FEDERAL HEALTH UPDATE

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Produced by Kate Connelly Theroux in collaboration with the U.S. Medicine Institute for Health Studies

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Congressional Schedule
• The House passed H.R. 2642, Military Construction and Veterans Affairs Appropriations for FY 2008, on June 15, 2007. The bill provides $64.7 billion for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2008, and for other purposes.

• The Senate Committee on Homeland Security and Governmental Affairs held a hearing on June 19, 2007, to examine the issue of juvenile diabetes and research. This is a part of the Fifth Annual Children’s Congress by Juvenile Diabetes Research Foundation (JDRF). Mary Tyler Moore, JDRF international chairman; Adam Morrison, NBA player for the Charlotte Bobcats; and Dr. Griffin P. Rogers, director of the National Institute of Diabetes and Digestive and Kidney Diseases were among those who testified.


The House of Representatives Committee on Veterans’ Affairs held a hearing on June 20, 2007, regarding Priority Group 8 veterans. The hearing focused on the impact of the decision on veterans and the Department of Veterans Affairs (VA) health care system to ban enrollment of priority 8 veterans. The committee also discussed whether the VA should continue this enrollment ban and the effect of potentially bringing Priority Group 8 veterans back into the VA health care system. The Committee requested a report from the VA to detail the cost, including infrastructure and employee needs, for the VA to provide health care to Priority Group 8 veterans.

Military Health Care News

• Delta Dental of California announced that enrollment in the TRICARE Retiree Dental Program (TRDP) now exceeds 1 million covered lives, a new milestone for a program that continues as the nation’s largest, voluntary, all-enrollee paid dental program. The TRDP was first authorized by Congress in 1997 and continues today to offer one of the few affordable,
comprehensive dental benefit programs available to the nation's Uniformed Services retirees and their family members.

According to Lowell Daun, DDS, senior vice president for Delta Dental’s Federal Services division, high satisfaction and renewal rates among existing enrollees explain the program’s growing penetration of the estimated 4 million uniformed service retirees and family members who are eligible for the program.

Dr. Daun notes that another large part of the program’s success stems from the tremendous support the program receives from the various beneficiary liaison and military association contacts assisting in making the eligible population aware of the TRDP. The TRDP offers coverage for diagnostic and preventive services, basic restorative services, periodontics, endodontics, oral surgery, dental emergencies and a separate dental accident benefit available immediately on the effective date of coverage. Additionally, the waiting period for a greater scope of benefits in the enhanced program is only 12 months, after which coverage for crowns, bridges, full/partial dentures and orthodontics goes into effect.

TRDP enrollees can seek care from any licensed dentist in all 50 states, plus the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands and Canada.

http://home.businesswire.com/portal/site/google/index.jsp?ndmViewId=news_view&newsId=20070620005308&newsLang=en

- The Department of Defense (DoD) published a notice in the Federal Register on June 15, 2006 to advise interested parties of a demonstration project in which the DoD will evaluate allowing selected over-the-counter (OTC) drugs to be included on the TRICARE uniform formulary. The Secretary will evaluate the costs/benefits and beneficiary satisfaction of providing OTC drugs under the pharmacy benefits program when the selected OTC drugs are determined to be clinically effective. The demonstration project will be available for beneficiaries within the United States, Puerto Rico, Virgin Islands, and Guam.

This demonstration project is mandated by Section 705 of the John Warner National Defense Authorization Act for 2007, with an implementation deadline of May 1, 2007. Therefore, the DoD is waiving the regulation requiring at least 30 days notice of a demonstration project prior to its effective date. Waiver of the notice period is deemed necessary to avoid delay in implementing program changes.

- The Defense Department Director of the Computer/Electronic Accommodations Program (CAP) Dinah F.B. Cohen was
honored as one of the finalists for the Service to America Awards. The “Sammies” award program recognizes outstanding members of the federal workforce whose innovative and dedicated efforts resulted in significant contributions addressing national needs.

