SUMMARIES OF FDA REQUESTED PATIENT LISTENING SESSIONS ON ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

March 8, 15, and 22, 2024

FDA Patient Affairs
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Combined Summary for ADHD Sessions 1, 2, and 3

March 15, 22, and 29, 2024

Objectives of All Three Sessions:

To gain a better understanding of the experience of individuals who have Attention Deficit/Hyperactivity Disorder (ADHD). FDA staff wants to hear from adults living with ADHD to better understand their diagnosis and perspectives on risks and benefits associated with stimulant and non-stimulant treatment for ADHD and fill the knowledge gap in adult prescribing data.

Discussions in FDA Listening Sessions are informal and not meant to replace, but rather complement, existing patient engagement opportunities in the Agency. All opinions, recommendations, and proposals are unofficial and nonbinding on the FDA and all other participants. This report summarizes the input provided by persons from the ADHD community at the meeting. To the extent possible, the terms used in this summary describe the health needs, perspectives, preferences, and impacts reflect those of the individual participants. This report is not meant to be representative of the views and experiences of the entire ADHD population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report. Any products, treatments, or organizations mentioned in this report were mentioned by persons from the ADHD community during the meeting and are not an endorsement by the FDA.

Summary of Three Discussions by Question

Round 1: Diagnosis and Symptoms

1. **Please share at what age you noticed symptoms of ADHD and when you were first treated for ADHD.**
   - Fourteen patients indicated that they first noticed symptoms of ADHD in early childhood.
   - Two participants shared that they first noticed symptoms as a teenager.
   - One participant said that they noticed symptoms when they were 45.
   - One participant indicated that they first noticed ADHD symptoms in their early-50s.

   a. **Can you describe what symptom(s) prompted you to seek treatment for your ADHD and how your condition changed over time?**
      - Five participants stated that their inability to focus and concentrate prompted them to seek treatment for their ADHD.
        - One participant said that their emotional dysregulation likely prompted the decision to get treated.
        - Three participants indicated that COVID had a negative impact on their symptoms, and that's when they started to look into ADHD.

- Four participants noted that they began to explore treatments for ADHD when their coping mechanisms lost effectiveness.
- One participant stated that they tried their child's ADHD medications and felt great impact from it.
- One participant stated that they had an increase in stress in their life that worsened their symptoms.

2. **Tell us about how you were diagnosed with ADHD (e.g., in-office visit, telehealth/virtual).**
   a. **Please share the types of evaluations or assessments you underwent.**
   b. **Did your healthcare provider use a survey or computer-based assessment to assist with your diagnosis?**
   c. **Did you undergo a psychological evaluation or other health screening?**
      - Seven of the participants mentioned completing formal questionnaires/ assessments during their initial evaluation.
      - Four participants indicated that they initially did a general interview with their medical provider and did not do any specific test or survey before receiving their diagnosis.
      - Two participants mentioned that their children's ADHD diagnoses led them to seek diagnosis.
      - One participant was initially evaluated over the phone.

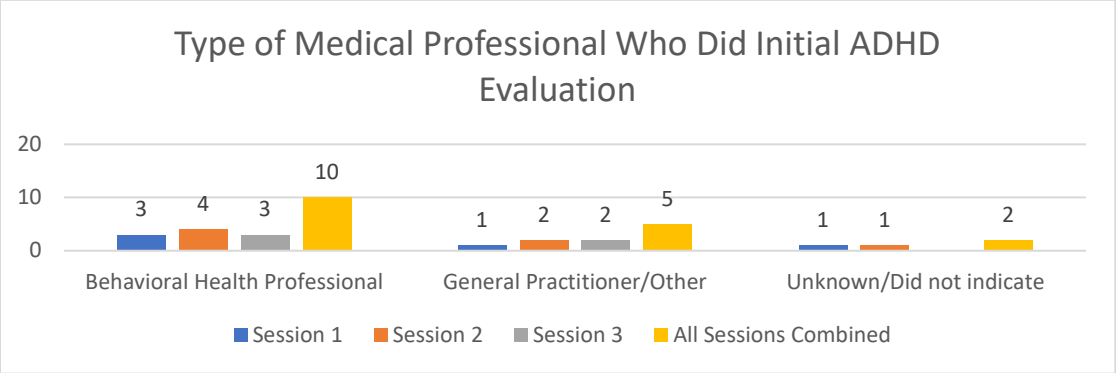

Figure 1: Summary of the participants responses about what type of medical professional completed their initial ADHD evaluation. The majority of participants in each session were evaluated initially for their ADHD by a behavioral health professional. No number listed for a category indicates that there were no responses for that category in that particular session.

3. **How often do you discuss your current ADHD treatment regimen and concerns, (e.g., side effects, length of medication use) with your healthcare provider (HCP)?**

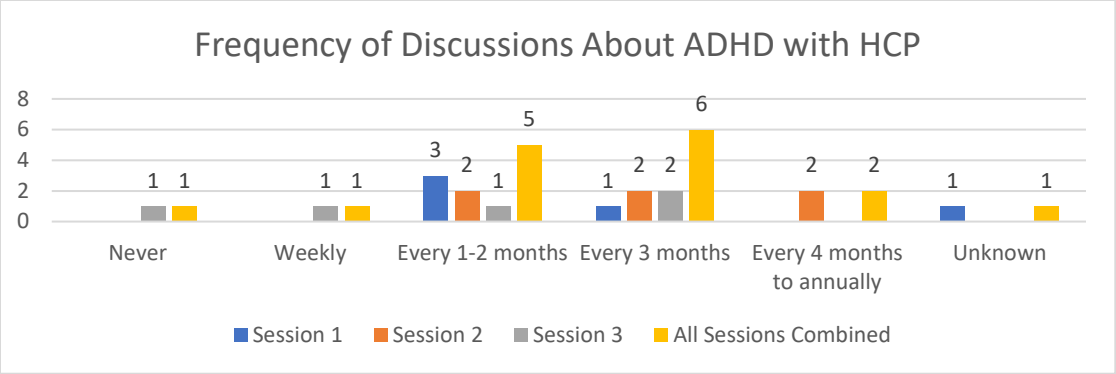

Figure 2: Summary of the participants responses about how frequently they discuss their ADHD treatment regimen with their HCP. The majority of participants have these discussions with their HCP every 1-3 months. No number listed for a category indicates that there were no responses for that category in that particular session.

