2023

JUVENILE HUNTINGTON'S DISEASE

Time is simply something we don't have. We are fighting for the day that the pain and suffering the children are forced to endure is lifted, because of new life-saving therapies and quality-of-life treatment options are finally available.

FDA PATIENT LISTENING SESSION SUMMARY

SESSION DATE: FEBRUARY 10, 2023

HELP 4 HD INTERNATIONAL

Contents

Session Attendee's

Session Presenters:

- Katie Jackson – Help 4 HD International
- Melissa Walschburger - Caregiver
- Angela Dealba - Caregiver
- Erika Eiger - Caregiver
- Jennifer Nerat - Caregiver
- Natalie Salazar - Caregiver
- Londen Tabor - Caregiver
- Holly Matthews - Caregiver

Listening Attendees:

- Katrina Hamel - Help 4 HD International
- Michael Sabado - Help 4 HD International
- Louise Vetter – HDSA
- Jenna Heilman – HDYO
- Shelby Lentz – Champions for HD
- Kristin Strazdins – HSG

FDA Attendees:

Office of the Commissioner (OC) – 3 *offices*

- OC/OCPP/PAS – Office of Clinical Policy and Programs/ Patient Affairs Staff *(organizer)*
- OC/OCPP/OOPD – Office of Clinical Policy and Programs/Office of Orphan Products Development
- OC/OCPP/OPT – Office of Clinical Policy and Programs/Office of Pediatric Therapeutics

Center for Biologics Evaluation and Research (CBER) – *2 offices/divisions*

- CBER/OCD – Office of the Center Director
- CBER/OTAT/DCEPT/GMBII – Office of Tissues and Advanced Therapies/Division of Clinical Evaluation and Pharmacology/Toxicology/General Medicine Branch II

Center for Devices and Radiological Health (CDRH) – *5 offices/divisions*

- CDRH/OM/DMS/AC – Office of Management/Division of Management Services
- CDRH/OPEQ/OHTIII -- Office of Product Evaluation and Quality/Office of Health Technology III
- CDRH/OPEQ/OHTIII/DHTIIIA -- Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology III A
- CDRH/OPEQ/OHTIII/DHTIIIC – Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology III C
- CDRH/OSTPI/DAHRSSP – Office of strategic Partnership and Technology Innovation/Division of All Hazards Response, Science and Strategic Partnerships

Center for Drug Evaluation and Research (CDER) – *6 offices/divisions*

- CDER/OCD – Office of the Center of the Director
- CDER/OND/ODES/DCOA - Office of New Drugs/Office of Drug Evaluation Science/Division of Clinical Outcome Assessment
- CDER/OND/ON—Office of New Drugs/Office of Neuroscience
- CDER/OND/ON/DNI – Office of New Drugs/Office of Neuroscience/Division of Neurology I
- CDER/OND/ORDPURM/DRDMG – Office of New Drugs/ Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine/ Division of Rare Diseases and Medical Genetics
- CDER/OTS/OB/DBIII – Office of Translational Sciences/Office of Biostatistics/Divisions of Biometrics III

FDA Patient Listening Session Goals and Topics:

We hope:

- The FDA will have a greater understanding of JHD.
- To provide the FDA with the patient perspective for JHD to consider for regulatory decisions.
- To help the FDA understand the risks the parents are willing and not willing to take when it comes to their children participating in clinical trials.
- To create an understanding for our JHD community that the FDA does care about JHD and understands the urgency.

Meeting Topics:

- JHD symptoms
- Difference between JHD and adult-onset HD
- Symptom differences in siblings with JHD

Clinical Trials:

- The most burdensome symptoms of JHD that are the most important to families to find treatments for and the impact on the child as well as the caregiver.
- How the parents feel about the lack of clinical trials for their children and the risks they would and would not be willing to take for their children to be part of a clinical trial.
- If a treatment or therapy is approved for adult-onset HD, could there be a way that the approval could be for broad spectrum HD: JHD, prodromal, and adult-onset to eliminate years of delay for these subpopulations to get access?