CAP, established in 1990, is a centrally-funded assistive technology program that buys and delivers the hardware, software and services that people with disabilities need to function in the workplace. The technology makes the electronic environment accessible to and usable by individuals with hearing, visual, dexterity, cognitive and communications disabilities. CAP has filled more than 57,000 requests for accommodations. In addition to serving military departments and defense agencies, CAP partners with 64 other federal agencies, including the Department of Veterans Affairs. This includes more than 2,400 accommodations to wounded Service members and Cohen has partnered with the Defense Department military treatment facilities to integrate assistive technologies into occupational therapy and rehabilitation services, housing facilities and employment training centers to support the transition back to reemployment.

CAP also trains organizations to promote understanding of CAP’s mission and services in support of federal goals to increase employment opportunities for people with disabilities. This training provides instruction on how to create and manage the essential elements of disability employment programs such as recruitment, placement, promotion and retention.


**Veterans Health Care News**

• On July 19, 2007, the Department of Veterans Affairs (VA) announced it will expand programs and open new facilities for seriously disabled veterans with spinal cord injuries. The new spinal cord injury center at the Milwaukee VA Medical Center is a $32.5 million building and will open by 2010 to replace an existing converted ward in the hospital. It comes on the heels of another ground-breaking by Nicholson just a month ago for a new $20 million spinal cord injury center attached to the VA medical center in Minneapolis.
VA is a leader in spinal cord injury health care research and rehabilitation, providing a coordinated lifelong continuum of services for eligible veterans with spinal cord injuries of all ages. VA’s expertise in this area ranges from emergency care and surgical stabilization to rehabilitation, preventive care, and long-term care. Responding to the needs of the latest generation of combat veterans, VA has developed a network of poly-trauma rehabilitation centers that bring together specialists in spinal cord injury and other experts into multidisciplinary teams that aid injured troops with other severe disabilities such as traumatic brain injury, amputation, blindness, and complex orthopedic injuries, auditory disorders and mental health concerns.

About 80 percent of veterans with spinal cord injuries and disorders are at least 50 years of age. However, many of the approximately 450 newly injured veterans and active-duty members who received rehabilitation at VA’s spinal cord injury centers last year are young adults.

Treatment and technology have improved so that veterans with spinal cord injuries have increasingly longer life expectancies. Maintaining health, preventive medicine and early treatment of new conditions are important parts of VA’s lifelong care.

Last year, VA provided a full range of care to nearly 26,000 veterans with spinal cord injuries and diseases. VA’s specialized services are delivered through 135 primary care teams or support clinics for spinal cord injuries at VA medical centers and through 23 regional spinal cord injury centers. http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1349

The Department of Veterans Affairs announced that the 153 VA medical centers will extend their operating hours in order to provide more health care for more veterans, especially mental health services. Although the extra hours apply to many hospital-based programs and services, this decision was based upon a desire to ensure VA’s more than 9,000 mental health professionals are available when veterans need them.

VA operates the largest integrated health care system in the country and the nation’s largest mental health program. About 5.5 million veterans are expected to seek health care from VA’s nationwide system this year, accounting for about 800,000 hospitalizations and 60 million outpatient visits.

In recent months, VA has announced a number of initiatives to improve mental health care for returning combat veterans, including the hiring of suicide prevention coordinators for each medical center, 100 new adjustment counselors for VA’s 207
Vet Centers, and 100 new medical center employees to serve as advocates for the severely wounded.

VA’s mental health experts will gather in Washington in July for a four-day conference reassessing the Department’s programs for veterans, especially veterans from the conflict in Iraq and Afghanistan.
http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1348

Health Care News

• The Department of Health and Human Services (HHS) established a public health advisory panel concerned with chemical, biological, nuclear or radiological agents. The National Biodefense Science Board will give the HHS Secretary guidance on preventing, preparing for, and responding to release of such agents, whether they are naturally occurring, accidental, or deliberate.

The board, which was authorized by the Pandemic and All-Hazards Preparedness Act, will advise the Secretary about trends, challenges and opportunities in the field. At the Secretary’s request, it will also provide recommendations for research and development.