- Another participant said that they just recently started seeing a healthcare provider again, so they have yet to establish a regular cadence.
- One participant said they do not meet with a healthcare provider to discuss their treatment regimen or concerns, because where they live, ADHD symptoms are often discounted or attributed to a lack of will power.

a. **Did you use any resources to learn more information on the risks associated with ADHD treatments?**

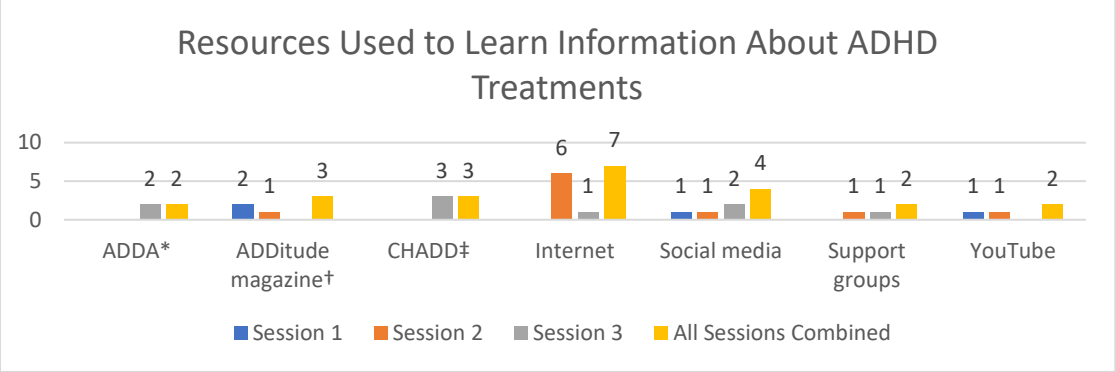

Figure 3: Summary of the participants answers the resources they use to learn more about their ADHD treatments. The majority of participants used the internet and social media as resources. No number listed for a category indicates that there were no responses for that category in that particular session. *Attention Deficit Disorder Association (ADDA); †ADDitude magazine; ‡ Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD)

- Three participants indicated their work as medical professionals offer them access to professional resources.
- One participant indicated that they use scholarly journals, books from the library, and will ingest and consider anything.
- One participant stated that they could not tell the group all of the ways that they have learned, but that it is a lot. They have done a lot of research.

- One participant stated that they are always reviewing the latest research, medications, and side effects and long-term effects.
- One participant shared that they have hired an ADHD coach who they work with monthly.
- Podcasts were also mentioned as useful resources.

Round 2: Treatment Regimen

4. **Are there any side effects or new/other conditions that have arisen since your ADHD diagnosis or starting ADHD treatment?**[1]
   a. **How do you manage/treat these side effects or other conditions?**[1]
      - Six participants indicated that they have experienced dry mouth as a side effect of their ADHD treatments.
        - Two participants stated that they just drink more water to treat it.
      - One participant stated they have increased heart rate.
      - One participant also stated that they started having migraines, gastrointestinal (GI) issues, pre-menstrual issues, kidney issues and diabetes issues after their ADHD diagnosis, but are not sure that these symptoms are related to their ADHD treatment.
      - Two participants noticed they were eating less.
        - One participant is diabetic and said that they will forget to eat, causing low blood sugar.
        - The other participant did not consider eating less to be a bad side effect.
      - Four of the participants have high blood pressure and are being treated for it.
        - Three participants stated that they do not feel that their ADHD treatment has worsened their blood pressure.
      - Two participants stated that they have trouble sleeping.
      - One participant noticed their inattentive symptoms were not well controlled on methylphenidate. They indicated that they did pharmacogenetic testing that indicated that methylphenidate was making their symptoms worse.

   b. **Which of these are/have been most bothersome to you? (*All sessions*)**[2]
      - Five participants indicated that one of their most bothersome side effects from ADHD treatments is insomnia (difficulty sleeping).
      - In addition to insomnia:
        - One participant stated that her ADHD treatments have caused tachycardia (high heart rate).
        - One participant said that his side effects that he notices are anxiety and restlessness.

[1] Question 4 was updated after session #1. Question 4 and 4a was answered by Session 2 & 3 participants.
[2] This question was updated after session #1. Part b of this question was answered by all participants.

    - One participant indicated that her ADHD treatment causes issues with dry mouth and anger.
    - One participant stated that she has struggled with appetite suppression from her ADHD treatment.
- Two participants indicated that they had issues with sexual dysfunction/libido.
- Three participants stated that dry mouth is their most bothersome side effect from their ADHD treatments.
- One participant shared that the only side effect they have experienced while using ADHD treatments is an increase in their resting heart rate.
- One participant has had an increase in migraines that they attribute to their ADHD treatment.
- Three participants indicated that their biggest hurdles with their ADHD treatments have been access to medication rather than physical side effects.
- One participant noted that their medications becoming ineffective and the effects from that ineffectiveness are most bothersome thing stemming from their ADHD treatment.
- Two participants indicated that their ADHD treatments have caused high blood pressure.
- One participant is not sure if their ADHD medication is affecting their blood pressure or not, but states that they are becoming concerned about it.
- One participant, who has not been treated for high blood pressure, stated that their blood pressure has increased since starting stimulants. They said that while their doctor is not concerned about this, the doctor should be.
    - This participant is concerned that if they bring up concerns about their high blood pressure to their doctor, they will be taken off of their ADHD treatment.

5. Has your treatment regimen been changed or interrupted in the past?[3]

- One participant stated that they have not had any treatment interruptions.
- Four participants said that their treatment regimens have been interrupted or changed due to medication shortages.
- Two participants said that they had many treatment changes when trying to find a medication that worked for them.
- One participant stated that they began taking illicit methamphetamines due to an inability to afford ADHD medications.
- One participant indicated that they stopped their treatment regimen as a teenager due to the stigma associated with having ADHD.
- Another participant said that they discontinued their medication as they were unaware of alternative treatment options.

[3] Due to time constraints, questions 5 and 5a were not asked to the participants of session #2.

- One participant lost access to all prescription ADHD treatments when they moved out of the country and still does not have access to these medications.

a. **If so, how did this impact your day-to-day activities, symptoms, and relationships (e.g., with friends, family, and/or coworkers)?**
   - One participant found that when they were taking a past stimulant, they were much more intense when meeting with people.
   - One participant struggled with their relationships with people at home. The participant stated that they had trouble regulating emotional or sensory things. They also stated that they are alone in their room a lot.
   - One participant said that they do not think there has been a large impact from treatment changes or interruptions.
   - One participant stated that being without prescription ADHD treatment has caused them to struggle for years. They have few relationships.
   - Two participants said they avoid driving when they don't have their medication as their inattentiveness is especially problematic.

