Pediatric Medical Devices Workshop

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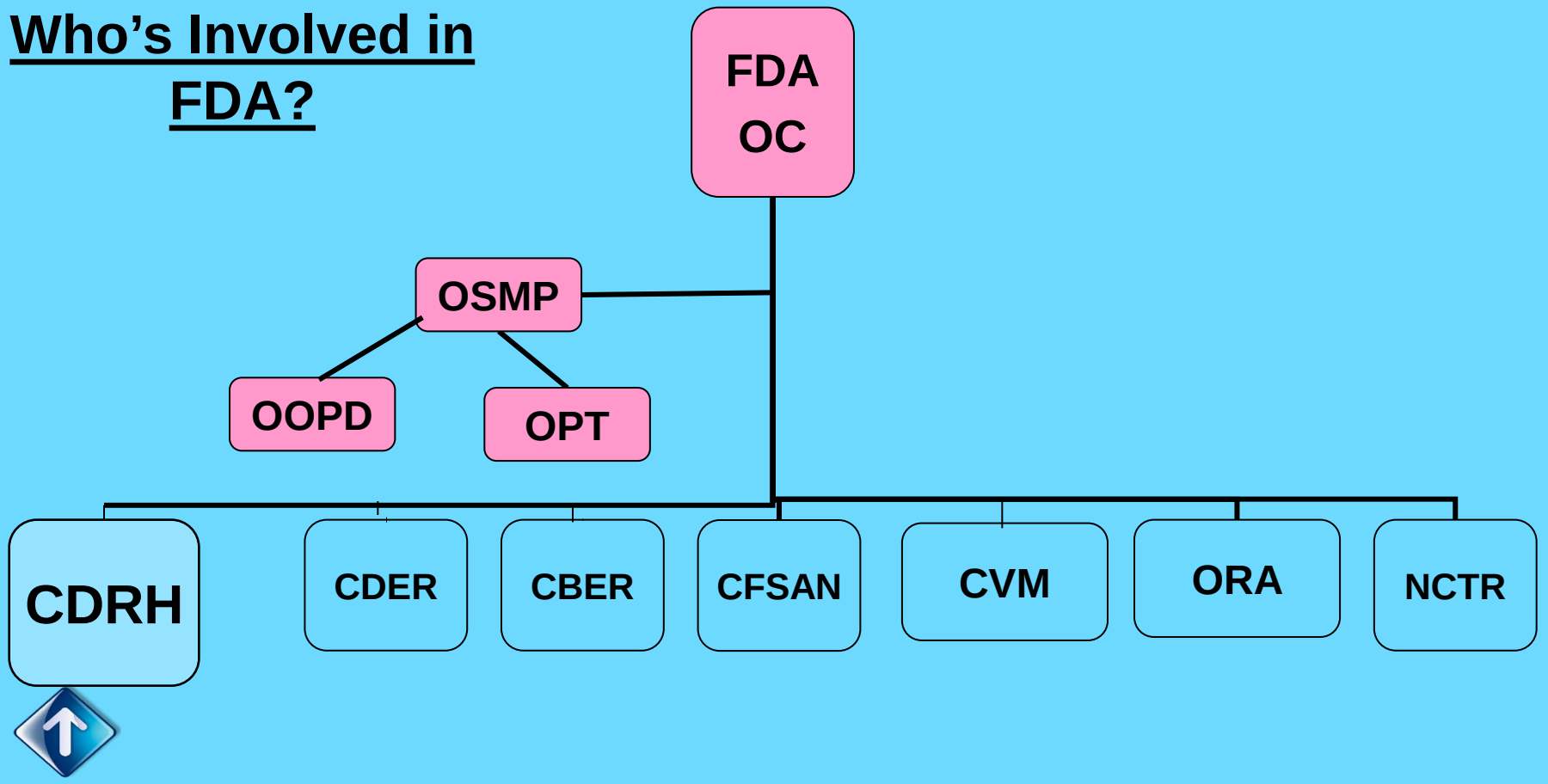
September 24, 2012

Disclaimer

- **This presentation represents the professional opinion of the speaker and is not an official document, guidance or policy of the U.S. Government, the Department of Health and Human Services, or the Food and Drug Administration, nor should any official endorsement be inferred.**
- **This talk is not intended to promote any medical products as safe or effective. Any discussion mentioning specific devices is solely intended to illustrate a point.**
- **No conflicts to declare**

Who's Involved in FDA?



