TRANSPORTATION: HOUSE COMMITTEE MARKS UP COMPREHENSIVE TRANSPORTATION REAUTHORIZATION BILL

On February 2, 2012, the House Committee on Transportation and Infrastructure began marking up the American Energy and Infrastructure Jobs Act, a $260 billion energy and transportation package (H.R. 7).

H.R. 7 is the Committee’s rewrite of major federal surface transportation programs, previously authorized under the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU). H.R. 7 also encompasses energy bills (H.R. 3407, 3408 and 3410) marked up and passed by the House Natural Resources Committee on February 1 (see related in this Bulletin).

The following is the Committee’s summary of the bill's major provisions:
- Authorizes approximately $260 billion over five years to fund federal highway, transit and safety programs, consistent with current funding levels
- Provides long-term stability for states to undertake major infrastructure projects. Contains no earmarks, compared to the previous transportation law which contained over 6,300 earmarks
- Consolidates or eliminates nearly 70 federal programs
- Eliminates mandates that states spend highway funding on non-highway activities
- Allows states to set their own transportation priorities
- Delegates more project approval authority to states
- Condenses deadlines for federal agency project approvals
- Accelerates the approval process for projects in an existing right-of-way
- Encourages states to partner with the private sector to finance and build projects
- Streamlines the project delivery process and reduces regulatory burdens for rail projects
- Calls for the funds collected for the improvement of the nation's harbors to be invested for that purpose
- Ensures the safe, efficient transportation of hazardous materials
In related news, the Congressional Budget Office (CBO) has reported that the Highway Trust Fund faces insolvency sometime in the next fiscal year, which will begin October 1, 2012. The CBO states that the Fund will run a deficit of about $10 billion in the fiscal year, as Congress has authorized more in spending than the Fund will attain from taxes in the coming years.

At the opening of the markup on Thursday, the Committee had over 80 amendments pending to the bill, and the mark up was expected to be quite long. House Majority Leader Eric Cantor (VA) said this week that he hopes to have the H.R. 7 package considered on the floor by as early as the week of February 13, 2012.

For an extended summary of the bill, go to: http://republicans.transportation.house.gov/Media/file/112th/Highways/2012-01-31-Final_Rollout.pdf.

For the bill text and proceedings, see: http://thomas.loc.gov/cgi-bin/bdquery/z?d112:hr7

For the House Committee on Transportation and Infrastructure’s website, where information on the bill is available, go to: http://transportation.house.gov/.

TRANSPORTATION: SENATE COMMITTEE REPORTS REAUTHORIZATION OF FEDERAL PUBLIC TRANSPORTATION PROGRAMS

The Senate Banking, Housing and Urban Affairs Committee held a markup of the Federal Public Transportation Act of 2012 on Thursday, February 02, 2012. The Committee favorably reported the amended $8.36 billion bill to the Senate floor by a voice vote. The Committee intends the bill to be passed in conjunction with the Senate's pending $109 billion two-year surface transportation reauthorization bill (S. 1813). S. 1813 was approved by the Senate Environment and Public Works Committee, chaired by Sen. Barbara Boxer, in November 2011.

As approved, the Federal Public Transportation Act would provide a two-year reauthorization to public transportation programs, keeping their funding at current levels. It would also give the Transportation Secretary extended powers of enforcement and oversight of safety at public transportation agencies. These powers would include the ability for the Secretary to retain grants and/or impose civil penalties as consequences of agencies' safety violations. Both actions would require Congressional notification beforehand. The bill also streamlines the transportation grant system while giving the federal government authority to mandate stricter conditions and reporting requirements. Furthermore, the bill creates a new "State of Good Repair Program" designed to help public transportation systems address "backlog of maintenance needs."

This week, Senate Majority Leader Harry Reid (NV) stated that he would like to initiate debate on S. 1813 as soon as work on the Federal Aviation Administration reauthorization bill, H.R. 658, is finished. The current extension of surface transportation authorization (PL 112-30) will expire in less than two months at the end of March.