Round 3: Quality of Life

6. **What lifestyle interventions and/or changes have you tried, and how they have helped you?**[4]
   a. **For example, have you used any behavioral therapy/strategies?**
      - Five participants indicated that they have used various therapy methods including cognitive behavioral therapy (CBT) and eye movement desensitization and reprocessing (EMDR).
        - Two of these participants indicated that they did not find CBT to be effective, with one saying they believe it has made their symptoms worse.
      - Four participants stated that they have begun practicing mindfulness.
        - Two of these participants stated that they practice yoga also but are not consistent about yoga or mindfulness.
      - Three participants said they have hired an ADHD coach.
        - One of these participants has seen great success with this.
      - Three participants use their phone to help keep them organized.
      - Another participant indicated that improved technology has aided in managing their ADHD symptoms as they are better able to structure their days.
      - A participant said that they began hormone replacement therapy (HRT) after perimenopause negatively impacted their treatment's effectiveness, and that HRT has been helpful.
      - One participant indicated that they believe their use of a GLP-1 Receptor Agonist[5] for weight loss has resulted in a lessening of their ADHD symptoms.

[4] Question 6 was updated after session #1. Questions 6 and 6a were asked to all participants.
[5] GLP-1 Receptor Agonists are a class of medications utilized to treat type 2 diabetes mellitus (T2DM) and obesity.

- Two participants indicated they have used lists to help with day-to-day tasks.
- Two participants stated that they use exercise to help manage their ADHD and found it very helpful.
- One participant mentioned body double work and sleep as additional current interventions.

b. **Have you used other substances not prescribed by your healthcare provider to help relieve or lessen your ADHD symptoms?[6]**
   - Four participants indicated that they relieve their ADHD symptoms with caffeine use.
     - One of the participants also listed sugar and alcohol as substances they use to manage help relieve their ADHD symptoms.
   - Two participants indicated that they take over the counter supplements such as omega-3/fish oil and B vitamins.
   - One participant mentioned that aromatherapy oils has been most helpful for them.

[6] Question 6 was updated after session #1. Question 6b was asked to participants of sessions 2 and 3.

ADHD Session #1 - FDA-Requested Listening Session: Adults with ADHD Diagnosed in Childhood

March 15, 2024

Objectives of Session #1

To gain a better understanding of the experience of individuals who have ADHD. FDA staff wants to hear from adults living with ADHD to better understand their diagnosis and perspectives on risks and benefits associated with stimulant and non-stimulant treatment for ADHD and fill the knowledge gap in adult prescribing data.

Discussions in FDA Listening Sessions are informal and not meant to replace, but rather complement, existing patient engagement opportunities in the Agency. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report summarizes the input provided by persons from the ADHD community at the meeting. To the extent possible, the terms used in this summary describe the health needs, perspectives, preferences, and impacts reflect those of the individual participants. This report is not meant to be representative of the views and experiences of the entire ADHD population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report. Any products, treatments, or organizations mentioned in this report were mentioned by persons from the ADHD community during the meeting and are not an endorsement by the FDA.

Participants Represented

- **Number of Participants:** Five
  - Three participants identified as female. Two participants identified as non-binary.
  - Four participants were assigned female at birth. One participant was assigned male at birth.

- **Education Level**: Participants' self-reported highest level of education ranged from high school diploma to bachelor's degree.

- **Geographic Location***:
  - Three participants were from the South, United States (U.S.).
  - One participant was from the Midwest, U.S.
  - One participant was from the Northeast, U.S.

  *Please click **here for a map** of the geographic regions referenced

- **Ages:** Participants' ages ranged from 30 to 47 years of age.

- **Disease Severity**: All five participants self-rated their ADHD severity as severe. All five participants were diagnosed and initially treated for ADHD before the age of 18 years (as children/adolescents).

Summary of Discussion by Question (Session 1)

Round 1: Diagnosis and Symptoms

1. **Please share at what age you noticed symptoms of ADHD and when you were first treated for ADHD.**
   - Two participants noted that they first noticed symptoms of ADHD in their teenage years.
   - Three participants shared that they first noticed symptoms early in childhood.
     - Two participants stated they first remember noticing symptoms around elementary/middle school age.
     - The other participant mentioned that they can recall noticing ADHD symptoms from their earliest memories.

   a. **Can you describe what symptom(s) prompted you to seek treatment for your ADHD and how your condition changed over time?**
      - One participant indicated that their struggling with concentration and focus prompted them to seek treatment for ADHD.
      - One participant believed that emotional dysregulation was the symptom that was most significant in driving their parents' decision to have them treated for ADHD.
      - One participant shared that their focus and memory as they related to work began to suffer which led them to seek a diagnosis.

2. **Tell us about how you were diagnosed with ADHD (e.g., in-office visit, telehealth/virtual).**
   a. **Please share the types of evaluations or assessments you underwent.**
   b. **Did your healthcare provider use a survey or computer-based assessment to assist with your diagnosis?**
   c. **Did you undergo a psychological evaluation or other health screening?**
      - Three participants indicated they received evaluations from behavioral health professionals (psychologists, psychiatrists, etc.).
      - One participant noted that they were tested at a community health center over a two-week period to come to their diagnosis.
      - Another participant stated that their diagnosis was withheld from them at a young age, so they were unsure of how they were diagnosed. They did share that they were re-evaluated by a psychiatrist in their late teenage years.

3. **How often do you discuss your current ADHD treatment regimen and concerns, (e.g., side effects, length of medication use) with your healthcare provider?**
   - One participant indicated they meet with their healthcare provider every three months to discuss their ADHD treatment regimen and concerns.
   - Three participants stated that they meet with a healthcare provider monthly.

    - Of these three participants, one individual explained that every three months, one of these appointments has to be in person.
- Another participant said that they just recently started seeing a healthcare provider again, so they have yet to establish a regular cadence.

a. **Did you use any resources to learn more information on the risks associated with ADHD treatments?**
    - Two participants mentioned ADDitude magazine as a valuable resource.
    - Two participants indicated their work as medical professionals offer them access to professional resources.
    - One participant stated that they watch YouTube videos to gather information about risks associated to ADHD treatments.
    - One participant indicated that they follow social media content creators who have followed similar journeys.
    - One participant shared that they have hired an ADHD coach who they work with monthly.
    - One participant shared that they search for the medication online to learn about side effects.

