HEALTH: SENATE PASSES COMPREHENSIVE FDA USER FEE LEGISLATION

By a resounding vote of 96-1, the Senate on May 24, 2012 passed S. 3187, the Food and Drug Administration Safety and Innovation Act. The legislation reauthorizes various FDA programs for five years, including the Prescription Drug User Fee Act and Medical Device User Fee Act, and authorizes new user fee programs – the Generic Drug User Fee Act and Biosimilars User Fee Act – to facilitate the review and approval of drugs and medical devices. The legislation also includes provisions to streamline the device approval process, modernize FDA’s global drug supply chain authority, and prevent and mitigate drug shortages, and improve incentives for pediatric trials. Negotiations that started more than a year ago, and included all the major stakeholders in the bill, resulted in the overwhelmingly bipartisan bill that was supported by the industry and other organizations.

During floor consideration, the Senate considered 17 amendments, most of which were defeated, including an amendment that would have allowed the import of prescription drugs from Canada, which was defeated by a vote of 43-54. Another amendment to require manufacturers of dietary supplements, including energy drinks, to register and provide information with the FDA was tabled, 77-20. And an amendment that would have discouraged generic drug manufacturers from entering into “pay for delay” deals was also defeated, 28-67.

The House is expected to take up its legislation after the Memorial Day district work period.

For a detailed summary of the bill as reported by the Health, Education, Labor, and Pensions Committee, go to: http://www.help senate.gov/imo/media/audio/042312_Manager%27s_%20FDASIA_Final_Sec_by_Sec.pdf.

HOMELAND SECURITY: SENATE APPROPRIATIONS COMMITTEE APPROVES FY13 FUNDING LEGISLATION

On May 22, 2012, the Senate Appropriations Committee approved the Fiscal Year 2013 Homeland Security Appropriations legislation by a vote of 27-3. The bill approves $45.2 billion in discretionary budget authority for the Department of Homeland Security, a reduction of $1 billion below the fiscal year 2012 enacted level.
Highlights of the bill include:
- U.S. Customs and Border Protection (CBP) would be provided $11.973 billion, $378 million above fiscal year 2012.
- U.S. Immigration and Customs Enforcement (ICE) would be provided $5.642 billion, $220 million below fiscal year 2012.
- United States Citizenship and Immigration Services (USCIS) would receive $117 million in direct appropriations, $14.5 million above fiscal year 2012.
- Science and Technology (S&T) would be provided $831 million, $163 million above fiscal year 2012, bringing S&T funding back to fiscal year 2011 levels.
- Federal Emergency Management Agency (FEMA) would receive $6.089 billion for the Disaster Relief Fund, of which $5.481 billion is provided pursuant to the Budget and Control Act disaster relief adjustment. The bill also provides funding for policy programs such as dam safety and hurricane and earthquake preparedness, as well as funding for modernization of information technology systems.

The bill provides $1.41 billion for state and local grant programs, $369 million above the comparable fiscal year 2012 level. Included in state and local grant funding is:
- $415 million for State Homeland Security Grants;
- $55 million for Operation Stonegarden;
- $664 million for the Urban Area Security Initiative;
- $13 million for Non-profit Security Grants;
- $119 million for Transit and Rail Security Grants;
- $13 million for Amtrak security; and
- $132 million Port Security grants.

Other grants and programs that received funding include the following:
- $337.5 million each for the fire equipment grant program and the firefighter hiring grant program ($675 million total);
- $350 million for Emergency Management Performance Grants;
- $7.5 million to reimburse State and local governments for prevention and preparedness costs related to National Special Security Events;
- $35 million for Predisaster Mitigation grants;
- $97.3 million for Flood Mapping and Risk Analysis;
- $44 million for the United States Fire Administration;
- $150 million for the Emergency Food and Shelter Program;
- $158 million is for the National Domestic Preparedness Consortium;
- $26 million for continuing training grants; and
- $17.8 million for the Emergency Management Institute National Protection and Programs Directorate (NPPD) ($1.2 billion in total)

For more information:

The California Institute will prepare a more detailed report from a California perspective in the near future.
SOCIAL SERVICES/WELFARE: HOUSE SUBCOMMITTEE HOLDS HEARING ON STATE TANF SPENDING AND ITS IMPACT ON WORK REQUIREMENTS

The House Ways and Means Subcommittee on Human Resources held a hearing on Thursday, May 17, 2012, to review State spending or "maintenance of effort" (MOE) requirements in the Temporary Assistance for Needy Families (TANF) program, and their interaction with TANF work requirements.