Survey

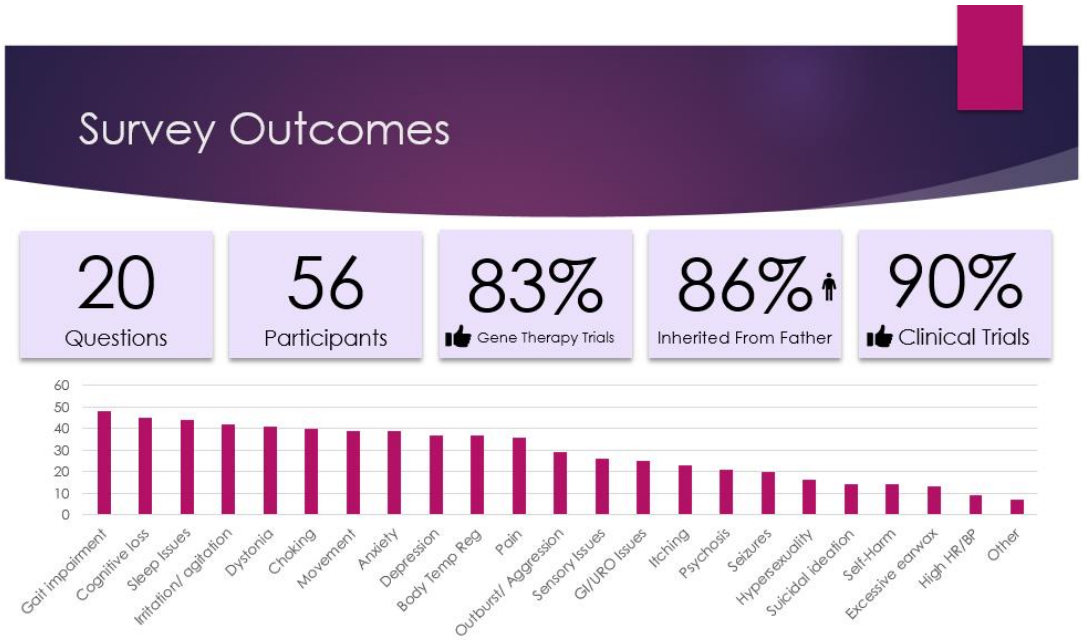
In preparation for the Patient Listening Session, Help 4 HD International put out a 20-question survey for families impacted by Juvenile Huntington's disease to participate in.

The 20 Questions that were asked in the survey were:

1. Gender
2. Age of Diagnosis
3. CAG Repeat
4. Inheritance from mother or father?
5. Number of siblings at risk?
6. Number of siblings diagnosed?
7. Multiple choice of symptoms to identify your child has experienced.
8. If there was a clinical trial available for your child to participate in, would you be willing?
9. If the clinical trial involved a more invasive approach like brain surgery or spinal injections, would you want your child to participate?

10. Would you have your child participate in a gene therapy trial like stem cells, CRISPR, or any biologic therapy?
11. If your child has experienced seizures, have you had trouble finding a medication to help your child with the current medications available?
12. Comments for above question.
13. If your child suffers from seizures, how many medications have they been on that have been ineffective?
14. If your child suffers with dystonia or dystonic storms, are current medication and therapy options helpful?
15. If your child experiences pain, have you found the current pain medication options available helpful for your child? If not, how many medications have you tried?
16. If your child suffers from sleep disturbance, have you found the current medication options available helpful? If not, how many medications have you tried?
17. Does your child experience falls and injuries? If so how often?
18. Has your child been hospitalized? If so, how many times?
19. To help families in the future, can you list what medications you have found helpful and for what symptoms.
20. Contact

For a full report of the data collected from this survey please contact Katie Jackson at Katie@Help4HD.org. This survey remains open to continue to collect data to continue to support the JHD community and any future clinical trials that include children with Juvenile Huntington's disease.



