

Legislative Update: Pediatric Research

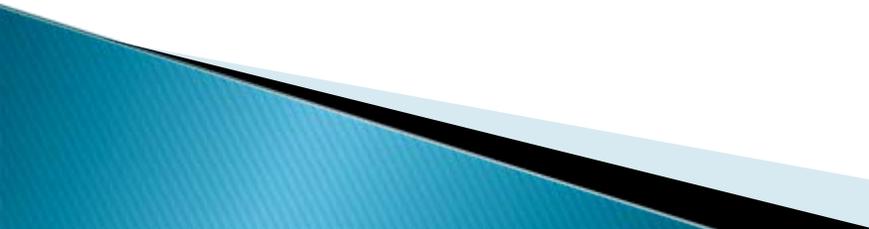
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Child Health and Human Development

Since the Children's Health Act of 2000...

- ▶ Ongoing Congressional support (via appropriations process) for NCS
 - ▶ The NIH Reauthorization Act of 2006
 - ▶ Disease/Condition-specific Legislation
 - ▶ Health Care Reform
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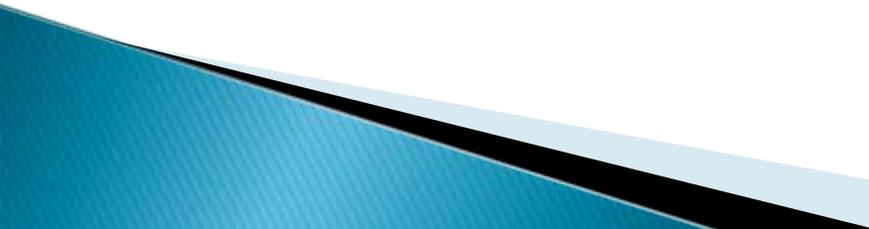
NCS Appropriations

- ▶ FY 2001-2006 -- NICHD and its federal partners fund early planning stages of NCS
 - ▶ FY 2007-2010 – Congress provides specific funding for NCS through NIH OD
 - ▶ FY 2011 – President's Budget requests full funding
 - ▶ Annual appropriations committee report language
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FY 2010 House Report Language

- ▶ OFFICE OF THE DIRECTOR
- ▶ The Committee includes bill language within the Office of the Director account allocating \$194,400,000 to continue the National Children's Study (NCS). The Committee is aware that the NCS is now projected to exceed its original budget by a substantial margin. The Committee believes NIH is prudent in taking the step to 'pause' the research before initiating the full study in order to test in advance the feasibility, acceptability, and cost of each element. However, the Committee remains firmly committed to the NCS, believing it will provide important answers about the influence of the environment on children's health and development.

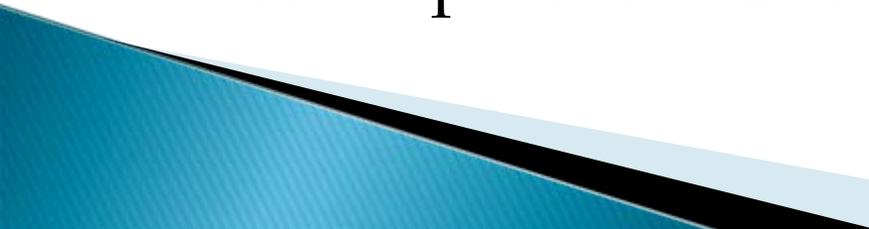
Congressional Oversight Authority

- ▶ Authorizing legislation: Section 400 of the Public Health Service Act
 - ▶ Authorizing Committees: House Energy and Commerce Committee; Senate Health, Education, Labor and Pensions Committee
 - ▶ Frequent requests for briefings, correspondence
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The NIH Reauthorization Act of 2006

- ▶ Goal: preventing future disease/condition-specific legislation
- ▶ Consolidated and reconciled previous piecemeal NIH legislation
- ▶ Retained (reauthorized) pediatric provisions already in law:
 - NCS
 - Pediatric Research Initiative
 - Autism, Fragile X, Contraceptive Research

Major Pediatric Laws Passed Since 2006

- ▶ Combating Autism Act (2006)
 - ▶ “PREEMIE” (prematurity research and services) (2006)
 - ▶ Food and Drug Administration Amendments Act (2007)
 - ▶ Newborn Screening Saves Lives Act (2008)
 - ▶ Traumatic Brain Injury Act (2008)
 - ▶ Paul Wellstone Muscular Dystrophy CARE Act (2008)
 - ▶ Prenatally and Postnatally Diagnosed Conditions Awareness Act (2008)
 - ▶ Christopher and Dana Reeve Paralysis Act (2009)
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And, of course...

- ▶ Public Law 110-154 (2007): renamed the NICHD:

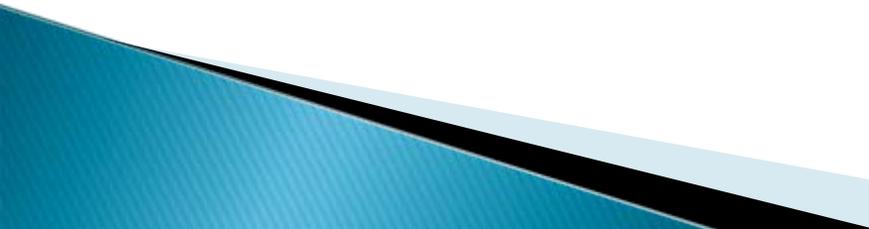
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Pending Legislative Proposals

- ▶ S. 353 (Brown)/H.R.758 (DeGette) - **Pediatric Research Consortia**
- ▶ H.R.2149 (Kennedy)/S.1158 (Stabenow) - **Spinal Muscular Atrophy**
- ▶ H.R.521(King)/H.R.3212(Pallone)/S.1445(La utenberg) - **Stillbirth**
- ▶ H.R.3656 (McMorris-Rodgers) - **Down Syndrome**
- ▶ Discussion draft (Fudge) - **Childhood Obesity**

Patient Protection and Affordability Act

- ▶ Cures Acceleration Network
 - ▶ Comparative Effectiveness Research
 - ▶ Postpartum Depression Research
 - ▶ Pain Research
 - ▶ Emergency Medicine Research
 - ▶ Access to Clinical Trials
 - ▶ Home Visitation Programs
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Thank You

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