LEGISLATIVE REPORT

SEPTEMBER 2007

OVERVIEW

A busy fall lies ahead, as Congress returns from recess with a lengthy list of bills to complete by the start of the new fiscal year on October 1. Among these, the State Child Health Insurance Program (SCHIP) must be reauthorized before it expires on September 30. Calls to Congress are needed to ensure that this deadline is met and that the reauthorization legislation that is passed strengthens and improves health care for more uninsured children and adolescents and provides adequate funding for this program. Also expiring on September 30, the *Best Pharmaceuticals for Children Act* (BPCA) and the *Pediatric Research Equity Act* (PREA) must be reauthorized when Congress returns in September.

Moreover, the appropriations bills that dictate how much funding goes to various agencies and programs are due to be completed by October 1. While it is anticipated that Congress will miss this deadline and be forced to pass stopgap measures to continue running the government at current funding levels in the interim, much work must be done to ensure that when these bills are finalized—whenever that may be—that children and adolescents have been made a priority.

Members of Congress must hear from their constitutes, including the pediatric community, about how and why these programs are important to their districts and states. *Your* advocacy is going to be crucial as these matters are debated on Capitol Hill.

To that end, the following is an update and summary of federal legislative and regulatory actions pending in the first session of the 110th Congress. We hope that this information will assist you in your advocacy efforts in the weeks and months ahead. We encourage you to share this information with your colleagues and to reach out to your Members of Congress to advocate on these vitally important issues. Your advocacy efforts really do make a difference!

This report includes information on the following issues:

- **Pediatric Workforce**
- **Access to Health Care**
- **FY 2008 Budget & Appropriations**
- **Maternal and Child Health Block Grant**
- **Environmental Health**
- **Pediatric Research**
- **Pediatric Drugs and Devices**
- **Immunizations**
- **Pandemic Influenza**
- **Emergency Medical Services for Children**
- **Congressional Calendar**

- **How to Contact Congress and the President**
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PEDIATRIC WORKFORCE

Title VII Health Professions Program and Title VIII Nursing Professions Program – ***Appropriations:*** The APA continues to participate in and support the advocacy efforts of the Health Professions and Nursing Education Coalition (HPNEC), led by the AAMC. The coalition supports adequate funding for the Title VII Health Professions Training Programs and the Title VIII Nursing Programs. This has been a particularly challenging task over the past several years. Title VII has received substantial funding cuts year after year. In FY 2005, Title VII received a final appropriation of $300 million. However, in FY 2006 and FY 2007 funding was slashed. Current funding stands at $185 million.

Congress has not been the only obstacle to fully funding Title VII. President Bush's Budget requests have repeatedly recommended funding only the Scholarships for Disadvantaged Students program (SDS)—at $10 million—with no funding whatsoever for the myriad of other programs, including primary care medicine, that make-up Title VII. This pattern continued in the Administration's FY 2008 budget proposal. In previous Administrations Title VII funding has also been decreased.

In its FY 2008 bill, the House-passed L-HHS-E Appropriations bill allocated $228.3 million to Title VII, while the Senate Appropriations Committee provided only $187.7 million. Both allocated $48.9 million to the "Primary Care Cluster," Section 747. The overall Title VII allocation in the Senate Committee and as passed in the House fell far short of the $300 million request made by members of HPNEC to at least restore funding to FY 2005 levels. In particular, the Senate allocation was disappointing, considering that 54 Senators—a bipartisan majority—joined a June 20 "Dear Colleague" letter circulated by Senators Jack Reed (D-RI) and Pat Roberts (R-KS) calling for a restoration of Title VII funding to FY 2005 levels of $300 million. The FY 2008 letter included the signatures of 6 first time signers and 10 Appropriations Committee members. A similar letter was sent to House Appropriators in March. Representatives Diana DeGette (D-CO) and Cathy McMorris Rodgers (R-WA) spearheaded the effort behind the House letter, which was signed by 98 representatives. The APA was very instrumental in getting members of Congress to sign onto both the House and the Senate letters.

The continued decrease in funding for the Title VII program is having a significant and adverse impact on the funding of new and continuing pediatric programs. APA members should use this opportunity to "tell your story" about the Title VII program in your institution and community. The ongoing objection that is raised by Congress and the Administration is proving the value of the Title VII program. The more specific examples that can be provided to your members of Congress the better. For further information and the amount of Title VII funding in your state visit the HPNEC web site at http://www.aamc.org/advocacy/hpnec/start.htm.

In light of these allocations, the pediatric community will continue to advocate for increased funding for Title VII throughout the FY 2008 appropriations process. To that end, on September 12, a group of pediatric residents and fellows from Johns Hopkins will participate in HPNEC's annual Capitol Hill Day. President-Elect of the APA, Tina Cheng, MD, will also attend. During

that event, the member organizations of HPNEC visit Capitol Hill offices to advocate for increased Title VII funding. In addition, HPNEC is currently planning a February 2008 "Health Professions Open House" for Capitol Hill staff.

