

Partners in Progress: Cancer Patient Advocates and FDA

Sponsored by the Food and Drug Administration (FDA)

Oncology Center of Excellence (OCE)

Supported by: American Association for Cancer Research (AACR), American Society of Clinical Oncology (ASCO), & American Society of Hematology (ASH)

Location: Food and Drug Administration, 10903 New Hampshire Ave, Great Room 1503 A, B & C,
Silver Spring, MD 20993

Date: November 13, 2017 9am-4pm

Time	Topic	Speaker
9:00 AM-	Introductory Comments & Welcome	Paul Kluetz (OCE)
9:30 AM		Annie Ellis (Patient Advocate)
		Jon Retzlaff (AACR)
		Jeannine Salamone & Shimere Sherwood (ASCO)
		Suzanne M. Leous (ASH)
9:30 AM-	Role/Mission of FDA Centers	Moderator: Paul Kluetz Richard Pazdur (OCE) Peter Marks (CBER) Jeffrey Shuren (CDRH)
10:20 AM		
	Q&A	
10:20 AM-	BREAK	
10:40 AM-	FDA Myth Busters	Virginia Kwitkowski (DHP)
12:00 PM		Gideon Blumenthal (OCE)
		Deb Miller (OHCA) Kevin Wright (OPDP)
		Q&A
12:00 PM-	LUNCH	
1:00 PM-	How Patients and Advocates are Crucial to Our Mission	Patty Spears (Patient Advocate) & Aviva Krauss (DHP)
2:00 PM		Paul Kluetz (OCE) Vishal Bhatnagar (DHP) Heather Benz (CDRH)
		Q&A
	Current FDA Outreach Efforts (PFDD, Patient Experience data in labeling)	
	Q&A	

2:00 PM-	Introductory Comments	Janet Woodcock (CDER)
3:00 PM	Expanded Access to Investigational Drugs	Joohee Sul (DOP2)
	Exploration of Real World Data	Carol Pamer (OSE)
	Q&A	
3:00 PM-	<ul style="list-style-type: none"> • Updates from OCE Centers on Recent Cancer Product Approvals • What's new and exciting? 	Steven Lemery (DOP2)
3:30 PM		Tara Ryan (CDRH) Najat Bouchkouj (CBER)
3:30 PM-	<ul style="list-style-type: none"> • Q&A • Adjourn 	Moderator: Paul Kluetz (OCE)
4:00 PM		

CBER=Center for Biologics Evaluation and Research; CDER=Center for Drug Evaluation and Research; CDRH=Center for Devices and Radiological Health; DHP=Division of Hematology Products; DOP2=Division of Oncology Products 2; OHCA=Office of Health and Constituent Affairs; OPDP= Office of Prescription Drug Promotion; OSE=Office of Surveillance and Epidemiology