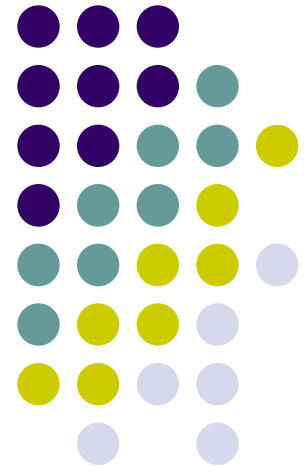


# FDA & Pediatric Medical Device Development

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PMDI Consortium Conference  
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# Today's Talk

- Children are not little adults
- How devices are used in children
- Broad swatch of medical device world
- How devices are used in children
- Issues and themes to date
- Device vs Drug development & regulation

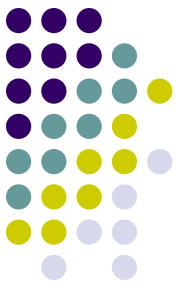
# Children are not little adults...



# Children are Not Little Adults



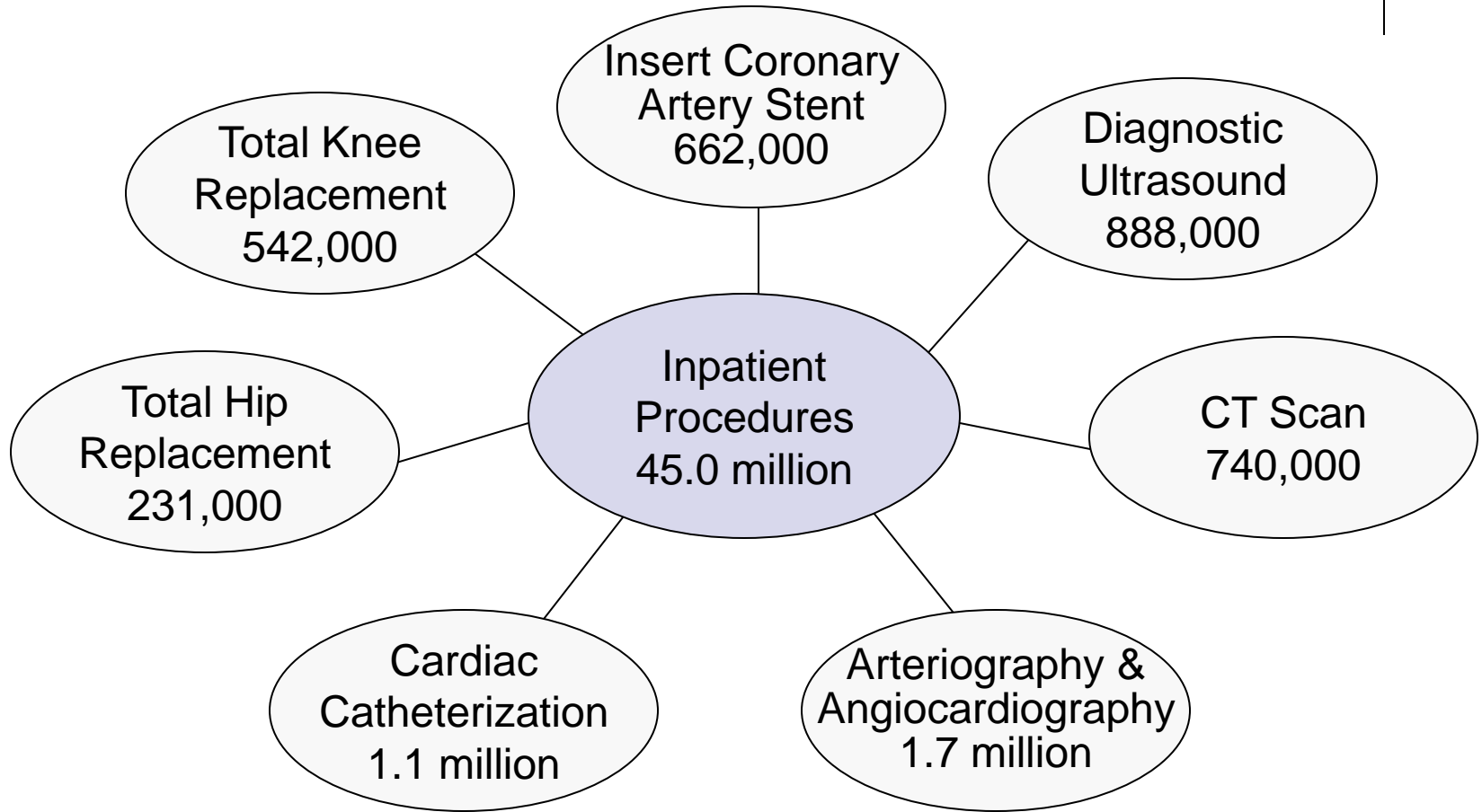
- Undergo a rapid developmental trajectory
  - From Birth to 1<sup>st</sup> birthday
    - Triple birth weight
    - limited head control to cruising/immature gait
    - Newborn cry to pointing and single words
  - Puberty
  - Linear growth trajectory
- Long “shelf life”



# A Medical Device is...

- Defined in law—Food, Drug & Cosmetic Act Medical Device Amendments (May 28, 1976)
- Section 201(h) of the Act:
  - Diagnosis, cure, mitigation, treatment or prevention of disease or condition
  - Affects structure or function of the body
  - Does not achieve intended use through chemical action
  - Is not metabolized to achieve effect