For more information, visit: http://banking.senate.gov/public/index.cfm?FuseAction=Newsroom.PressReleases&ContentRecord_id=3ed03afe-fbd1-901a-ab4e-3c8c916d8994.
HEALTH: HOUSE ENERGY & COMMERCE CONSIDERS PDUFA REAUTHORIZATION


Witnesses included: The Honorable Margaret A. Hamburg, M.D., Commissioner, U.S. Food and Drug Administration; Mr. Geno Germano, President and General Manager Specialty Care and Oncology, Pfizer, Inc.; Dr. David L. Gollaher, President and CEO, CHI-California Healthcare Institute; Mr. Richard F. Pops, Chairman and CEO, Alkermes, on behalf of Biotechnology Industry Organization; Mr. Allan Coukell, Director, Medical Programs, Pew Health Group, The Pew Charitable Trusts; Ms. Diane Edquist Dorman, Vice President Public Policy, National Organization of Rare Disorders; and Dr. David E. Wheadon, Senior Vice President, Scientific and Regulatory Affairs, Pharmaceutical Research and Manufacturers of America.

The Prescription Drug User Fee Act was first authorized in 1992 and the user fee in the Act was last in 2007. Under the user fee authority, the Food and Drug Administration collects funds from drug sponsors to help expedite the human drug approval process. The funds collected come from the following three basic types of user fees: application review fees, establishment fees, and product fees. Under the statute, the FDA and industry were required to negotiate an agreement regarding the size and scope of the user fee for FY 2013-2017. Under this proposed "PDUFA V" agreement, the industry would pay approximately $713 million in FY 2013 and higher amounts in the remaining four years. On January 13, 2012, FDA sent its final legislative recommendations on the agreement to the Energy and Commerce Committee as required by statute. PDUFA IV expires on September 30, 2012.

Commissioner Hamburg told the Committee that of the total $931,845,581 obligated in support of the process for the review of human drug applications in FY 2010, PDUFA fees funded 62 percent, with the remainder funded through appropriations. The cost of the agreed upon PDUFA V enhancements, she stated, translates to an overall increase in fees of approximately six percent. Hamburg also testified that the Tufts Center for the Study of Drug Development found that the time required for the FDA approval phase of new drug development (i.e., time from submission until approval) has been cut since the enactment of PDUFA, from an average of 2.0 years for the approval phase at the start of PDUFA to an average of 1.1 years more recently.

Commissioner Hamburg also discussed the challenges FDA faces in the current drug program. For instance, she noted, while new authorities from 2007 amendments have strengthened drug safety, they have also put strains on FDA’s ability to meet premarket review performance goals and address post-market review activities. In addition, the significant increase in the number of foreign sites included in clinical trials to test drug safety and effectiveness, and an increase in the number of foreign facilities used in manufacturing new drugs for the U.S. market has increased the need to travel much farther for pre-approval inspections, and other issues.

She outlined some of the improvements she believes PDUFA V incorporates, including:
- an enhanced review program for new drug applications, new molecular entities, and original biologics license applications
- changes to enhance regulatory science and expedite drug development
- expanded implementation of FDA’s benefit-risk framework in the drug review process
- improved post-market, safety-focused initiatives.

Dr. Gollaher began by informing the Subcommittee that California's biomedical industry is among its leading high-tech employers, directly accounting for about 270,000 jobs whose salaries average $76,000 a year. While supporting PDUFA V, Dr. Gollaher nonetheless pointed out some of the discrepancies that FDA must still address. For instance, he noted that "there are significant deviations in average review times, depending on a product’s therapeutic area. Oncology and anti-infective drugs, for example, experience the
fastest reviews, on the order of 10-15 months. For other categories – cardiovascular, central nervous system, gastrointestinal, respiratory, etc. – average review times stretch from 20 to 30 months. As a consequence, a drug’s therapeutic area influences both the time it spends under review and the probability of its being approved first in the U.S. or Europe.