Witnesses included: Ms. Kay E. Brown, Director, Education, Workforce, and Income Security, U.S. Government Accountability Office; Mr. Grant Collins, Senior Vice President for Workforce Services, ResCare; Ms. Carol Cartledge, Director, Economic Assistance Policy Division, North Dakota Department of Human Services; Mr. Peter Palermino, TANF Administrator, Connecticut Department of Social Services, Representing the American Public Human Services Association; and, Dr. LaDonna Pavetti, Ph.D., Vice President for Family Income Support Policy, Center on Budget and Policy Priorities.

Topics discussed included:
- The specific requirements of TANF's MOE provisions, which include specified state spending levels and general requirements on the use of funds, and can include reparations and reduction of federal funding if requirements are not met.
- Total MOE spending reported by states, which showed that in 2005 spending remained relatively stable around the required minimum spending level of $11 billion through that fiscal year, and then increased to about $4 billion higher than this minimum in fiscal years 2009 and 2010.
- States' use of MOE spending to help them meet TANF work participation rates. Most states have engaged less than the required 50 percent of families in required activities in each year since TANF was created, and various policy and funding options in federal law and regulations, including credit for state MOE expenditures that exceed required spending levels, have allowed most states to meet the rate requirements even with smaller percentages of families participating.
- The negative effect of excess MOE spending on employment rates. Testimony indicated that after the Deficit Reduction Act of 2005 passed, excess MOE spending resulted in 21 states and 1 territory having an effective work requirement of zero percent. By 2009, 32 of the 45 states that met the work requirement claimed MOE credits. Of those, 17 would not have met the requirements without the MOE credits.
- How third party spending can be counted towards TANF MOE spending, i.e. volunteers' time in an afterschool program or expenditures from a nonprofit food bank that serves likely TANF families and the overall TANF purpose.
- How other state spending on programs such as childcare or after school programs, pre-kindergarten classes, or state-funded Earned Income Tax Credits can be considered for MOE credits.
- The impact of using the Work Performance Rate as the sole measure of the TANF program's success.


EDUCATION: RAND HOLDS CONGRESSIONAL BRIEFING ON ESEA REAUTHORIZATION

On Tuesday, May 22, 2012, the RAND Corporation held a congressional briefing titled Maintaining Accountability and Nurturing Innovation through a Reauthorized ESEA. RAND speakers at the briefing included: Susan M. Gates, Ph.D., Senior Economist; Laura Hamilton, Ph.D., Senior Behavioral Scientist; Jennifer L. Steele, Ed.D., Ed.M., Policy Researcher; and, Darleen Opfer, Ph.D., Director of RAND Education.

The briefing focused on continuing debate over the reauthorization of the Elementary and Secondary Education Act (ESEA) of 2001, which expired more than four years ago. Both the House and the Senate have this year introduced legislation or held hearings on reauthorization of the bill, which is more popularly known as The No Child Left Behind Act (or NCLB).
According to the panel, reauthorization of NCLB during its "second round" will require "several critical decisions" about the bill's contents and its unintended consequences as seen during its implementation since 2001. The panel focused its discussion around three main recommendations and reiterated several times that it believes NCLB reauthorization can promote both innovation and accountability.

First, NCLB reauthorization should retain student assessment on state core standards while encouraging states to make their standards more challenging and more applicable to college and career readiness. Citing inconsistent definitions of "proficiency," the panel made clear that some sort of consistency would be needed within "standards and assessments across states" in order to enable "policymakers and the public to compare outcomes among states." In addition, "high-quality assessments" remain "an indispensible ingredient in an accountability system that promotes beneficial responses."

Second, school district and individual school performance measures and results must continue to be made available to the public. They must be easily understood by parents and other interested members of the public, but school districts must also take efforts to combat "unintended problems" of such transparency by also providing multiple measures (including proficiency and progress), and including sections within the published scores and measures that caution readers as to what the scores imply, and what they do not.

Finally, the panel recommended reauthorization of ESEA focus on building accountability and capacity for improvement at all grade levels and at all levels of the school system (individual schools, districts, states, and the federal level). This includes addressing teachers' competencies. The panel noted that a recent study found "virtually no evidence" that pay-for-performance teaching pay scales "in and of themselves" increased educational outcomes. The panel recommended that federal policy makers shift focus from these pay systems and instead funnel money into creating better teacher evaluation systems. Ideally, teacher evaluation systems would provide teachers "actionable information" that could be used for improvement, and would also evaluate school administrators. This dual system has had good results in Pittsburgh public schools, the panel stated.

