HEALTH: HOUSE OVERWHELMINGLY APPROVES FDA USER FEE BILL

By a vote of 387-5, the House on May 31, 2012 passed H.R. 5651, the Food and Drug Administration Reform Act. The bill is the culmination of more than a year of bipartisan work and negotiations in the House, that also included private stakeholders.

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. Performance goals and reforms to ensure patients receive quality care and timely access to new therapies are included in the bill, as well as provisions to improve the drug approval process for drugs that treat rare diseases.

Additionally, the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) are permanently authorized. They are aimed at incentivizing testing to allow for the safe use of prescription drugs by children.

To address current drug shortages, H.R. 5651 would require the FDA to inform the public through a drug shortages list, alleviate shortages by modifying current reporting requirements and expediting the approval of drugs in need, and authorize GAO to conduct a study to examine the causes and make recommendations to prevent a shortage. The bill also provides FDA with greater flexibility to investigate drug manufacturing facilities overseas to ensure that drugs and ingredients entering the United States are safe.

Although the House and Senate bills are substantially similar, a conference will be required to resolve the remaining differences. The Senate passed its bill, S. 3187, on May 24, 2012, by a vote of 96-1. Both the House and Senate negotiators have indicated that they want to resolve the outstanding issues as quickly as possible, and send the bill to the President by the Fourth of July break.

For further information, go to:
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**Technology: House Subcommittee Holds Hearing on International Proposals to Regulate the Internet**

On May 31, 2012, the House Energy and Commerce Subcommittee on Communications and Technology held a hearing on international proposals to regulate the Internet. The hearing reviewed the potential consequences of recent proposals by the international community to regulate the Internet that will be the subject of discussion at the upcoming World Conference on International Telecommunications (WCIT) in December in Dubai.

Rep. Mary Bono Mack (Palm Springs), Chair of the Commerce, Manufacturing, and Trade Subcommittee, along with full Committee Chairman Fred Upton (MI), Ranking Member Henry A. Waxman (Los Angeles), Communications and Technology Subcommittee Chairman Greg Walden (OR), and Ranking Member Anna Eshoo (Palo Alto), recently introduced a resolution, H. Con. Res. 127, to reject the proposed international takeover of the Internet that is expected to be discussed at the WCIT meetings and preserve the current “multi-stakeholder” model of governance.

Witnesses testified on two panels. The first included: Ambassador Philip Verveer, Deputy Assistant Secretary of State and U.S. Coordinator for International Communications and Information Policy; and Commissioner Robert McDowell, Federal Communications Commission. Panel II included: Ambassador David A. Gross, Former U.S. Coordinator for International Communications and Information Policy, U.S. Department of State, on Behalf of the World Conference on International Telecommunications Ad Hoc Working Group; Ms. Sally Shipman Wentworth, Senior Manager, Public Policy, Internet Society; and, Mr. Vinton Cerf, Vice President and Chief Internet Evangelist, Google.

According to the Subcommittee’s supplementary documents, "pending international proposals to regulate the Internet could jeopardize not only its vibrancy, but also the economic and social benefits it brings to the world. Nations from across the globe will consider changes to the International Telecommunications Regulations at the December 2012 World Conference on International Telecommunications (WCIT) in Dubai. These regulations, adopted by treaty, govern the international operation of traditional telephone service. Some countries, however, are proposing to expand them and the jurisdiction of the United Nations International Telecommunications Union to apply to the Internet."

The Subcommittee states that "proposals by Russia and China to establish an "information security" regime are of particular concern. They: 1) appear to enshrine an international cybersecurity regime; 2) could serve as a justification for countries to engage in Internet censorship in the name of national security; and 3) seek to authorize regulation of the Internet by an international governmental body within the ITU, replacing the multi-stakeholder model that has served the Internet and the world so well."

Ambassador Verveer stated "it is imperative to note that international proposals on Internet issues have been recently discussed in multiple bodies under the aegis of the United Nations," but that the U.S. has thus far "successfully opposed such proposals" and stands against "the extension of
intergovernmental controls over the Internet." Furthermore, "remitting the Internet to intergovernmental control" would "diminish" its "dynamism" while opening the door for "introduction of extraneous considerations, the most noxious of which would be censorship or content controls by repressive regimes."

Instead, the Ambassador stated that the U.S. proposes that governments utilize the "established, successful multi-stakeholder, transparent environment to achieve international public policy goals and strengthen international cooperation," with one such forum being the recent "high-level ministerial meeting at the Organisation for Economic Co-operation and Development (OECD) in June 2011."

His further testimony focused on describing "how the absence of governmental or intergovernmental controls greatly aided the Internet's development thus far," provided "background about the International Telecommunication Union," and described "efforts undertaken by the U.S. Government thus far in advance and in preparation for the 2012 World Conference on International Telecommunications (WCIT)."

Commissioner McDowell began his testimony by painting a picture of the ITU's statements on this issue, which have ranged from public declarations negating intentions to "regulate Internet governance" to "saying that any regulations should be of the 'light-touch' variety." He testified that while the ITU has some jurisdiction over phone numbers, that should not mean it has jurisdiction over the Internet, despite the "alleged worldwide phone numbering 'crisis'" attributed to Internet programs such as Skype. In addition to other attempts to make seemingly minor changes that could have big impacts on the freedom of the Internet, he gave specific examples, such as China's proposal to create "a system whereby Internet users are registered using their IP addresses."

The Commissioner summed up his testimony by stating that should "efforts to expand the powers of intergovernmental bodies over the Internet even in the smallest of ways" succeed, "such a scenario would be devastating to global economic activity" and "would hurt the developing world the most."

Mr. Cerf stressed in his testimony that: "We need a global coalition to ensure transparency, openness, and an outcome that preserves the features of the Internet and its operation that have been so productive over the past 30 years."

For more information:

**TAXES: WAYS & MEANS MARKS UP BILLS AFFECTING HEALTH CARE ACT**

The House Ways and Means Committee met on May 31, 2012 to mark up four bills relating to aspects of the Affordable Care Act. Among them was H.R. 436, “Protect Medical Innovation Act of 2011, which would repeal a tax placed on medical device manufacturers in the 2010 health care act. The Committee reported the bill favorably by a vote of 23-11.

The tax was included as an offset to raise $20 billion over ten years to pay for other provisions in the law. After December 31, 2012, a tax of 2.3 percent of the sale price is set to be imposed on the sale of medical devices. Proponents of the bill argue that the impending tax is already leading device manufacturers and importers to forego hiring new employees, and in fact is causing layoffs, and undermining the U.S. industry’s competitiveness. Although the bill has over 238 cosponsors, because it would repeal the tax without addressing offsetting revenue losses, some members argue against enacting it.

The other bills dealt with the tax treatment and restrictions placed on tax-preferred health savings accounts. One, H.R. 5842, “Restoring Access to Medication Act,” would allow consumers to
use money in their tax-preferred health accounts to pay for over-the-counter drugs. It was reported by a vote of 24-9.

The other bills, also dealing with tax-preferred health accounts, were also successfully reported. H.R. 1004, “Medical FSA Improvement Act of 2011,” by a vote of 23-6; and H.R. 5858, “To amend the Internal Revenue Code of 1986 to improve health savings accounts, and for other purposes”, by a vote of 21 - 7.

For more information, go to:

**HOUSING: SENATE COMMITTEE HOLDS HEARING ON HOMEOWNER REFINANCING ACT**

On Thursday May 24, 2012, the Senate Committee on Banking, Housing, and Urban Affairs held a hearing titled "The Responsible Homeowner Refinancing Act of 2012," S. 3085.
Witnesses included: Mr. Bill Emerson, CEO, Quicken Loans, Inc.; Mr. Christopher Papagianis, Managing Director, e21; Mr. Moe Veissi, 2012 President, National Association of Realtors; and, Dr. Mark Zandi, Chief Economist, Moody's Analytics.

Mr. Emerson explained that while the Home Affordable Refinance Program, initially known as HARP 1.0, had helped more than 900,000 homeowners, there was "a missed opportunity" - those who paid on time are not able to take advantage of lower interest rates because they owed more on their mortgages than their homes are worth. Of the "roughly four million" in this position, "only some 200,000 eligible homeowners have been helped" to date. He expressed support for HARP 2.0, but cautioned that it still does not do enough to help underwater homeowners. In regards to S. 3085, Mr. Emerson testified in support of its eligibility, appraisals, re-subordination of second liens, mortgage insurance, consistency, removal of barriers, and automated underwriting.

Mr. Papagianis noted that there are still "significant strains" on the housing economy, but that "it's important to acknowledge that many of the major negative trends that have dominated the headlines," such as new delinquencies, "are now well off their post-crisis peaks." He further stated that in his opinion, the market is "close to equilibrium." Despite this, the market is still subject to "micro-policy uncertainty," as characterized in uncertainty within loan servicing, among other aspects.
In regards to S. 3085, or HARP 3.0, he stated the following: "This HARP 3.0 proposal can be considered across two dimensions with regards to take-up and eligibility. First, what can or should be done to further increase the penetration of HARP - or the original pool of borrowers that were targeted. Second, should the scope of the HARP program get adjusted - to pull in new borrowers that would not have been eligible previously. My view is that the merits or case for the second objective is much more limited than the first."

Mr. Veissi expressed NAR’s support for S. 3085, saying it would offer "relief to homeowners who continue to meet their mortgage obligation during this on-going period of economic unrest" while encouraging "lenders to return to the home mortgage market."

Mr. Zandi called on policymakers to "act to substantially increase mortgage refinancing activity." S. 3085 "would substantially increase the pool of homeowners eligible to refinance and remove impediments to more refinancing." Furthermore, if enacted fully, "this legislation would increase the number of homeowners eligible to refinance and 'in the money' to nearly 21.5 million, covering almost half of all loans outstanding."
TAXES: HOUSE SUBCOMMITTEE HOLDS HEARING ON ESTATE TAXES AND SMALL BUSINESSES

On May 31, 2012, the House Small Business Subcommittee on Economic Growth, Tax and Capital Access held a hearing titled “Planning for the Death Tax: Can Small Businesses Survive?”. The focus of the hearing was the estate tax and its impact on small businesses and family-owned small firms. The current estate tax law rate is 35% and the estate tax exemption is $5 million. The law will revert to pre-2001 levels of a 55% rate and a $1 million exemption on January 1, 2013, without congressional action this year.

Witnesses included: Neil D. Katz, Managing Partner, Katz, Bernstein & Katz, LLP, Syosset, NY; Karen Madonia, Chief Financial Officer, Illco, Inc., Aurora, IL, on behalf of the Heating, Air-Conditioning Refrigeration Distributors International; Michael G. Flesher, Owner, Taylor Rental Center, Vestal, NY, on behalf of the American Rental Association; and, Thala Taperman Rolnick, Owner, Thala T. Rolnick, CPA, PLLC, Phoenix, AZ.

Topics discussed included:
- Calls for total repeal of the tax, and absent that, reauthorization of current personal exemption and gift and estate tax rates.
- The effects of letting the law revert to pre-2001 levels.
- The cost to a small business to design a plan to address the estate tax, which can cost from $5,000 - $50,000, and often result in the creation of entities such as trusts, which can complicate the businesses process.
- The emotional affects of an owner having to choose between passing on a business' interests prematurely before they are ready, and risking the business' viability after his or her death. One consideration is if a person does pass on his or her business interests before death, it can negatively impact his or her take home income.
- How difficult the estate tax system is to understand, even for lawyers and accountants, and its uncertainty.
- How the tax is based on what the business would be worth if sold, and not the amount it brings in yearly for its owners.
- The nine month deadline to pay the estate tax after a death, and how most small businesses do not have the cash reserve to pay. In this instance, they may take out life insurance for the business. If they do have cash reserves, they may choose to spend them on the tax. Either way, the cost of the payment or premiums can be debilitating.
- The complicated nature of the estate tax as it applies to businesses with multiple owners.


WATER: PPIC RELEASES REPORT HIGHLIGHTING THE RISKS OF WATER SCARCITY AND ITS EFFECT ON ECONOMIC GROWTH

On May 30, 2012, the Public Policy Institute of California (PPIC) released a report titled Water and the California Economy. The Report was authored by: Ellen Hanak, Jay Lund, Barton "Buzz" Thompson, W. Bowman Cutter, Brian Gray, David Houston, Richard Howitt, Katrina Jessoe, Gary Libecap, Josué Medellín-Azuara, Sheila Olmstead, Daniel Sumner, David Sunding, Brian Thomas, and

The main finding of the Report is that California's economy can grow and prosper despite droughts and water shortages caused by a changing climate - but only if threats to the water system are addressed now.

The Report calls on the continued expansion of water management tools such as efficient use of water, water markets, reuse of highly treated wastewater, and underground storage, or water "banking" to conserve and use water, which is vital to California's economy.

The Report points to key trends - expected to persist - that shed light on the role of water in the economy:
- Agricultural water use has declined since the 1980s.
- Urban water use has leveled off since the mid-1990s despite population growth.
- The manufacturing and service industries account for a small fraction of total water use.
- Demand for environmental water is growing.

Periodic drought and long-term decline in water availability from climate change are not the primary concerns in state water sources. Rather, the authors state the following are of more significant concern:
- Catastrophic disruptions in the water supply, in some instances due to earthquake propensity or due to major reliance on one water source for a particular urban area.
- Continuing uncertainty about the reliability of water supplies, especially regarding the Delta, which discourages business and infrastructure investments.
- Declining groundwater basins due to mismanagement and nitrate contamination, mostly in rural areas.
- Increasing risk of catastrophic floods due to chronically and woefully underfunded flood protection mechanisms. This is especially prevalent in the Sacramento area, and climate change has predicted increased flood risk inland from the coast.