Dr. Gollaher also noted that while FDA is beginning to address the issue, it still "focuses almost exclusively on the direct risks of drugs: side effects, adverse events and so forth. These are comparatively discrete and measurable. But indirect risks are both difficult to observe and subject to a much longer time horizon. Where are data that allow one to calculate the harm to public health if investors avoid an important disease because the FDA’s demands for data are so extensive and its standards for drug approval so uncertain?"

Dr. Gollaher also pointed out the importance (a) regularly gathering and analyzing the best possible data; (b) updating performance metrics during the next PDUFA cycle in order to track performance consistently and longitudinally; and © ensuring that there is agreement among the FDA, industry, and Congress that the data and how they are reported are the most accurate possible measures of agency performance.

For the testimony of all the witnesses, go to: http://energycommerce.house.gov

INFORMATION TECHNOLOGY: SENATE JUDICIARY EXAMINES VIDEO PRIVACY PROTECTION ACT

The Senate Judiciary Subcommittee on Privacy, Technology and the Law held a hearing entitled “The Video Privacy Protection Act: Protecting Viewer Privacy in the 21st Century,” on January 31, 2012. The focus of the hearing was on the extent to which the VPPA, enacted in pre-Internet 1988, limits a person's right to control his or her privacy on the Internet because the law restricts a durable sharing option.

Witnesses included: David Hyman, General Counsel, Netflix, Inc., Los Gatos, CA; and Marc Rotenberg, Executive Director, Electronic Privacy Information Center, Washington, DC.; and Christopher Wolf, Director, Privacy and Information Management Practice, Hogan Lovells US LLP, and Founder and Co-Chair, Future of Privacy Forum.

Mr. Wolf explained that the VPPA was designed to prevent prying into people's video rental history, by putting control in the hands of consumers to allow them to decide whether to share their video-watching information. The statute requires, however, that the consent of the consumer must be given "at the time the disclosure is sought." Today, users of Facebook and similar sites commonly utilize a one-time authorization – a durable choice option – to share a wide range of information with their friends. But, Mr. Wolf stated, "their ability to use such an authorization to share video-watching experiences arguably is thwarted by the restrictive, outdated language of the statute."

Mr. Hyman testified that Netflix's instant streaming video service has grown exponentially in the past few years, and offers new opportunities for individuals and businesses when combined with social networking sites such as Facebook. As a result, Netflix has been offering its members outside the United States the opportunity to share movies through the Facebook platform. However, it does not offer this service in the United States because under the VPPA it is unclear whether users can give ongoing consent to Netflix to share the shows and movies they've instantly watched through Netflix. Mr. Hyman supported H.R. 2471, which the House passed in December by a vote of 303-116. It clarifies consumers' rights to share, on an ongoing basis, the movies and shows they have watched. Netflix also supports the House bill's retention of the "opt-in" standard for privacy.

Mr. Rotenberg opposed the House bill and testified in support of the VPPA's continuing importance in safeguarding privacy. He cited examples of Netflix and others being sued for violating consumer privacy. He stated that under the proposed amendment to the VPAA, "companies such as Netflix and Facebook could
obtain consent once, and subsequently disclose hundreds or thousands of movie selections linked with personally identifiable information for years or decades to come. Companies could also make the blanket consent provision a condition of using their services, thereby removing all meaningful consent and effectively eviscerating the Act.26 Either approach would gut the Video Privacy Law."

For the testimony of all the witnesses, go to: http://judiciary.senate.gov.

ENERGY: HOUSE COMMITTEE MARKS UP ENERGY COMPONENTS OF H.R. 7, TRANSPORTATION OVERHAUL

On February 1, 2012, the House Natural Resources Committee marked up three bills encompassing the energy elements of the House GOP energy and transportation package titled the American Energy and Infrastructure Jobs Act of 2012 (H.R. 7). One of the bills, the Energy Security and Transportation Jobs Act (H.R. 3410), would impact drilling off the coast of California. The other bills were: the Alaskan Energy for American Jobs Act (H.R. 3407), and the Protecting Investment in Oil Shale the Next Generation of Environmental, Energy, and Resource Security Act or "PIONEERS Act" (H.R. 3408). The trio of bills would make several major changes to energy production in the U.S.