Other topics of discussion included:
- Adequate yearly progress support and sanctions, and the average time a school is on "improvement"
- Charter school accountability when the school is operated outside of the umbrella of a school district
- Student motivation on standardized tests, which often are not counted towards high stakes school results such as grades or graduation
- "Gaming" of the system, i.e. when school districts shuffle students from school to school in order to stay under the threshold for reporting improvement and scores for student subgroups
- Common core standards and how the federal government can capitalize on this state-level compact between 46 states
- How teaching to the test is manifested throughout science, social science, and even English and math curricula

For more information, go to: [http://www.rand.org/congress/activities/2012/05/22.html](http://www.rand.org/congress/activities/2012/05/22.html).

**HEALTH: RAND RELEASES REPORT ON CONSUMER-DIRECTED HEALTH INSURANCE PLANS**

In May 2012, the RAND Corporation released an external publication titled *Growth of Consumer-Directed Health Plans to One-Half of All Employer-Sponsored Insurance Could Save $57 Billion Annually*. According to the publication, insurance plans that feature personal healthcare savings accounts and high deductibles are becoming increasingly popular. These plans are thus referred to as "consumer-directed."
The publication states that consumer-directed plans currently make up about 13 percent of all employer-sponsored health insurance. If consumer-directed plans were to increase in number and make up 50 percent of the market share within employer-sponsored coverage, annual health care spending could be reduced by approximately $57 billion. In other words, an increase to 50 percent of that market share would mean a real decrease of 4 percent in health care costs for the nonelderly.

The publication does note, however, that a substantial increase in consumer-directed plans could "reduce the use of recommended health care services, as well as . . . increase premiums for traditional health insurance plans, as healthier individuals drop traditional coverage and enroll in consumer-directed plans."

The publication explores options that policy makers and employers facing these challenges should consider, including "more refined plan designs and decision support systems to promote recommended services."


**STATE BUDGET: LAO RELEASES REPORT ON THE MAY REVISE**

On May 18, the Legislative Analyst's Office released a report titled *The 2012-13 Budget: Overview of the May Revision*.

According to the Report, revenues since the beginning of the year have declined, while obligations from Prop 98 have increased. This means that the state's general fund budget gap for the 2012-2013 fiscal year has increased from $9.2 billion in January to $15.7 billion in May, as estimated by the Governor's Office.

The Report states that the Governor's May revise makes additional cuts and balancing actions to fill the gap, and also assumes that the Governor's proposed revised tax initiative measure will pass on the June ballot. The May revise also updates the so-called "trigger cuts" that will be made if that initiative fails. These cuts "continue to be heavily focused on schools." According to the Governor's office, the whole May revise, including extra cuts and the passage of the tax initiative, would result in a "$1 billion reserve at the end of 2012-2013."

The Report says that the LAO finds "the Governor's May Revision economic and revenue forecasts to be reasonable," as its "revenue estimates are just a few hundred million dollars below the administration's in each year." Despite this, the LAO is "concerned" that the Administration is overestimating the funding that schools will gain through the proposed elimination of Redevelopment Agencies (RDAs). The LAO's "rough estimate is that this causes the state's budget problem to be around $900 million greater than assumed by the administration because these lower property tax revenue distributions would increase the state's 'workload budget' Proposition 98 obligations."

According to the Report, "one of the largest May Revision proposals is to strengthen the state's authority to expedite the transfer of the former RDAs' liquid assets (cash) to local governments, including school and community college districts." While the "administration estimates that the proposal would generate $1.4 billion of General Fund benefit in 2012-13 and $600 million in 2013-14 by reducing General Fund Proposition 98 obligations," the LAO states that estimates of "liquid assets available for distribution is subject to considerable uncertainty."

Furthermore, the LAO recommends the following focuses for the 2012-2013 budget: "(1) retiring the accumulated deficit of recent years, now estimated by the administration to be $7.6 billion; and (2) making additional solid progress toward addressing the ongoing annual operating, or structural, deficit-which we think is somewhere around $10 billion-through realistic and ongoing budget actions."

While the LAO calls the Governor's "one-time actions" to decrease the deficit "appropriate," it cautioned that "more ongoing actions – principally multiyear or permanent reductions in program spending; revenue increases; and reductions in tax expenditures, such as tax deductions, credits, and exemptions" are
necessary. The Administration has made suggestions "that would go a long way to addressing the operating deficit."

The Report also highlights some alternatives to the Governor's basic budget plan and the trigger cuts proposals. For example, "the alternative to the Governor's basic budget plan would reduce the 2012-13 minimum guarantee by $1.9 billion but still maintain programmatic spending at virtually the same level as the Governor. This would free up funds that could be used to mitigate proposed reductions in other areas of the budget." In addition, "the alternative to the Governor's trigger plan would achieve somewhat less total budget solution than the Governor but has the significant benefits of (1) cutting programmatic funding for schools and community colleges notably less than the Governor and (2) avoiding problematic new rebenchings. It would, however, require other parts of the budget to share more in trigger reductions."