Round 2: Treatment Regimen

4. **Of the side effects you have experienced with current and past ADHD treatments, which side effects are most bothersome to you?**
    - All five participants indicated that their ADHD treatments have led to insomnia (difficulty sleeping).
    - In addition to insomnia:
        - One participant stated that their ADHD treatments have caused tachycardia (rapid heart rate).
        - Two participants indicated that their ADHD treatments have caused high blood pressure.
        - One participant said that the side effects that they notice are anxiety and restlessness.
        - One participant noticed their inattentive symptoms were not well controlled on methylphenidate. They indicated that they did pharmacogenetic testing that indicated that methylphenidate was making their symptoms worse.
        - One participant indicated that their ADHD treatment causes issues with dry mouth and anger.
        - One participant stated that they have struggled with appetite suppression from their ADHD treatment.
        - Two participants indicated that they had issues with sexual dysfunction/libido.

5. **(Follow-up question) Which participants had pharmacogenetic testing?**

- Two participants responded that they had pharmacogenetic testing done.

6. **Has your treatment regimen been changed or interrupted in the past?**
   - Each participant indicated that their treatment regimen has been changed or interrupted at some point in their life.
   - Each participant said that their treatment regimens have been interrupted or changed due to medication shortages.
   - One participant stated that they began taking illicit methamphetamines due to an inability to afford ADHD medications.
   - One participant indicated that they stopped their treatment regimen as a teenager due to the stigma associated with having ADHD.
   - Another participant said that they discontinued their medication as they were unaware of alternative treatment options.

   a. **If so, how did this impact your day-to-day activities, symptoms, and relationships (e.g., with friends, family, and/or coworkers)?**
      - Four participants indicated that interruptions/changes in their treatment regimen have significant effects on their day-to-day lives.
      - Two participants shared that they find it difficult to complete basic life activities when their treatment regimen is interrupted.
      - Two participants said they avoid driving when they don't have their medication as their inattentiveness is especially problematic.

7. **(Follow-up question) Were you referring to a prescribed methamphetamine?**
   - *This question was directed at a specific participant.*
   - One participant indicated that the methamphetamines they were referring to were illicit methamphetamine and not prescribed methamphetamine.

Round 3: Quality of Life

8. **What lifestyle interventions and/or changes have you tried, and how they have helped you? For example, have you used any behavioral therapy/strategies to help relieve or lessen your ADHD symptoms?**
   - Two participants indicated they have used cognitive behavioral therapy in an attempt to relieve their ADHD symptoms.
     - Neither participant found it to be effective, with one saying they believe it has made their symptoms worse because they learned that they should not mask their symptoms.
   - Two participants stated that they have begun practicing mindfulness.
   - One participant said they have hired an ADHD coach and have seen great success.

- Another participant indicated that improved technology has aided in managing their ADHD symptoms as they are better able to structure their days.
- A participant said that they began hormone replacement therapy (HRT) after perimenopause negatively impacted their treatment's effectiveness, and that HRT has been helpful.

9. **(Follow-up question) Does anyone on the call use digital devices or digital applications to help with your management of ADHD?**
   - One participant indicated that they don't use any technological aides. They prefer writing things down.
   - One participant shared that they have worked with another individual virtually who sits on video camera with them to hold them accountable to completing tasks.
   - One participant said that their partner has suggested using Trello as a way to write out customized to-do lists.
   - One participant stated that they have used the Calm app to help with symptoms.
   - One participant indicated that they have tried various digital applications including Tiimo and Habitica. They also noted that they intend to explore using artificial intelligence (AI) to aide in their symptom management.

10. **How do you think ADHD affects you differently than it might some others because of your age, gender, or particular life experiences?**
    - Three participants indicated that they believe their ADHD experiences are similar to the other participants.
    - Three participants stated that they believe their gender has played a role in how ADHD impacts them as hormonal changes can greatly affect symptoms.
    - One participant indicated that growing up as a young girl, they believe their gender and its associated stereotypes impacted how their parents decided to treat their ADHD.

<u>Follow-up questions (order by priority)</u>

11. **How and where do you find support services, including those related to medical and mental healthcare, that you may need?**
    - Two participants indicated that they use Reddit as a resource to connect and engage with other people living with ADHD.
    - One participant said that Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) and ADDitude magazine are the resources they find the most helpful.
    - One participant stated that they tend to find support services through talking with their therapist and/or psychiatrist.
    - Three participants highlighted local ADHD and harm reduction support groups.

12. **(Follow-up question) What advice would you give to adults living with ADHD or parents raising kids with ADHD?**
    - Two participants stressed the need to have patience both with yourself and with your children.
    - One participant indicated that their advice would be to value emotional acceptance of yours or your child's ADHD diagnosis. They also recommended psychoeducation.
    - One participant said that their advice would be to seek help if needed and to never be afraid to ask for support.

FDA Offices & Divisions in Attendance

- **Office of the Commissioner (OC) – *5 offices***
    - OC/OCPP/PAS – Office of the Commissioner/Office of Clinical Policy and Programs/Patient Affairs Staff (organizer)
    - OC – Office of the Commissioner
    - OC/OCPP – Office of the Commissioner/Office of Clinical Policy and Programs
    - OC/OCPP/OPT – Office of the Commissioner/Office of Clinical Policy and Programs/Office of Pediatric Therapeutics
    - OC/OEA/SES – Office of External Affairs/Stakeholder Engagement Staff

- **Center for Biologics Evaluation and Research (CBER) – *3 offices/divisions***
    - CBER/OCD – Office of the Center Director
    - CBER/OTP/OCE/DCEGM/GMB1 – Office of Therapeutic Products/Office of Clinical Evaluation/Division of Clinical Evaluation General Medicine/General Medicine Branch 1
    - CBER/OTP/OCE/DCEGM/GMB2 - Office of Therapeutic Products/Office of Clinical Evaluation/Division of Clinical Evaluation General Medicine/General Medicine Branch 2

- **Center for Drug Evaluation and Research (CDER) – *11 offices/divisions***
    - CDER/OCD – Office of the Center Director (requestor)
    - CDER/OCOMM/PASES – Office of Communications/Professional Affairs and Stakeholder Engagement Staff
    - CDER/OMP – Office of Medical Policy
    - CDER/OND/ODES/DCOA – Office of New Drugs/Office of Drug Evaluation Science
    - CDER/OND/ON – Office of New Drugs/Office of Neuroscience
    - CDER/OND/ON/DP - Office of New Drugs/Office of Neuroscience/Division of Psychiatry
    - CDER/OTS/OB/DBI – Office of Translational Sciences/Office of Biostatistics/Division of Biometrics I

- CDER/OTS/OB/DBII - Office of Translational Sciences/Office of Biostatistics/Division of Biometrics II
- CDER/OTS/OB/DBIII - Office of Translational Sciences/Office of Biostatistics/Division of Biometrics III
- CDER/OTS/OCP – Office of Translational Sciences/Office of Clinical Pharmacology
- CDER/OTS/OCP/DCEP - Office of Translational Sciences/Office of Clinical Pharmacology/Division of Cardiometabolic and Endocrine Pharmacology

