

FEDERAL HEALTH UPDATE

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

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Congressional Schedule

- On Sept. 1, 2007, Senator Larry E. Craig (R-Idaho) announced his resignation from the Senate, effective Sept. 30, 2007. On Sept. 5, Craig announced that he would resign only if he was unable to rescind his guilty plea to disorderly conduct in Minneapolis, Minn., which he entered on Aug. 8, 2007.
- On Sept. 6, 2007, the Senate passed H.R. 2642 as Amended; Military Construction and Veterans Affairs Appropriations Act, 2008.

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Military Health Care News

- TRICARE Management Activity launched a new Member Choice Center (MCC) as part of the services provided to ease registration for the TRICARE Mail Order Pharmacy (TMOP).

By using this new service, not only will the beneficiary obtain TMOP enrollment assistance, but the MCC

also will actually contact the physician to obtain new prescriptions and forward them to the TMOP for processing, making the switch from retail to mail order virtually effortless for the beneficiary.

Beneficiaries can register on the “My Benefit” portal on www.tricare.mil or to www.express-scripts.com/TRICARE or by calling the MCC directly at 1-877-363-1433 to switch from the retail program to TMOP. <http://www.tricare.mil/pressroom/news.aspx?fid=310>

- On Aug. 22, 2007, the Army Long-Term Family Case Management (ALTFCM), a one-stop resolution center providing 24/7 long-term support to families of fallen soldiers, expanded its [Web site](#) services to include 11 new categories to the support program. Each category page contains brief summaries and contact information for both national and local programs related to careers, children and youth, counseling, finances, emotional support, education, healthcare, legal assistance, military and government, peer support, religion, and substance abuse.

ALTFCM will provide information such as:

- Survivor benefits: Death Gratuity and the Service Members Group Life Insurance (SGLI);
- Reports regarding service member's line of duty investigation and autopsy;
- Support programs: career, education, and legal;
- Soldier services including awards and citations, and unpaid pay and allowances.

Army Long-Term Family Case Management’s (ALTFCM) support coordinators personally provide ongoing support to Families of fallen soldiers the months and years following their loss. ALTFCM is provided by the Army’s Casualty and Mortuary Affairs Operation Center (CMAOC). To date, ALTFCM has served over 3,000 family members and distributed more than 600 million dollars in retroactive benefits. <https://www.hrc.army.mil/site/active/tagd/cmaoc/altfcm/documents/WebUpdatesRelease.pdf>

- TriWest Healthcare Alliance, the managed care support contractor for the TRICARE West Region, which provides health care services to over 2.9 million uniformed services beneficiaries, active and retired, announced it is offering an innovative program to help military leaders respond to families who have lost a loved one in service to our country. Responding to the needs of National Guard and Reserve unit commanders, TriWest is partnering with noted author and nationally certified counselor, Joanne Steen, a widow of a naval aviator killed in the line of duty.

Through a first-of-its-kind partnership, TriWest and Steen will offer "Grief Solutions" to military leaders in communities hit hardest by casualties, to provide them with a deeper understanding of how to support and assist survivors, as they are the first to respond once families within their units have been notified of a loss.

Programs will be offered to active-duty, National Guard and Reserve units throughout the 21-state TRICARE West Region administered by TriWest Healthcare Alliance.

Steen, co-author of *Military Widow: A Survival Guide*, has assisted hundreds of spouses, parents and children of fallen service members, as well as providing military leaders with practical skills to cope with the complexities of military death.

This partnership is one of many behavioral health initiatives developed by TriWest to support the ongoing needs of U.S. service members and their families. More information is available on [TriWest's Behavioral Health Portal](#).

- [Humana Military Healthcare Services' \(HMHS\)](#) and ValueOptions, the TRICARE South Region subcontractor for mental health, launched a new online educational resource developed by ValueOptions for Behavioral Health, Employee Assistance Program (EAP) and Work/Life called AchieveSolutions®. This new online portal, which was launched August 30, offers TRICARE beneficiaries a secure, safe environment to seek information, educational materials and self-assessment tools on behavioral health, addiction and recovery, life events, and daily living skills.