Title VII Health Professions Program—*Reauthorization:* It remains to be seen what action, if any, will take place during the 110th Congress on reauthorizing Title VII. There has been some interest by members of the Senate to move various parts of the Title VII program forward, but other Senate offices has expressed concern that a "piecemeal" approach to reauthorization will further damage a program already struggling for funds.

GME Financing for Children's Hospitals (CHGME)–*Appropriations*: Children's Hospitals GME is currently funded at $297 million. The President's FY 2008 Budget request for CHGME was a mere $110 million—a 63% cut. The APA, working under the leadership of the National Association of Children's Hospitals (NACH) in conjunction with the Academy and others, urged the House and Senate Appropriations Committees to increase funding for the CHGME program to $330 million for FY 2008.

However, despite these efforts, when the Senate Appropriations Committee approved their FY 2008 Appropriations bill, they had cut CHGME by 33% - from $297 million to $200 million. CHGME fared far better in the House, where the House Appropriations Committee allocated and the House approved $307 million for the program. Members of the pediatric academic societies are urged to call members of the Senate and advocate for the higher House FY 2008 allocation--$307 million—for this vitally important program.

Physician Shortages: In February, both the Senate and House introduced the bipartisan *R*esident *Physician Shortage Reduction Act,* S. 588/H.R. 1093. The legislation would increase the number of residency positions for which Medicare payments will be made to teaching hospitals in states with a shortage of resident physicians. Specifically, the bill would allow teaching hospitals in states that have resident physicians to 100,000 population ratios below the national median, to be eligible to increase their resident caps, pending an allocation method determined by the Secretary of Health and Human Services. According to the bill's formula, teaching hospitals in 24 states would be eligible to receive additional resident cap slots. The Secretary is required to take into account whether the hospital will be able to fill the positions over a 3-year period, as well as whether the filled positions will be in primary care, preventive medicine, or geriatrics. The total number of additional cap slots granted to teaching hospitals in each eligible state cannot exceed 25% of the number of residents needed to increase that state to the national median. Overall, approximately 1,200 additional cap slots would be added to the national resident limit. Increases in the number of positions eligible for federal funding would be phased in over a 5-year period. The Senate bill has 8 cosponsors, while the House version has 46.

Student Loans: In March, Rep. Phil English (R-PA) introduced the *Higher Education Affordability and Equity Act of 2007,* H.R. 1407. The bill would amend the Internal Revenue Code to expand certain tax incentives for education. Among other provisions, the bill:

- repeals the current $2,500 limitation on deductions of interest paid on qualified educational loans;

- increases the income levels that trigger an eligibility phase out to between $100,000-$115,000 ($200,000-$230,000 for joint returns); and
- excludes amounts received as part of a scholarship, fellowship or grant from taxable income if used for qualified higher education expenses for undergraduate and graduate students.

Loan Deferment: Earlier this year, Senator Chris Dodd (D-CT) introduced S. 1066, the *Medical Education Affordability Act.* The bill would revise regulations regarding student loan repayment deferment with respect to borrowers who are in postgraduate medical or dental internship, residency, or fellowship programs. Specifically, the legislation extends the Economic Hardship Deferment from 3 years to the length of a medical or dental residency.

The *College Cost Reduction Act of 2007*, H.R. 2669, which passed on the House floor on July 11 by a vote of 273 to 149 eliminates the maximum length of time for Economic Hardship Deferment completely, allowing resident physicians to postpone federal loan repayments as long as they qualify.

On July 20, the *Higher Education Access Act,* also H.R. 2669, passed on the Senate floor by a vote of 78-18. The Senate version increases the cap on the Economic Hardship Deferment from 3 years to 6 years.

Because of this and other differences between the versions of H.R. 2669 passed by the House and the Senate, the two bills must be reconciled and then approved again before going to the President for his signature. This process will not begin until after the August congressional recess.

ACCESS TO HEALTH CARE

Reauthorization of the State Child Health Insurance Program (SCHIP): On August 1, the House voted 225-204 to approve legislation, H.R. 3162, the *Children's Health and Medicare Protection Act*, which would reauthorize the State Child Health Insurance Program (SCHIP) and make changes to the Medicare program. Five Republicans voted with 220 Democrats to pass the measure, while 10 Democrats and 194 Republics voted against. SCHIP is set to expire on September 30. The legislation would increase SCHIP funding by $50 billion over five years. The House bill would reduce payments to Medicare Advantage plans and increase the federal cigarette tax by 45 cents per pack to boost funding. In order to meet "Pay as you go" guidelines, Democrats agreed to reduce the amount of funding allotted for bonuses to states for enrolling children in the program. Under the bill, states would have the option to cover children of documented immigrants and establish their own methods of verifying citizenship. The APA supports the House legislation, which has been endorsed by a number of organizations, including the Academy, Republican and Democratic governors, the AAMC, AARP, and the AMA. In a veto threat issued by the White House in response to the House bill, the Administration called the legislation a "wholesale, unapologetic move to government-run health care for large classes of children."

