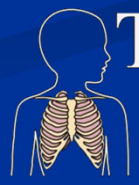
Dynamics of Pediatric Device Innovation

Mike Vitale
Bob Campbell



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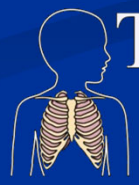
Is there a problem?



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Pediatric Medical Device Innovation, Regulation, and Legislation: Unmet Needs from the Pediatric Orthopaedist's Perspective

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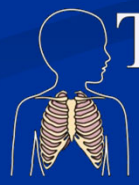
Pediatric Orthopaedic Surgery

Dynamics of pediatric device innovation fundamentally different than *adults*

- Markets are small
- Financial incentives weak
- Liability concerns
- Methodological challenge to premarket trials and post market surveillance
  - Size, outcomes,

- => unmet need for novel, *child specific*, medical devices



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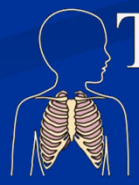
Dynamics of pediatric device innovation fundamentally different from *pharmaceuticals*

- Structure of industry
- Incremental improvements = moving target
- Role of academic health centers (tertiary care)
- Companies capture relatively limited sales from any single product
- Device life cycle short and patents not as strong

- => unmet need for novel, child specific, medical *devices*



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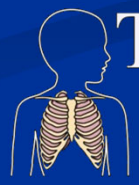
Orphan Drug Legislation '83

- Powerful legislation
  - <200,000 people!

- 50% tax credit
- Grants for trials
- FDA regulatory asssitance
- 7 yr marketing exclusivity ****



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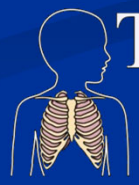
Devices: Growth Modulation

The Future of Scoliosis Surgery

- Staples approved for anterior deformity with pedicle screws and rods... Irrelevent indication
- Shape memory alloy staple on-label use is confined to non-spinal osteotomy fixation (feet) !
- Teaching and Research is a challenge
- Innovation and Development Difficult



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Campbell's Turn

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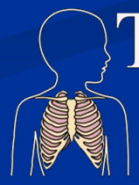
Barriers to Pediatric Device Development in USA

- FDA Small Group Pediatric Device Task Force Meetings, Washington, DC, 2004
  - The Academy of American Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation
  - Industry, FDA, NIH, NORD, Nat Assoc of Children's Hospitals, pediatric clinical specialists.
  - Orthopaedic, cardiac, GI, pulmonary, other devices
- Barriers
  - Economic
  - Regulatory
    - Humanitarian Exemption Law
  - No data on extent of unmet pediatric device needs



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AAOS Pediatric Device user survey Feb, 2005

- 525 Pediatric Orthopaedic Society of North America (POSNA) members
- 318 Scoliosis Research Society (SRS) members,
- 185 members with dual membership in POSNA and SRS.
  - 318 members responded (31 %)
    - Approx 100 volunteered for future ped device surveys

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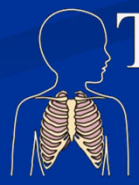
Survey Results

- 55% of respondents were full time academicians in practice for an average of 19 years.
- 30% of respondents reported participating in pediatric device development.

- 33.3% used adult-sized devices on children in the past 36 months
- 25% had ordered custom pediatric devices in the past 36 months
- 1 out of 3 respondents had used devices "off label" on children in the past 36 months.

- Children age 2 to 12 years, had the greatest need for pediatric devices.
- Infants (age 1 month to 2 years) were ranked 2nd.



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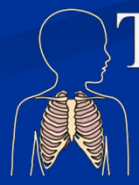
Respondents indicated device manufacturers are somewhat meeting the needs of their pediatric patients.



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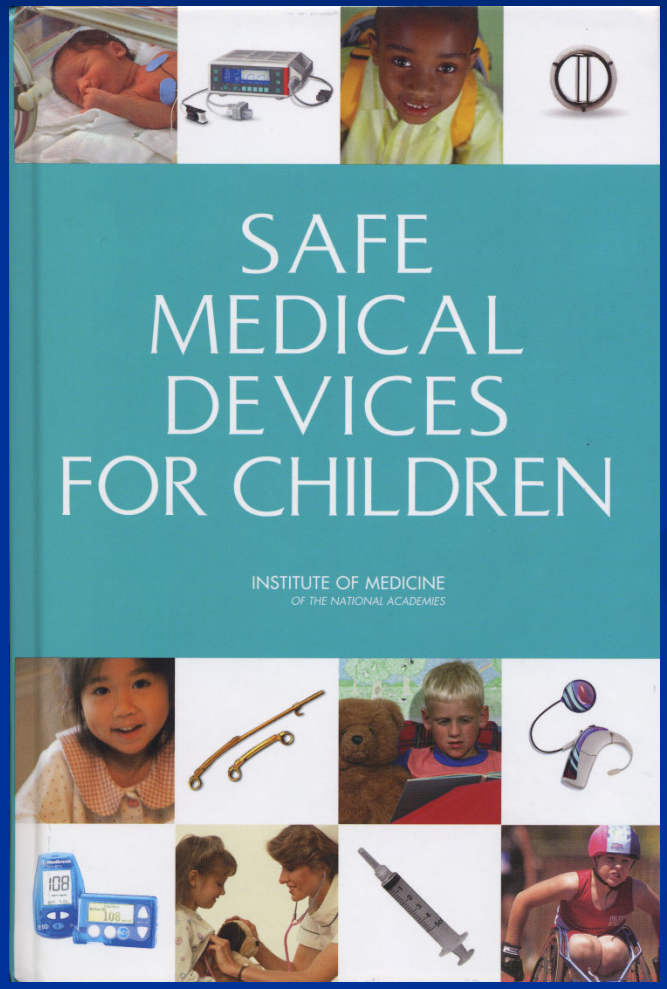
IOM report



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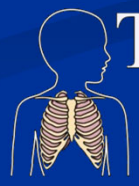
Pediatric Device Safety and Improvement Act of 2007

- Profit allowed for HDE products
- FDA/NIH to define device needs and gaps in pediatric device research
- Grants for pediatric device non-profit consortium to mentor inventors
- Monitor progress



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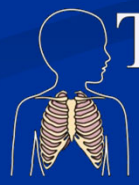
Current Status

- FDA becoming more pro-active about pediatric devices
- NIH directly involved in promoting pediatric device development
- Funding for consortiums?
- Joint SRS-POSNA task force for advancement of pediatric device development



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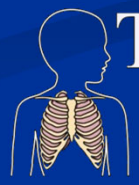
NIH Pediatric Device Stakeholders meeting Jul 08

- Report to Congress Sept 08
- Needs assessment from surveys of clinicians
- "Holistic" proposal for funding of pediatric device development
- Point person at NIH for pediatric devices :

  Dr Steven Hirschfeld



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Thank You!