your current situation.

DR. EGGERS: Okay. Thanks a lot. Brian.

BRIAN: I would echo John's approach on that, but I would also add that we're not taking this medication to get rid of a sinus infection for two weeks. We're taking this indefinitely. So it's a little bit different situation than just looking at -- because every medication says those on the label.

DR. EGGERS: Good point John -- Brian. Thank you. Okay. Back there.

UNIDENTIFIED SPEAKER: I would ask if there was data on the other comorbid factors from the study. What kind of improvements were there for patients, or lack of improvement, and other comorbid factors with the disease?

DR. EGGERS: Okay. Thank you. I'll go to Caleb, and then we'll go to web.

CALEB: Yeah. Just to echo what John was assaying a minute ago. You know, what is the statistical significance of defining rare? And is it more rare that I'm going to have better luck getting struck by lightning than catching cancer from this, or do I have better luck catching cancer than getting struck by lightning?

And in which case to building off of what Brian mentioned a minute ago is what about the longitudinal effects? It may be statistically small that I might get cancer now, but what about 20 years from now. And I know that there's really no way to really test and validate that at this moment. But what are the comparisons between that, and what could that mean.

DR. EGGERS: Right. Okay, let's see what we're getting on the web for that.

MS. ANGELASANI: Okay. So a few people said they'd sign up right away. Others said no right away, saying there were too many side effects. But others said they'd want to know more information on safety, how frequently these side effects occurred. One person said when contrasting these side effects with the treatments they're currently on the side effects that are mentioned here are worse, so they wouldn't do it. And then they wanted to know how many people signed up for the study.

DR. EGGERS: Okay, thanks. We're not going to be able to address -- oh, Pagida. Well, one more.

MS. VIDA: Thank you. I would actually ask, because all of us we have different locations with psoriasis. And it says here 75 percent clearance of skin lesions. Now, I would ask like specifically where these skin lesions were, and how well they cleared up on the different spots on our bodies. So that would be my question.

DR. EGGERS: Thank you. Thank you for that. This is something that I'll put out if you can address this in your docket comments and put some thought into this. We can't give you much information. It's a scenario question. So we know that there are more questions. So if you just like a Jeopardy game give it to us in the form of a question about what'd you want to know more about.

That's really informative as we think more broadly about what needs to be communicated about these products. We have someone on the phone, so I'm just going to ask the phone to hold off one second. Let's go to next polling question. I think that -- Is the last polling question? This might be the last.

And we're going to read through this polling question, and once we get that finished we'll go to the phone for the phone caller. So we set up this to be able to ask this type of question. Thinking of -- there are so many factors that go into these decisions. We've picked a few -- however many pages of things that we would like feedback on.

So of these factors knowing that there are many other factors which two would you rank as most important to your decisions about using treatments to help reduce or control the spread of our psoriasis? So A, how the medication administered -- we heard some of that today -- B, the frequency in length of the treatment; C, your access to treatment. And here we're getting into the insurance and the cost issues that have been mentioned several times today.

D, whether the drugs showed effectiveness for you on the specific benefit, or benefits that are most meaningful to you. So is it addressing what you want it to be addressing? Even if it's addressing something else is it addressing that specific benefit for you, and how it did so?

E, the common side effects of the treatment such as risk of infection fatigue, etcetera; F, the possibility of rare but serious side effects such as blood disorders or certain cancers; G, your previous response to a similar treatment; and H whether there are still other treatment options in your arsenal that you can try, or conversely whether this is, you know, whether you're running out of options in other words.

Okay. We throw the hardest question last. Okay. So it looks like whether the drug showed effectiveness for the specific benefits that are most meaningful to you had the most frequent number of responses.

Of course, acknowledging almost half of you in the room here acknowledge the importance. It's one of the top two of the access issues for you followed by the possibility of rare but serious side effects.

I'm going to make a guess, E, the common side effects was not as frequently mentioned. One could interpret that being that you willing to tolerate some nuisance side effects for the benefit.

Okay. So let's go to the phone line if we can. Oh wait. I have to say something. Operator -- I really have to say this. Operator, can we have our caller please?

OPERATOR: I have Melissa, your line is open.

DR. EGGERS: Hello.

MELISSA: I had comments about some of the side effects. I was once covered at 90 percent. And I went into a drug trial that helped tremendously. The problem is, as I am (inaudible) and then I lost that ability to have that drug after the trial is over. I am now back to 90 percent coverage.

DR. EGGERS: Okay.

MELISSA: My comment is, you know, you guys were mentioning if you could get a drug that would be available by a trial what do you do afterwards?

DR. EGGERS: Yeah. That's a very -- and could we have your name please?

MELISSA: I'm Melissa.

DR. EGGERS: Melissa. Thank you, Melissa. You've raised a point that has been I think underlying in several comments that we've heard. And I think John wants to follow up on that comment.

