Appropriations: Short-Term CR Passed; FEMA Disaster Funding Issue Defused

On September 29, 2011, the House in **pro forma** session passed a Continuing Resolution to keep the government funded through October 4, 2011. The move was part of a solution worked out with the Senate on breaking the impasse over FEMA funding that confronted the two bodies as they adjourned for a week long district work period on September 23rd.

The deadlock over whether and how to offset FY11 emergency funding for the Federal Emergency Management Agency was defused earlier this week, after FEMA announced that it had enough money to keep operating through the end of the fiscal year. Prior to that finding, the House was standing firm on the need to offset an additional $1 billion in FY11 funding to the agency by cutting $1.5 billion from the Department of Energy’s programs.

In light of FEMA’s announcement, the Senate passed two measures on September 26, 2011 to keep the government funded after the start of FY 2012 on October 1st. H.R. 2017 is a clean CR that operates until October 4th, giving the House time to deal with a longer term CR once it comes back into session next week. The Senate also passed H.R. 2608, which continues funding through November 18, and includes $2.65 billion for FEMA in additional FY12 spending, rather than the $3.65 billion the House supported in its earlier CR.

The Senate started the ball rolling on September 26th by first failing to invoke cloture, 54-35, on the House-passed CR that included the FY11 FEMA money and also the offsets. The Senate then stripped out the contested provisions and easily passed the amended CR (H.R. 2608), 79-12, and the clean short-term CR (H.R. 2017) by voice vote.

All of the CRs considered by the House and the Senate so far have agreed on one thing -- the bottom line for total government funding in FY2012. They track the $1.043 trillion limit set by the debt limit law, rather than the $1.019 billion level set in the House-passed budget resolution (H.Con.Res. 34) in April.

Congress now has until close of business Tuesday, October 4, 2011 to pass another CR, probably H.R. 2608, running through November 18.
HEALTH: CALIFORNIA FIELD HEARING HELD ON MEDICAL DEVICE AND DRUG REGULATION ISSUES

On September 26, 2011, the House Energy and Commerce Subcommittee on Health held a field hearing in La Jolla, CA entitled “Impact of Medical Device and Drug Regulation on Innovation, Jobs and Patients: A Local Perspective.”

Witnesses were: David L. Gollaher, Ph.D., President and Chief Executive Officer, California Healthcare Institute; Steven J. Mento, Ph.D., on behalf of Biotechnology Industry Association, President and Chief Executive Officer, Conataus Pharmaceuticals, Inc., San Diego; Sharon Stevenson, on behalf of the National Venture Capital Association, Director, Okapi Venture Capital, LLC, Laguna Beach; Don Casey, Chief Executive Officer, West Wireless Health Institute, La Jolla; Joe Panetta, President and Chief Executive Officer, BIOCOM, San Diego; , Bill Walton, on behalf of CONNECT, La Jolla; and Kevin T. Larkin, President and Chief Executive Officer, TherOx, Inc., Irvine.

In his opening remarks, Rep. Brian Bilbray (Imperial Beach) detailed the importance of the San Diego life science cluster. Noting that it is one of the largest in the world, he explained that “there are approximately 40,000 employees at more than 700 companies, including biotechnology, medical device, diagnostic companies, and research institutes. San Diego is internationally recognized for its innovation, producing some of most important discoveries in the world.” He argued, however, that regulatory delays and other government barriers are adversely impacting the strength and growth of the industry and must be reformed.

Dr. Gollaher focused his testimony on the need to reform the product review and approval process at the Food and Drug Administration. The biggest concern CHI’s companies have expressed recently, he said, is “the frustration over regulatory processes and communications that have become increasingly uncertain, unpredictable, and inefficient.” He stressed that CHI supports a strong FDA, but argued that slower processes and approval do not meaner safer, and that both high safety and efficiency can be obtained. Among other recommendations on how to bring about the necessary reform, Dr. Gollaher called for a more balanced benefit-risk calculus in the FDA approval process.

Mr. Walton called on Congress “to cultivate a statutory and regulatory atmosphere with clear rules and guidelines so that medical innovators can continue to keep the United States leading the world in the creation of life-saving medical devices, drugs and healthcare.”

Ms. Stevenson discussed the important role of venture capital in translating promising research into breakthrough treatments, promoting jobs and economic growth. However, she said, venture capitalists are becoming more reluctant to back potential new drug therapies, because of the average $800 million to $1 billion and 10 years to 15 years necessary to bring a new drug to market in the United States. She argued that the “uncertain regulatory environment is a key contributor to escalating costs, extended approval timeframes and “unmanageable” risk.” She also several recommendations on how to improve the situation, including supporting allowances for variation in benefit-risk assessments to ensure patient-centric drug and medical device development and approval.”

The testimony of all the witnesses can be found at: http://energycommerce.house.gov.
EDUCATION: PRESIDENT OBAMA ANNOUNCES WAIVERS TO PROVIDE FLEXIBILITY UNDER NO CHILD LEFT BEHIND ACT

On September 23, 2011, President Barack Obama announced that states would be able to apply for a new waiver program that would allow them increased flexibility within the Education and Secondary Education Act, which since 2002 has been known as the No Child Left Behind Act (NCLB).

Speaking from the East Room of the White House, the President stated that although “the goals behind No Child Left Behind were admirable,” reality was that “its implementation . . . had some serious flaws that are hurting our children instead of helping them.” He went on to say that reform is necessary, but that “despite the good intentions of some . . . Congress has not been able to fix these flaws so far.”

The President then outlined the general aspects of the program, which would give states more flexibility to meet high standards, so that they could determine what works best for their students. In addition, the President repeated twice that “this does not mean that states will be able to lower their standards or escape accountability.” Rather, the administration claims that the way the program is designed requires states to set higher, more honest standards, and prove that they are working toward meeting these before any flexibility is given.

Education Secretary Arne Duncan concurred, saying, “We want to get out of the way and give states and districts flexibility to develop locally-tailored solutions to their educational challenges while protecting children and holding schools accountable for better preparing young people for college and careers.”

In a letter to State Educational Authorities, he states: “This voluntary opportunity will provide educators and State and local leaders with flexibility regarding specific requirements of NCLB in exchange for rigorous and comprehensive State-developed plans designed to improve educational outcomes for all students, close achievement gaps, increase equity, and improve the quality of instruction. This flexibility is intended to build on and support the significant State and local reform efforts already under way in critical areas such as transitioning to college- and career-ready standards and assessments; developing systems of differentiated recognition, accountability, and support; and evaluating and supporting teacher and principal effectiveness.”

The letter also indicates that the first round of waivers will be valid through the 2013-2014 school year and that states are encouraged to notify the U.S. Department of Education of their intent to pursue a waiver by October 12, 2011.

Reactions from California leaders were mixed. The California State Superintendent of Public Instruction Tom Torlakson issued a statement the same day as the President’s announcement, stating that his Agency is “carefully examining the proposal, which would appear to cost billions of dollars to fully implement, at a time when California and many other states remain in financial crisis.” He also expressed “hope that the Administration is prepared to provide the funds necessary to implement these provisions, or provide greater flexibility to California, which already has a strong school accountability system in place.” Although this new program “represents an acknowledgment by the Administration that the one-size-fits-all policies of No Child Left Behind are unworkable” he said that he “will continue to advocate for Congress to approve a new Elementary and Secondary Education Act.”

Rep. George Miller (Martinez), senior Democrat on the Education and the Workforce Committee, supports the waivers. In a statement given after the President’s announcement, Rep. Miller said he supports the move, and that “a full comprehensive reauthorization is everybody’s first choice and something I hope to continue working toward but in the absence of action by Republicans in Congress, President Obama is outlining a path to success for our country and our economy with these waivers.”

The Chairman of the House Education and the Workforce Committee, Rep. John Kline (MN), also gave a statement to the Washington Examiner on Sept. 23. Rep. Kline said the waivers proposal "could mean less transparency, new federal regulations, and greater uncertainty for students, teachers, and state and local
officials." He also stated that "the move also raises legal questions" regarding the "little precedent for tying waivers to reforms not authorized by Congress." The nonpartisan Congressional Research Service has also stated that if waivers were challenged in court, they could run into problems.

Education groups have also begun to weigh in on the new program, with Oakland-based Education Trust-West and the National Education Association expressing support.

The Senate Health, Education, Labor, and Pensions Committee has announced that it will mark up a comprehensive revision of the No Child Left Behind law on October 18, 2011. The House Education and the Workforce Committee chose to pass several smaller measures dealing with separate segments of the law.

For more information, please visit: http://www.ed.gov/esea/flexibility.

REPORT: DIESEL TECHNOLOGY FORUM RELEASES REPORT ON CLEAN DIESEL AND THE ECONOMY

On September 28, 2011, the Diesel Technology Forum, in conjunction with the Aspen Environmental Group and M. Cubed, released a report detailing the economic impact of diesel on the U.S. economy. The report favorably views diesel as a sustainable, green, and high value added industry critical to the U.S. economy and shows that diesel makes and moves the vast majority of goods and services that Americans use in everyday life.

The report concentrated on quantifying the direct contribution of clean diesel engines, equipment manufacturing, and fuel refining to the U.S. economy as well as the indirect contributions and influence of the diesel industry on 16 diesel-reliant sectors of the economy. In total, the report estimates that in 2009 the diesel technology producing and servicing sectors directly contributed $183 billion to the U.S. economy and also supported 1.25 million jobs, with another $300 billion in indirect and induced ripple effects. Beyond producing engines and fuel, diesel technology and fuel powered another $455 billion in 2009 from key diesel-reliant industries. The total Gross Domestic Product (GDP) contribution from the diesel industry as a whole was $638 billion in 2009.

Included in the focus on diesel-reliant sectors, the report concentrates on the agriculture industry’s dependence on diesel. In 2009, it is estimated that 35-percent, or about $40.3 billion, of the agricultural sector’s total contribution to the GDP could be directly attributed to the contribution and influence of diesel. Agriculture primarily relies on diesel to fuel heavy farming equipment - such as tractors - for which, according to the report, there is no other viable cost-effective fuel available. Diesel is also increasingly used in equipment used to plant, water, fertilize, harvest, and transport the actual crop itself.

For more information, please visit: Http://www.dieselforum.org/economicreport.

REPORT: CALIFORNIA BUDGET PROJECT RELEASES REPORT ON CALIFORNIA’S JOB MARKET

On September 6, 2011, the California Budget Project released a report entitled On the Edge: California’s Workers Still Face the Toughest Job Market in Decades. The report examines recent employment, wage, and income data and assesses how California’s workers and their families have fared during the extended economic crisis.

Specifically, the report finds that although economists believe that the so-called “Great Recession” ended in 2009, the past few years can be considered “recovery” in name only. In fact, the report calls the past few years “a recovery-less recovery” and references economists’ worries that “the Great Recession will transform into the Great Stagnation.”

Findings of the report include:

- California has gained back only about one-sixth of the 1.4 million jobs it lost during the recession and still faces a major jobs deficit.
- For the period of June 2010 - June 2011, the state lost 1.1 percent of its government sector jobs, or about 24,500 jobs. As a whole, California has lost government jobs at twice the rate of the nation as a whole in the last three years.
- Of California’s 28 metropolitan areas, only nine gained jobs from June 2010 - June 2011, and many continued to lose jobs.
- The income gap between middle class Californians and the top one-percent of earners in the state continues to widen and is twice as large as the gap that existed in 1987.
- Men have gained nine out of ten jobs added in the nation from June 2010 - June 2011, while women have continued to lose jobs at a greater rate in sectors where men are gaining jobs.
- The inflation-adjusted hourly wage of California’s average worker has declined 1.9 percent between 2006 and 2010.
- The typical 2010 inflation-adjusted hourly wage had less purchasing power in that year than in any point in the last 10 years. Diminishing spending power is restraining recovery.
To obtain the report, go to: http://www.cbp.org.

REPORT: PPIC RELEASES STATEWIDE SURVEY ON CALIFORNIANS AND THEIR GOVERNMENT

A Public Policy of California survey released on September 21, 2011 shows that Californians' worries about jobs and the state of the economy have "hit a record high" and that "most say Obama's economic policies have not helped," although Californians are more apt to "trust him [Obama] over Republicans in Congress."

Not only are jobs a high concern, but the survey also shows that over fifty-percent of those surveyed fear that "someone in their family will lose a job in the next year." Additionally, 67 percent of Californians see jobs and the economy as the most important issue facing the country. When asked about the state of their State, economic concerns also dominate - "nearly all think California is in a recession (50% serious recession, 32% moderate recession, 7% mild recession)." Survey participants were also asked their opinions on reducing the deficit versus spending to aid the recovery of the economy, with a majority choosing to spend to help the economy (likely voters were more evenly divided).