According to Committee documents, H.R. 3410, would "promote new energy leasing and production off the coast of California using existing infrastructure, which will allow new energy resources to be developed without using new rigs or equipment." The bill was favorably reported by the Committee by a vote of 25-19.

H.R. 3407, which would establish an oil and gas leasing program for the Coastal Plain of Alaska, including the Arctic National Wildlife Refuge (ANWR), was favorably reported to the House by a vote of 29-13. H.R. 3408 would set rules for the development of oil shale resources, maintain an oil shale leasing program for public lands created under the Bush administration, and allow experimental extraction techniques to proceed in Western states. The bill was reported by a vote of 27-16.

Natural Resources Committee Chairman Doc Hastings (WA) stated that enactment of the bills would provide "new revenues that can be used to build roads and infrastructure projects," suggesting that revenue made by these bills could be used to backfill the current $12 billion funding gap for transportation and infrastructure programs in the next two years. Other members claim the proposals would only generate $5 billion over the next decade.


ECONOMY: HOUSE COMMITTEE Examines EFFECT OF FEDERAL REGULATIONS ON EMPLOYMENT

On Wednesday, February 1, 2012, the House Committee on Education and the Workforce held a hearing entitled "Expanding Opportunities for Job Creation." The hearing assessed difficulties that affect the strength of the country's workforce. It focused on federal regulatory policies and the need for solutions that would create job growth, including possible reform of American job training systems.

Witnesses included: The Honorable Rick Snyder, Governor, State of Michigan and The Honorable Dannel "Dan" Malloy, Governor, State of Connecticut; Ms. Kellie Johnson, President, ACE Clearwater Industries, Torrance, CA; Dr. Jared Bernstein, Senior Fellow, Center on Budget and Policy Priorities, Washington, D.C.; and Dr. Matthew Mitchell, Senior Research Fellow for Economics, The Mercatus Center at George Mason University, Arlington, VA.

Ms. Johnson testified that "The uncertainty of our regulatory and economic environments makes it almost impossible for short or long-term business growth, especially for a capital intensive industry like manufacturing." Furthermore, this results in her customers sometimes making "the decision to migrate to places they believe care more about manufacturing." She also cited several specific regulatory initiatives
from the U.S. Environmental Protection Agency, National Labor Relations Board and the Occupational Safety and Health Administration. She stated that "to be compliant with the newest regulations and rules takes time away from running the day-to-day operations of a business. Resources are constantly rerouted away from customers, resulting in lower productivity and lower customer satisfaction."

Ms. Johnson offered the following improvements, including: "innovations that include capital budgeting and planning, prioritizing and funding transportation projects of regional and national significance, a welcoming climate for private infrastructure investment, new federal bonding approaches, environmental permit streamlining and elimination of redundant state and federal regulations that promote greater flexibility to the states."

Other topics discussed included:
- Reauthorization of the Workforce Investment Act (H.R. 2295)
- The Streamlining Workforce Development Programs Act (H.R. 3610) and the Local Job Opportunities and Business Success Act (or Local JOBS Act, H.R. 3611)
- The impact of small businesses on job creation
- Loan enhancement and export financing incentive programs
- Successes of the U.S. Small Business Administration (SBA) State Trade and Export Promotion (STEP) program
- Career shifting programs, focusing on training for professionals who want to transition to small business
- Career transition programs to benefit veterans
- Viewing the education system as Pre-K - "Grade 20" (college and graduate school) vs. just K-12
- Immigration laws' effects on attracting and retaining talent
- The need for investment in infrastructure - including transportation - to spur manufacturing growth.

For more information, see:

TRANSPORTATION: HOUSE SUBCOMMITTEE HOLDS OVERSIGHT HEARING ON HARBOUR MAINTENANCE TRUST FUND AND TAX

On February 1, 2012, the House Ways and Means Subcommittees on Oversight and Select Revenue Measures held a joint hearing on harbor maintenance funding and maritime tax issues. The hearing focused on the Harbor Maintenance Trust Fund and Harbor Maintenance Tax, maintenance underfunding, and the tax treatment of foreign shipping operations.

