Heterogeneity of Treatment Effect
and
Pediatric Medical Device Development

FDA – Johns Hopkins University CERSI
Workshop 2018

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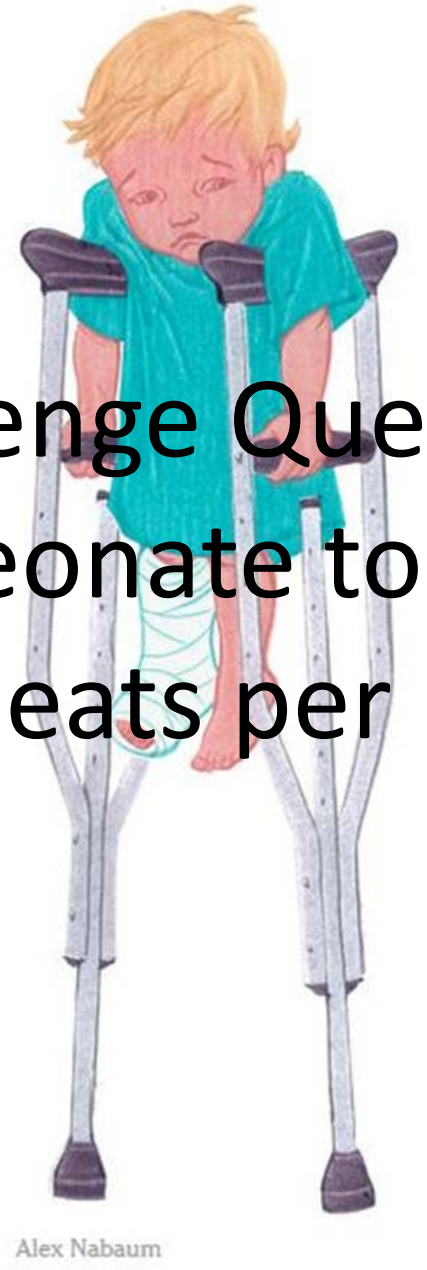

Challenge Question:
How long can a neonate tolerate a heart rate of 220 beats per minute?

FDA CDRH - Pediatrics and Special Populations

Pediatric Age Groups

Birth – 28 days | 29 days - < 2yrs | 2yrs - < 12yrs | 12yrs - < 22yrs

Contains Nonbinding Recommendations

Pediatric Information for X-ray Imaging Device Premarket Notifications

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Guidance for Industry and Food and Drug Administration Staff

Document issued on November 28, 2017.

The draft of this document was issued on May 10, 2012.

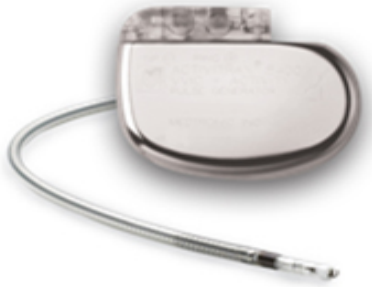
A world where it can be made for children first is here…

