

Navigating the Center for Drug Evaluation and Research: What You Should Know for Effective Engagement

March 31st, 2016

- 8:00 a.m. **Registration**
- 8:30 a.m. **Introduction and Opening Remarks**

SESSION ONE: BUILDING BLOCKS OF ENGAGEMENT...WHEN, WHY, AND HOW

- 8:45 a.m. **Can You Hear Me Now?** *The Importance of Patient Advocates*
- 9:00 a.m. **An NDA at the FDA** *Understanding the Drug Approval Processes*
- 9:30 a.m. **Engagement with the FDA**
- 9:55 a.m. **PFDDs and Me** *Promoting Patient Perspectives*
- 10:25 a.m. **Break**
- 10:40 a.m. **Drug Availability** *Shortages and Demand*
- 11:00 a.m. **Generic Drugs** *Busting the Myths*
- 11:30 a.m. **Lunch**
- 1:00 p.m. **Jeopardy** *Let's Play Jeopardy*

SESSION 2 – ENGAGEMENT...PUTTING THE PIECES TOGETHER

- 1:30 p.m. **Making Sure My Meds Are Safe** *Manufacturers and Quality Controls*
- 1:55 p.m. **The Small Print** *Reporting Side Effects*
- 2:20 p.m. **ABC's of OTC's** *Little-Known Facts about Over-the-Counter Drugs*
- 2:45 p.m. **Break**
- 3:00 p.m. **Learn from the Pros** *Stories of Engagement from Advocacy Groups*
- 3:40 p.m. **Final Words of Wisdom**