JOHN: Yes, I had that experience when I was on clinical trials humira. They got approved by the FDA, basically when it got approved by the FDA the trial was over. And I have -- you know so what do I do? And so I was on a group plan at my employer's insurance. I called them. I said it had been approved. I wanted to continue on it. They denied me coverage.

First phone call from my dermatologist who is world renowned, and I expected very much, and I told him my situation. My next phone call was the National Psoriasis foundation, and they said you let us handle it. We will help you. And so, but the first call was what did it. My dermatologist wrote the insurance company a letter. I never saw the letter. I don't know what it said. But it was like within 30 days I got a notification that I had been approved.

DR. EGGERS: Okay. Thank you John.

JOHN: So.

DR. EGGERS: We won't be able to get into the topic. We welcome docket comments on this. Okay, one second. Okay. One -- so as we're making our way to that commenter over there let me ask just for a show of hands how many of you have faced the frustration that Melissa voiced over the phone, and that John first had before it got resolved. So how many of you have experienced that frustration participated in a clinical trial, or somehow had access to a treatment and then was taken away from you for lack of a better word. You can raise your hand. We'll just get a show of hands.

Okay, one back there. Okay. And just a show of hands, was it resolved the way John's was for you? Show of hands. So still not resolved. One -- you and back there. Resolved. Okay. So if you wanted to comment more on that please do so in the docket. We have one comment back there.

MR. BROOK: Hi there. My name is Michael Brook. I'm from UC San Francisco with the department of dermatology. And we do a lot of the clinical trials that we're discussing here today. And we put through a lot of these biologic medications.

So it's great to see all the support from all of you guys, and really hear a lot of heartfelt stories. And I want to thank FDA in general. I think this is a really important point to echo. And that when we do all these clinical trials, and we've got all these phenomenal medications that ultimately come to market a lot of our patients as we're hearing and seeing have a very difficult time getting those medications once they're out there.

So, you know, we've got all these people fighting behind the scenes, fighting here on the front lines for that. And you've got a great medication that nobody can really get access too once it's out on the market. We have a lot of patients that have to go through one, two, three, four, five steps before they get on something like cosentyx, or Stelara, or anything in between.

So I don't know how much pull FDA has in terms of that. But I know we were out over on Capitol Hill the other day fighting pretty hard to get that going. I just want to echo that support for all you guys.

DR. EGGERS: Thank you very much. Thanks. So we have my green alarm clock -- it's just luck that it was green for St. Patrick's day, but it keeps me on track. That's my biggest job really is to make sure that we stay on time. It's not the most glamorous job. But so it means we're going to have to wrap up our discussion. Before we do, any burning questions from FDA? Patricia, yes, please.

PATRICIA: In one of the earlier questions about treatments used there was a category where people had given up. What were some of the reasons for that?

DR. EGGERS: So not taking anything.

PATRICIA: Right. Yeah, for not taking any treatment.

DR. EGGERS: Okay. Anyone who did that, and want to quickly explain why you said that question, you're not taking anything.

UNIDENTIFIED SPEAKER: Thank you so much for that question. I am counterintuitively as a medical provider not currently on any treatments. And there's really a number of reasons for that. So, one, I have topical fatigue. I have spent 30 some years using topicals, and I know when I stop then I go back to where I was before.

I have done phototherapy for a while. I simply in my schedule do not have time to make that treatment effective. And I'm also a woman of child-bearing age. I currently have an infant that I'm breastfeeding. And I have over the last 10 years gone on and off of biologic treatments for that reason. And I don't have enough information even now to know what is safe, and that is the mom in me and not the scientist in me, because I know some of that information exists.

And then when you come off of treatments they become ineffective. And when you go back on them, and they're not effective again, and women really face that problem with pregnancy. And then the final reason actually gets to this polling question as well, which are the common side effects.

I have five young children at home, and I work with kids all day. When I was on biologic treatments I was constantly mildly ill. And it just got to a point of what am I balancing. And am I balancing the colds and fevers. I luckily had no serious side effects. But the balance then went into the favor of dealing with my disease without treatment.

DR. EGGERS: Thank you very much. Any other, Diane did you --

DIANE: Hi. I've been on a biologic for a long time, and it worked great. I had private insurance. This year January 1st, because I'm retiring I dropped the private insurance and now I'm on Medicare. Medicare will not approve what I've taken or any of the other biologics that might work. Only some TNF blockers that don't work for me. And I can't afford to pay for the biologic that are out there, so I'm on nothing, and it's starting to come back.

DR. EGGERS: Thanks Ellen – and I, I -- Ellen. Any other -- yes, we have --

ELLEN: Just with regard to marketed products if we could just get a show of hands on people who have had trouble getting access to marketed products because of insurance denial.

DR. EGGERS: So FDA approved products, right?

DR. MARCUS: Correct. No clinical trial.

DR. EGGERS: If you are on the web you would be seeing a large show of hands that’s maybe in the order of 30. So very good question. Thanks a lot Kendall.

