

Public Policy Council
Washington Update
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AAP Committee on Drugs Chair Testifies Before House Subcommittee on Safe & Effective Drugs for Children

Last Wednesday, AAP Committee on Drugs Chair Daniel A.C. Frattarelli, MD, FAAP, [testified](#) before the House Energy & Commerce Health Subcommittee, urging Congress to reauthorize two critical laws for children: the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). The hearing's webcast is available [here](#).

Dr. Frattarelli offered five recommendations to the Subcommittee to improve these two laws: plan pediatric studies earlier in the drug development process; improve accountability; promote studies in younger age groups; increase transparency provisions to increase access to important pediatric information; and make PREA permanent since basic safety and efficacy provisions for adults do not expire.

Reauthorization of the programs received support from Food and Drug Administration Commissioner Margaret Hamburg as well as members of Congress from both political parties. Many of the PPC member organizations are signing a [coalition document](#) with priorities for the reauthorization.

PPC Advocate Fly-In Day

AAP Washington staff are working with PPC representatives in order to coalesce a group of pediatric advocates in Washington, DC on **Thursday, March 22** for a day of Hill and administration visits. Meetings would be to thank Members of Congress for their support in keeping funding strong for the NIH in the FY12 megabus, to look ahead to the FY13 budget and to possibly meet with the Office of Management and Budget. If you are interested in attending, please speak with your PPC representatives or Becca Davison rdavison@aap.org in the AAP Department of Federal Affairs in order to get full details.

National Advisory Child Health and Human Development Council Meeting

On Thursday, January 26, the National Advisory Child Health and Human Development Council had its first meeting in 2012. Alan Guttmacher, MD, Director of the National Institute of Child Health and Human Development (NICHD) led off the council meeting with an NICHD and NIH update. *A link to Dr. Guttmacher's presentation can be found [here](#).*

NICHD Update

- The [NICHD Visioning project](#) will soon be culminating in a published article in a major scientific journal.
- 2012 is the NICHD's 50th Anniversary. Various anniversary-related events will be held throughout the course of the year. More information to come as events are announced.
- It was announced that Steven Hirschfeld, MD, has officially had "acting" dropped from his title, and is now the permanent director of the National Children's Study.

NIH Update

- Dr. Guttmacher announced the establishment of the National Center for Advancing Translational Sciences (NCATS) in the Fiscal Year 2012 appropriations package, budgeted at \$576 million. He spoke about his excitement for the new center, the progress being made under the temporary leadership of acting director Tom Insel, MD and deputy director Kathy Hudson, PhD, and how the hiring process is well underway to fill the permanent leadership positions at the new center.
- Fiscal Year (FY) 2012 Funding Updates
 - There will be no inflationary increases for non-competing awards. This covers this fiscal year and any out-years in awards. This means that all grants will essentially be flat-funded.
 - The average size of grants will be at FY11 levels or lower.
 - This is to reflect the general belt-tightening mood across the country. Director Collins thought it both fiscally and politically prudent.
 - The annual salary cap level for all salaries across the Department of Health and Human Services set by the FY12 appropriations legislation is Executive Level II (\$179,700)
 - This applies to FY12 grant awards issued on or after December 23, 2011. Those issued before Dec. 23 at Executive Level I (\$199,700) remain at that level for FY12, but the out-years of awards will be adjusted to lower levels (FY 13 appropriations legislation will set that).
 - See [NIH Guidance on Implementing the Reduced Salary Cap](#)
- The NIH was appropriated \$30.7 billion in the FY12 funding legislation (which is essentially at the FY11 level), however the across-the-board rescission written into the legislation brings the total funding down to \$30.63 billion. For FY13, if the current "sequestration" budget remains unchanged, the NIH is looking at an approximate 8 percent reduction (below FY12 levels) beginning in January 2013. The NIH and NICHD are making necessary preparations, but there is a general assumption that the FY13 budget will not be known until after the November elections.
- The NICHD was appropriated \$1.32 billion for FY12, which is actually a 0.3% increase over FY11 levels.