The Department of Defense's (DoD) Task Force on Mental Health recently stated in its June 2007 report to Secretary of Defense Robert M. Gates that 74 percent of DoD active-duty personnel cope with stress by talking with a friend or family member. These individuals play a key role in influencing service members to seek help. As such, family members, as well as service members, need to be equipped with resilience-building skills, the ability to recognize distress, and the knowledge of how and where to seek assistance. The AchieveSolutions site provides such education and skill building opportunities.

Both HMHS and ValueOptions point out that many of life's events have the ability to create stress, and this can lead to more significant issues if not addressed proactively. AchieveSolutions builds off of ValueOptions' expertise and understanding of human behavior and the importance of prevention to provide quality information and education to TRICARE beneficiaries at the touch of a fingertip.

Resources provided on the Web site, which are offered in both English and Spanish, include: access to self-referral tools, behavioral health program information, interactive self-assessment applications with solutions, health risk assessment tools and benefit information.

AchieveSolutions contains over 6,000 articles covering more than 200 topical areas such as: information on advocacy, emotional well-being, family concerns, dealing with illness, loss and grief, alcoholism and substance abuse. The content of the site is continually updated to reflect new research, articles and material. The information is clinically credible, current and consistent with ValueOptions' focus on quality.

In addition, to ensure users' privacy, the Web site is a VeriSign secure site, which means that all traffic to and from the server is secured by encryption. http://home.businesswire.com/portal/site/google/index.jsp?ndmViewId=news_view&newsId=20070904005867&newsLang=en

- The DoD Task Force on the Future of Military Health Care met on Sept. 5, 2007, to examine

the Military Health System (MHS) command and control, in particular the concept of a unified medical command. Representatives from Rand Corporation, the Center for Naval Analyses and the Department of Defense discussed the current command structure and options for a more effective command organization. The task force was very interested in the status of the command structure for the National Capitol Region, which has been scrutinized by the media.

Veterans Health Care News

- The Department of Veterans Affairs (VA) awarded three grants totaling more than \$2.2 million for facilities in Ft. Dodge and Winfield, Kansas.

At the Ft. Dodge home, one grant of \$810,153 will pay for life-safety renovations and another for \$496,617 will provide back-up generators. The home in Winfield is receiving \$939,634 for a generator, a sprinkler system and other renovations.

VA's grants cover up to 65 percent of the actual cost of construction. The total cost of the Ft. Dodge projects is more than \$2 million. The total construction cost at Winfield is more than \$1.4 million.

This year, VA expects to spend nearly \$687 million in Kansas to serve more than 233,000 veterans living in the state. VA operates major medical centers in Leavenworth, Topeka and Wichita, 17 community-based outpatient clinics across the state, three nursing homes and a Vet Center in Wichita.

<http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1377>

- The Department of Veterans Affairs (VA) is providing two grants totaling more than \$1.3 million to Georgia for renovations at the 20-acre state veterans' home in Milledgeville. VA's grants cover 65 percent of the estimated \$2 million cost for the new renovations.

Georgia's veterans homes are available to war veterans who have been discharged under other than dishonorable conditions. Veterans must have resided in Georgia for at least five years immediately preceding the date of application. <http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1378>

- The Department of Veterans Affairs (VA) awarded nearly \$1.6 million to Minnesota for improvements at the state veterans' home in Minneapolis. The grant will cover emergency electrical and back-up generator upgrades. Total estimated cost of the Minneapolis project is \$2,457,000, with VA's grant covering up to 65 percent of the cost.

Last year, VA spent more than \$1.2 billion in Minnesota to serve more than 410,000 veterans who live in the state. VA operates major medical centers in Minneapolis and St. Cloud, a nursing home in St. Cloud and eight community-based outpatient clinics across the state. <http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1379>

Health Care News

- On Aug. 30, 2007, the Department of Health and Human Services (HHS) announced that another \$75 million will be available to states, territories and four metropolitan areas to help strengthen their capacity to

respond to a pandemic influenza outbreak.

The supplemental funding will be used to:

- Establish or enhance stockpiles of critical medical equipment and supplies;
- Continue development of plans for maintenance, distribution and sharing of those resources;
- Plan for and develop pandemic alternate care sites; and
- Conduct medical surge exercises.