Okay. We need to be able to move into the open public comment portion. So I will close out by expressing sincere gratitude for our panel members, and for those of you in the audience participating, and over the web participating today.

Thank you so much for all of your insight, your wisdom, your experience. It’s been very helpful, and a very -- I think very effective dialog today. Again, if you have more to say please do so through the docket. We do read through those. And with that I will close out this facilitated discussion portion, and we’ll move into the open public comment with Pujita. Thank you.

MS. VAIDYA: Hello everyone. I’d like to thank you all for coming today. We are now moving into the open public comments session. And for those of you who are not aware the purpose of this session is to allow an opportunity for those who have not had a chance to speak on issues that are not related to our two main discussion topics. So please keep in mind that we are not responding to your comments, but they will be transcribed and part of the public record.

Since we would like to be transparent in this process we encourage you to note any financial interests that you may have related to your comments. If you do not have any such interests you may state that for the record as well. So we've collected sign-up for the meeting, and we have 15 people signed up, and about 30 minutes for this session. So each person we'll give you about two minutes.

And we ask that you stick to that two minute time frame. I'll be keeping track of time here. And once I see that you are approaching the two-minute mark I'll need to ask you to start wrapping up. So I'll run through the order of speakers, and then I apologize if I mispronounce your name.

So the order is we'll have Dr. Ken Joller first, Carol Selby, Tammy Saretti, Melissa Leliu, Laura Lenly, Sharon West, Ben Lockshon, Michelle Johnson, Brian Lafrey, Jazmin Kercorian, Todd Bellow, Alicia Bridges, Nolia Farerra, and the Julie Cerrone. So first may I have Ken Joller to the mic. We probably need a mic up there sorry.

MR. JOLLER: All right. So thank you for the opportunity to address you here today. My name is Ken Joller. I'm the Executive Vice President and heading of research and development for Leo Pharma.

First of all, great, thank you for the FDA for putting this meeting together in patient (inaudible) development. But I think first and foremost and big thanks for all of you that have share your history with us here today. Signs and symptoms of psoriasis insights that I can guarantee you I've never come across in any of the books that I've been reading through my times in medical school. So thank you very much.

Leo Pharma is a company fully dedicated to dermatology. And about one-third of our pipeline is within psoriasis. We're fortunate enough four years ago with the help of the National Psoriasis Foundation to enter into a meeting very similar to this.

The feedback from the patients we met at the point in time was striking similar to many of the things that we've heard today. Among other things than itches one of the most bothersome symptoms of psoriasis?

Having heard that and cheered ourselves for being experts within psoriasis clinical trials that we had been running for more than 30 years we went back to see how often we have actually captured itch in our clinical studies. Not so proud to say, not once.

Now the interesting thing is psoriasis come from the Greek word spora meaning itch. So I think in the last 2000 years we sort of missed out on something. Now the passage goal that we use of course addresses many of the challenges that you've also highlighted today, the redness, the scaliness, the flakiness of the disease, the extent of the psoriasis disease. But it does not capture it. It does not capture the pain, the burning sensation, the fatigue.

Having listened to what you said today passage going and improvement in that it's only thing of helping psoriasis. Maybe it's only the tip of the ice berg. And that's why I think this initiative is so important. So make sure that we catch some of the important outcomes that we need to have in future trials to much better see if we make a real difference for people living with psoriasis. Are we basically providing more days of well-being? Thank you.

MS. VIDA: Thank you Dr. Ken. Next could I have Carol Selby?

MS. SELBY: Thank you. I have four points. The first point is I would like to ask that we please stop managing symptoms and start managing whatever the cause is because we can talk about treatments and symptoms all day long. That's my first point.

My second point, I would like to just throw out a few somewhat unrelated things that I have not heard mentioned that I have experienced. I have 58 percent oxygen efficiency with every breath I take because after 43 years of methotrexate I suffered a drug-induced respiratory failure last year, and I was intubated for a week. They had to restart my heart twice.

Number two, in 1989 I also nearly died. I had histoplasmosis, which is usually a very mild condition. I had it so severely that I was hospitalized for seven weeks.

Number three, I was -- for four years when I was young 100 disabled with pustular psoriasis. I have not heard much about that. It's not nice. Next point, I have squamous cell carcinomas from all the phototherapy I have taken. I have both PUVA and UVB. We have got to get to the cause and stop treating the symptoms.

Next point, I would like to ask some attention on clinical trial processes. I have never been well enough to survive a washout period, and participate in a clinical trial. And I suspect that's true of many in this room.

And consequently, we simply don't experience the advertised benefits of these drugs. I read these statistics. I have washed out of -- I've – excuse me. I have failed Remicade while simultaneously taking methotrexate. I have failed Enbrel while simultaneously taking methotrexate. I have failed Stelara while simultaneously taking methotrexate.

Next week I go onto cosentyx after a six month fight to get it. So that'll be number four. We'll see how that goes.