Board members are yet to be selected. There will be 13 members, appointed by the HHS Secretary, from among leading experts in science, public health and medicine. Four will be from the pharmaceutical, biotechnology and device industries. Four will be from academic institutions. Of the remaining five, one must be from an organization representing health care consumers and one must be a practicing health care professional. The Secretary also will appoint federal officials to support the board’s functions. http://www.hhs.gov/news/press/2007pres/06/pr20070619a.html

• On June 20, 2007, the Centers for Medicare and Medicaid Services (CMS) announced a new project expanding its efforts to encourage Medicare beneficiaries to take advantage of Internet-based tools to track their health care services and provide them with other resources to better communicate with their providers.
This pilot program, expected to run for eighteen months, will enable certain beneficiaries to access and use a Personal Health Record (PHR) provided through participating health plans, and accessible through www.mymedicare.gov. In general, a PHR is a collection of information about an individual’s health or health care services, such as medical conditions, hospitalizations, doctor visits and medications. The data that will be made available to the beneficiaries include registration information such as name, address, and policy number as well as lists of their medications and medical conditions.

The PHR tools will allow beneficiaries to look up information about their own medications and medical conditions to help them manage their own health care. The beneficiary is in charge of his or her own PHR and will control who is able to see the information it contains. Sharing this information with healthcare providers from the PHR will be entirely up to the beneficiary.

This month, CMS will launch the program in conjunction with four health plans to test the use of their PHRs. The plans are: HIP USA, Humana, Kaiser Permanente, and the University of Pittsburgh Medical Center. Each plan has a unique PHR tool that will be accessible to beneficiaries. The availability of different tools will provide valuable information to CMS on the various features offered, including which are most popular and useful to the individual.

CMS will collect both quantitative and qualitative data to assess the use, usefulness, usability, and feature preferences of the tools. The goals of the project are to:

- Determine the features that are most attractive to Medicare beneficiaries;
- Identify the minimum content and functionality for the PHRs tools; and
- Assess the best methods for outreach and education to encourage adoption and ongoing use.

CMS NR 06-20-07

- The U.S. Food and Drug Administration (FDA), the European Commission (EC), and the European Medicines Agency (EMEA) have agreed to expand their current cooperative activities in several important areas. The ultimate goal of the initiative is to promote and protect public health, reducing regulatory burden and costs, and bringing innovative products to patients in a timely manner. Furthermore, important safety information about medicinal products is shared among the parties.

Building on the achievements in cooperation on vaccines, oncology, and pharmacogenomics, it was agreed to expand further
the interactions in the areas of pediatrics and medicinal products for rare diseases (“orphan drugs”). Furthermore, scientific
dialogue has been widened to include extensions of therapeutic indications and risk management plans. Based upon the newly
adopted pediatric legislation in the EU, a “Principles of Interactions” document that will facilitate the timely exchange of
information on scientific and ethical issues for pediatric therapeutics has been finalized.

The Implementation Plan on transatlantic medicines regulatory cooperation was revised to describe under what circumstances
information will be shared among the parties. Following the Framework for Advancing Transatlantic Economic Integration
between the EU and the FDA, new areas of transatlantic regulatory cooperation were discussed, notably regulatory cooperation
on medical devices and on cosmetics. Discussions on these topics will continue.

In an effort to avoid future disharmony, upstream regulatory cooperation on new medicines legislation was discussed. In
addition, planning progressed on a Transatlantic Workshop on Administrative Simplification in Medicines Regulation on Nov.
28, 2007 in Brussels, Belgium.

Transatlantic regulatory cooperation under the EC, EMEA and US FDA collaboration has allowed each side to share common
experiences and gain an understanding of each other’s regulatory system. Additionally, each side strives to reduce unnecessary
differences in regulations and reduce associated costs to the consumer and industry. All parties concur that this activity
continues to be a success in fostering transatlantic cooperation and promoting public health

• On June 15, 2007, the Center for Medicare and Medicaid Services (CMS) announced that in response to concerns about
marketing practices, seven health care sponsors have signed an agreement to suspend voluntarily the marketing of Private-Fee-
For-Service (PFFS) plans. This suspension for a given plan will be lifted only when CMS certifies that the plan has the systems
and management controls in place to meet all of the conditions specified in the 2008 Call Letter and the May 25, 2007
guidance issued by CMS. The signatories include: United Healthcare, Humana, Wellcare, Universal American Financial
Corporation (Pyramid), Coventry, Sterling, and Blue Cross/Blue Shield of Tennessee.

The agreement is effective five business days from June 15 and will continue to apply to individual plans until they have
demonstrated to CMS that they have the systems and management controls in place to ensure that they can meet all the CMS
requirements. CMS review will begin as soon as plans indicate they are ready. Plans signing the agreement will be actively
monitored to ensure they do not engage in marketing while the voluntary suspension is in place. Violations will be subject to a full range of available penalties, which can include suspension of enrollment, suspension of payment for new enrollees, civil-monetary penalties, and termination of the plan’s involvement in the Medicare program. The full range of updated conditions will be in effect for all sponsors of PFFS plans beginning Oct. 1, 2007, and violations of those conditions will be subject to the same types of penalties.

Primary provisions that the plans signing the agreement must meet to have the suspension lifted (and that all PFFS must meet beginning Oct. 1, 2007) are summarized below:

- All materials, including but not limited to advertisements, enrollment materials, and materials used at sales presentations by employees or contracted representatives of a health insurance company will include the model disclaimer language provided by CMS in its May 25, 2007 guidance.
- All representatives selling the product to beneficiaries on behalf of the plan sponsor will pass a written test that demonstrates their thorough familiarity with both the Medicare program and the product they are selling.
- A provider outreach and education program will be in place to ensure that providers have reasonable access to the plan terms and conditions of payment, and that provider relations staff are readily accessible to assist providers with questions concerning the plan.
- Outbound education and verification calls will be made to all beneficiaries requesting enrollment to ensure that they understand the plan rules.
- Lists of planned marketing and sales events provided to CMS will include events sponsored by delegated brokers and agents as well as those sponsored by the plan.
- When asked by CMS, plan sponsors will provide a complete list of all representatives marketing a PFFS product and authorize CMS to make that list available to State Insurance Departments on request.

CMS NR 06-15-07

- The U.S. Food and Drug Administration (FDA) approved Letairis (ambrisentan) for the treatment of pulmonary arterial hypertension, a rare, life-threatening condition characterized by continuous high blood pressure within the arteries of the lungs.

In pulmonary arterial hypertension, the small arteries in the lungs become narrowed or blocked, and the heart must work harder...
to pump the blood through them. Over time, the overworked heart muscle may become weak and lose its ability to pump enough blood through the lungs. Symptoms include shortness of breath, fatigue, chest pain, dizzy spells and fainting. About 100,000 people in the United States have pulmonary arterial hypertension.

Letairis, manufactured by Gilead Sciences, Inc., Foster City, Calif. was granted a priority review by FDA. A priority review designation is intended for those products that address unmet medical needs. For priority drug applications, FDA sets a target date of six months after the date of receipt for the agency to complete all aspects of a review and to take action. It was granted orphan drug status by FDA because it treats a rare disease and meets other criteria. Orphan designation qualifies the drug's sponsor for a tax credit and marketing incentives.

The safety and effectiveness of Letairis were demonstrated in two international clinical trials involving 393 patients. Letairis significantly improved physical activity capacity compared with a placebo, as shown by a six-minute walk, a standard test. Letairis also delayed the worsening of the pulmonary hypertension.


• Beginning June 18, 2007, John Bucher, Ph.D., will serve as the new associate director of the National Toxicology Program (NTP), and will begin managing the day-to-day operations of the program. The NTP is an interagency program with the mission to coordinate, conduct and communicate toxicological research across the U.S. government.

For 29 years, the NTP has evaluated chemicals and other agents that may be damaging to human health. Through its extensive testing program, the NTP has examined the safety of more than 2,500 substances. In addition, the NTP prepares and issues the biennial Report on Carcinogens, which so far has identified 246 cancer-causing agents including substances like lead and diesel exhaust, and viruses like Hepatitis B and C.

The NTP is located in Research Triangle Park, North Carolina, at the National Institutes of Environmental Health Sciences (NIEHS), one of the National Institutes of Health. David Schwartz, M.D., serves as the director of the NIEHS and the NTP. Bucher, an internationally recognized expert in the design and interpretation of cancer bioassays, was selected from 33 applicants. A 14-member search committee conducted a national recruitment and selected four finalists. After a series of interviews at NIEHS, Bucher was offered the job.
Bucher joined the NTP team as a toxicologist 24 years ago and since then has played a key role in shaping the program’s research and policies. Bucher oversaw the development and evaluation of several non-traditional testing methods including current efforts with high throughput automated screening. He organized one of the first conferences to explore the field of nanotoxicology and has advised congressional staff about this critically important emerging area of science. Bucher provided oversight and guidance for the development of the NTP Center for the Evaluation of Risks to Human Reproduction. He also played a major role in developing the NTP Vision and Roadmap for the 21st Century, a plan for toxicology research to advance as a predictive science, building on the knowledge gained from traditional single-agent studies in living organisms, in vivo studies. http://www.nih.gov/news/pr/jun2007/niehs-15.htm

• The American Medical Association (AMA) will launch a new peer-reviewed journal, *Disaster Medicine and Public Health Preparedness*, the first comprehensive and authoritative publication emphasizing the science of disaster planning, and recovery. The quarterly journal will serve as a unifying resource for all health professionals, the emergency management community and others in the public and private sector who are essential to emergency planning and response.

*Disaster Medicine and Public Health Preparedness* was created by the AMA to promote public health preparedness and the science of disaster medicine. The journal will serve as a unifying resource for all health care and public health professionals, the emergency management community and others in the public and private sector who are essential to emergency planning and response. Studies featured in the first edition include: “Excess Mortality in the Aftermath of Hurricane Katrina: A Preliminary Report” and “Characteristics of Physician Relocation Following Hurricane Katrina.” http://www.ama-assn.org/ama/pub/category/17711.html

**Reserve/Guard**

• The total number of Guard and Reserve currently on active duty has increased by 478 from the last report to 92,462. The totals for each service are Army National Guard and Army Reserve, 75,154; Navy Reserve, 4,927; Air National Guard and Air Force Reserve, 5,924; Marine Corps Reserve, 6,099; and the Coast Guard Reserve, 358. www.defenselink.mil

• The GAO issued “Veterans Affairs: Continued Focus on Critical Success Factors Is Essential to Achieving Information Technology Realignment,” (GAO-07-844) on June 15, 2007. In the report, the GAO examines whether the department's realignment plan includes critical factors for successful implementation and how the centralized management approach is to ensure that the chief information officer (CIO) is accountable for the department's entire IT budget. http://www.gao.gov/new.items/d07844.pdf

• The GAO issued “Influenza Pandemic: Efforts to Forestall Onset Are Under Way; Identifying Countries at Greatest Risk Entails Challenges,” (GAO-07-604) on June 20, 2007. The report describes U.S. and international efforts to assess pandemic risk by country and prioritize countries for assistance; and steps that the United States and international partners have taken to improve the ability to forestall a pandemic. http://www.gao.gov/new.items/d07604.pdf

Legislation

• **H.R.2737** (introduced June 15, 2007): To amend the Internal Revenue Code of 1986 to allow previously uninsured individuals a refundable credit for health insurance costs and to provide tax incentives to encourage small business health plans was referred to the House Committee on Ways and Means.
  Sponsor: Representative Leonard L. Boswell [IA-3]

• **H.R.2739** (introduced June 15, 2007): To amend title 10, United States Code, relating to payment of mental health counselors under TRICARE was referred to the House Committee on Armed Services.
  Sponsor: Representative Robin Hayes [NC-8]

• **H.R.2741** (introduced June 15, 2007): To amend title XVIII of the Social Security Act to provide a wage index floor for hospitals and home health agencies located in certain areas under the Medicare Program was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
  Sponsor: Representative Carol Shea-Porter [NH-1]

• **H.R.2746** (introduced June 15, 2007): To amend titles XIX and XXI of the Social Security Act to provide States with the option to expand or add coverage of pregnant women under the Medicaid and State children's health insurance programs, and for other purposes was referred to the House Committee on Energy and Commerce.
  Sponsor: Representative Diana DeGette [CO-1]

• **H.R.2749** (introduced June 15, 2007): To amend title XVIII of the Social Security Act to provide for a transition to a new voluntary quality reporting program for physicians and other health professionals was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
  Sponsor: Representative Bart Gordon [TN-6]
• **H.R.2762** (introduced June 18, 2007): To amend the Public Health Service Act to reauthorize the special diabetes programs for Type I diabetes and Indians under that Act was referred to the House Committee on Energy and Commerce.  
  Sponsor: Representative Diana DeGette [CO-1]

• **H.R.2769** (introduced June 19, 2007): To establish improved mandatory standards to protect and enhance the health of miners was referred to the House Committee on Education and Labor was referred to the House Committee on Education and Labor.  
  Sponsor: Representative George Miller [CA-7]

• **S.1655** (introduced June 19, 2007): A bill to establish improved mandatory standards to protect miners during emergencies and for other purposes was referred to the Committee on Health, Education, Labor, and Pensions.  
  Sponsor: Senator Edward M. Kennedy [MA]

**Hill Hearings**

• The Senate Veterans Affairs Committee will hold a hearing on **June 27, 2007**, to examine the nomination of Charles L. Hopkins, of Massachusetts, to be an Assistant Secretary of Veterans Affairs (Operations, Preparedness, Security and Law Enforcement).

• The Senate Veterans Affairs Committee will hold a hearing on **July 11, 2007**, to examine Veterans Affairs health care funding.

• The Veterans Affairs committees for the Senate and House will hold a joint hearing on **Sept. 20, 2007**, to hear the American Legion's legislative presentation.
Meetings / Conferences

• The Global Medical Readiness Conference will be held **June 25 – 28, 2007**, in Orlando, Fl. [https://secure.giuffrida.org/airforce/index.html](https://secure.giuffrida.org/airforce/index.html)

• The Department of Veterans Affairs’ Advisory Committee on OIF/OEF Veterans and Families will hold a town hall meeting on **June 27, 2007**, in Las Vegas, Nev. [www.va.gov/oifoef](http://www.va.gov/oifoef)

• The Society of Ghana Women's Medical and Dental Practitioners, the 27th International MWIA Congress is scheduled for **July 31** to **Aug. 4, 2007** in Accra, Ghana. [www.mwiainghana.org](http://www.mwiainghana.org)


• The 2007 Advance Technology Applications for Combat Casualty Care (ATACCC) Conference will be held on **Aug. 13-15, 2007** in St Petersburg Beach, Fla. [http://www.usaccc.org/ATACCC/index.htm](http://www.usaccc.org/ATACCC/index.htm)


• 46th Annual Research in Medical Education (RIME) Conference will be held **Nov. 2-7, 2007**, in conjunction with the AAMC Annual Meeting in Washington, D.C.

• The 13th International Congress on Infectious Diseases will be held **June 19-22, 2008**, in Kuala Lumpur,
If you need further information on any of the items in the Federal Health Update, please contact Kate Connelly Theroux at (703) 447-3257 or by e-mail at kate@usminstitute.org. To subscribe, please visit http://usminstitute.org/subscriber.cfm. To unsubscribe, please send an email to update@usminstitute.org with UNSUBSCRIBE as the subject.