Huntington's Disease Organizations Statements of Support

Huntington's Disease Society of America: New York, New York -- Juvenile onset Huntington's disease (JoHD) is the tragedy of Huntington's disease magnified by the loss of childhood and adulthood. Unlike adult-onset Huntington's disease, which robs function from an individual in the prime of life, JoHD steals lives early, denying them the hopes and dreams of independent lives.

The current tools for developing new treatments for Huntington's disease have limited application to JoHD community. The symptoms of JoHD are different, challenging the utility of today's clinical assessments. The disease progression is accelerated, requiring a unique risk benefit ratio and shorter, more innovative approaches to identifying therapeutic solutions.

Furthermore, the Huntington's Disease Integrated Staging System (HD-ISS), which could have profound impact on identifying interventions for pre-symptomatic adults who inherit the HD gene expansion, has limited value in JoHD where stages 0 and 1 are unidentified due to how JoHD is diagnosed.

While all families affected by Huntington's disease require the partnership of the US Food and Drug Administration to bring forward effective therapeutic solutions, the unique needs of the JoHD community demand special consideration and immediate attention.

HD Reach: We at HD Reach understand the importance of research and finding treatment for the JOHD community. We hope this opportunity will help to amplify their voices and the need for increased research opportunities for ALL who are impacted by Huntington's Disease.

Champions for HD: It is crucial families with JHD have the opportunity to participate in clinical trials. When a child receives a terminal illness at such a young age, there often feels like little hope for them and their families who are watching them suffer and acting as caregivers. The only way we can cure this terrible disease is to have as many patients as possible participate so no future generations have to suffer. This not only gives them hope, but purpose in knowing their struggles and battles will go to furthering this research while they are here.

Huntington's Disease Organizations Statements of Support (Continued)

HDYO: JoHD is an extremely debilitating and devastating disease for the patient, caregivers and their families. Their experiences and journeys are crucial to better understand JoHD and learn about their passion to participate in clinical trials. This listening session is an essential step in doing so while also encouraging the research community to focus on developing comprehensive treatments for patients.

As a family member and researcher focusing on JoHD, I have the dual perspective of understanding how patients and families need to be represented in the research we facilitate. Despite much progress being made in HD research, this has mainly focused on adult HD. Our 'HD experts' often have little to no experience of JoHD so the current understanding of the disease is lacking. The true experts are those who have been impacted directly by JoHD, whether the patient themselves or their caregivers. Their perspective given through stories like through this listening session, is a huge step forward so we can work as hard as we can to find an effective treatment and care pathway for this devastating disease.

Meg's Fight for a Cure: She was in so much pain most of the days of her short life. She passed away at 15 years old. Hardly a chance to begin living. Anything has to be better than what this poor child endured. Please, please consider this.

Patient Listening Session Presentation Overview

FDA Patient Affairs team opened the meeting welcoming everyone, going over the financial disclosure, and the ground rules of the session.

Katie Jackson, CEO of Help 4 HD International, opened the patient/caregiver section of the patient listening session.

"Huntington's disease is often referred to as the worse disease known to mankind, we are all here to tell you Juvenile Huntington's disease is worse, and time is simply something we do not have". ~ Katie

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Katie Jackson opened with the goals and topics that would be discussed throughout the listening session.

Katie Jackson explained that the FDA's compassionate/expanded use and access pathways often puts a huge burden on families who are already significantly burdened. It requires filling out paperwork, talking to and leaning on their healthcare providers, to get the FDA and industry all the proper paperwork. She explained that these mothers have attempted this path and have yet to be successful on being granted compassionate use or access. Also, she explained they all understand that drugs can be used off label. She then explained this also puts a huge burden on the family to fight with insurance companies because it is off-label and/or an expensive therapy or treatment, which insurance companies use as an excuse to not cover the therapy or treatment. If isn't approved for this disease, third-party payers often won't pay for it.