The one-time pandemic influenza response planning grants will supplement the \$430 million HHS announced on June 28, 2007, to strengthen the ability of hospitals and other health care facilities to respond to bio-terror attacks, infectious diseases, and natural disasters that may cause mass casualties. Detailed information on state and local funding allocations is available at

<http://www.pandemicflu.gov/news/allocation.html>.

<http://www.hhs.gov/news/press/2007pres/08/pr20070830a.html>

- On Aug. 30, 2007, the U.S. Food and Drug Administration approved Somatuline Depot (lanreotide acetate injection) for the treatment of acromegaly, a rare and potentially life threatening disease in adults caused by abnormal secretion of growth hormone (GH), commonly from a benign tumor located in the pituitary gland located in the brain.

The approval is limited to long-term treatment of patients with acromegaly who have had inadequate response to or cannot be treated with surgery and/or radiation therapy. This new treatment lowers the levels of certain hormones in the body, including GH and insulin-like growth factor. Excessive GH secretion, working through insulin-like growth factor, can cause enlargement of the hands, feet, facial bones, and enlargement of internal organs such as the heart and liver. If untreated, patients with acromegaly often have a shortened life span because of heart and respiratory diseases, diabetes mellitus, and colon cancer.

FDA designated Somatuline Depot as having orphan status, because the drug treats a rare disease and meets other criteria. Orphan products are developed to treat rare diseases or conditions that affect fewer than 200,000 people in the United States. The Orphan Drug Act provides a seven-year period of exclusive marketing to the first manufacturer who obtains marketing approval for a designated orphan product. Acromegaly affects approximately 15,000 people in the United States and Canada and is most commonly found in middle-aged adults. Patients with acromegaly have reduction in life expectancy of 5 to 10 years.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01692.html>

- The U.S. Food and Drug Administration has licensed a new vaccine to protect against smallpox, a highly contagious disease with the potential to be used as a deadly bio-terror weapon.

The vaccine, ACAM2000, is intended for the inoculation of people at high risk of exposure to smallpox and could be used to protect individuals and populations during a bioterrorist attack. It will be included in the Center for Disease Control and Prevention's (CDC) Strategic National Stockpile of medical supplies.

A worldwide vaccination program eradicated smallpox in the human population. The last case of naturally occurring smallpox in the U.S. was in 1949, and the last case in the world was reported in Somalia in 1977.

Known stockpiles of the virus are kept only in two approved labs in the United States and Russia. The CDC considers it a Category A agent, meaning it presents one of the greatest potential threats for harming public health.

Smallpox is caused by the variola virus, a virus that emerged in human populations thousands of years ago. It spreads through close contact with infected individuals or contaminated objects, such as bedding or clothing. There is no FDA-approved treatment for smallpox, and the only prevention is vaccination.

ACAM2000, manufactured by Acambis Inc. of Cambridge, England, and Cambridge, Mass., is made using a pox virus called vaccinia, which is related to but different from the virus that causes smallpox. The vaccine contains live vaccinia virus and works by causing a mild infection that stimulates an immune response that effectively protects against smallpox without actually causing the disease. The vaccine is derived from the only other smallpox vaccine licensed by FDA, Dryvax, approved in 1931 and now in limited supply because it is no longer manufactured.

Although smallpox vaccination ended in the United States in 1972 because it was no longer needed for prevention, the U.S. military resumed vaccination of at-risk personnel in 1999, after concluding that the disease posed a potential bioterrorism threat.

Because ACAM2000 contains live vaccinia virus, care must be taken to prevent the virus from spreading from the inoculation site to other parts of the body, and to other individuals. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01693.html>

- The U.S. Food and Drug Administration approved a second test for the detection of West Nile virus (WNV) in blood and organs.

The cobas TaqScreen WNV test, manufactured by Roche Molecular Systems Inc. of Pleasanton, Calif., is an automated test that's able to detect the genetic material of the virus itself early in the infection. Such nucleic acid testing improves blood and organ safety, detecting whether donated blood and organs have been infected even before the donor's body has begun to produce antibodies against the virus.