Finally, I am grateful for the Food and Drug Administration Safety and Information Cct of 2012 that brings us all here today, and that will bring the other 19 disease communities here to do a similar exercise.

I cannot adequately express how grateful I am to the FDA for bringing me, and everyone else, and my new friends here today. And I would just say that a lot of what we have collectively said seems to be if I'm reading body language correctly, surprising. And I would really hope that going forward that we continue to have a voice as new therapies, and God hopes a cure. As these things are researched please, please, please ask us back. Thank you very much.

MS. VIDA: Thank you Carol. Next could I have Tammy Saretti?

MS. SARETTI: I have microphonophobia so -- I've had psoriasis for the last 20 some years. Until this past June I was never clear. I went on cosentyx in June, and now I'm 100 percent clear, which is amazing because in June I had no hair. My psoriasis got so bad that I had no hair.

My inverse was so bad I carried packs of underwear in my car, in my purse, because I was changing all the time, because when you have, you know, under your arms and all the girls bits and every time you sit down you just start bleeding, and every time you stand up you start seeping. And your hair is following out in clumps you need everything with you, duck tape, masking tape, just a little bit of everything, a little goody bag.

When the psoriasis goes away when it goes into a medical remission, which means on cosentyx I could be six weeks from a relapse if I didn't have my medicine. The fear doesn't go away. I mean it stays. I mean this is, you know, I still live this -- this is my life. This could come back any time.

My biggest fear in the world is that one day that's all I'm going to be is psoriasis and psoriatic arthritis. There's going to be no me left. My family lives with this. My friends live with this. And I appreciate the fact that I got to sit here last night, and today, and talk to all of you people, and you guys get me. And I figured when I came here one person got me, then I would be thrilled. And I just want to thank all of you for getting me. And my hugs go out to all of you.

MS. VIDA: Thank you Tammy. Next, could I have Melissa Wool?

MS. WOOL: Hi. Thank you so much. I think the panel did a great job of addressing many of the problems that we face every day, and so many of the topics have resonated really deeply with me.

I would like to make a point of clarification about one thing in particular though. I think that we kind of glimpsed over the burden -- the emotional burden specifically in pediatric patients. And as a former pediatric patient I would like to advocate for better treatments.

Specifically to a child psoriasis means something different, and it's something that should not be overlooked. Psoriasis means long sleeves, long pants, and long scarves all year long. It means hiding. A clothing choice seems nearly innocuous.

But it’s it. It means feeling ashamed, and it means being ashamed. It means thinking twice before moving, or going out, or getting up in the morning. And it means thinking twice before being yourself. And no child should have to think twice before learning to express themselves. Thank you.

MS. VIDA: Thank you Melissa. Next could I have Laura Wenly, or Wevly sorry.

MS. WINELY: Winely.

MS. VAIDYA: Winely, okay.

MS. WINELY: And that’s my -- that’s my bad doctor’s handwriting. So I appreciate having been able to make comments as a patient. And I’m standing up now to make comments as a treating physician.

When I told people I was coming here today I was flooded by other providers and researchers who wanted to make comments on their behalf. And I think that’s really important for everybody to know. But specifically the Society for Pediatric Dermatology, the American Academy of Pediatrics section on Dermatology, and the Pediatric Dermatology research alliance.

What I want to do though is just briefly share my personal story, because I think that it highlights all of the points that they wanted me to make.

When I was diagnosed with psoriasis, severe psoriasis as a child over 32 years ago my treatment options were topical therapies, which took hours a day, light therapies which are very difficult on my family, and methotrexate, which had a lot of side effects.

Over 30 years later these are the exact same options that I can offer my patients. It is disheartening at best. That is that I have for them that is readily available. In addition, I think we all have the concerns of the pace of current approval of pediatric treatments.

Whether it's topical treatments, or systemic treatments, but many of our patients will run out of therapies, because they're going to have this disease for a long time. But I think there's a lot of people out there that are doing research. It's not that we don't have research. We do. It is just not led through the whole process yet, and partially that's because treatment for pediatric psoriasis it's still the numbers are smaller.

The population of kids is just smaller, and we're not necessarily getting to the numbers although as organizations we are certainly trying to provide as much of that data as possible to the FDA.

As there are increasing treatment options in adults, these treatment options we've heard today some of them are leading to 100 percent clearance. Much above the standard of the PASI 75 that is currently used in those trials. And the side effect profiles really tend to be better in some of the treatments as well.

But yet I still am disheartened that I'm no closer to being able to offer these options to the children that I see in-clinic. So I'm urging that there's a renewed focus on pediatric treatment options and to consider I think a few things that are unique to kids So one is that it matters if it hurts. And it matters if needles are involved in the treatment. It matters if they miss school whether it's for side effects or for their treatment options.

And it particularly matters to my patients that they know all these treatments are out there, and yet I can’t offer them to the patients and the families. Thank you.

MS. VIDA: Thank you Laura. And Sarah wants to say something really quick.