She then explained that if the industry puts in approval for the children to participate in these adult trials and the FDA approves, this would remove the burden for families and hopefully get children quicker access to possible future lifesaving therapies or quality of life treatments, even if that takes the sponsor having to follow the children for an extended time and watch the children report back to the FDA data on safety and efficacy. This would eliminate the long wait for the children to get access to the therapy as well as eliminate a placebo group, which as the FDA heard from the parents, would be almost cruel. The disease progresses so rapidly why can't the children be their own control group?

She then went over some of the data that was collected from the JHD families who participated in the survey that was put out to help prepare information for the Patient Listening Session.

Katie finished by presenting a slide with five Huntington's disease organizations showing their support for the JHD Patient Listening Session and expressing the need for urgency.

Katie Jackson then introduced Melissa Walshburger, the first of seven caregivers who spoke that day to the FDA.

Melissa and Ava

"We are the 'Reluctant Experts' our children's lives depend on. Most importantly, they depend on you". ~Melissa

- Ava was diagnosed at 13
- Ava's symptoms started at the age of 8
- CAG repeat is 79
- Melissa is currently the caregiver for Ava and Ava's father living with Huntington's disease.

Melissa was the first caregiver to present. Melissa cares for her child living with Juvenile Huntington's disease while also caring for her husband who is living with Huntington's disease.

Topic I: How HD/JHD differs

- Progression is more rapid in JHD
- Ava (JHD) experiences itching, Michael (HD) does not
- Ava (JHD) experiences pain/neuropathy, Michael (HD) does not
- Ava (JHD) has dystonia in her feet and other deformities due to muscle deterioration, Michael (HD) does not
- Ava (JHD) has tremors, Michael (HD) has chorea

Topic II: Symptoms that effect Ava's quality of life:

- Speech
- Pain
- Mobility
- Eating/Choking
- Independence

Melissa finished the talk by explaining the risks she is willing and not willing to take when it came to her child having access to participating in a clinical trial.

Angela Dealba & Family

"Due to gene expansion each generation continues to get younger and younger. We now have multiple cases of Juvenile Huntington's disease in the family". ~Angela

- Harley was diagnosed at 11
- Dominick was diagnosed at 11
- Harley started showing symptoms at 8
- Dominick started showing symptoms at 4
- Harley's CAG repeat is 57, Dominick's CAG repeat is 65
- The boys' father is still alive in end-stage Huntington's disease with a CAG of 49

Angela was the second caregiver speaker of the day. Angela takes care of her two sons who are living with Juvenile Huntington's disease. She is also caring for her husband who is currently in late-stage Huntington's disease.

Topic I:

The differences between her two boys that are both impacted by Juvenile Huntington's disease.

Harley's Symptoms

- Hallucinations/Psychosis
- Sleep Disturbance
- Seizures
- Memory Loss

Dominick's Symptoms

- Pain
- Anxiety/Social Withdrawal
- Self-Harm
- Mood Swings

Topic II: Risks Willing to Take

The risks Angela and her family are willing and not willing to take for her sons to have access to clinical trials.

- Spinals/Brain Surgery
- Biologics
- Travel to Other Countries

Erika & Olivia

"'Why can't if a drug is approved for HD that it is a broad-spectrum approval so the prodromal and JHD families get access to the therapy or drug as well ". ~ Erika

- Olivia was diagnosed at the age of 12
- Olivia's symptoms started at 11
- CAG repeat is 78
- Olivia's father passed away from Huntington's disease at 47

Erika was the third caregiver for the day to speak. Erika focused her presentation predominately on dystonia.

Topic I: Current treatments that Olivia is on

Not one of these treatments fully relieve the pain and suffering that Olivia endures everyday living with severe dystonia.

- Botox®
- Baclofen
- Trihexyphenidyl
- Massage
- CBD Cream/Oil
- Physical Therapy

Topic II: How dystonia affects quality of life.