Most often, WNV is transmitted to humans by mosquitoes. But WNV can also be transmitted by blood transfusion or organ transplantation from infected donors. While WNV infection is common in Africa, Asia, and the Middle East, it did not appear in the United States until 1999. Since then, WNV has become endemic in most of this country, with from 1 million to 3 million cases between 1999 and 2006, according to the Centers for Disease Control and Prevention.

The cobas TaqScreen WNV test is approved for the detection of the virus in plasma specimens from human donors of whole blood and blood components (plasma, red or white cells, platelets) and living donors of cells, reproductive cells and other tissues. It is also intended for use in testing plasma specimens of organ donors when specimens are obtained while the donor's heart is still beating. The test is not intended for use on samples of cord blood or as an aid in the diagnosis of WNV infection. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01691.html>

- The U.S. Food and Drug Administration approved Evithrom (human thrombin), a blood-clotting protein

used to help control bleeding during surgery.

Evithrom, manufactured by Omrix Biopharmaceuticals, Ltd., Ramat Gan, Israel. is the first human thrombin approved since 1954 and is the only product currently licensed. It is derived from human plasma obtained from carefully screened and tested U.S. donors and has undergone steps to further reduce the risk for transfusion-transmitted diseases.

Evithrom is indicated as an aid to stop oozing and minor bleeding from capillaries and small veins and when control of bleeding by standard surgical techniques is ineffective or impractical. The product is applied to the surface of bleeding tissue and may be used in conjunction with an absorbable gelatin sponge. Evithrom must *not* be injected into blood vessels, which would result in serious clinical complications and may even be fatal. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01690.html>

- The nation's childhood immunization rates remain at or near record levels for routinely recommended vaccines, according to 2006 estimates released today by the Centers for Disease Control and Prevention (CDC). This continues the trend of more children being protected against vaccine-preventable diseases each year.

According to the CDC's annual National Immunization Survey (NIS), the percentage of U.S. children 19 to 35 months of age who have received the recommended series of childhood vaccines was 77 percent in 2006, statistically similar to the 76.1 percent in 2005.

The recommended series consists of four doses of diphtheria, tetanus and pertussis vaccine, three doses of polio vaccine, one or more doses of measles, mumps and rubella vaccine, three doses of *Haemophilus influenzae* type b vaccine (Hib), three doses of hepatitis B vaccine and one or more doses of varicella or chickenpox vaccine. This set of immunizations begins shortly after a child is born and continues up to 2 years of age.

This year, for the first time, the National Immunization Survey included estimates of the percentage of 13- to-17-year-old children who had received recommended immunizations for measles-mumps and rubella vaccine, hepatitis B vaccine, varicella vaccine, tetanus-diphtheria or tetanus, reduced diphtheria and acellular pertussis and meningococcal conjugate vaccine. The tetanus, reduced diphtheria and acellular pertussis and meningococcal conjugate vaccines, which are specifically targeted for use in adolescents, were licensed and recommended in the U.S. in 2005.

The percentage of adolescents who had received recommended vaccines varied widely by both vaccine and age, with the Nation's Healthy People 2010 goals for adolescents ages 13-15 years not being met for any of the vaccines. The Health People 2010 goals are for 90 percent coverage for adolescents 13 to 15 years of age with three doses of Hepatitis B vaccine, two doses of measles, mumps and rubella vaccine, one dose of either tetanus-diphtheria or tetanus, diphtheria and acellular pertussis vaccine, and one dose of varicella vaccine for those who have not previously had chickenpox.

For more information, visit <http://www.cdc.gov/vaccines/default.htm>.
<http://www.cdc.gov/od/oc/media/pressrel/2007/r070830.htm>

- On Aug. 27, 2007, the Centers for Medicare and Medicaid Services (CMS) issued final regulations prohibiting physicians from referring Medicare patients for certain items, services and tests provided by businesses in which they or their immediate family members have a financial interest.

This regulation is the third phase of the final regulations implementing the physician self-referral prohibition commonly referred to as the Stark law.

This third phase of rulemaking (Phase III) responds to public comments on the Phase II interim final rule published March 26, 2004, in the *Federal Register*. The rule does not establish any new exceptions to the self-referral prohibition, but rather makes certain refinements that could permit or, in some cases, require restructuring of some existing arrangements, CMS officials explained.