- **Center for Devices and Radiological Health –** ***17 offices/divisions***
  - CDRH/OCD – Office of the Center Director
  - CDRH/OM/DAS/CONT – Office of Management/Division of Acquisition Services/Contractors
  - CDRH/OPEQ/OHTI – Office of Product Evaluation and Quality/Office of Health Technology I
  - CDRH/OPEQ/OHTI/DHTIA - Office of Product Evaluation and Quality/Office of Health Technology I/Division of Health Technology IA
  - CDRH/OPEQ/OHTI/DHTIB - Office of Product Evaluation and Quality/Office of Health Technology I/Division of Health Technology IB
  - CDRH/OPEQ/OHTI/DHTIC - Office of Product Evaluation and Quality/Office of Health Technology I/Division of Health Technology IC
  - CDRH/OPEQ/OHTII/DHTIIC - Office of Product Evaluation and Quality/Office of Health Technology II/Division of Health Technology IIC
  - 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 IIIA
  - CDRH/OPEQ/OHTIII/DHTIIIB - Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology IIIB
  - CDRH/OPEQ/OHTIII/DHTIIIC - Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology IIIC
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  - CDRH/OPEQ/OHTV/DHTVB - Office of Product Evaluation and Quality/Office of Health Technology V/Division of Health Technology VB
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  - CDRH/OSPTI – Office of Strategic Partnerships and Technology Innovation
  - CDRH/OSPTI/OEID/DPCD - Office of Strategic Partnerships and Technology Innovation/Office of Equity and Innovative Development/Division of Patient

Centered Development

- **Center for Tobacco Products – *2 offices/divisions***
  - CTP/OS/DIHS – Office of Science/Division of Individual Health Science
  - CTP/OS/RS – Office of Science/Research Staff

Non-FDA Attendees

- Reagan-Udall Foundation for the FDA
- Patients

Financial Interest

Participants did not identify financial interests relevant to this meeting and are not receiving compensation for participation in this listening session.

ADHD Session #2 - FDA-Requested Listening Session: Adults with ADHD Diagnosed in Adulthood

March 22, 2024

Objectives of Session #2

To gain a better understanding of the experience of individuals who have ADHD. FDA staff wants to hear from adults living with ADHD to better understand their diagnosis and perspectives on risks and benefits associated with stimulant and non-stimulant treatment for ADHD and fill the knowledge gap in adult prescribing data.

Discussions in FDA Listening Sessions are informal and not meant to replace, but rather complement, existing patient engagement opportunities in the Agency. All opinions, recommendations, and proposals are unofficial and nonbinding on the FDA and all other participants. This report summarizes the input provided by persons from the ADHD community at the meeting. To the extent possible, the terms used in this summary describe the health needs, perspectives, preferences, and impacts reflect those of the individual participants. This report is not meant to be representative of the views and experiences of the entire ADHD population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report. Any products, treatments, or organizations mentioned in this report were mentioned by persons from the ADHD community during the meeting and are not an endorsement by the FDA.

Participants Represented

- **Number of Participants:** Seven
  - Six participants identified as female. One participant identified as non-binary.
  - All seven participants were assigned female at birth.

- **Education Level**: Participants' self-reported highest level of education ranged from bachelor's degree to Doctorate or higher.

- **Geographic Location***:
  - Five participants were from the South, United States (U.S.).
  - One participant was from the Midwest, U.S.
  - One participant was from the West, U.S.

  *Please click **here for a map** of the geographic regions referenced

- **Ages:** Participants' ages ranged from 39 to 47 years of age.

- **Disease Severity**: Four participants self-rated their ADHD severity as severe, and three participants self-rated their ADHD severity as moderate. All seven participants were diagnosed for ADHD in adulthood (early 30s to late 40s).

Summary of Discussion by Question (Session 2)

Round 1: Diagnosis and Symptoms

1. **Please share at what age you noticed symptoms of ADHD and when you were first treated for ADHD.**
   - Each participant indicated that they first noticed symptoms as young children.
     - None of the participants were aware their symptoms could be related to ADHD until well into adulthood.
     - Four participants shared that their children had been diagnosed with ADHD and noticed similar symptoms.
   - Four participants stated that they were initially diagnosed for ADHD in their 40s.
   - One participant was first diagnosed in their late-30s.

   a. **Can you describe what symptom(s) prompted you to seek treatment for your ADHD and how your condition changed over time?**
      - Three participants indicated that the COVID-19 pandemic had a negative impact and worsened symptoms, such as executive functioning, anxiety, and that's when they started to look into ADHD.
      - Four participants noted that they began to explore treatments for ADHD when their coping mechanisms lost effectiveness.

2. **Tell us about how you were diagnosed with ADHD (e.g., in-office visit, telehealth/virtual).**
   a. **Please share the types of evaluations or assessments you underwent.**
   b. **Did your healthcare provider use a survey or computer-based assessment to assist with your diagnosis?**
   c. **Did you undergo a psychological evaluation or other health screening?**
      - Four participants indicated they received evaluations from behavioral health professionals (psychologists, psychiatrists, etc.).
      - Two participants stated that they were evaluated by their general practitioner.
      - One participant was initially evaluated over the phone.
      - Six of the participants mentioned completing formal questionnaires/assessments during their initial evaluation.
        - Two of these participants mentioned completing the Wechsler Adult Intelligence Scale (WAIS).
          - One of these participants also completed The Barkley Adult ADHD Rating Scale (BAARS).
        - Another participant indicated that they and their family completed the Connor's Comprehensive Behavior Rating Scale.
        - One participant stated that they completed the Brown's Attention-Deficit Disorder Symptom Assessment Scale (BADDS).

3. **How often do you discuss your current ADHD treatment regimen and concerns, (e.g., side effects, length of medication use) with your healthcare provider?**
    - Two participants indicated they meet with their healthcare provider every three months to discuss their ADHD treatment regimen and concerns.
        - Of those two, one individual explained that the frequency of their meetings with a healthcare provider is dependent on their state's regulations.
    - One participant stated that they meet with a healthcare provider every one to two months.
    - One participant shared that they meet with their healthcare provider at least one time per year, but that the frequency depends on what is going on with them.
    - One participant indicated that they meet with their psychiatrist a couple of times per year.
    - Another participant stated that they meet with their psychiatrist at least quarterly, and that lately it has been every six weeks.

    a. **Did you use any resources to learn more information on the risks associated with ADHD treatments?**
        - Six of the seven participants indicated that they use the internet to learn more about risks associated with ADHD treatment.
            - One participant indicated that they are a medical professional and use medical resources, social media, and ADDitude magazine for information about risks associated with ADHD treatment.
            - One participant stated that they could not tell the group all of the ways that they have learned, but that it is a lot. They have done a lot of research.
            - One participant stated that they are always reviewing the latest research and medications and side effects and long-term effects.
            - One participant indicated that they use scholarly journals, YouTube videos, books from the library, and will consider anything.
            - Another participant indicated that they primarily use ADHD podcasts and that a lot of the information is anecdotal to learn about experiences of women with late diagnosis of ADHD.
        - One individual is a member of an informal group for individuals in their profession with ADHD and gets information from there.