- Falls/Injuries
- Swallowing/Chewing
- Pain
- Speech
- Social Impact

Topic III: Disease Impact

- Loss of Friends
- Social Impact/Bullying
- Mobility
- "Normal" is Gone

Jennifer and Aliyah

"She no longer enjoys or can do the things she loved: swim, travel, movies, roller skating, playing with her friends…" ~ Jen

- Diagnosed with JHD at the age of 11
- Started showing symptoms of JHD at the age of 4
- CAG repeat is 74
- Aliyah's father passed away from Huntington's disease at the age of 41

Jennifer was our fourth caregiver to present. Jennifer's daughter is going into the final stage of Juvenile Huntington's disease, so Jennifer's presentation provided more of the life span of Juvenile Huntington's disease.

Topic I: JHD Impact

- Impact of Social Interactions
- Speech/Communication
- Cognitive Decline
- Sensory Issues
- Physical Decline/Pain
- Agitation/Depression
- Lack of Awareness
- Family Impact

Topic II: What is forever lost because of Juvenile Huntington's disease.

- She will never drive.
- She will never have a first date or love.
- She will never go to college.
- She will never have a career.
- She will never get married.
- She no longer enjoys or can do the things she loved: swim, travel, movies, roller skating, playing with her friends, etc.

Natalie & Khloe

"The pain and suffering Khloe has to go through every day is unimaginable. She is living with pain and multiple seizures daily. Our children need help. No child should be forced to live like this with no help in sight." ~Natalie

- Khloe was diagnosed with JHD at the age of 4
- Khloe started symptoms at the age of 2 years old
- CAG repeat is 115
- Both of Khloe's parents have no symptoms of Huntington's disease currently.

Natalie was our fifth caregiver presenter for the day. Natalie spoke a lot about the extremely challenging symptoms Khloe endures and their family deals with to manage her care.

Topic I: Most Challenging symptoms for Khloe and their family

- Seizures/Tremors/Shaking
- Full Body Itching
- Mobility/Bedbound
- Inability to Swallow and Retain Nutrients

Topic II: Video

For this part of Natalie's talk, she showed a one-minute video of the pain and suffering Khloe has to endure daily with no help. Natalie explained that Khloe often will have up to five grand mal seizures a day. She also showed in this video Khloe shaking and screaming out in pain during these seizures.

To watch the video within the presentations please go to:

https://youtu.be/ANHk4wMoW04?t=2241

Londen & Autumn

"I grieve the past. I grieve the present. I grieve the future. How is it okay that grief becomes your whole life? Change NEEDS to happen"! ~ Londen

- Autumn was diagnosed with JHD at the age of 11
- Autumn started showing symptoms of JHD at the age of 9
- CAG repeat is 72
- Autumn's father passed away from Huntington's disease at the age of 36 with a CAG of 59

Londen was the sixth presenter of the day. Londen spoke on many topics and expressed her frustration that there aren't any trials available for her child impacted by HD, even though there are so many clinical trials for adult-onset HD.

Topic I: Family Story Timeline

- Family
- Growing Up
- Changes
- Diagnosis
- Regression

Topic II: Clinical Trials

Londen spoke at the end about her frustration with not having any clinical trials in sight for her daughter to participate in. She even expressed to the FDA that she realizes it may be too late now for her daughter. Londen spoke about the risks her family was willing to take in order to be able to be a part of a clinical trial with Autumn.

Holly & Bella

"There is no cure, no therapy, nothing to slow or stop this disease! My hope for this session is that someone will listen to our pleas for help, someone will hear us, and hopefully, someone will help us save our children". ~ Holly

- Bella was diagnosed with JHD at the age of 10
- Bella started showing symptoms of JHD at the age of 8
- CAG repeat is 74
- Bella's father is currently in end-stage Huntington's disease at 44 years old

Holly was the seventh and final caregiver presenter for the day. Holly spoke about her frustrations with trying to use compassionate use pathways multiple times and every time she was turned away.