SARAH: Sarah again. Hearing the last two commenters brought to mind something a colleague had asked as a question during the lunch period, and I’m going to throw it out for the docket response. Either the past two commenters, and anyone else who’s going to comment on this.

The question was how many of you in the room, or people that you know get other pediatric -- people who had pediatric conditions to write the docket. Were you diagnosed, or did your symptoms really manifest before the age of 12. Before the age of 6, and in both of those cases what was the -- as an indicator of the severity what was the body -- percent body coverage. If you could answer those questions that was one thing that a colleague -- we’ll leave it for the docket, but it's one thing that a colleague brought up. So thank you.

MS. VIDA: Okay. Next, could I have Sharon West? Sorry.

MS. WEST: Hello. Thank you very much for this opportunity to speak. I have psoriatic disease since I was approximately eight years old. I have had all types of psoriasis. Different places on my body. And I have been treatments all of that we've discussed including – I don't know if anyone's ever had Grenz rays.

So when I was first diagnosed as an eight-year-old child it started in my scalp, in my years, and I used to get these rays that they said wouldn't go passed the skin. And it helped. And I actually -- had very good care. But I will say that having psoriatic disease has impacted my life deeply, and in all different ways. One, for me for career opportunities it a very unpredictable disease and it's a painful disease. And one moment it may disappear for some -- you don't even know what reason, and then it appears.

And so you're never quite sure what's coming around. So you feel very out of control. And I'll just speed it up a bit, and I do have psoriatic arthritis. It was in the original humira trial, and it put me into remission for five years, and then it stopped working as if all the psoriasis that was all over my body landed in my right foot.

And this has been -- I went through PUVA, soriatane, I've been on prednisone, you name it. And also I have psoriatic arthritis. And it is very painful. After being on Stelara, Remicade, Simponi, and Enbrel, which none of those worked. I'm finally on cosentyx, and I'm feeling a bit relieved.

But I will say that if I had to just say one thing after a lifetime of this really, painful, dreadful disease is that we need to educate the public and those who make vast great decisions for people with this terrible disease is that it is that. It is a systemic disease.

And that we need to get a little angry, and demand respect for what we go through. No one should have to be talked down to, other diseases, as diabetes, and other very serious diseases. The community, the world needs to know that this is fore -- first and foremost a disease of serious impact on our lives. Thank you so much.

MS. VIDA: Thank you Sharon. Next, could I have Ben Lockshon?

MR. LOCKSHON: Hi. Good afternoon. I'm Ben Lockshon. I come actually wearing a few hats, as a dermatologist, as a clinical researcher, and as member of the National Psoriasis Foundation. I'm on the board of directors.

So I want to first talk about the emotional impact, and something that you have all talked about, and I want to thank everyone for coming. But this is a condition that not only effects your skin and joints but effects your holistically as a person.

From intimacy, to our job, to making friends, to going to the pool, everyone is touched differently, but everyone is touched by this disease. I'm going to focus most of my attention about the – what the National Psoriasis Foundation has done to really help all of us out here.

For the last 50 years as you guys know the National Psoriasis Foundation has been the patient advocacy for the US psoriatic disease community. It's the largest charitable funder of psoriasis disease research worldwide. It is approximately by 2.1 million people annually through educational programs and services.

From the experiences you've heard today you can understand why we're relentless in our mission to find a cure for psoriasis and psoriatic arthritis to eliminate their devastating effects through research advocacy and education. And I thank all of you guys who are tapped into the national psoriasis foundation have experienced this.

When the FDA posted the notice on November of 2014 inviting organizations to comment on the next round of patient focused drug-development meetings we can understand why the MPF responded. We knew that it was very important for the FDA to have the opportunity to hear directly from patients like you guys about what this is like to live with psoriasis.

What it's like on a daily basis, you know, what you guys go through. Because many time when you’re within the walls of the NIH, or the FDA, or these research institutions you just see this disease process based on numbers, based on CASII scores, based on statistics. These are real people affecting every single part of what we do.

Our goal as the MPF as dermatologists, as clinical researchers is not only to find new medications but really to find new medications that are tailored to individuals and that might be based on genetics. That might be based on disease severity and symptoms. I’m hurrying up. I promise. I’ll be done in about 20 to 30 minutes.

About 15 years ago when I was thinking about a specialty in dermatology to take up I decided to focus on psoriasis, because I thought we were right at the point where we were making huge strides. And I didn’t realize that was just the tip of the iceberg.

When the first biologics came out just about 20 years ago now I thought this is going to change the world. And now with the various medications that we have I feel that we’ve got many tools to manage these patients appropriately. But as you can here from everyone else around here we're not curing everybody, and we're not meeting the needs of treating these diseases.

So on behalf of the National Psoriasis Foundation and the 7.5 million people living with psoriatic disease I want to thank everyone for the dialogue today. I look forward to submitting a written comment with the MPF and to the docket detailing the MPF patient survey data, and other resources were referenced that speak to the topics discuss and look forward to hearing the voices of the patient report that will come out this fall. So I thank everyone today for coming out.