4. **(Follow-up question) Has ADHD changed or worsened since stopping meds?**
    - *This question was directed at a specific participant.*
    - The participant confirmed that their ADHD has worsened since stopping medication.
        - They indicated that they would revisit medication but have had difficulties finding a provider that was covered by their insurance.

Round 2: Treatment Regimen

5. **Are there any side effects or new/other conditions that have arisen since your ADHD diagnosis or starting ADHD treatment?**
   a. **How do you manage/treat these side effects or other conditions?**
   b. **Which of these are/have been most bothersome to you?**
      - Three participants indicated that they have experienced dry mouth as a side effect of their ADHD treatments.
        - Two participants stated that they drink more water. Of those two participants, one added using throat lozenges to treat it.
        - One participant said that the dry mouth likely led to a painful salivary stone.
      - One participant shared that the only side effect they have experienced while using ADHD treatments is an increase in their resting heart rate.
      - One participant has had an increase in migraines that they attribute to their ADHD treatment. This participant also stated that they started having gastrointestinal (GI) issues, pre-menstrual issues, kidney issues and diabetes issues after their ADHD diagnosis, but are not sure that this is related to their ADHD treatment.
      - Three participants indicated that their biggest hurdles with their ADHD treatments have been access to medication rather than physical side effects.

Round 3: Quality of Life

6. **What lifestyle interventions and/or changes have you tried, and how they have helped you?**
   a. **For example, have you used any behavioral therapy/strategies to help relieve or lessen your ADHD symptoms?**
   b. **Have you used other substances not prescribed by your healthcare provider to help relieve or lessen your ADHD symptoms?**
      - Two participants said that they have hired ADHD coaches.
      - Three participants indicated that they relieve their ADHD symptoms with caffeine use.
        - One of the participants also listed sugar and alcohol as substances they use to manage help relieve their ADHD symptoms.
      - Another participant mentioned that they used alcohol and illicit drugs, before their diagnosis, in college. This participant also mentioned that they now use medical marijuana to help with their anxiety.
      - Three participants indicated that they have used various therapy methods including cognitive behavioral therapy (CBT) and eye movement desensitization and reprocessing (EMDR).

- One participant indicated that they believe their use of a GLP-1 Receptor Agonist[7] for weight loss has resulted in a lessening of their ADHD symptoms.
- One participant mentioned running as being helpful for managing their ADHD symptoms.

Follow-up questions (order by priority)

7. **For those married or living w/ others who have ADHD any household strategies you would perceive as unique?**
   - One participant indicated that because their children are also on ADHD medication, they have to teach their children about the different medications that each of them use and have had conversations informing the children not to disclose what medications they're taking to other people.
   - One participant has a digital assistant that chimes every 15 minutes to help them with their time blindness. This participant states that this strategy will not work if they are not taking their ADHD medications.
   - Three participants shared that they related to all the remarks made throughout the course of the session. Of the three, two participants stressed the impact the COVID-19 pandemic had on their ADHD.

FDA Offices & Divisions in Attendance

- **Office of the Commissioner (OC) – *8 offices***
  - OC/OCPP/PAS – Office of the Commissioner/Office of Clinical Policy and Programs/Patient Affairs Staff (organizer)
  - OC – Office of the Commissioner
  - OC/OCPP – Office of the Commissioner/Office of Clinical Policy and Programs
  - OC/OCPP/OOPD – Office of the Commissioner/Office of Clinical Policy and Programs/Office of Orphan Product Development
  - OC/OCPP/OPT – Office of the Commissioner/Office of Clinical Policy and Programs/Office of Pediatric Therapeutics
  - OC/OEA/SES – Office of External Affairs/Stakeholder Engagement Staff
  - OC/OMHHE – Office of Minority Health and Health Equity
  - OC/OWH –Office of Women's Health

- **Center for Biologics Evaluation and Research (CBER) – *3 offices/divisions***
  - CBER/OCD – Office of the Center Director
  - CBER/OTP/OCE/DCEGM/GMB1 – Office of Therapeutic Products/Office of Clinical Evaluation/Division of Clinical Evaluation General Medicine/General Medicine Branch 1

[7] GLP-1 Receptor Agonists are a class of medications utilized to treat type 2 diabetes mellitus (T2DM) and obesity.

- CBER/OTP/OCE/DCEGM/GMB2 - Office of Therapeutic Products/Office of Clinical Evaluation/Division of Clinical Evaluation General Medicine/General Medicine Branch 2

- **Center for Drug Evaluation and Research (CDER) – *8 offices/divisions***
  - CDER/OCD – Office of the Center Director (requestor)
  - CDER/OND/ODES/DCOA – Office of New Drugs/Office of Drug Evaluation Science
  - CDER/OND/ON/DP - Office of New Drugs/Office of Neuroscience/Division of Psychiatry
  - CDER/OND/ORO/DROII - Office of New Drugs/Office of Regulatory Operations/Division of Regulatory Operations for Immunology & Inflammation
  - CDER/OTS/OB/DBI – Office of Translational Sciences/Office of Biostatistics/Division of Biometrics I
  - CDER/OTS/OB/DBII - Office of Translational Sciences/Office of Biostatistics/Division of Biometrics II
  - CDER/OTS/OB/DBIII - Office of Translational Sciences/Office of Biostatistics/Division of Biometrics III
  - CDER/OTS/OCP – Office of Translational Sciences/Office of Clinical Pharmacology