On August 2, the Senate passed, by a vote of 68-31, the *Children's Health Insurance Program Reauthorization Act of 2007*, S. 1893/ H.R. 976. The 5-year, $35 billion reauthorization package preserves the enrollment of 1.9 million beneficiaries who would likely lose overage under current funding levels, enrolls 1.6 million SCHIP-eligible children not yet in the program, and expands SCHIP eligibility to 1.1 million more children. The funding increase is offset by a 61 cents per pack increase in federal tobacco taxes and a series of SCHIP cuts beginning in FY 2014. The package reconfigures the SCHIP allotment formula, reduces to 2 years the time states may access their allotments before redistribution, and establishes an "Incentive Bonus Pool" to fund state Medicaid and SCHIP expansions that exceed "a defined baseline." The bill also establishes a "Contingency Fund" for addressing state funding shortfalls, streamlines the enrollment process, permits coverage of prenatal care, and transitions SCHIP parents into new block grants with expenditures matched at the Medicaid level. Childless adults will be transitioned out of the program.

The House and Senate must now reconcile their disparate SCHIP packages. This process is set to begin following the August congressional recess. The pediatric community will be called upon to work with all members of Congress to pass a comprehensive and adequately funded SCHIP reauthorization bill by or before September 30, 2007. At the time of this writing, the key messages to convey to Congress remain:

- In the 10 years since it was enacted, SCHIP and Medicaid have reduced the number of uninsured children by more than one-third. Despite this, there are still 9 million uninsured children in America, the vast majority of who are in families with jobs that do not offer their children access to affordable coverage.
- Uninsured children are twice as likely as insured children to miss doctor visits and check-ups - and less likely to receive care for illnesses such as sore throats, earaches and asthma. When uninsured children go without needed care, small health problems can grow into bigger ones.
- Pass SCHIP legislation that contains the full $50 billion in new funding to reach millions of the children who are eligible for SCHIP or Medicaid but unenrolled.

Any SCHIP legislation must also strengthen and improve health care for children by including a fair physician payment component, addressing citizenship and documentation issues, and strengthening pediatric quality measurement.

CMS Guidelines: On late Friday evening, August 17, the Centers for Medicare and Medicaid Services (CMS) issued an advisory letter to states that took away the flexibility given to states under SCHIP. http://www.cms.hhs.gov/smdl/downloads/SHO081707.pdf CMS set new criteria for states that wish to raise eligibility for SCHIP above 250 percent of the federal poverty level (FPL), and instituted year-long waiting periods and other requirements to assure that children and adolescents are not leaving private health plans for public coverage. There is broad agreement that these requirements will be virtually impossible to meet. Tens of thousands of children and adolescents across the country could lose SCHIP coverage. Further, states would be prohibited from building on the program's success by expanding children's access to coverage in the future. There are several states that have or are planning to expand past 250% FPL – these include California, Connecticut, District of Columbia, Hawaii, Indiana, Louisiana, Maryland,

Massachusetts, Minnesota, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, Vermont, Washington**.**

The APA vigorously opposed the CMS guidelines and expressed that in a press statement issued shortly after the guidelines were released urging "the White House to reverse the new guidelines and focus on working collaboratively with a bipartisan U.S. Congress to reauthorize and fund a strengthened SCHIP bill." The press statement highlighted the important research of the APA membership that has shown that SCHIP has:

- Improved child health insurance coverage, covering millions of US children
- Improved preventive care, immunization rates, and primary care among children who enroll
- Enhanced the quality of care and quality of life of children who enroll and their families
- Improved quality of care for the most vulnerable children with chronic diseases such as asthma
- Reduced racial/ethnic disparities in access, unmet need, and continuity of care

FY 2008 BUDGET & APPROPRIATIONS

Following the release of the President's FY 2008 Budget proposal in February, the House and Senate drafted, debated and then finally completed their work on the FY 2008 Congressional Budget Resolution (S. Con. Res. 21) in mid-May.

Congressional Budget Resolution: The Conference Agreement assumes $54.965 billion for Function 550 discretionary health spending, $2.9 billion (5.5%) above last year and $3 billion (5.8%) above the President's request. It sets the overall non-defense discretionary spending cap at $450 billion, which is $23 billion above the final FY 2007 level and $21 billion above the President's request. The House approved the Conference Agreement by a vote of 214-209, while the Senate cleared it 52-40. The Budget Agreement includes several non-binding, deficit neutral reserve funds for FY 2007 through FY 2012 to support, among other programs, the State Children's Health Insurance Program (SCHIP). The Budget Resolution provides for "up to" $50 billion for SCHIP.

Senate L-HHS-E Appropriations Bill: On June 21, the Senate Appropriations Committee approved its version of the FY 2008 Labor-HHS-Education Appropriations Bill. The bill, which had been approved by the Senate Labor-HHS-Education Appropriations Subcommittee on June 19, funds HRSA at $6.869 billion in FY 2008, compared to the $6.416 billion the agency received in FY 2007. Within HRSA, the bill cuts the Children's Hospital Graduate Medical Education (CHGME) program by $97 million (3%) to $200 million. The Title VII Health Professions Training Programs are level-funded at the FY 2007 level of $184.7 million, while the Title VIII Nursing Programs receive a $20 million increase to $169.7 million. The Senate Committee bill also provides $329.6 million for the Agency for the Healthcare Research and Quality (AHRQ), which is a $10.6 million (3.3%) increase over last year. Finally, the Senate Committee's bill includes $29.9 billion for NIH. It is currently believed that the Senate

Committee's bill will be conferenced with the House-approved bill (see below) and will not be brought to the Senate floor for a vote by the entire chamber before that time.

