



Parkinson's Disease Public Meeting on Patient-Focused Drug Development



September 22, 2015

12:30 – 1:30 pm	Registration
1:30 – 1:35 pm	Welcome Soujanya S. Giambone, MBA <i>Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA</i>
1:35 – 1:40 pm	Opening Remarks Billy Dunn, MD <i>Director, Division of Neurology Products (DNP), Office of New Drugs (OND), CDER, FDA</i>
1:40 – 1:50 pm	Overview of FDA's Patient-Focused Drug Development Initiative Theresa Mullin, PhD <i>Director, OSP, CDER, FDA</i>
1:50 – 2:00 pm	Background on Disease Area and Treatment Susanne Goldstein, MD <i>Medical officer, DNP, CDER, FDA</i>
2:00 – 2:05 pm	Overview of Discussion Format Soujanya S. Giambone, MBA <i>OSP, CDER, FDA</i>
2:05 – 2:35 pm	Panel #1 Comments on Topic 1 Topic 1: Disease symptoms and daily impacts that matter most to patients. A panel of patients and patient representatives will provide comments to start the discussion.
2:35 – 3:10 pm	Large-Group Facilitated Discussion on Topic 1 Patients and patient representatives in the audience are invited to add to the dialogue.
3:10 – 3:20 pm	Break
3:20 – 3:50 pm	Panel #2 Comments on Topic 2 Topic 2: Patient perspectives on current approaches to treating Parkinson's Disease. A panel of patients and patient representatives will provide comments to start the discussion.
3:50 – 4:25 pm	Large-Group Facilitated Discussion on Topic 2 Patients and patient representatives in the audience are invited to add to the dialogue.
4:25 – 4:55 pm	Open Public Comment
4:55 – 5:00 pm	Closing Remarks Eric Bastings, MD <i>Deputy Director, DNP, OND, CDER, FDA</i>

Discussion Questions

Topic 1: Disease symptoms and daily impacts that matter most to patients

1. Of all the symptoms that you experience because of your condition, which **1-3 symptoms** have the most significant impact on your life? (Examples may include difficulty moving, pain, constipation, difficulty concentrating or remembering, daytime sleepiness etc.)
2. Are there **specific activities** that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include daily hygiene, feeding, dressing, etc.)
 - a) How do your symptoms affect your daily life on the **best days**? On the **worst days**?
3. How has your ability to cope with symptoms **changed over time**?
 - a) Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?
4. What **worries you most** about your condition?
5. Are there friends or family that you can no longer visit because of your illness?

Topic 2: Patients' perspectives on current approaches to treating Parkinson's Disease

1. **What are you currently doing** to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as diet modification, exercise.)
 - a) What specific symptoms do your treatments address (for example; depression, constipation, memory difficulty, sleepiness)?
2. **How well** does your current treatment regimen treat the most significant symptoms of your disease?
 - a) How well do these treatments improve your ability to do specific activities that are important to you in your daily life?
3. What are the most significant **downsides to your current treatments**, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, need to visit your doctor or take medications frequently cause sleepiness, etc.)
4. Assuming there is no complete cure for your condition, what specific things would you look for in an **ideal treatment** for your condition?