HOUSE PASSES FDA BILL IN ELEVENTH HOUR; SENATE TO FOLLOW

With the possibility of layoffs looming at the Food and Drug Administration, the House, under suspension of the rules, passed a comprehensive reauthorization of several important FDA programs on September 19, 2007 by a vote of 405-7. The bill, H.R. 3580, represents months of negotiations between the House and Senate to craft an acceptable compromise. The Senate is expected to pass the bill shortly and the President to sign it before reductions in force (RIFs) are required because the existing authorization expires at the end of the month.

The legislation reauthorizes the Prescription Drug User Fee Program and the Medical Device User Fee Program, which assess fees of almost $400 million from drug companies and device manufacturers seeking approval of their products in order to expedite the process. The bill also contains provisions to improve postmarket safety programs in order to prevent injuries and deaths from drugs and medical devices. FDA will now have the authority to require that drug sponsors conduct postmarket clinical trials and make label changes, if warranted. The FDA will also be able to impose additional requirements on a drug in the form of a risk evaluation and mitigation strategy when it is needed to ensure that a drug's benefits outweigh its risk. Additionally, the bill authorizes the collection of $225 million in new user fees dedicated for drug safety activities.

H.R. 3580 also authorizes the Best Pharmaceuticals for Children Act and the Pediatric Research and Equity Act which are intended to ensure that accurate, timely pediatric use information is developed and made available to pediatric physicians. The bill also retains the current six month period of market exclusivity that companies receive to do additional testing in pediatric populations.

For the first time, the legislation establishes a national database for information on clinical drug trials, which will be monitored by the National Institutes of Health, and which will contain data on the results of the trials.

The House passed an earlier version of the bill, H.R. 2900, on July 11, 2007, by a vote of 403-16; the Senate passed its version, S. 1082, by a vote of 93 - 1 on May 9, 2007. One of the major obstacles in the negotiations was House language that some Senators argued would make drug companies more vulnerable to lawsuits. The language remains in the bill, but Sen. Richard Burr (NC) has indicated he
will not hold the bill up any longer. Enactment of H.R. 3580 will obviate the need for FDA to send out as many as 2,000 RIF notices at the end of September, when the FY07 fiscal year expires.

**HOUSE FHA BILL INCREASES AMOUNT FOR INSURED MORTGAGES**

On September 19, 2007, prior to passing H.R. 1852 aimed at reducing mortgage foreclosures and protecting buyers from risky mortgages, the House approved an amendment by voice vote to increase the size of mortgages the Federal Housing Administration (FHA) can insure. This has been an important issue for California, where housing prices significantly exceed the national average.

The amendment, offered by Reps. Dennis Cardoza (Atwater), Gary Miller (Diamond Bar), and others, raises the size of the single family home mortgage that FHA can insure to 125 percent of the median area home price or 175 percent of the Fannie Mae conforming loan limit in high-cost areas, whichever is lower. The Department of Housing and Urban Development (HUD) could also raise the new limit by as much as another $100,000 “if market conditions warrant.” Currently $417,000 is the conforming loan limit on the size of loans that Fannie Mae and Freddie Mac can purchase. The current limit for FHA-backed loans is $362,000 in high-cost areas. Loans over $417,000 have been harder to obtain, because they cannot be backed up by the two giant government-endorsed organizations.

The House move may provoke problems with the Senate, however. The Senate Banking, Housing and Urban Affairs Committee approved its version of the legislation on September 19, by a vote of 20-1, without similar language. The Committee and the White House believe the House bill may overly burden the FHA’s ability to insure loans. Supporters of the proposal counter that it is need so low- and middle-income residents can buy homes in high-cost markets like California.

The House also adopted by voice vote another amendment offered by Rep. Gary Miller, which will allow qualified down-payment assistance providers, such as nonprofits and government entities, to participate in FHA programs under certain conditions. Current law requires a 3 percent cash down payment on most FHA-insured loans. The amendment would allow the agency to consider any amounts gifted by family members, employers or labor unions, or qualified homeownership assistance entities as cash, if there is no obligation to repay the gift.

The vote on final passage of H.R. 1852, sponsored by Rep. Maxine Waters, Chair of the Financial Services Subcommittee on Housing and Community Opportunity, was 348 - 72. The bill will allow the FHA to serve more subprime borrowers at lower rates and better mortgage terms, recapture borrowers that have had to turn to predatory loans in recent years because FHA-financing was not available, and offer affordable loan refinancing options to homeowners who are now struggling to make their mortgage payments given the current crisis in the mortgage market.
**House Ways and Means Passes TAA Extension and FAA Bills**

On September 18, 2007, the House Ways and Means Committee held a full committee mark up on three bills, two dealing with the nation’s aviation system and one extending the Trade Adjustment Assistance Act.