House L-HHS-E Appropriations Bill: On July 18, the House of Representatives passed its 2008 Labor-HHS-Education appropriations bill, H.R. 3043, by a vote of 276 to 140 following three days of rancorous debate and votes on dozens of amendments to modify funding for specific programs. A total of 53 Republicans voted for the bill; the only Democrat to vote "no" was Rep. Melissa Bean (IL). Prior to the final floor vote, the APA signed a letter in support of the bill's passage, joining nearly 1100 education, training, disability, public health, health and biomedical research, aging and child welfare organizations, elected officials and labor unions representing the full range of stakeholders in the programs of the Departments of Education, Health and Human Services, and Labor. This was the culmination of an aggressive advocacy campaign that included the participation of the APA to move the appropriations process forward to ensure funding increases in several programs. The House bill provides $6952.8 million for HRSA and $228.3 million for the Title VII Health Professions Training Programs, a $43.6 million (23.6%) increase over FY 2007. It also includes a $307 million allocation for Children's Hospital GME, compared to a $297 million allocation for that program in FY 2007. AHRQ receives $329.6 in the House bill. For NIH, the bill includes $29.650 billion.

The House defeated (181-249) an amendment offered by Rep. Joe Barton (R-TX) to prevent funds from the bill from being transferred from NIH under the Secretary's program evaluation authority. A total of 19 Republicans, including most Republican members of the Labor-HHS-Education Appropriations Subcommittee, joined 230 Democrats to vote against the amendment; no Democrats voted for it. Originally authorized in statute at 1.1 %, appropriators have increased the transfer authority in recent years to 2.4% of the budgets of NIH and other HHS agencies. The transferred funds are used to support approximately two-thirds of the budget of the Agency for Healthcare Research and Quality (AHRQ) as well as the National Center for Health Statistics and other programs at CDC and the Department of Health and Human Services.

Prior to final passage, the House rejected by a vote of 206 to 213 a motion by Rep. Jerry Lewis (R-CA), the Ranking Member of the House Appropriations Committee, to recommit the bill to the Committee and a series of amendments offered by Republicans to cut the bill across-the-board by amounts ranging from 0.25% to 4.6%.

During House Appropriations Committee mark-up, Rep. Dave Weldon (R-FL) introduced the following amendment, which passed by voice vote and was included in the final bill: "None of the funds appropriated in this Act may be used to administer to any child under 3 years of age an influenza vaccine during the 2008-2009 influenza season for which thimerosal is listed on the labeling as an ingredient." The pediatric community joined the public health community in aggressively opposing this amendment.

In a Statement of Administration Policy (SAP) issued on July 17, the White House said it "strongly opposes H.R. 3043 because, in combination with the other FY 2008 appropriations bills, it includes an irresponsible and excessive level of spending and includes other objectionable provisions." The Administration noted that the House bill exceeds the President's

FY 2008 funding request by nearly $11 billion. The SAP also included a statement opposing the Weldon amendment: "The Administration strongly opposes any restriction on the use of funds under section 317 and the Vaccines for Children program to deliver flu vaccine to children under three years of age if it contains thimerasol. The provision could result in children not receiving any flu vaccine." The Senate Appropriations Committee Bill is also opposed by the Administration.

MATERNAL AND CHILD HEALTH BLOCK GRANT

The President's FY 2008 budget requested $693 million for the Maternal and Child Health Block Grant. This is the same amount the program received in FY 2006 and in the current fiscal year, FY 2007. The Academy requested $750 for the program, a request that the House-passed L-HHS-E Appropriations Bill granted. However, the Senate Appropriations Committee cut the block grant by $20 million to $673 million. Members of the APA are urged to call their members of Congress in support of the House Bill's allocation of $750 million.

ENVIRONMENTAL HEALTH

Environmental Health and Injury Prevention at CDC: In the current fiscal year, FY 2007, CDC received $287.5 million for its environmental health and injury prevention efforts. The President's FY 2008 Budget called for level funding for these programs. The House-passed FY 2008 Appropriations Bill included $305.2 million, while the Senate Committee-passed bill allocates $296.3 for environmental health and injury prevention at CDC.

National Institute of Environmental Health Sciences (NIEHS): NIEHS received $640.7 million in FY 2007. The President recommended cutting the FY 2008 appropriation for the institute to $637 million. The House L-HHS-E Appropriations Bill allocated $652.3 million for NIEHS in FY 2008, while the Senate Committee's bill provided $656.2 million.

PEDIATRIC RESEARCH

Agency For Healthcare Research And Quality (AHRQ): As a member of the "Friends of AHRQ," the APA urged the House and Senate Appropriations Committees to include $350 million for AHRQ in the FY 2008 spending bill. AHRQ received $319 million in FY 2007, while President Bush requested $329.6 million for the Agency in his FY 2008 Budget. Both the House-passed bill and the Senate Appropriations Committee followed the President's lead, providing $329.6 million for AHRQ for FY 2008. Out of this total, both the House and Senate Committees allocated $30 million for comparative effectiveness research and $78.9 million for patient safety initiatives. At this time, the long overdue reauthorization of AHRQ is not on the agenda of either the House or Senate.

