

FDA-OCE: Childhood Cancer Advocacy Forum

March 15, 2019

FDA White Oak Campus Building 31

White Oak Great Room

10903 New Hampshire Avenue

Silver Spring, Maryland

AGENDA

9:00 a.m.	Welcome and Meeting Objectives	Gregory Reaman, M.D. Associate Director, Pediatric Oncology, OCE, OMPT, OC OHOP, OND, CDER, FDA
9:05	FDA's External Engagement and Patient Advocacy: A Dialogue to Better Inform FDA of Patient Needs and Priorities	Rea Blakey Associate Director, External Outreach and Engagement
9:20	Discussion	
9:35	Avoiding Pitfalls in Drug Development	Nicholas Richardson, DO, MPH Medical Officer DHP, OHOP, OND, CDER, FDA
9:50	Approved Cancer Drugs in Children	Amy Barone, M.D. Medical Officer DOP2, OHOP, OND, CDER, FDA
10:05	BPCA/WR Study Results	Denise Casey, M.D. Medical Officer DOP2, OHOP, OND, CDER, FDA
10:20	Expanded Access to Investigational Drugs	Aviva Krauss, M.D. Medical Officer DHP, OHOP, OND, CDER, FDA
10:35	Discussion	Gregory Reaman M.D
11:00	<i>Break</i>	
11:15	FDARA Implementation	Nicole Drezner, M.D. Medical Officer DOP2, OHOP, OND, CDER, FDA

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11:30	Pediatric PROs: Are they feasible?	Inside FDA Speaker
11:45	What's new in CBER?	Megha Kaushal
12:00	Discussion	Gregory Reaman, M.D.
1:00	<i>Adjourn</i>	