MS. VIDA: Thank you B. So in the interest of time could you all please stick to the 2-minute mark, because we are running out of time, and do I want everyone to get a chance to speak. So next could I have Michelle Johnson to the mic, please?

MS. JOHNSON: Hello, everyone. My name is Michelle Johnson. And I work every day in a capacity under the federal regulatory for reliability for the electrical system of this country. And I consider that my service to all of you, and to the country.

And I want you to know that I'm able to do that, because of biologic drugs. I have had psoriasis since I was 13, and I was diagnosed with psoriatic arthritis at 31, which I probably had from the time I was 17.

And I'm here in front of you today, because I want to make a plea to you as a dermatologist that you are the frontline defense to the people like me who don't understand that there may be an arthritic component, but it is not what is culturally know as osteoarthritis.

Please let people know that stiffness welling, and in explained pain are the symptoms that you have with psoriatic arthritis. Mine went unchecked for probably 15 years. And now, I'm severely disabled, because the vertebrae in my back have torsioned so badly it's in a corkscrew. I pretty much can't sit very long. Any kind of millibar drops when a cold front comes through will affect the static pressure on all of my joints and cause severe pain.

And my employer does not understand that if they want me to fly up to DC in the morning and then come back that night the pressure differentials between the plane -- which feels great while you’re in it and getting off will wipe you out for next two or three days. So please if you’re a dermatologist let this be known.

Teach your patients this is what they need to look out for. It should’ve never taken this long for me. Number two, keep it up. FDA I thank you for allowing us to come and voice our concerns, and to listen to us. Researchers I thank you for being here to also listen, because these kinds of things being able to put this out there, and understand that these issues are out there. And we as patients deal with this every day.

We have a lot I think that we can teach each other, and I appreciate that. And number three patients, self-care. Please talk to your doctors. I know there a lot people who may be embarrassed to talk to them, or they don’t know what to ask. I know in the Facebook profiles and such I get a lot of questions from patients who ask me how did this biologic work for you? And I can tell you how it worked for me. And I, you know, help you if you want the assistance to chat about I, to just give someone else who understands. And another one is just stress relief.

A lot of indications that I had, I had fibromyalgia, I had CFS, I had all these different things that once I found out, and got on a good biologic for me all went away, and that was because of I was able to get on the right medication, get rid of whatever it was, unless it was just arthritic related, which it probably was.

And I just wanted to astound the virtues of meditation to you for stress relief. It really makes a huge difference. I have a hugely stressful job, stressful life, and I was able to finally put a lot of that aside. And because I was able to do that through meditation, and through relaxation a lot of the symptoms were to abate. Thank you.

MS. VIDA: Thank you Michelle. Next could I have Brian McCoy?

MR. MCCOY: Thank you for having us today, and for listening to our stories, and hopefully you've gained a little bit of insight on what it's like to be a psoriasis patient. I'd like to address specifically today the importance of treatment options with manageable side effects.

I've had severe plaque psoriasis for 25 years, and I suffered for a lot of those years, because I refused to go on anything other than topical medications. And the reason I did is because I watched my father when I was younger go through his treatments at the time where he was given the state of the art oral medications.

And after taking that for a period of time he lost his hair, lost part of his vision, lost his toenails, and he's about my size, and lost about half his body weight. So he ended up not taking that any longer, which I think saved his life. So the years that I suffered, and refused to go on anything else besides topicals biologics were already out.

Ten years ago I was diagnosed with psoriatic arthritis. And before that I was misdiagnosed to the point where they performed exploratory surgery on my hand where it first developed and all that did was basically create a new source of trauma for my psoriasis. I ended up diagnosing myself.

Went to my dermatologist, and he confirmed that. And that's when I finally made the decision to go on a biologic, which changed my life. So by doing that it restored my quality of life for me although every day I still wonder what the long term effects of that.

I have a 14-month old daughter. I have a son on the way. And I pray every night that they don't have to go through what I've gone through, and that I don't have to deal with them having psoriasis, as they grow older. I hope that if that does happen though there will be some treatments out there that are going to be manageable and don't have the side effects that we have in treatments today. Thank you.

MS. VIDA: Thank you Brian. Next, could I have Jazmin Kercorian?

MS. KERCORIAN: Had to adjust the microphone. Jazmin Kercorian. I'm a pediatric dermatologist here in Washington, DC. I'm lucky enough to take care of Xavion and his family. And it's been a real struggle as you guys have heard for a number of reasons.

And the primary one I think we've said, and it bears repeating is that nothing is approved for children. So everything is a fight. Just we find it miraculous that we got stelara approved. I still don't know how I did it.

But basically it was maybe a strongly worded letter, maybe it was an act of God, but that shouldn't be the way that we get medications approved for children. So I think it's very important that we really start to include children in clinical trials and that we then eventually actually get approval so it's not a battle every time, because there aren't that many pediatric dermatologists, and it shouldn't be that way.