National Institutes of Heath (NIH)—*Appropriations*: The President requested $28.858 billion for the National Institutes of Health for FY 2008—a $511 million cut from the FY 2007 funding

level. The Ad Hoc Group for Medical Research, which includes the APA as a participant, spearheaded an effort to increase NIH funding by 6.7% over FY 2007 levels, totaling $30.8 billion for FY 2008. However, When the House and Senate Appropriations Committees completed work on their chambers' respective Appropriations bills, the results were mixed. The House-passed bill allocated $29.650 billion, while its Senate Committee-passed counterpart dedicated $29.9 billion to the NIH for FY 2008. The APA will continue to support adequate funding for the NIH, including increased funding for pediatric research.

National Institute of Child Health and Human Development (NICHD)—
***Appropriations*: **The APA, as part of the Friends of NICHD, supported an allocation of $1.337 billion for the National Institute of Child Health and Human Development (NICHD). The House-passed Appropriations Bill included an allocation of $1.274 billion for NICHD, while the Senate Committee provided $1.282 billion for NICHD in FY 2008.

National Children's Study—*Appropriations*: The funding picture for the NCS is much brighter this year, as both the House-passed Appropriations Bill and the Senate Appropriations Committee have provided the full $110.9 million necessary to continue funding the study in FY 2008, despite the President's request that the study be zero-funded in his FY 2008 budget. The $110.9 million allocation (new funds) matches the advocacy community's request, which was made in a May 9 sign-on letter, circulated by the AAP and the March of Dimes. Over 50 organizations, including the APA, joined the letter sent to House and Senate Appropriators. The next steps are to push for completion of the appropriations process with the inclusion of $110.9 million of new money for the NCS.

National Children's Study— *Research Plan:* The National Children's Study Research plan was made available for public review and comment in July. The Research Plan describes the Study's background, design, measures, and the rationale for those selections in sufficient detail so that readers can understand the basis of the Study and how it will be carried out. The Plan is available online at: http://www.nationalchildrensstudy.gov/research/research_plan/index.cfm. On July 26, an official request for public comments was published in the *Federal Register*. Comments are due by September 25. In addition to seeking public comment, the NCS Program Office has sought review by the National Academy of Sciences (NAS). The NAS had commenced their review of the plan, which was anticipated to take approximately 6-9 months. .

National Children's Study— *Request for Proposals:* In March 2007, following passage of the FY 2007 joint funding resolution providing $69 million for the NCS, NIH issued a Request for Proposals (RFP) to award contracts to up to 20 new NCS study centers. These centers will manage operations in up to a total of 30 communities across the United States. The NCS has identified a statistically representative group of 105 total communities across the United States where it will recruit and enroll eligible participants. Contracts for the study centers will be awarded to interested medical research organizations based on the quality of their proposals and geographic proximity to the study communities over a three-year period (reaching the 105 total in year three). These new study centers must successfully demonstrate such capabilities as collection and management of biological and environmental specimens; the capacity to develop community networks for identifying, recruiting, and retaining eligible mothers and infants; and

the ability to secure the privacy of the data collected. The contract awards are anticipated in September 2007.

Further information and updates on the NCS may be found at: http://www.nationalchildrensstudy.gov.

NIH Consultation Meeting on Peer Review with Professional Societies: On July 30, 2007, the Peer Review Working Group of the Advisory Committee to the Director of the National Institutes of Health (NIH) hosted a consultation meeting with professional societies on the NIH peer review process. Dr Elias Zerhouni, Director of the NIH, and Drs. Keith Yamamoto and Lawrence Tabak, Co-Chairs of the Peer Review Working Group, were the moderators. Tina Cheng, MD, President-Elect of APA; Renée Jenkins, MD, President-Elect of AAP; Phyllis Dennery, MD, President of SPR; and Elizabeth Goodman, MD, liaison to the AAP's Committee on Pediatric Research, representing the Society for Adolescent Medicine; and Washington Office staff represented the pediatric and adolescent health community at the meeting. Participants commented on a variety of topics, including who should serve on study sections, how the review process should be structured, how the burden on reviewers can be decreased, and how the plethora of NIH grant mechanisms can be consolidated or simplified to streamline the review process. Individuals may submit comments on the peer review process via the web at: http://grants.nih.gov/grants/guide/rfi_files/rfi_peer_review_add.htm until September 7. In addition, three consultation meetings have been scheduled across the country - on September 12 in Chicago, October 8 in New York City and in San Francisco on October 25. Registration for these local meetings is available at http://enhancing-peer-review.nih.gov/. APA members are encouraged to participate in these local meetings.