- **Center for Devices and Radiological Health – *17 offices/divisions***
  - CDRH/OCD – Office of the Center Director
  - CDRH/OPEQ/OHTI – Office of Product Evaluation and Quality/Office of Health Technology I
  - CDRH/OPEQ/OHTI/DHTIA - Office of Product Evaluation and Quality/Office of Health Technology I/Division of Health Technology IA
  - CDRH/OPEQ/OHTI/DHTIB - Office of Product Evaluation and Quality/Office of Health Technology I/Division of Health Technology IB
  - CDRH/OPEQ/OHTI/DHTIC - Office of Product Evaluation and Quality/Office of Health Technology I/Division of Health Technology IC
  - CDRH/OPEQ/OHTII/DHTIIC - Office of Product Evaluation and Quality/Office of Health Technology II/Division of Health Technology IIC
  - 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 IIIA
  - CDRH/OPEQ/OHTIII/DHTIIIB - Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology IIIB
  - CDRH/OPEQ/OHTIII/DHTIIIC - Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology IIIC
  - CDRH/OPEQ/OHTIV/DHTIVA – Office of Product Evaluation and Quality/Office of Health Technology IV/Division of Health Technology IVA

- CDRH/OPEQ/OHTIV/DHTIVB - Office of Product Evaluation and Quality/Office of Health Technology IV/Division of Health Technology IVB
- CDRH/OPEQ/OHTV/DHTVB - Office of Product Evaluation and Quality/Office of Health Technology V/Division of Health Technology VB
- CDRH/OPEQ/OHTVIII/DHTVIC - Office of Product Evaluation and Quality/Office of Health Technology VIII/Division of Health Technology VIC
- CDRH/OPEQ/OHTVIII/DHTVIIIC - Office of Product Evaluation and Quality/Office of Health Technology VIII/Division of Health Technology VIIIC
- CDRH/OPEQ/RPGS - Office of Product Evaluation and Quality/Regulation, Policy, and Guidance Staff
- CDRH/OSPTI - Office of Strategic Partnerships and Technology

- **Center for Tobacco Products – *1 office/division***
  - CTP/OS/DIHS – Office of Science/Division of Individual Health Science

Non-FDA Attendees

- Reagan-Udall Foundation for the FDA
- Patients

Financial Interest

Participants did not identify financial interests relevant to this meeting and are not receiving compensation for participation in this listening session.

ADHD Session #3 - FDA-Requested Listening Session: Older Adults with ADHD (>60 years old) Diagnosed at Any Time

March 29, 2024

Objectives of Session #3

To gain a better understanding of the experience of individuals who have ADHD. FDA staff wants to hear from adults living with ADHD to better understand their diagnosis and perspectives on risks and benefits associated with stimulant and non-stimulant treatment for ADHD and fill the knowledge gap in adult prescribing data.

Discussions in FDA Listening Sessions are informal and not meant to replace, but rather complement, existing patient engagement opportunities in the Agency. All opinions, recommendations, and proposals are unofficial and nonbinding on the FDA and all other participants. This report summarizes the input provided by persons from the ADHD community at the meeting. To the extent possible, the terms used in this summary describe the health needs, perspectives, preferences, and impacts reflect those of the individual participants. This report is not meant to be representative of the views and experiences of the entire ADHD population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report. Any products, treatments, or organizations mentioned in this report were mentioned by persons from the ADHD community during the meeting and are not an endorsement by the FDA.

Participants Represented

- **Number of Participants:** Five
  - Three participants identified as female. Two participants identified as male.

- **Education Level**: Participants' self-reported highest level of education ranged from bachelor's degree to master's degree.

- **Geographic Location***:
  - Two participants were from the South, United States (U.S.).
  - One participant was from the Midwest, U.S.
  - One participant was from the Northeast, U.S.
  - One participant was from Mexico.

  *Please click **here for a map** of the geographic regions referenced

- **Ages:** Participants' ages ranged from 61 to 75 years of age.

- **Disease Severity**: One participant self-rated their ADHD severity as severe, and four participants self-rated their ADHD severity as moderate. All five participants were diagnosed after age 39.

Summary of Discussion by Question (Session 3)

Round 1: Diagnosis and Symptoms

1. **Please share at what age you noticed symptoms of ADHD and when you were first treated for ADHD.**
   - Three participants indicated they had noticed symptoms in early childhood; however, they did not receive an ADHD diagnosis until much later in life.
   - One participant shared that the first noticed symptoms when they were 45 years old.
   - One participant said they were in their early 50s when they noticed ADHD symptoms.

   a. **Can you describe what symptom(s) prompted you to seek treatment for your ADHD and how your condition changed over time?**
      - One participant stated that they tried their child's ADHD medications and felt great impact from it.
      - Three participants stated that they struggled to focus.
      - One participant stated that they had an increase in stress in their life that worsened their symptoms.

2. **Tell us about how you were diagnosed with ADHD (e.g., in-office visit, telehealth/virtual).**
   a. **Please share the types of evaluations or assessments you underwent.**
   b. **Did your healthcare provider use a survey or computer-based assessment to assist with your diagnosis?**
   c. **Did you undergo a psychological evaluation or other health screening?**

      - Three participants indicated they received evaluations from mental health medical professionals (psychologists, psychiatrists, etc.).
      - Two participants indicated they received evaluations from general medical providers such as general practitioner.
      - Four participants indicated that they initially did a general interview with their medical provider and did not do any specific test or survey before receiving their diagnosis.
      - One participant indicated that they initially did a computerized test when receiving their diagnosis.

3. **How often do you discuss your current ADHD treatment regimen and concerns, (e.g., side effects, length of medication use) with your healthcare provider?**
   - Two participants indicated they meet with their healthcare provide every three months to discuss their ADHD treatment regimen and concerns.

- One participant stated that they meet with a healthcare provider on a monthly basis.
- One participant said that they meet with their healthcare provider weekly.
- One participant said they do not meet with a healthcare provider to discuss their treatment regimen or concerns, because where they live, ADHD symptoms are often discounted or attributed to a lack of will power.

a. **Did you use any resources to learn more information on the risks associated with ADHD treatments?**
   - Three participants mentioned Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) as a resource for information on ADHD treatments.
     - One of these three participants is an active member of a CHADD group, and they gather and share information during the monthly Zoom meetings.
     - Two of these three participants also mentioned Attention Deficit Disorder Association (ADDA) as another resource and are a part of ADDA as a member or volunteer.
   - Two participants indicated that social media is a resource that they use to learn more about their medications.
     - One of these two participants mentioned that they also use the internet in general for more information about their ADHD treatments.
     - One participant specifically mentioned Reddit as the social media that they use.