# Inpatient Medical Devices use in the United States



# CDRH Regulates all Medical Devices



***Simple***



***Complex***

Tongue Depressor

Bandage

Crutches

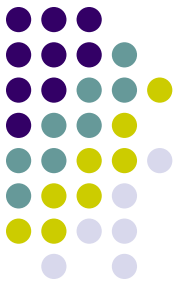
Thermometer

Computerized Tomography Machine

Robotic Surgery Device

Implanted Defibrillator

Lasers



# How Medical Devices are developed or put to use for Children

# Design or Adaptation of Medical Devices for Children

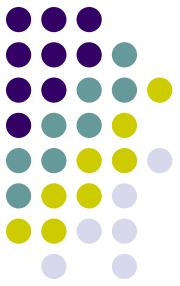


- Devices unique to children
  - Infant incubator
  - Newborn hearing screener
- Devices developed primarily for children, also used in adults
  - Atrial septal defect occluder
  - Cerebrospinal fluid shunt
- Same core device, different child accessories
  - Pulse oximeter with infant sensor attachment
  - AED paddles that deliver shocks according to pediatric specific algorithms

# Design or Adaptation of Medical Devices for Children



- Variation in device use or technique to accommodate developmental differences
  - Adjustment in radiation dose & frequency for CT scans
  - Use in pediatric cardiac procedures of adult bile duct stents
  - Shift in implantation site for implanted pacemaker in young children
- Variation in device size for use with smaller patients
  - Bronchoscopes
  - Heart valves
  - Testicular prostheses



# Adult Devices Used in Children

## Class 1



Tanning booth



Crutches



Exam glove

## Class 2



Orthopedic hardware



Tampon



Contact lens

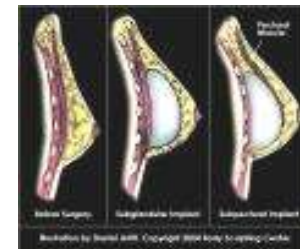
## Class 3



Insulin pump



HIV testing

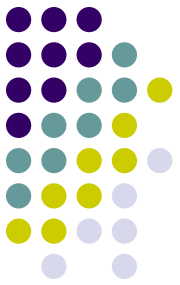


“Cup & gown”



# Issues & Themes to date

- Infant sleep positioner safety alert
- Environmental exposures from medical devices
  - Tanning Beds—Should children have access?
  - Medical sources of radiation exposure
- Tremendous off label use
- Barriers to development pathway
  - IRBs don't get device trials
  - Privacy issues



# Infant Sleep Positioners

- 510(k) Class I device
- Approved since 1980's—variety of indications
- “Back to Sleep” –1994 to present
- Recent submission—reviewer started to delve into history; one death report
- CPSC – Safe infant sleep initiative underway
  - Informed us of 12 other deaths, shared reports
- Safety notice, regulatory activities
- Educational campaign ongoing



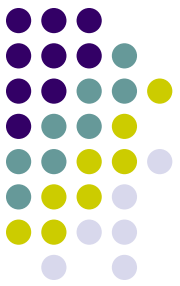
# Lessons Learned

- Value of partnering with sister federal agency
  - FDA vs CPSC clout & resources
- Complexity of the marketplace
  - CPSC Reach—big retailers, Amazon.com, eBay, gray market (2<sup>nd</sup> hand stores, hand-me-downs)
  - FDA Reach--Health & Regulatory
- Unintended consequences

# Environmental Exposures from Medical Devices



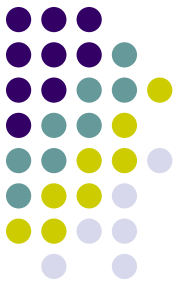
- Tanning beds
  - Higher UV radiation exposure
  - Evidence of “addictive tanning behavior”
  - Should access by children & youth be restricted?
- Radiation from medical devices
  - Potential impact on children with complex diseases living longer who need monitoring (example: congenital heart disease)
  - CDRH initiative to optimize use & dosing



# Device vs Drug Development

Developmental Feature	Device	Drug
Rate of Technology Change	Fast	Slow
Ease of in vitro assessment	High	Low
Reimbursement during clinical trials	Frequent	Rare
Influence of MD technique on results	High	Low
Ability to visualize performance after use	High	Low
Definition of “orphan” (# of patients)	4,000	200 k
# of full scale studies usually required	1	2
# of regulatory classes	3	1

# Pediatric Drug Regulation— Observations



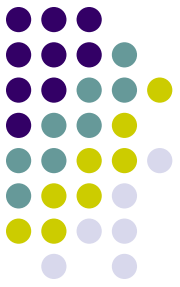
- What has worked
  - Having a pediatric committee oversee drug studies
  - On-patent written request process
  - Strong requirement to conduct pediatric studies
  - Asking for pediatric plans early
  - The pediatric section of labeling
  - Transparency requirements
    - Pediatric studies
    - Pediatric labeling
    - FDA reviews of pediatric studies



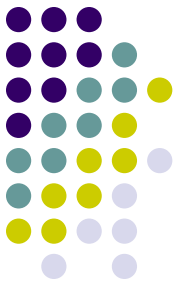
# Where are the Challenges

- Finding the right mix of incentives and requirements to foster pediatric device development
- Complexity, especially with combination products
- Fostering successful partnerships between government agencies
- Moving beyond the “drug development” paradigm

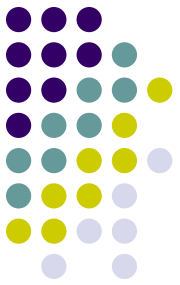
# FDA/CDRH Themes and Commitments



- Foster development of rare disease therapies
- CDRH— objectives embodied in 510(k) reform
  - Fostering medical device innovation
  - Enhancing regulatory predictability, reliability, & efficiency
  - Improving patient safety
- Other CDRH improvement efforts
  - Unique Device Identifier (UDI)
  - Electronic labeling
- Critical Path—smarter product development
- Partnering within and without



**Shout out for FDA!!**



**Thank You!!**

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