H.R. 3539 and H.R. 3540, sponsored by Chair Charles Rangel (NY), extend the funding and expenditure authority of the Airport and Airway Trust Fund. HR 3539, approved by voice vote, would retain the current financing system and raise aviation fuel taxes from 19.3 cents per gallon to 24.1 cents per gallon. The new revenue would be dedicated to air traffic control modernization. The measure is expected to be added to a larger reauthorization bill covering the Federal Aviation Administration (HR 2881) through fiscal 2011.

Ways and Means also approved HR 3540 by voice vote, which would extend the FAA’s authorization through Dec. 31, allowing the agency to collect, at current rates, the excise taxes that fund most of its budget. The current authorization (PL 108-176) expires Sept. 30, 2007 and Congress must act before then to keep funds flowing into the system. Both bills reject the Bush Administration’s call for a sweeping overhaul of the way the nation’s aviation system is financed.

The Committee also reported by voice vote H.R.3375, sponsored by Rep. Wally Herger (Marysville), which would extend the Trade Adjustment Assistance program through Dec. 31, 2007. The program provides training and other aid to U.S. workers in manufacturing jobs lost because of international trade. Manufacturers and some farmers are also eligible for some assistance. The Committee is continuing to draft a comprehensive overhaul of TAA, which may extend the program to service workers affected by globalization. The Senate is also expected to act on an extension before the program expires.

For more information, please visit: [http://waysandmeans.house.gov](http://waysandmeans.house.gov).

**Senate Subcommittee on Water Quality Evaluates Wastewater Infrastructure**

On September 19, 2007, the Senate Environment and Public Works Subcommittee on Transportation, Safety, Infrastructure Security, and Water Quality held a hearing entitled “Meeting America’s Wastewater Infrastructure Needs in the 21st Century,” which examined the Clean Water Act. The Act helps build new sewage treatment plants. Initially, grants were used to pay for them, but since 1987, loans through the State Revolving Fund (SRF) have been used. Estimates are that Combined Sewer Overflows spill 850 billion gallons of contaminated stormwater into U.S. waterways each year and EPA estimates it will take $170 billion over the next 20 years to fix these sewer systems. The hearing featured testimony from two panels of experts including Christopher Westhoff, Assistant City Attorney, Public Works General Counsel for the City of Los Angeles.

A few key points from the hearing included:
- Of the 222.8 million people served by wastewater treatment facilities, more than 98.5% (219.5 million people) are served by “secondary treatment” (or better). Secondary treatment may remove up to 90% of remaining biological matter such as human waste, food waste, soaps and detergent.
- The three most important water priorities facing the nation’s cities are: rehabilitating aging water and wastewater infrastructure; security/protection of water resources infrastructure; and water supply availability
- The federal government has invested more than $72 billion since 1972 to help cities build publicly-owned treatment works (POTWs). However, federal assistance has not kept pace with needs, declining more than 70 percent since 1980 – resulting in a funding gap of $300 billion to $500 billion over 20 years between current levels of spending for wastewater infrastructure and total funding needs, according to the U.S. Environmental Protection Agency (EPA) and the Congressional Budget Office.
- Local communities now pay more than 95 percent of the cost of meeting their Clean Water Act obligations
- In the 1990’s alone, Los Angeles spent over $1.6 billion on the upgrade of the Hyperion Wastewater Treatment Plant to full secondary treatment
  For more information, please visit: http://epw.senate.gov.

**GOVERNOR PROPOSES $9 BILLION FOR CALIFORNIA WATER NEEDS**

Governor Arnold Schwarzenegger on September 18, 2007 proposed a new $9 billion water bond package to improve the state’s water supply and delivery system and address the ecological crisis in the Sacramento-San Joaquin River Delta. The new proposal will be considered by the state legislature meeting now in a special session called by the Governor to deal with water issues and comprehensive health care.

The proposal calls for new investments in surface and groundwater storage and references the three potential sites now under consideration: the Sites Reservoir in Colusa County; the Los Vaqueros expansion project in Contra Costa County; and the Temperance Flat Reservoir in Fresno County.

Additional investment in regional programs is also proposed for Delta sustainability and water supply reliability to provide for a long-term, sustainable resource management plan for the Delta that will protect the environment while ensuring reliable water deliveries to families, farms and businesses. The plan also calls for targeting additional water conservation grants to local communities to yield additional water and protect water quality, and funding to support natural resources projects including the Klamath River, Salton Sea, San Joaquin River, Sacramento River and its tributaries, as well as in the Delta.