CDRH - Center for Devices and Radiological Health
OOPD - Office of Orphan Drug Products
OPT - Office of Pediatric Therapeutics
OSMP - Office of Special Medical Programs
OC - Office of the Commissioner

FDA Device Definition-1998 US Congress Federal Food, Drug, & Cosmetic Act, Sec. 201.[321].

- Instrument
- Apparatus
- Implement
- Machine
- Contrivance
- Implant
- In vitro reagent
- Similar articles

- Not metabolized in the body
- Not a drug, biologic, or food

How are children defined by the FDA?





CDRH definition birth through 21 years, 2003 Guidance

NIH and AAP definition <21 years

CDER definition <16 years (CFR 201.57)

CDRH (Center for Devices and Radiological Health/FDA)
CDER (Center for Drug Evaluation and Research/FDA)
AAP (American Academy of Pediatrics)

Pediatric age categories
CDRH Guidance

Neonate	**Birth - 1 month**
Infant	**>1 month - 2 years**
Child	**>2 - 12 years**
Adolescent	**>12 - 21 years**

History for Pediatric Devices

- 2002 Meetings with AAP and other external stakeholders to assess unmet needs for pediatric devices
- 2003 CDRH Draft Pediatric Guidance
- 2007 Pediatric Medical Device Safety & Improvement Act
  - Provides for waiver of limitation on profit making for HDEs being developed for pediatrics
  - Requires periodic safety and annual review for pediatric HDEs by the Pediatric Advisory Committee for those devices utilizing the profit making waiver
  - Authorizes the Pediatric Device Consortia Program
- 2008 NIH Pediatric Medical Devices Stakeholders Workshop/ Draft Pediatric Device Development Plan
- Pediatric Device Consortium - 5 grants have been issued since 2009

2012 FDA Safety and Innovation ACT (FDASIA)

The 2012 legislation

- Renews and strengthens pediatric device development
- Reauthorizes and preserves the pediatric HDE profit incentive
- Retains pediatric-focused safety review by the Pediatric Advisory Committee for pediatric HDEs with profit-making waiver
- Requires companies to submit pediatric information in device applications
- Reauthorizes the successful Pediatric Device Consortium for 5 years