<u>Round 2: Treatment Regimen</u>

4. **Are there any side effects or new/other conditions that have arisen since your ADHD diagnosis or starting ADHD treatment?**
   a. **How do you manage/treat these side effects or other conditions?**
   b. **Which of these are/have been most bothersome to you?**
      - Three participants stated that they struggle with dry mouth from their ADHD treatment.
        - All three of these participants noted that this was their most bothersome effect from their ADHD treatment.
      - One participant noticed themselves clenching their jaw with a previous stimulant. They state that this is not as bad on their current stimulant.
      - One participant noted that their medications becoming ineffective and the effects from that ineffectiveness are most bothersome thing stemming from their ADHD treatment.
        - One specific example the participant noted was when they received specific brands of their stimulant, it gave them a stimulant crash that made them irritable. This participant noted that it was so significant that they could not take the medication anymore.

- Two participants noticed they were eating less.
  - One participant is diabetic and said that they would forget to eat, causing low blood sugar.
  - The other participant did not consider eating less to be a bad side effect, but they were unable to eat while the treatment was effective.
- Two participants stated that they have trouble sleeping.
- Five participants mentioned high blood pressure. Four of the five participants are being treated for it.
  - Three participants stated that they do not feel that their ADHD treatment has worsened their blood pressure.
  - One participant is not sure if their ADHD medication is affecting their blood pressure or not, but states that they are becoming concerned about it.
  - The one participant, who has not been treated for high blood pressure, stated that their blood pressure has increased since starting stimulants. This participant said their doctor is not concerned about the high blood pressure. This participant stated the doctor should be concerned about their high blood pressure though. This participant worries that if they bring up concerns about their high blood pressure to their doctor, they will be taken off their ADHD treatment.

5. **Has your treatment regimen been changed or interrupted in the past?**
   - One participant stated that they have not had any treatment interruptions.
   - One participant lost access to all prescription ADHD treatments when they moved out of the country and still does not have access to these medications.
     - This participant indicated that they utilize behavioral techniques to help cope such as the Pomodoro Technique to help manage their time.
   - Three participants have had several changes or interruptions to their ADHD treatment regimen.
     - Two of these participants stated that the reason for this was finding a medication that worked for them.
     - One participant indicated that the ADHD medication shortages have been the reason for their treatment interruptions.

   a. **If so, how did this impact your day-to-day activities, symptoms, and relationships (e.g., with friends, family, and/or coworkers)?**
      - One participant found that when they were taking a past stimulant, they were much more intense when meeting with people.
      - One participant struggled with their relationships with people at home. The participant stated that they had trouble regulating emotional or sensory things with others, so they go to their room a lot to be alone.
      - One participant said that they do not think there has been a large impact from treatment changes or interruptions.

- One participant stated that being without prescription ADHD treatment has caused them to struggle for years. They have few relationships.

Round 3: Quality of Life

6. **What lifestyle interventions and/or changes have you tried, and how they have helped you?**
   a. **For example, have you used any behavioral therapy/strategies to help relieve or lessen your ADHD symptoms?**
   b. **Have you used other substances not prescribed by your healthcare provider to help relieve or lessen your ADHD symptoms?**

- Two participants indicated they have used lists to help with day-to-day tasks.
- Two participants stated that they use exercise to help manage their ADHD and found it very helpful.
- Two participants indicated that they take over the counter supplements, such as omega-3/fish oil and B vitamins.
- Three participants use their phone to help keep them organized.
- Two participants stated that they practice yoga and mindfulness but are not consistent about it.
- One participant mentioned that aromatherapy oils has been most helpful for them.
- One participant mentioned body double work and sleep as additional current interventions.
- One participant said they were drinking nine cups of black coffee per day and did not realize they were self-medicating with coffee until they received their ADHD diagnosis.

FDA Offices & Divisions in Attendance

- **Office of the Commissioner (OC) – *5 offices***
  - OC/OCPP/PAS – Office of the Commissioner/Office of Clinical Policy and Programs/Patient Affairs Staff (organizer)
  - OC/OCPP/OCliP – Office of the Commissioner/Office of Clinical Policy and Programs/Office of Clinical Policy
  - OC/OCPP/OOPD – Office of the Commissioner/Office of Clinical Policy and Programs/Office of Orphan Product Development
  - OC/OCPP/OPT – Office of the Commissioner/Office of Clinical Policy and Programs/Office of Pediatric Therapeutics
  - OC/OWH –Office of Women's Health

- **Center for Biologics Evaluation and Research (CBER) – *4 offices/divisions***

- CBER/OCBQ/DIS/PSB – Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Program Surveillance Branch
- CBER/OCD – Office of the Center Director
- CBER/OTP/OCE/DCEGM/GMB1 – Office of Therapeutic Products/Office of Clinical Evaluation/Division of Clinical Evaluation General Medicine/General Medicine Branch 1
- CBER/OTP/OCE/DCEGM/GMB2 - Office of Therapeutic Products/Office of Clinical Evaluation/Division of Clinical Evaluation General Medicine/General Medicine Branch 2

- **Center for Drug Evaluation and Research (CDER) – *6 offices/divisions***
  - CDER/OCD – Office of the Center Director (requestor)
  - CDER/OCOMM/PASES – Office of Communications/Professional Affairs and Stakeholder Engagement Staff
  - CDER/OMP – Office of Medical Policy
  - CDER/OND/ODES/DCOA – Office of New Drugs/Office of Drug Evaluation Science
  - CDER/OND/ON/DP - Office of New Drugs/Office of Neuroscience/Division of Psychiatry
  - CDER/OTS/OCP – Office of Translational Sciences/Office of Clinical Pharmacology

- **Center for Devices and Radiological Health – *7 offices/divisions***
  - CDRH/OPEQ/OHTI/DHTIB - Office of Product Evaluation and Quality/Office of Health Technology I/Division of Health Technology IB
  - CDRH/OPEQ/OHTI/DHTIC - Office of Product Evaluation and Quality/Office of Health Technology I/Division of Health Technology IC
  - CDRH/OPEQ/OHTIII/DHTIIIA - Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology IIIA
  - CDRH/OPEQ/OHTIII/DHTIIIB - Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology IIIB
  - CDRH/OPEQ/OHTIII/DHTIIIC - Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology IIIC
  - CDRH/OPEQ/OHTIV/DHTIVA – Office of Product Evaluation and Quality/Office of Health Technology IV/Division of Health Technology IVA
  - CDRH/OPEQ/OHTV/DHTVB - Office of Product Evaluation and Quality/Office of Health Technology V/Division of Health Technology VB

- **Center for Tobacco Products – *2 offices/divisions***
  - CTP/OS/DIHS – Office of Science/Division of Individual Health Science
  - CTP/OS/RS – Office of Science/Research Staff

Non-FDA Attendees

- Reagan-Udall Foundation for the FDA
- Patients

Financial Interest

Participants did not identify financial interests relevant to this meeting and are not receiving compensation for participation in this listening session.