**SENATE FINANCE COMMITTEE EXAMINES METH SMUGGLING**

On September 18, 2007, the Senate Committee on Finance held a full-committee hearing to review the progress of combating the methamphetamine problem in America. The hearing, entitled “Breaking the Methamphetamine Supply Chain: Meeting Challenges at the Border” focused on a number of successful Anti-Meth campaigns, including The Combat Meth Act. The Combat Meth Act imposed limits on the sale of medicines containing ephedrine and pseudoephedrine, which are the most common chemicals that can be converted into meth. The Act also requires that purchasers provide identification and sign a sales log.

Meth is still deemed the number one law enforcement problem in the U.S., with the National Association of Counties finding that it is the number one illegal drug problem for 47 percent of the counties in the country. The hearing featured testimony from a wide selection of specialists and experts, including Thomas M. Siebel, Chairman of the Meth Project in Palo Alto, California.

A few key points from the hearing include:
- One national standard for retail availability is important because a patchwork of requirements is confusing to consumers, law enforcement, and retailers -- especially for chain pharmacies
- One of the specific goals of the Act was to reduce the number of domestic methamphetamine labs by 25 percent over three years. In fact, in 2006, there was a 41 percent reduction over the previous year
- Most of the methamphetamine consumed in the United States is produced by Mexico-based and California-based Mexican traffickers
- In September 2006, DEA initiated a joint program with Customs and Border Protection (CBP) identified as the “Long Beach Port Project” which was designed to further combat the diversion of precursor chemicals from source countries destined for Mexico that transit the Long Beach Port
- The UN also estimates that 15-16 million people consume methamphetamine on a global scale
- According to local press reports, as many as 80 percent of drug addicts in Tijuana and Mexicali are using methamphetamine
  For more information, please visit: http://finance.senate.gov

**HOUSE HOMELAND SECURITY COMMITTEE HEARING EXAMINES SAFETY OF 9/11 FIRST RESPONDERS**

On September 20, 2007, the House Committee on Homeland Security held a full committee hearing to discuss the health and safety of volunteers and first responders, specifically those working with the clean up efforts of September 11, 2001. The hearing, entitled “Safety of our First Responders in the Wake of Catastrophic Disasters” also evaluated other disasters such as Hurricane Katrina and the failings of safety precautions for those first responders. The hearing featured testimony from two panels representing the Department of Homeland Security, the Center for Disease Control and Prevention (CDC), the Government Accountability Office, Mount Sinai School of Medicine, and the International Association of Fire Fighters.

The following are a few key points from the hearing:
- In the days, weeks, and months that followed September 11, 2001, more than 50,000 Americans from across the United States helped in the search, clean up, and reconstruction efforts
- The dust inhaled by first responders on September 11, 2001 contained pulverized cement (60-65% of the total dust mass), uncounted trillions of microscopic glass fibers and glass shards, asbestos, lead, polycyclic aromatic hydrocarbons, hydrochloric acid, polychlorinated biphenyls (PCBs), organochlorine pesticides, furans and dioxins.
- Over 21,000 WTC responders have received initial comprehensive medical and mental health monitoring evaluations from the Centers of Excellence consortium. More than 7,250 of these responders have also received at least one follow-up examination
- 46.5% reported experiencing new or worsened lower respiratory symptoms during or after their work at Ground Zero; 62.5% reported new or worsened upper respiratory symptoms; and overall 68.8% reported new or worsened symptoms of either the lower and/or the upper respiratory tract
- One third of responders had abnormal pulmonary function test results
- Congress appropriated $75 million to CDC to further support existing Health and Human Services WTC programs and provide screening, monitoring, and medical treatment for responders
  For more information, please visit: http://hsc.house.gov

**RAND REPORTS ON LOCAL IMPLEMENTATION OF NCLB**

RAND, in cooperation with the American Institutes for Research, presented the findings about teacher quality from two longitudinal studies, the National Longitudinal Study of No Child Left Behind (NLS-NCLB), and the Study of State Implementation of Accountability and Teacher Quality Under No Child Left Behind (SSI-NCLB). In August 2007, RAND released the second volume in the series entitled “State and Local Implementation of the No Child Left Behind Act (NCLB): Teacher Quality Under NCLB.”

The September 2007 report describes the progress that states, districts, and schools have made implementing the teacher and paraprofessional qualification provisions of the No Child Left Behind Act through 2004–05. In general, the SSI-NCLB and NLS-NCLB studies indicate that states and districts are working to implement and comply with the NCLB requirements for teacher and paraprofessional qualifications. However, variation in state policies concerning highly qualified teachers raises questions about whether some states have set sufficiently high standards for considering teachers to be highly
qualified, and enduring inequities in access to highly qualified teachers continue despite NCLB’s goal of ensuring that all students have knowledgeable and effective teachers.

