

Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases

FDA OOPD and CDRH Public Workshop

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American Academy
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Disclosure

I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services discussed in this session.

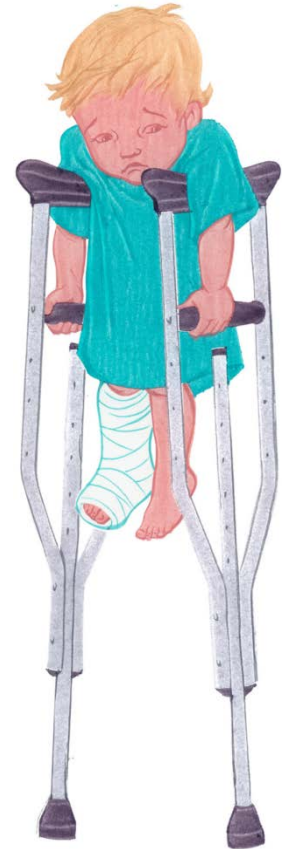


What Has Been Done...

- Stakeholder meetings beginning in 2004
- 2007 and 2012 FDA legislation on pediatric Humanitarian Device Exemption incentive
 - New pediatric HDEs
 - Increased pediatric HUDs
 - Heightened awareness of gaps and needs
- Pediatric Device Consortia (PDC) program

What Needs to be Done...

- Full funding for the PDC program
- Insurance coverage
- Extrapolation guidance
- Tracking for potential pediatric uses
- Engagement with broader stakeholders



What *Could* be Done...

Political feasibility – cost,
competing legislative priorities,
risk vs benefit, willing
stakeholders

- IRBs
- Lessons learned from pediatric drug laws (BPCA and PREA)



What *Could* be Done...

- Increase pediatric expertise at CDRH and on FDA advisory committees
- Build on success of PDC program
- Shift paradigm around pediatric device needs and impact of regulation





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