Comments on NIH National Center for Research Resources (NCRR) Strategic Plan: On July 6, the National Institutes of Health (NIH) National Center for Research Resources (NCRR) published a notice in the *Federal Register* requesting comments and input as it develops a new Strategic Plan covering 2009 - 2013. The purpose of the plan is to ensure that NCRR remains responsive to the emerging needs of biomedical researchers and provides them with the infrastructure, tools, and training they need to understand, detect, treat, and prevent a wide range of diseases. The NCRR requested input from biomedical scientists, by August 31, to define future needs for shared research resources and technologies that facilitate NIH-supported biomedical research. Widely disseminated in the pediatric community with individual pediatricians encouraged to submit comments through the web site. One of the notable comments expressed was the concern that the Clinical and Translational Science Awards'(CTSA) current configuration and focus on "institution-specific awards" may bring unintended consequences and potentially jeopardize pediatric clinical research. The pediatric community, including APA, will continue to monitor this issue.

A strategic planning forum will be held by NCRR in December 2007. Additional information on the strategic plan is available online at: http://www.ncrr.nih.gov/strategicplan.

Stem Cells: For the second time in two years, President Bush vetoed the *Stem Cell Research Enhancement Act of 2007*, S. 5, on June 20, 2007. This legislation would expand the number of stem cell lines that are eligible for federal funding and allow federal funding for research using stem cells derived from embryos originally created for fertility treatments and willingly donated

by patients. Currently, federal funding for embryonic stem cell research is allowed only for research using embryonic stem cell lines created on or before Aug. 9, 2001, under a policy announced by President Bush on that date.

On the day following the veto, June 21, the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, attached a stem cell provision to the L-HHS-E Appropriations bill that would allow federal funding for embryonic stem cell research if the embryos were derived before June 15, 2007, while adding ethical guidelines for such research. No such provision was included in the House L-HHS-E Appropriations bill. It is doubtful, at the time of this writing, that this provision will remain in the final version of the FY 2008 L-HHS-E Appropriations Bill.

Genetic Information Nondiscrimination Act (GINA): H.R. 493/ S.358 *The Genetic Information Nondiscrimination Act* (GINA) was reintroduced in the House of Representatives and the Senate in January. The House bill passed by a vote of 420-3 on April 25. The Senate bill still awaits a vote on the Senate floor. A vote had been scheduled to occur prior to adjournment for the August congressional recess; however, Senator Tom Coburn (R-OK) placed a hold on the legislation delaying such a vote from moving forward.

GINA prohibits discrimination on the basis of genetic information with respect to health insurance and employment. Its purpose is to establish basic legal protections that will enable and encourage individuals to take advantage of genetic screening, counseling, testing, and new therapies that will result from the scientific advances in the field of genetics. The legislation also prevents health insurers from denying coverage or adjusting premiums based on an individual's predisposition to a genetic condition, and prohibits employers from discriminating on the basis of predictive genetic information. Additionally, *GINA* would stop both employers and insurers from requiring applicants to submit to genetic tests, maintain strict use and disclosure requirements of genetic test information, and impose penalties against employers and insurers who violate these provisions. The APA continues to support genetic nondiscrimination legislation.

PEDIATRIC DRUGS AND DEVICES

The *Best Pharmaceuticals for Children Act* (BPCA) and the *Pediatric Research Equity Act* (PREA): The pediatric community, including the APA, supports the reauthorization of BPCA and PREA, which have been remarkably effective in generating important information on pediatric drugs. Both laws will expire on September 30, 2007, unless reauthorized by Congress. PREA gives FDA the authority to require pediatric studies of drugs for the on-label indication. When PREA was codified in 2003, it for the first time established the presumption that certain new drugs and biologics must be tested for children and be produced in formulations appropriate for children. BPCA provides an incentive to drug manufacturers of an additional six months of marketing exclusivity for conducting pediatric studies of drugs that FDA determines may be useful to children. Under BPCA, the FDA can issue requests for pediatric studies on both on- and off-label uses of drugs.

The pediatric community has been working closely with leaders in the House and Senate to improve and reauthorize these laws. Rep. Eshoo (D-CA) championed BPCA and PREA in the House and Senators Dodd (D-CT) and Clinton (D-NY) championed BPCA and PREA, respectively, in the Senate. The modifications the pediatric community advocated for improve the transparency of the programs while ensuring that BPCA and PREA work well together as an integrated package to improve pediatric drug information. Working closely with the AAP, the APA and other partners have also sought to enhance post-market adverse event reporting as well as the speed and quality of label changes. The APA also joins the Academy in supporting making PREA a permanent requirement by eliminating its sunset and is also on record supporting a BPCA exclusivity adjustment for blockbuster drugs that will reduce consumer costs without reducing the strength of the incentive.

BPCA and PREA were considered in the House and Senate in the context of a large FDA package that included the reauthorization of the Prescription Drug User Fee Act and drug safety legislation. The House FDA bill, *The Food and Drug Administration Amendments Act of 2007* (H.R. 2900), was sponsored by Rep. Dingell (D-MI), while the Senate FDA bill, *The Food and Drug Administration Revitalization Act of 2007* (S. 1082) was introduced by Senators Kennedy (D-MA) and Enzi (R-WY). The Senate passed its FDA bill on May 9 by a vote of 93-1, and the House passed its version on July 11, 403-16.