Testimony was heard from: The Honorable Michael Strain, Commissioner, Louisiana Department of Agriculture and Forestry; Mr. Gary LaGrange, President and Chief Executive Officer of the Port of New Orleans; Mr. Steven A. Fisher, Executive Director, American Great Lakes Ports Association; Mr. Morten Arntzen, President and Chief Executive Officer, Overseas Shipholding Group; Mr. James C. McCurry, Jr., Director of Administration, Georgia Ports Authority; and Mr. Michael Leone, Port Director, Massachusetts Port Authority.

All witnesses supported various measures currently under consideration by Congress. Mssrs. Strain, LaGrange, Fisher and Leone testified in support of the Realize America's Maritime Promise (RAMP) Act, or H.R. 104 (Mr. McCurry testified in support of the general ideas embodied it). Mr. Arntzen testified in support of the American Shipping Reinvestment Act (H.R. 1031).

Topics discussed included:
- Recent free-trade agreements with Colombia, Panama, Korea, and the Panama Canal extension (scheduled to be complete in 2014), and their potential impact on the need for waterway infrastructure improvements.
- The RAMP Act, which would ensure funds in the Harbor Maintenance Trust Fund (HMTF) are utilized for the intended purpose of dredging and maintaining coastal ports, harbors and waterways.

- The American Shipping Reinvestment Act (H.R. 1031), which would make substantial changes to taxes and earnings regulations of foreign shipping companies doing business in the U.S.

- Misuse of Harbor Maintenance Tax revenues (including $6.1 billion in unspent funds in the Trust Fund). Some believe that this underfunding is causing an increasing need for major dredging operations to keep shipping routes viable.

- The concepts of "sort sea shipping" and "marine highways."

- The Harbor Maintenance Tax, which may discourage companies from shipping by water when other options exist. This includes "double taxing" of cargo taken from freighters and further shipped by smaller craft.

  For the testimony of the witnesses, go to: http://waysandmeans.house.gov.

**INTELLECTUAL PROPERTY: HOUSE JUDICIARY ASSESSES PRIOR USER RIGHTS**


Witnesses included: The Honorable David Kappos, Under Secretary of Commerce for Intellectual Property, Director of the United States Patent and Trademark Office (USPTO); Mr. Robert A. Armitage, Senior Vice President and General Counsel, Eli Lilly and Company; Mr. Dan Lang, Vice President, Intellectual Property, Cisco Systems, on behalf of the Coalition for Patent Fairness; and Dr. John C. Vaughn, Executive Vice President, Association of American Universities.

Director Kappos focused on the “prior user rights” defense and the report prepared by the United States Patent and Trademark Office (USPTO) pursuant to section 3(m) of the Leahy-Smith America Invents Act (AIA). The prior user defense protects third parties who can demonstrate that they were commercially using an invention for at least one year prior to the filing date of a patent application by another relative to that invention. He testified that: "Among the many important components of the AIA are the expansion of the “prior user rights” defense to infringement and the broadening of the classes of patents that are eligible for the new defense. The prior user defense protects third parties who can demonstrate that they were commercially using an invention for at least one year prior to the filing date of a patent application by another relative to that invention. As I’ve said in previous testimony in front of this committee, I believe that expanding the prior user defense is pro-manufacturer, pro-small business, and, on balance, good policy, so I was happy to see that a compromise was reached and that a prior user right defense was included in the final version of the AIA."

After a public comment period, the USPTO made several recommendations regarding the prior user rights defense, including that no changes to the provisions need to be made at this time, but that the USPTO should reevaluate the economic impacts of prior user rights when better evidence as to its impacts might be available.

Mr. Lang strongly supported a robust prior user rights defense as necessary to protect American innovation and jobs. The Coalition did recommend some technical amendments to the law to clarify the intended scope of the prior user rights defense and to align the defense with the protections that foreign competitors enjoy abroad.