Topic I: Symptoms and symptom impact on quality-of-life

- Depression/Social Withdrawal/Apathy
- Cognitive Loss
- Swallowing/Speech
- Fine Motor Skills

Topic II: Compassionate Use Pathways, Clinical Trials, and Child Labeling

Holly discussed her multiple attempts to use compassionate use pathways, all of which have failed to date. She expressed her hope that children would be included in clinical trials to alleviate the burden of filling out paperwork and waiting for an extensive amount of time required for compassionate use approval.

Furthermore, Holly suggested that children in clinical trials could serve as their own controls. She expressed concern that subjecting children to a double-blinded placebo clinical trial would be almost cruel. Given the rapid progression of the disease, sponsors and the FDA should determine whether the treatment or therapy is effective right away and eliminate the need for a placebo group.

Finally, Holly hoped that the FDA would consider including children in labeling. She explained that excluding children from labeling places an unnecessary burden on families, who then have to fight with care providers, third-party payers, and others to gain access to quality-of-life treatments for their child. This is an added stress that families shouldn't have to endure, especially as they are already dealing with the immense burden of caring for a terminally ill child.

Meet the Children

After the presentations were completed, everyone shared their screens. Olivia, presenter Erika Eiger's daughter who has Juvenile Huntington's disease, came on the Zoom so all members in attendance could meet her.

Q and A with the FDA

FDA Patient Affairs led a 15-minute Q and A session.

An Office of Neuroscience member opened up the Q and A Session by expressing how important these listening sessions are for the FDA to be able to listen to and absorb all they can from the patients and caregivers. He expressed to our presenters that at this meeting the FDA was the students and the presenters were the experts.

He then expressed the session did a good job illustrating something they already knew, that the smaller patient population groups have more challenges participating in clinical trials.

He assured us that in addition to being very focused on the burden of Huntington's disease in all of its sub population groups it is also focused on the opportunities the disease provides the FDA to attempt these trials and leverage the science they already have, as fast as the science allows the FDA to do.

He also expressed the challenges when it comes to pediatrics but said that the FDA is very involved in talking to sponsors about the pediatric population in Huntington's disease.

He also addressed what we talked about during the session - that even when a therapy is approved, that's not always the end of our battles as far as access. He understood that third-party payers and others make it difficult for access. He then talked about what the FDA takes that into consideration when they are working on labeling. He expressed that the FDA is very thoughtful with the language used during this process, so they don't cause unnecessary burdens.

He finished with ensuring that the FDA wants to make sure that diseases with pediatric manifestations aren't abandoned or ignored. He applauded all of the speakers for their bravery and what they did to bring a greater understanding of JHD to the FDA.

A Division of Neurology I member came on, thanked all the presenters, and talked about how the presentations were very effective and moving. She said that the presentations gave them a clearer understanding of some of the challenges that the JHD population faces.

Question:

She asked a question about diagnosis. She talked about that if there was an effective treatment, having ideally early intervention may be best. She noted that in the presentations, many saw symptoms of JHD in their children's years before they were diagnosed. She wanted to know about the challenges in diagnosing children if any.

Answer:

Angie spoke about how her husband was adopted so there wasn't family history. She then spoke about how it was the family secret, and no one wanted to talk about it. Then she spoke about all the misdiagnoses that her children received before years later when they got the Juvenile Huntington's disease diagnosis.

Melissa spoke about her family not having any family history due to her husband's identity being withheld from them. She talked about the numerous misdiagnoses Ava went through before she was diagnosed with JHD.

Jennifer spoke about how she was told the family history was Hodgkin's disease not Huntington's disease. She also talked about the years of misdiagnoses of ADD, ADHD, Autism, etc. Jennifer then talked about how both her daughter and her daughter's father were diagnosed with HD and JHD at the same time.

Holly spoke about how she knew of the risk of Huntington's disease in the family. She talked about how the first time she went to the doctor to have her daughter looked at, she was told by the healthcare professional that she had nothing to worry about because only males could get Huntington's disease. Then she spoke about how she finally was able to get a test ordered for her daughter but was then turned away again because the lab refused to run the genetic test.