The House and Senate are currently trying to reach an agreement to reconcile the differences between the two versions of the bill. The pediatric community is working to encourage Congress to keep the PREA permanency established in the House bill and eliminate a provision in the Senate bill that would put up roadblocks to using PREA for already marketed drugs. Although Congress was not able to finish the reauthorizations before the August recess, it will almost certainly finish this work in September to avoid the expiration of the Prescription Drug User Fee Act that would result in massive layoffs of drug approval personnel at FDA.

Pediatric Medical Device Legislation: There are too few critical medical devices designed specifically with children's needs in mind. Like adults, children need medical devices that are safe, effective and designed for their needs. The *Pediatric Medical Device Safety and Improvement Act* (S. 830/H.R. 1494) provides assistance to device innovators, elevates pediatric device issues and improves incentives for devices for small markets while preserving the ability to ensure the safety of new products once on the market. The APA has endorsed the legislation. Specifically, the legislation, sponsored in the Senate by Sen. Dodd (D-CT) and in the House by Reps. Markey (D-MA) and Rogers (R-MI), would provide incentives to the medical device industry to produce new pediatric devices by lifting restrictions on profit from the Humanitarian Device Exemption (HDE). It would create new consortia to stimulate device development from idea to marketplace. The bill would also give FDA additional regulatory mechanisms to track pediatric device needs as well as provide increased post-market surveillance for adverse events in children as recommended by IOM.

APA and others, working in concert with the Academy, were successful in making sure that the pediatric device bill was considered alongside the must-pass medical device user fee reauthorization. Both of these device provisions were included in the omnibus FDA reform bills (S. 1082/H.R. 2900) passed this year by the House and Senate. Negotiators in both chambers are

currently working to reconcile differences between the House and Senate device portion of the FDA bill. A conference report and final passage of the bill are expected in September before the expiration of the user fee bills.

IMMUNIZATIONS

Section 317 Program: The APA, the Academy and their immunization advocacy partners have urged Congress to provide $802 million for Section 317 in FY 2008. This funding recommendation includes: $387 million for purchase of childhood vaccines, $88 million for purchase of adult vaccines, $200 million for childhood immunization operations/infrastructure grants to states (consistent with the Institute of Medicine recommendation), $45 million for adult operations/ infrastructure grants to states and $82.4 million for CDC prevention activities. The comparable FY 2007 funding level was $520 million. The President's FY 2008 funding request was a mere $407 million. The House-passed Appropriations Bill included $598 million for Section 317, while the Senate Appropriations Committee bill provided $520 million.

PANDEMIC INFLUENZA

One-Year Progress Report— *National Strategy for Pandemic Influenza Implementation Plan*: In July 2007, one year after the Bush Administration's release of its federal pandemic influenza preparedness plan, the *National Strategy for Pandemic Influenza Implementation Plan*, the White House Homeland Security Council reported that 86% percent of the plan tasks that were to be completed by 2007 were finished. The remaining 14% were expected to be completed by the end of the year. The White House reported that the federal government still has limited capacity to detect a disease outbreak and track its progress across the country. The nation also has little extra capacity in its hospitals and other health care facilities to deal with a huge surge in need that would accompany a mass disease outbreak. Further, the government has little ability to ensure that during an outbreak, when many workers would stay home, limited Internet capacity would go to essential work and not to children playing video games. A White House spokesperson also said that a decision had been made to keep U.S. borders open if a pandemic flu outbreak occurs somewhere in the world. The Administration noted that a significant remaining challenge is that the country has grown tired of pandemic flu warnings. More information on the *National Strategy for Pandemic Influenza* can be found at: http://www.whitehouse.gov/homeland/pandemic-influenza-oneyear.html.

At-Risk Populations Listening Session: On July 26, 2007, the Interagency Committee on Pandemic Influenza's Work Group on Pandemic Influenza and At-Risk Populations hosted a listening session for non-governmental organizations to seek information about gaps, barriers and best practices for addressing the needs of at-risk populations in State and local Pandemic Influenza plans. The session was moderated by Dr. Daniel Dodgen, Human Services Policy Coordinator in the Office of the Assistant Secretary for Preparedness and Response. Staff from the Washington Office attended the meeting and relayed some of the pediatric community's concerns regarding children and pandemic influenza, such as the need for further testing on the

use of N95 masks by children and the ramifications of prolonged school closure on children's emotional and physical health and well-being.

EMERGENCY MEDICAL SERVICES FOR CHILDREN

EMSC—*Reauthorization:* The EMSC program's authorization expired in late 2005, but the program has yet to be reauthorized. On the first day of the 110th Congress, Senators Inouye (D-HI) and Hatch (R-UT) introduced an EMSC reauthorization bill, S. 60, the *Wakefield Act*. Representatives Matheson (D-UT), Capps (D-CA) and King (R-NY) introduced a companion bill, H.R. 2464, in the House on May 23rd, National Emergency Medical Services for Children Day. No floor action has occurred in either chamber.