There aren't always going to be access to us. And the children shouldn't have to suffer for that reason. Another major issue I think in treating children, and it's one -- I have a child that I imagine I would ask is the side effects are even more important when you're thinking about it for your child because you're making a decision on their behalf not making it for yourself.

And it's difficult when drugs are newly approved to really say well I don't know. We'll see maybe in 10 years if there -- something comes up that's challenges. And Laura talked to this a little bit, but the society for pediatric dermatology and the pediatric research alliance are looking at creating registries, and I think actively are in the process of doing this so that we can look at such questions. And I think that's really important to support.

So I really appreciate hearing from the patients that renewed my commitment to medicine just to hear this is why we do it. And we want to continue to help, and especially help our pediatric patients who have limited options at this time. Thank you.

MS. VDA: Thank you Jazmin. Next could I have Todd Bellow?

MR. BELLOW: Thank you. I just want to thank everyone. What more can I say than what I've heard today. So I don't want to be redundant, because we've heard just about everything about psoriasis, and psoriatic arthritis. So what I want to say is how it affected me financially, and early on when I was first diagnosed.

It knocked me from my knees and basically I went into debt about $50,000. So we since then paid that all back. But that's a huge -- on a family of four it's a, it's a huge toll to pay back, and you know, when I was first diagnosed there was no medications like biologics that we have today.

Basically I went to the Dead Sea to receive my treatment. I've been there twice. My mother laid out $10,000 for me, and I had to leave work for four weeks the first time, and five weeks the second time. So it was a huge burden on our family. I was a fireman. I was a volunteer soccer coach. I had to give that all up. I was active in my community. I like to do things for helping people, and this is why I do what I do. I have a support group. I talk to a lot of people. I have plenty of thanks, and owe my life to the National Psoriasis Foundation for what they do for us.

They're the -- they're the strong voice of this disease, and I want to see it continue. And I think I can speak for everyone in here that we thank you for listening to all our stories, and they are similar. And I find that when I listen to other people's stories they're very similar to mine. So it's very -- they had me in tears.

So the next time we have a meeting, please hand out Kleenex. And let's see. What more can I say? That's about it. I mean, thank you. Thank you National Psoriasis foundation, and thank you all the pharma schools.

And one other thing, the FDA, I want to say thank you for expediting the process of getting the biologics to us. Because when we hear it it's a victory for everyone in this room when there's a new product on the market, because we are failing other medications, and we can switch over to the newer medication, which might not work. Obviously I was on full biologics. I was on otezla, and now I'm on cosentyx. And that's about it. Thank you.

MS. VIDA: Thank you Todd. Next could I have Alicia Bridges? Okay, Alicia says we're okay. Nolia Fererra.

MS. FERERRA: Close enough. First I wanted to say that I have guttate psoriasis, and a lot of the new biologics don't cater to guttate, and it's very frustrating. So that'd be a nice thing to see more medication for that.

Another thing is I have psoriatic arthritis, and psoriasis, so it's hard to find something that works for both. So that'd be nice. And my final comment is thank you for having us, and I'm also amazed that so many people are here. We're living with this chronic condition. I hope that you know that it was hard for us to get on a plane for many hours to sit here for many hours. So it's amazing and I applaud all of you for being here. Thanks.

MS. VIDA: Thank you. And last we have Julie Cerrone.

MS. CERRONE: Hello. My name is Julie Cerrone. I'm a certified holistic health coach and an autoimmune warrior as I have psoriatic arthritis, and

I am a very outspoken patient advocate, but I have been pretty quiet today, because I really have psoriatic arthritis. And psoriasis isn't my main issue of concern.

And, you know, psoriasis is more than skin deep, and we really need to look at it from a psoriatic disease perspective and remember that is really effects so much more than the joints.

But there is something that we have not even brought up at all that I think is really worth mentioning, you know, that most if not all chronic conditions are -- have a foundation in inflammation, an overactive immune system most of our immune system live out gut.

Seventy-five to 80 percent of our immune system is there. So I really urge the FDA to be very cognizant about the food that you're putting out into our mainstream USA. Genetically modified foods, pesticides, what the fillers are that are in these medications. Are they invoking an immune response?

I had the opportunity to work with a pharma company who created a topical for psoriasis, and they said what are the other ingredients that are in your medication, and do they invoke immune response. And the woman who has been creating this drug for the last 10 years looked at me and said, that is something that we have never thought of. And that just blew my mind. You know, we need to decrease inflammation, so these things need to be addressed. So I just would like to add that. Thank you.

MS. VIDA: Thank you Julie. So now I'd like to call Dr. Kendall Marcus to the stand for our closing. Before I do that could I ask you all to pass your clickers to the two ends of the room and then we'll have folks pick those up. Thank you. And lastly, Dr. Kendall Marcus.

DR. MARCUS: Well, I want to thank everybody for coming today. I have to say this has been a really helpful experience for me. And I believe also for my colleagues.

