

Pediatric Device Stakeholders Workshop

July 23, 2008

Jointly Organized by the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH)

Session #	TIME	AGENDA ¹ TOPICS
		<i>Background and Current Status</i>
-	7:30 – 8:00 AM	Registration
-	8:00 – 8:10 AM	Welcome and Introductions <ul style="list-style-type: none"> – Don Wright, Principal Deputy Assistant Secretary of Health, U.S. Department of Health and Human Services – Denise Dougherty (AHRQ)
1	8:10 – 8:40 AM	Introduction to the Legislation – an Overview of the Food and Drug Administration Act of 2007 <ul style="list-style-type: none"> – Tamar Magarik Haro (U.S. Senate HELP Committee) – Ann Halbower (University of Colorado)
2	8:40 – 9:30 AM	Panel Discussion on History, Current Status, Barriers, & Issues on Pediatric Device <ul style="list-style-type: none"> – Jon Abramson (American Academy of Pediatrics) – Susan Alpert (Medtronic) – Laurel Blakemore (Children’s National Medical Center/American Academy of Orthopaedic Surgeons) – Kurt Dasse (Levitronix) – Ann Halbower (University of Colorado)
3	9:30 – 10:45 AM	Pediatric Devices and the FDA <ul style="list-style-type: none"> • Pediatric Devices: The Premarket Perspective <ul style="list-style-type: none"> – Joy Samuels-Reid (FDA) • Orphan Products and Funding Opportunities <ul style="list-style-type: none"> – Linda Ulrich (FDA) • Humanitarian Device Exemptions for Pediatric Devices <ul style="list-style-type: none"> – Stephen Rhodes (FDA) • Pediatric Devices: The Postmarket Perspective <ul style="list-style-type: none"> – Tom Gross (FDA)
	10:45 – 11:00 AM	<i>BREAK</i>
4	11:00 – 11:15 AM	Review of Current Pediatric Device Programmatic Efforts & Funding Opportunities <ul style="list-style-type: none"> – Marva Moxey-Mims (NIH) – AHRQ, FDA to provide speakers
5	11:15 – 12:00 PM	Crossing the Threshold - Evidence needed to procure additional funding and strategies for further development <ul style="list-style-type: none"> – Tom Roberts (Noonday Global Management) – Brian Duncan (Cleveland Clinic Foundation/Society of Thoracic Surgeons) – Greg Frykman (Washington Research Group) – Aaron Kowalski (Juvenile Diabetes Research Foundation) – William Lawrence (AHRQ) – Beverly Lorell (King and Spalding, LLP) – Evan Nadler (New York University School of Medicine)

¹ Note that the agenda is subject to change depending on speaker availability

		<ul style="list-style-type: none"> - Aaron Sandoski (Norwich Ventures) - Ross Trimby (The Institute for Pediatric Innovation)
6	12:00 – 12:10 PM	Review of Request for Information (RFI) Comments <ul style="list-style-type: none"> - Carol Blaisdell (National Heart, Lung, and Blood Institute/NIH)
	12:10 – 12:30 PM	LUNCH PICK-UP BREAK
		<i>Small Group Discussions - WORKING LUNCH</i>
7	12:30 – 2:00 PM	<ul style="list-style-type: none"> • Needs identification and analysis <ul style="list-style-type: none"> - Susan Alpert (Medtronic) - Laurel Blakemore (Children’s National Medical Center/American Academy of Orthopaedic Surgeons) - Anne Elixhauser (AHRQ) - Ross Trimby (The Institute for Pediatric Innovation) - Liza Jenkins (Children’s Interstitial Lung Disease Foundation) • Safety monitoring for diagnostic devices <ul style="list-style-type: none"> - Don Frush (Duke University Medical Center) - Don Hagler (Mayo Clinic, Minnesota) • Strategies and mechanics to adapt devices for pediatric use <ul style="list-style-type: none"> - Evan Nadler (New York University School of Medicine) - Allen Browne (Nationwide Children’s Hospital) - Ann Gettys (Children’s Interstitial Lung Disease Foundation) • Challenges to device development <ul style="list-style-type: none"> - Robert Campbell (University of Texas/National Organization for Rare Disorders, Inc.) - Franck Gougeon (AGA Medical Corporation) - Jody Raus (AGA Medical Corporation) - Malvern Benjamin (Rheomedix)
	2:00 – 2:15 PM	BREAK
		<i>Review of Small Group Discussions</i>
8	2:15 – 3:30 PM	<ul style="list-style-type: none"> • Report of lunch group discussions with opportunity for questions from the floor <ul style="list-style-type: none"> - Judy Cope (FDA) - Anne Trontell (AHRQ)
		<i>Open Discussion</i>
9	3:30 – 3:45 PM	<ul style="list-style-type: none"> • Unmet Needs in Pediatric Device Research and Development <ul style="list-style-type: none"> - Steven Hirschfeld (<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development/NIH) - Moderator
		<i>Discussion on Draft Research Plans</i>
10	3:45 – 4:45 PM	Panel Discussion and Questions on Draft Agency Plans <ul style="list-style-type: none"> - Steven Hirschfeld - Moderator - Jon Abramson - Susan Alpert - Robert Campbell - David Feigal, Jr. - Ann Gettys - Ann Halbower
11	4:45 – 5:00 PM	<ul style="list-style-type: none"> • Next Steps

		- David Feigal, Jr.
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