Dr. Vaughn reiterated that the America Invents Act includes "a carefully crafted set of prior user rights provisions that addresses the concerns raised by the higher education community while responding to the legitimate interests of private sector companies." He outlined, from a university perspective, the most critical provisions of the AIA prior user rights scheme, including
All university patents are exempt from the assertion of a prior use defense, save those resulting from research that could not have been conducted with federal funds. Because the exemption inheres in the patent, the protection against the assertion of a prior use defense extends to university licensees.

The product or process to which prior user rights may be applied must have been in commercial use at least one year before the effective filing date of a patent against which a prior use defense could be asserted. A product or process eligible for prior user rights must also have been in commercial use at least one year in advance of a disclosure qualifying for the one-year grace period; this provision protects early disclosure and supports the university mission to disseminate the results of research quickly and broadly.

The one-year separation of commercial use from a patent filing or disclosure qualifying for the grace period is important for university licenses, most of which are start-up companies or small businesses.

For the testimony of all the witnesses, go to: http://judiciary.house.gov.

**EDUCATION: SENATE HELP COMMITTEE EXAMINES RISING COLLEGE TUITION RATES**

On Thursday February 2, 2012, the Senate Health, Education, Labor and Pensions Committee held a hearing titled *Innovations in College Affordability*.

While the Committee examined college costs, it did not take up the Administration's recent proposals to curb rising tuition costs using federal aid as an incentive. The President initially revealed this proposal during his State of the Union address on January 24. Chairman Tom Harkin (IA) said the Committee lacked enough information to hold a hearing on that specific proposal. Instead, Chairman Harkin stated that the hearing would focus on the driving factors behind college cost increases in the last 30 years.

Witnesses included: The Honorable Martha Kanter, Under Secretary, U.S. Department of Education; Mr. Kevin Carey, Education Policy Director, Education Sector, Washington, DC; Mr. Charlie Earl, Executive Director, Washington State Board for Community and Technical Colleges, Olympia, WA; Dr. Robert Mendenhall, President, Western Governors University, Salt Lake City, UT; and Dr. Carol Quillen, President, Davidson College, Davidson, NC.

Ms. Kanter testified on the Administration's efforts to boost affordability, including investment of over $40 million in Pell Grants (extending aid to 3 million new recipients) and creation of the American Opportunity Tax Credit. But she also cautioned that "the Federal Government cannot singlehandedly ensure college affordability while ensuring quality and promoting college access and success." She further suggested improvements to be made through team work between the federal government, states, and universities. These include decreasing degree completion time, reforming campus-based student aid, and providing better information to students and families.

Other topics addressed included:

- The difference between college prices (what students pay) and college costs (actual operating costs), and innovations needed to address each.
- The historical phenomenon that prices rise both when state funding is cut and increased, and why this is the case.
- Use of managerial and technology innovations to reduce costs, including the relatively new concept of hybrid learning (classes taught in person and online).
- Giving students quality education at untraditional, pared down universities that cut costs by reducing non-academic offerings.
- Competency-based learning models, which measure learning rather than time and allows students to earn their degrees by demonstrating their mastery of subject matter rather than spending time in class to accumulate credit hours.

For more information, see:
http://www.help senate.gov/hearings/hearing/?id=2f5ce9b3-5056-9502-5d14-2428cbd01c06.
HEALTH: HOUSE REPEALS CLASS ACT

The House passed the Fiscal Responsibility and Retirement Security Act of 2011 (H.R. 1173) by a vote of 267-159 on February 1, 2012. It would repeal the Community Living Assistance Services and Supports (CLASS) program.

The CLASS Program was originally conceived as a long-term care component of the 2010 health care law. It was designed to provide a $50 daily cash benefit to workers who previously paid into the fund and who need financial assistance while receiving long-term care.

The Department of Health and Human Services (HHS) worked for over a year and a half to implement the program. Despite this, it could not devise an implementation method that would fulfill the law's mandates, which require the program to be voluntary, self-sustaining and fiscally sound over a period of 75 years. In October 2010, HHS formally announced that it could not implement the program, spurring repeal legislation in both chambers.

The Senate is not expected to take up its similar measure, S. 720.

For more information, see: