2019 FDA-OCE Childhood Cancer Advocacy Forum

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Disclosures and Disclaimer

- No financial relationships to disclose
- No discussion of off label or investigational use of specific products/devices
- The views expressed are those of the speaker and do not necessarily represent the opinions of the Food and Drug Administration

Pediatric Access to New Therapeutic Agents

- FDA is committed to the development of effective and safe therapies for childhood malignancies.
- FDA initiatives assist pediatric development generally and pediatric cancer therapy development specifically.

Draft report to the U.S. Congress, Dept. of Health and Human Services, 2003

Principles of Pediatric Drug Development that Guide Regulations

- Pediatric patients should be given medicines that have been properly evaluated for their use
- Product development should include pediatric studies when pediatric use is anticipated.

AGENDA

1. FDA's External Engagement and Patient Advocacy: A Dialogue to Better Inform FDA of Patient Needs and Priorities
2. Avoiding Pitfalls in Drug Development
3. Approved Cancer Drugs in Children
4. BPCA/WR Study Results
5. Expanded Access to Investigational Drugs
6. FDARA Implementation
7. Clinical Outcome Assessment for Pediatric Clinical Trials
8. What's new in CBER?


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