An Office of Neuroscience member then came in and talked about how diagnosis in Huntington's disease has been a challenging problem for a long time. He talked about the struggle for a diagnosis in the past because they didn't want to diagnosis the disease too early. He then talked about the exciting new HD Staging System that was just published. He also said that patients are now taking their voice back and saying that it is their body, and doctors etc. don't get to tell them when they can and can't test.

Londen expressed the trouble of diagnosing too early as well, including that it may cause some mental health issues.

An Office of Neuroscience member expressed that diagnosis is a challenging topic. He brought up that if there was an effective therapy that would need early intervention, he believes this would change. All presenters agreed.

FDA Comment: An Office of Pediatric Therapeutics member thanked all presenters for coming and told the presenters about how much she learned and was going to take back to her office about this session.

FDA Comment: A CBER Office of Tissue and Advance Therapies member, told us that they look over some of the gene therapies in Huntington's disease. She came on to thank all presenters for coming and helping them learn more about Juvenile Huntington's disease. She said that she understood that the burden is unimaginable on the families. She talked about how she is a neurologist who saw families with Huntington's disease, but she would only see them every

couple of months. She talked about how the presenters take care of individuals living with the disease every day.

Question:

Another Division of Neurology I member echoed everyone in thanking the presenters. She then had a question about genetic counselors, whether that helps JHD families identify family history and how available genetic counseling was to families.

Answers:

Natalie talked about how a lot of the time genetics counseling isn't brought in till after the diagnosis. She talked about how both her and her fiancé are both at risk for HD and how an MRI showed her daughter having JHD. A genetics counselor was brought in later, after her diagnosis. They brought in the genetics counselor because her fiancé wasn't diagnosed with HD yet. If their daughter was diagnosed that would mean they were dealing with a double diagnosis. She then also expressed how the diagnosis was so important for their family for social security and benefits.

Holly talked about how she didn't receive genetic counseling because she is from a small town that doesn't know much about Huntington's disease. She spoke about in her small town, dealing with no knowledge about HD/JHD, how she was told by a doctor that girls were unable to get Huntington's disease.

Angie said that she did not receive genetic counseling because Huntington's disease care around her would not see children. She then talked about how she received one son's diagnosis from a phone call and the other son from a letter in the mail.

Session Summary:

In summary we felt that everyone who participated in the FDA Patient Listening Session walked away feeling heard and acknowledged. Often due to the adult indication of Huntington's disease, the families impacted by Juvenile Huntington's disease are pushed aside with no voice and are on the sidelines with no hope. There has never been a clinical trial for or that included children living with Juvenile Huntington's disease. It has been said to these families' numerous times that they will do the clinical trials on the adults first then look at the children. By the time the years that it takes to go through the clinical trial process, the children of the parents will be too sick with Juvenile Huntington's disease or already have passed away before that opportunity would be available for them. Time is something these children do not have, and the need is vast and urgent.

By the responses we received from the FDA, we all felt that the FDA understood the unimaginable need the families face and reassured us that they aren't trying to leave Juvenile Huntington's disease families behind or abandoned.

Our final hope coming out of this meeting is that the FDA, sponsors, and advocates all work together in urgency to finally give our children ability to participate in clinical trials and if there is a new treatment or therapy approved for Huntington's disease, the FDA and sponsors truly take that into consideration when labeling our children living with Juvenile Huntington's disease understanding the impact labeling will have as far as relieving or causing more burden to families impacted by Juvenile Huntington's disease when it comes to access.

Disclaimer

Discussions in FDA Patient Listening Sessions are informal. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report reflects the account of the perspectives of patients and caregivers who participated in the Patient Listening Session with the FDA. To the extent possible, the terms used in this summary to describe specific manifestations of Juvenile Huntington's disease, health effects and impacts, and treatment experiences, reflect those of the participants. This report is not meant to be representative of the views and experiences of the entire Juvenile Huntington's disease patient population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report.