EMSC—*Appropriations:* The President's FY 2008 Budget once again zeroed-out funding for the EMSC program. In May, the APA joined a sign-on letter to Senate and House Appropriations Committee members urging that they provide $25 million for the EMSC program in FY 2008. In July, the House Appropriations Committee voted to restore EMSC funding to the FY 2007 level of $19.8 million in FY 2008. Subsequently, during floor debate on the House bill, Rep. Reichert (R-WA) offered an amendment to add $2.5 million to the House Committee's allocation, for a total of $22.3 million. The amendment passed. In June, the Senate Appropriations Committee allocated $20 million for EMSC in FY 2008. The Appropriations Bill has not reached the Senate floor.

2007 CONGRESSIONAL CALENDAR (110th Congress – First Session)

October 1	Fiscal Year 2008 begins
October 26:	Target Adjournment (House)
November 16	Target Adjournment (Senate)

HOW TO CONTACT YOUR MEMBER OF CONGRESS:

Write: If you decide to write a letter, remember to be courteous, to the point, and include key information and personal examples to support your position. Address only one issue in each letter and, if possible, keep the length to one page. Due to increased security on Capitol Hill, you should fax or e-mail your letter, instead of using regular mail, to ensure that your communication arrives in a timely manner.

To a Senator:	**To a Representative:**
The Honorable (name)	The Honorable (name)
United States Senate	United States House of Representatives
Washington, DC 20510	Washington, DC 20515
Dear Senator ________:	Dear Representative ____:

Fax: Currently it is best to fax and **not** mail your letter to Congress. Fax numbers are available through the Capitol Hill Switchboard (202) 224-3121, or you can look up your members of Congress on "Thomas" the official website for Congress, available at http://thomas.loc.gov/, by going to "House Directory" or "Senate Directory" from the front page.

Call: You can contact your Senators and Representative's offices by calling the U.S. Capitol Hill Switchboard at (202) 224-3121. If you do not know who your Representative is, the switchboard operator will be able to direct you to the proper office. Ask to speak to the staff member who works on health care issues. Be prepared to leave a very short message as well as your name and address. You can also call your legislators in their home districts; if you are a member of the American Academy of Pediatrics, information about local offices is available on the AAP Member Center website, www.aap.org/moc. You can also go directly to www.senate.gov or www.house.gov for this information.

E-mail: All of members of Congress now have e-mail addresses, but there is no set format for them. On some members web sites there is a mechanism to directly email most notably if you are a constituent. We suggest calling the congressional office to get an accurate e-mail address or www.senate.gov or www.house.gov for this information. Be sure to identify, in the subject line, that you are a constituent along with the legislative topic of the email correspondence.

HOW TO CONTACT THE PRESIDENT

Write: The Honorable George W. Bush
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Call: 202-456-1414
Fax: 202-456-2461
E-mail: president@whitehouse.gov

FEDERAL ADVOCACY ACTION NETWORK (FAAN)

The Federal Advocacy Action Network (FAAN) is comprised of all AAP members for whom the Academy has an email address. FAAN alerts are sent when federal legislative efforts require large-scale advocacy efforts by the Academy's entire membership.

Coordinated by the AAP Department of Federal Affairs, FAAN is a network of AAP members who help support federal legislative and regulatory activities from their position as constituents. FAAN members play an important role in passing federal legislation that benefits children and pediatricians.

The AAP Department of Federal Affairs gives FAAN members the information and tools needed to persuade their legislators. The Members Only Channel (http://www.aap.org/moc) has

tools to make advocacy work easy. Find the names of congressional representatives, contact legislators via e-mail, read about congressional activity, and register to become a Key Contact.

If you have questions about the FAAN or if you have not been receiving FAAN alerts, please contact Priscilla Ring, AAP Department of Federal Affairs, pring@aap.org, or (800) 336-5475, ext. 3304.

KEY CONTACT PROGRAM

If APA members, who are members of the Academy, want to do more federal advocacy than responding to the FAAN alerts, we encourage pediatricians to join the American Academy of Pediatrics Key Contact program. Key Contacts have an interest in developing a stronger working relationship with their congressional delegation, and usually work on several AAP legislative issues. Key Contacts are contacted on a regular basis (approximately once a month when Congress is in session). Key contacts receive all the latest information and news, advocacy tips and tools, suggestions for improving relationships with members of Congress and more sophisticated advocacy assignments, such as media work and congressional visits (all with help from AAP staff).

To sign up to be an AAP Key Contact, log on to http://www.aap.org/moc (Member Login required, use your AAP member ID, it can be found on the AAP News or Pediatrics mailing label) and click on “Federal Affairs." For more information on the Key Contact program, contact Priscilla Ring, AAP Department of Federal Affairs, 800-336-5475, ext. 3304, or pring@aap.org.

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Submitted by:
Lisa Simpson, MB, BCh, MPH, FAAP Chair
APA Public Policy and Advocacy Committee

This legislative report is also available on the APA website at http://www.ambpeds.org/legupdate.cfm.

Additional information and resource materials on these and other child and adolescent health care issues is available from: Karen M. Hendricks, JD, khendricks@aap.org or Stephanie A. Russell, JD, srussell@aap.org, c/o AAP, Department of Federal Affairs 601 13th Street, NW, Suite 400 North, Washington, D.C. 20005, phone: 800/336-5475 fax: 202/393-6137.

September 1, 2007