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

## FDA OOPD and CDRH Public Workshop

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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

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# 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)

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# 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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