A few key points from the report include:

- Most teachers met their states’ requirements to be considered highly qualified under NCLB, but state policies concerning highly qualified teachers varied greatly
- The percentage of teachers who are not highly qualified under NCLB is higher for special education teachers, teachers of Limited English Proficiency (LEP) students and middle school teachers, as well as for teachers in high-poverty and high-minority schools
- About two-thirds of instructional paraprofessionals were considered qualified under NCLB, but 28% did not know their status or did not provide a response to the study questions
- Schools were more likely than districts to report needing and receiving technical assistance in the areas of recruitment and retention
- Less than 20 percent of districts reported that they needed state technical assistance for recruitment and retention — but large districts were most in need
- High-poverty and high-minority districts were most likely to offer financial incentives and alternate certification routes to recruit highly qualified applicants

For more information, please visit: www.rand.org.

PEW HISPANIC CENTER EVALUATES IMMIGRANT WAGE TRENDS

In August 2007, the Pew Hispanic Center released a report entitled “1995 – 2005: Foreign-Born Latinos Make Progress on Wages.” It finds that the proportion of foreign-born Latino workers in the lowest quintile of the wage distribution, when ranked by hourly wage, decreased to 36% from 42% while many workers moved into the middle quintiles.

Also, because they were older, better educated and more likely to be employed in construction rather than in agriculture, the report found that newly arrived Hispanic workers were less likely to be low-wage earners in 2005 than in 1995. Nevertheless, many Latino workers remain low-wage earners, Pew’s examination of recent Census Bureau data found.

The report also found that Asians significantly boosted their presence in the high-wage workforce.

To view the report, go to: http://pewhispanic.org/files/reports/78.pdf.

TEXAS TRANSPORTATION INSTITUTE STUDY SHOWS INCREASED CONGESTION; L.A. REMAINS NATION’S WORST

The Texas Transportation Institute (TTI) released the results of its 2007 Urban Mobility Report on Tuesday, September 18, 2007. According to the report, traffic congestion is worsening in American cities of all sizes, creating a $78 billion annual drain on the economy. This drain is caused by 4.2 billion lost hours and 2.9 billion gallons of wasted fuel - equivalent to 105 million weeks of vacation and 58 fully-loaded supertankers.

The Los Angeles region remains the nation’s most congested, yet also ranked number one in terms of operational improvements and number three in savings as a result of public transportation. “More than 1.5 million boarding passengers opt for improved bus and rail service in Los Angeles County on an average weekday and that cuts more than 28 million hours of travel delays for an annual savings of $459 million,” reported LA Metro CEO Roger Snoble in response to the report. “Hopefully, lawmakers in Sacramento and Washington will be jarred in to action by the congestion report, recognize the economic toll traffic takes and how investment in operational improvements, public transportation and other rideshare programs can and is making a substantial difference in Los Angeles County,” Snoble continued.
According to the TTI report, the average peak period traveler spends an extra 38 hours of travel time and consumes an additional 26 gallons of fuel per year. This results in an additional cost of approximately $710 per traveler. Researchers spent two years revising the methodology using additional sources of traffic information, providing more — and higher quality — data on which to base the current study.

For more information and to see where other California cities rank, go to: http://mobility.tamu.edu.

**Wednesday Briefing to Examine Federal Financial Aid and California**

On Wednesday, September 26, 2007, from 12:00 noon to 1:30 p.m., Californians in Washington will be briefed regarding federal financial aid programs and their impact for Californians. The California Institute for Federal Policy Research -- in conjunction with The California Community Colleges, the California State University, The University of California, and EdFund --- will host a luncheon briefing entitled “Financial Aid in California: What It Means To Students, Families and the State.” The briefing will be held in Room 2226 of the Rayburn House Office Building in Washington.

More than 3 million students are currently enrolled in California's public colleges and universities. A wide range of federal financial aid programs -- from Pell Grants to student loans to work study -- provide billions of dollars in assistance to California students each year. Changes in the federal laws governing such programs have a profound effect on our students and our state. The 110th Congress has recently passed legislation that will significantly impact California, and major additional proposals are on the table.

Attendees are invited to learn more about the federal financial aid programs that matter most to California from experts representing the state's three public postsecondary institutions -- the California Community Colleges, the California State University, and the University of California -- and EdFund (the non-profit organization that administers California's participation in the federal guaranteed student loan program).

For your information for determining compliance with Congressional gift ban rules, please note that all four presenting organizations are State of California entities and thus exempt from many limitations. Furthermore, the California Institute is a 501(c)(3) charitable nonprofit organization that does not employ lobbyists. Finally, we anticipate that this will be a widely-attended event.

To attend the briefing, call 202-974-6384, or send an email to rsvp@calinst.org.