External Pacemaker

1958

Implantable Pacemaker

1960



Rate Responsive Pacemaker

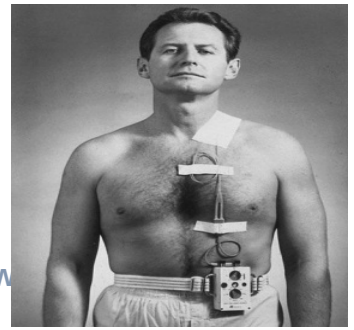
1986

MRI Conditional Pacemaker

2011

Intracardiac Pacemaker

Today



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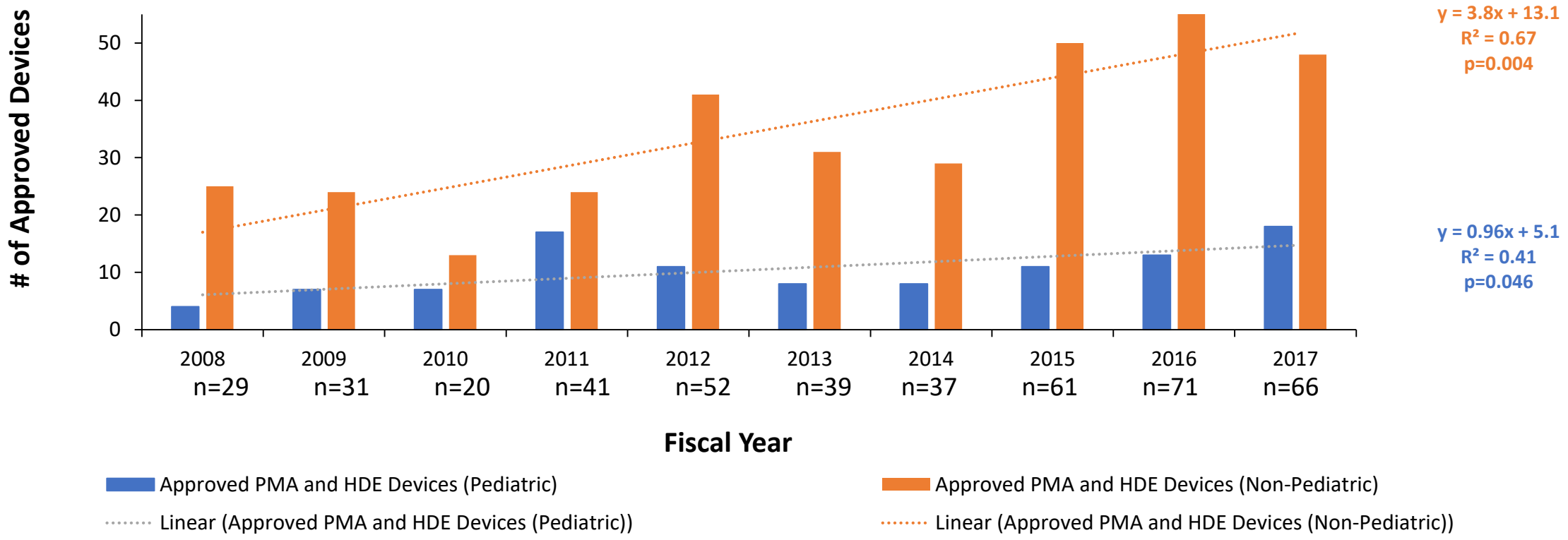
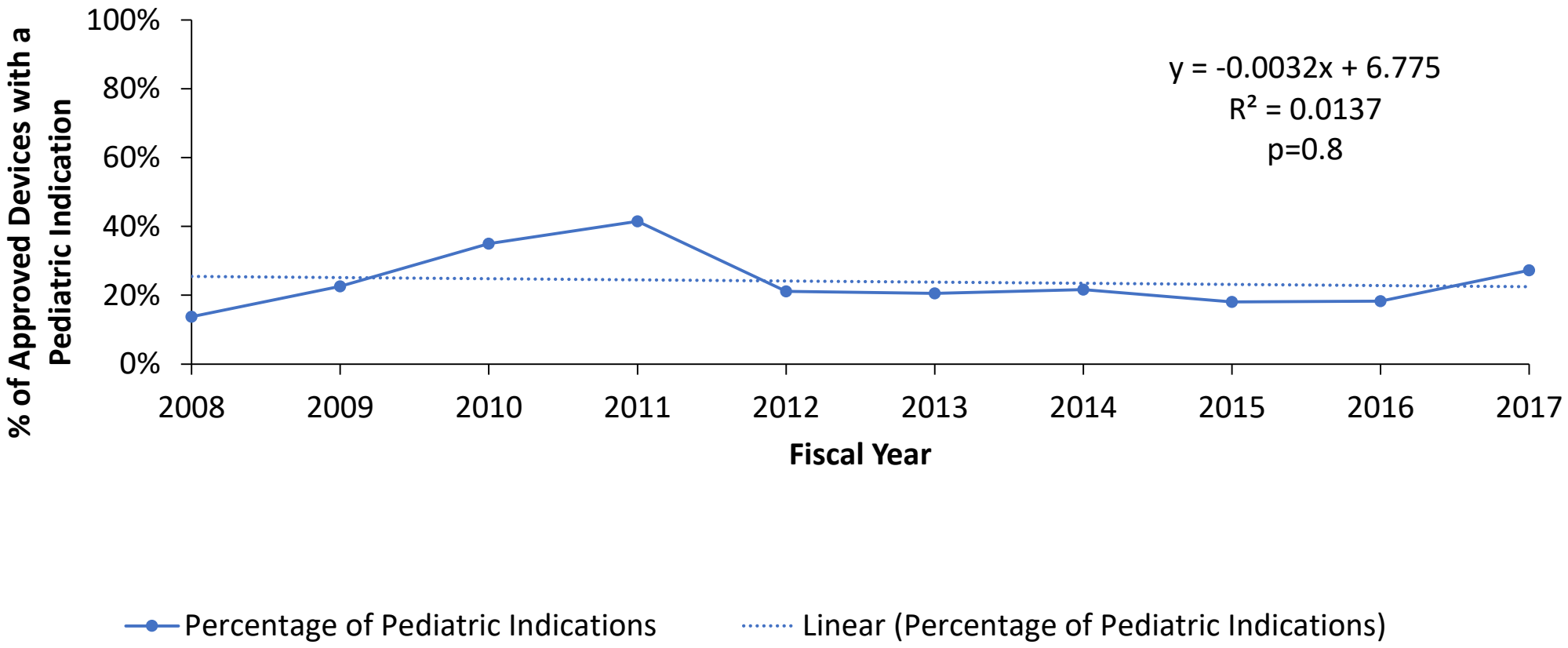
Adult Devices Increasing Faster than Pediatric



Upward trajectory in the total number of PMA and HDE applications
Adult approvals significantly greater than pediatric approvals

Little Change in Percentage of Pediatric Approvals



Novel devices are not being developed for children at a similar rate as for adults

Steps Toward a Contemporary System for Adults and Children

If we can foster a system that supports technology innovation that serves the complex needs of children, then we will accelerate device development for everyone

Thank You

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