NICHD Reorganization

As was discussed in the previous PPC Washington Update, prior to the NACCHD Council meeting, Dr. Guttmacher announced plans to reorganize the structure of the NICHD. Dr. Guttmacher's stated goal in the reorganization is to maximize opportunities for interdisciplinary work (de-siloing) at NICHD. Per NIH rules, reorganization within an institute or center (like NICHD) does not require Congressional approval but does require opportunities for public comment. Please see the [attached chart](#) for a complete breakdown of the proposed reorganization.

- Three out of the four centers are being eliminated (the National Center for Medical Rehabilitation Research, NCMRR, will remain). Dr. Guttmacher and the rest of the reorganization team believed that the current structure impeded work between and among the centers. The transition will allow the branches to work together more easily.
- Most of the eliminated centers and offices will be relocated to the Division of Extramural Research. A new set of Extramural Scientific Branches will be within the Division of Extramural Research. The Division of Extramural Research is [still looking](#) for a director.

After Dr. Guttmacher's presentation, the floor was opened for council discussion, then public comment. Comments can be emailed through March 1, 2012 to NICHDDirectorsOffice@mail.nih.gov

Public Health Advocates File Health Reform Amicus Brief to Supreme Court

Last week, public health advocates joined the National Health Law Program and several other organizations in filing an [amicus brief](#) to the U.S. Supreme Court in support of the federal government's position on the severability of the law's individual mandate. The amicus brief argues that should the Court ultimately determine that the law's individual mandate provision is unconstitutional, the public health and prevention portions of the Affordable Care Act should remain unaffected.

Unlike most other laws, the Affordable Care Act does not contain a severability clause, which would have clarified that even if one provision of the law is itself illegal, other provisions would not be affected. If the Supreme Court rules that the individual mandate (or any other provision) is unconstitutional but finds "implied severability," other components of the law could still be implemented as passed. If it reaches the severability issue, the Supreme Court would decide whether to leave the rest of the law intact, strike down the entire law, or strike down certain other provisions in the law

The administration, in its brief filed with the Supreme Court today, said that if the Court strikes down the individual mandate provision of the law, just two other provisions would need to be eliminated: one requiring health insurers to accept individuals regardless of their health status and the other prohibiting insurers from charging higher premiums based on an individual's medical history.

California Medicaid Equal Access Ruling; Supreme Court Decision Pending

Last Monday, U.S. District Court Judge Christina Snyder temporarily [blocked](#) a 10% cut to physician reimbursements through Medi-Cal, California's Medicaid program, saying the cuts would cause "irreparable harm" to beneficiaries.

The cuts, which California Gov. Jerry Brown (D) signed last year, were part of the state's strategy to alleviate its budget constraints. Several California health care organizations filed a lawsuit challenging the payment cuts, which was heard by the Supreme Court in October. Pediatric advocates joined an [amicus brief](#) in August 2011 in support of the health care organizations' right to sue under the equal access provision of the Medicaid Act in *Douglas v. Independent Living Center of Southern California*. A decision is pending.

Make Your Voice Heard: Opportunities for Public Comment

The Advisory Committee to the NIH Director (ACD) Working Group on Diversity in the Biomedical Research Workforce has [issued](#) a Request for Information (RFI) seeking comments to "help inform the development of recommendations to present to the ACD and the NIH Director on actions the NIH can take to increase the **diversity of the biomedical research workforce**." The Working Group has identified a number of specific issues on which it is seeking input. **Comments are due by February 24**, and can be submitted online using this [link](#).

Don't forget, the **Patient Centered Outcomes Research Institute (PCORI)** has [released](#) its first [National Priorities for Research and Research Agenda](#) for public comment. The document presented five guiding priorities and 10 research areas, including prevention, acute care, care coordination, safety, overuse and information technology infrastructure. Comments can be submitted to PCORI via their [online form](#), or mail, and will be open through 11:59 p.m. ET on **Thursday, March 15, 2012**.

At January's National Advisory Child Health and Human Development Council Meeting, Alan Guttmacher, MD, Director of the **National Institute of Child Health and Human Development (NICHD)** provided information regarding the upcoming reorganization of the NICHD. There will be another meeting in order for the public to make additional comments on the [proposed reorganization](#). Comments to the reorganization can be emailed through **March 1, 2012** to NICHDDirectorsOffice@mail.nih.gov