The survey also covered several other topics, including: the federal debt ceiling, Congress and national political parties, and several California state issues.

The survey was conducted by the PPIC, with funding from The James Irvine Foundation. For more information, please visit: http://www.ppic.org.

EVENT: UCSF CHANCELLOR TO ADDRESS GOLDEN STATE ROUNDTABLE

Dr. Susan Desmond-Hellmann, Chancellor, University of California, San Francisco (UCSF) will be the featured speaker at the California State Society’s Golden State Roundtable Breakfast on Thursday, October 13, 2011. The breakfast will be held at 8:30 a.m., in Room B-339, Rayburn House Office Building, in Washington, D.C. The topic of the Chancellor’s address, “The Future of Medicine: Connecting Patients with Promising Research,” will discuss how to ensure the United States becomes a leader at delivering the promising results of academic research to ailing patients.

Dr. Desmond-Hellmann, MD, MPH became the ninth Chancellor of UCSF on August 3, 2009. An oncologist and renowned biotechnology leader, Desmond-Hellmann oversees all aspects of the university and medical center’s strategy and operations. Prior to joining UCSF, she spent 14 years at Genentech, including from 2004-2009 as President, Product Development. In this role, Desmond-Hellman was responsible for Genentech’s pre-clinical and clinical development, process research and development, business development and product portfolio management. During her time at Genentech, several of the
company’s therapeutics were approved by the U.S. Food and Drug Administration, and the company became the nation’s No. 1 producer of anti-cancer drug treatments.

Desmond-Hellmann is the recipient of numerous honors and awards. In November 2009, Forbes magazine named Desmond-Hellmann one of the world's seven most "powerful innovators," calling her "a hero to legions of cancer patients." She was listed among Fortune magazine’s "top 50 most powerful women in business" for seven years and, in 2010, was inducted into the American Academy of Arts and Sciences and was elected to the Institute of Medicine.

One of the Chancellor’s top priorities is to make certain that UCSF continues to excel in bringing the best science to patients. This translates into a constant focus on innovation, which is proving extremely important as UCSF seeks new ways to partner with industry to translate lab discoveries into disease relief. UCSF is California’s largest recipient of funds from the National Institutes of Health (NIH). It is often credited with playing a key role in birthing the biotech industry, and an estimated 90 life science start-up companies have been spawned or spun off from UCSF’s labs – including 30 start-ups at its world-renowned Mission Bay campus. In addition, the UCSF Medical Center is consistently ranked among the Top 10 in the United States.

The breakfast is open to the public. Member of Congress and staff receive complimentary admission. Others may purchase tickets at http://www.californiastatesociety.com. The price is $35 per person for 2011 California State Society Members and $40 for non-members. For further information or to RSVP, please contact Jamie Whitelock at rsvp@californiastatesociety.com or 202-547-7854.

**BRIEFING: INSTITUTE TO HOST UPDATE ON BAY DELTA CONSERVATION PLAN**

The California Institute will host a congressional luncheon briefing on Monday, October 3, 2011 featuring a presentation on the development of the California Bay Delta Conservation Plan.

The briefing will be led by Jerry Meral, Deputy Secretary of the California Natural Resources Agency. It will provide an update on the schedule and ongoing activities, including progress on biological goals and objectives, development of alternatives for the EIR/EIS, the effects analysis preparation, and other key outstanding issues.

The presentation will include representatives of the State of California, the U.S. Departments of Interior and Commerce, and various stakeholder groups working on development of the Bay Delta Conservation Plan.

The Bay Delta Conservation Plan is a planning and environmental permitting process seeking to contribute to the recovery of key aquatic and terrestrial species in the Sacramento-San Joaquin Delta and improve water supplies for 25 million Californians and several million acres of farmland. Federal and state agencies, environmental organizations, fishery agencies, water agencies, and other organizations are working together to develop the Plan.

The briefing will be held in Room B-354 of the Rayburn House Office Building, Washington, D.C. on Monday, October 3, 2011. To attend, please RSVP to the California Institute at 202-785-5456 or sullivan@calinst.org.