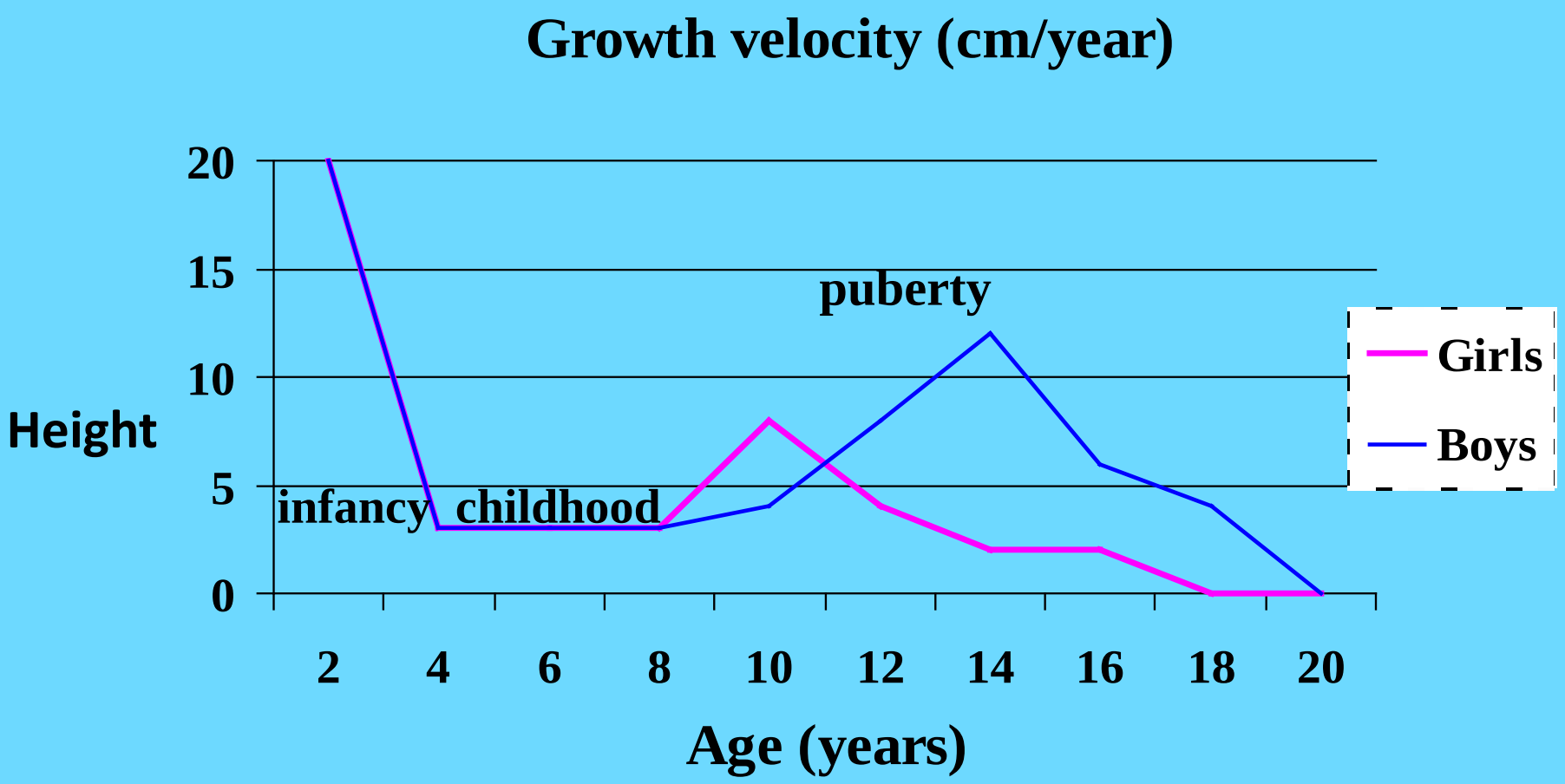
CDRH Pediatric Guidance and important issues to consider for the pediatric population

- Patient age, weight, and body size
- Growth and development including physical, physiologic and hormonal changes
- Specific subpopulations for diseases (pathophysiology, age at diagnosis, stage of disease)
- Behavioral and psychosocial factors
- Human factors
- Engineering to take into account biomaterials and exposures
- Pre-clinical bench or animal testing
- Published literature
- Safety and effectiveness in various subgroups

Pediatric “Particulars”

- Growth rates are variable across different pediatric sub-populations.
- Developmental changes may make children more vulnerable to the effects of system interventions (drugs, biologics or devices).
- Neonatal adverse events may be particularly difficult to assess because of both yet to be expressed development and underlying problems (e.g., seizures).
- Lack of validated endpoints in the very young populations in certain situations make it even more difficult to assess benefit.

Growth velocity for the pediatric population



Pediatrics

- Tremendous strides have been made in the development of drug therapies and studies in almost 500 products with new pediatric information in labeling over the last 15 years.
- Incentives and requirements helped make that happen.
- The process to do this for devices is evolving.

Thank you!