Normally, I'm pretty good at jotting down comments to speak on the fly. This is something I have to do on the regular basis. But I have to say I've just been riveted all day, and I really didn't even try and jot anything down until the last five minutes. So I'd just like to say I really admire everybody's -- the courage that is must have taken to come and speak openly here today, and talk about things that have caused you a tremendous amount of frustration, anxiety, physical illness and shame.

And you strike me as just a remarkable group of individuals who are courageous with resilience, and resourceful. And I think that you've really put a face on the disease of psoriasis for here at FDA and not just a face. But you've really filled out what a life experience is.

And when you have psoriasis, all of the ways that it impacts your life, the impacts of the disease on your health, the daily impact it has on your life, the grandeur impact it has on your life decisions in terms of choosing careers and having children, your ability to engage in social relationships both intimate ones, and just in navigating the social world of having friendships.

You know, I think that these types of impacts can be lost on people who are regulating the products that are created to treat the disease when they themselves have not treated individuals with the disease. And I think you commented on the looks of surprise that you saw perhaps as an indication to you that there's not an appreciation of the disease impact here. And perhaps it would be worthwhile for all of you to understand a little bit about who we are, and what we do.

I'm curious how many people sitting in the room you understand the importance of engaging with the FDA, but I'm not sure how clearly you understand who we are and what it is that we do. But I'm the director of the division of dermatology and dental products.

We have about 36 employees, and that's just employees within our direct division. That doesn't include what we call our co-locates. We also work on regulation of drug development, and post-marketing safety. So we have about 15 medical officers. We have about seven toxicologists who work on what we call the non-clinical evaluations of drug products. We have a team of about 10 project managers. And we also work with clinical pharmacologists. We work with statisticians, and we work with scientists in our office of product quality who ensure the safe manufacturing of all of these drugs.

And when a product is first submitted to the FDA for regulation it’s assigned a team of a single medical officer, single medical officer team leader, a single toxicologist, a toxicologist team leader etcetera. And so a team is formed that regulates the drugs. So you can imagine it’s a small team, and they have everybody has a portfolio of products so they’re not just reviewing a single product. They are reviewing and doing the work across an entire portfolio of thermatologic products.

And our job is to ensure that drugs are -- that the companies design studies that ensure the safety of participants who decide to enroll in these studies. And that the studies are well designed to demonstrate efficacy, provide safety information, and answer other questions that are necessary to adequately inform patients and physicians how to use the drugs when it is marketed. Who it’s indicated for, what potential side effects it may have, what potential drug interactions it may have. We don't direct research.

We can't tell drug companies what targets they should go after. They can't direct drug companies to focus on a cure. We don't regulate that type of research. But what we can do is have an impact on trial designs. And, you know, one of the things that we talk about here is whether or not we still need placebo controlled trials.

And, you know, I've heard today from one person who participated in a clinical trial, the experience of having to have a washout period, and having to spend 12 weeks on a placebo. And I imagine that could be a significant barrier to psoriasis patients wanting to enroll in clinical trials.

So I have to tell you just hearing that type of feedback alone, you know, is very helpful for us a regulators, and understanding the types of trial designs at this point in the treatment paradigm of psoriasis when there are other treatments available in an acknowledgment of the fact that people enrolling in clinical trials may already be taking therapies that are impacting their disease even though not adequately, and the impact that, that might have. So what we've heard from you today I think has already been helpful in that respect. So I feel like I'm rambling.

I just wanted to just to give you a little bit of an idea of what role we have in drug development. I think it's been very helpful to hear particularly about the emotional impact that the disease has on people. And I think that that's also been an area that's really been overlooked in drug development, and clinical trials capturing the emotional impact that the disease has on patients and the impact that it's had on treatment.

We've already heard from someone from industry that they too have heard that other symptoms have not necessarily been adequately captured, or evaluated in clinical trials, those of burning, itching and fatigue. I would have to say I think today is the first time I've really heard of fatigue as an important symptom that has a significant on patients with psoriasis, and that this is not necessarily addressed with successful treatment of the disease.

I just -- I'd like to acknowledge the pediatric dermatologists in the audience and the pediatric patients who are also in the audience as well as their parents. And I just want to say that I've heard you. It's certainly something that we've spent a lot of time talking about internally. It's not anything that I can go into in any depth as a regulator. But again I would just like to say that we've heard you.

So I think that, you know, I think that what you've heard today really has already had an impact as I've just said. You know, we've heard from a representative from the pharmaceutical industry. You've certainly informed the way I think about clinical trials is science moving forward. And I hope that you all walk away from today understanding that while nothing necessarily is going to happen tomorrow change takes time, and product development takes time.

But I think you've already done a tremendous service to all patients who have psoriasis by speaking out really as the voice of all patients who have psoriasis. So thank you very much for coming today. We really appreciate everything that you've done and your willingness to speak to us. So thank you.

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

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

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3/31/2016 Jessica Bodreau