Based on public comments on the Phase II rule, this final regulation includes the following actions:

- *Provides enhanced flexibility in structuring non-abusive compensation arrangements.* For example, the rules regarding physician recruitment and retention payments are expanded to permit recruitment of more physicians into extended areas when needed.
- *Provides relief for inadvertent violations of the self-referral prohibition under certain circumstances.* For example, the rules permit parties that inadvertently exceed the limit on non-monetary compensation to continue to satisfy the requirements of the exception if the excess non-monetary compensation did not exceed 50 percent of the permitted amount and is repaid within 180 days of its receipt or the end of the calendar year, whichever is earlier.
- *Reduces the regulatory burden for compliance with certain exceptions.* For example, the Phase III final rule eliminates the requirement that entities providing professional courtesy provide written notice to an insurer of a reduction of any coinsurance obligation.
- *Clarifies the agency's interpretation of existing regulations.* For example, the rule clarifies which provisions in office space and equipment lease agreements may be amended during the initial and subsequent terms of the agreements.

The final rule was to be published in the September 5, 2007, *Federal Register*. For more information, visit the CMS Web site at: http://www.cms.hhs.gov/PhysicianSelfReferral/CMS_NR_08-27-2007

- The Centers for Medicare and Medicaid Services (CMS) issued a [proposed rule](#) that will revise the requirements that ambulatory surgical centers (ASCs) must meet in order to bill Medicare for services furnished to beneficiaries on Aug. 24, 2007.

This proposed rule would update the existing ASC Conditions for Coverage (CfC) to reflect contemporary standards of practice in the ASC community, as well as recommendations from the HHS Inspector General. The new requirements will promote and protect patient access to quality services in ASCs.

ASCs are typically free-standing facilities that perform outpatient surgery. To participate in the Medicare program, they must meet Medicare's conditions for coverage.

The most commonly performed ASC procedures currently include cataract removal and lens replacement, other eye procedures, and colonoscopy. However, the specific types of procedures that will be covered

when performed in an ASC, and the payment rates that will apply, have been dramatically changed as a result of a final ASC payment methodology rule that was issued by CMS on July 16, 2007.

That final rule is intended among other things, to provide ASC payment for additional surgical procedures and create a rational relationship between payments for services furnished in ASCs and the same services when performed in either a hospital outpatient department or a physician's office. As a result of the added procedures to be paid in ASCs and the revised ASC payment rates for existing ASC services, there may be a significant change in the mix of services performed in ASCs and in the alternate settings.

CMS expects that some of the new ASC procedures currently performed in the hospital outpatient department and the physician's office will move to the ASC setting, and that there will also be migration of existing ASC procedures both into and out of ASCs as a result of the revised ASC payment system. [CMS NR 08-24-2007](#)

- The National Asthma Education and Prevention Program (NAEPP) issued the first comprehensive update in a decade of clinical guidelines for the diagnosis and management of asthma. The guidelines emphasize the importance of asthma control and introduce new approaches for monitoring asthma.

Updated recommendations for managing asthma include an expanded section on childhood asthma with an additional age group, new guidance on medications, new recommendations on patient education in settings beyond the physician's office and new advice for controlling environmental factors that can cause asthma symptoms.

Asthma is a chronic, treatable disease that causes narrowing of the airways, making breathing difficult at times. More than 22 million people in the United States have asthma, including 6.5 million children under age 18, according to the Centers for Disease Control and Prevention (CDC). Without appropriate treatment, asthma can significantly limit individuals' activities and result in asthma exacerbations, which can lead to hospitalization and even death. The CDC estimates that 4,000 Americans die from asthma exacerbations each year.

[Expert Panel Report 3 \(EPR-3\): Guidelines for the Diagnosis and Management of Asthma - Full Report, 2007](#) provides new guidance for selecting treatment based on a patient's individual needs and level of asthma control. The guidelines emphasize that while asthma can be controlled, the condition can change over time and differs among individuals and by age groups. The panel recommended that a patient's level of asthma control be regularly monitored so that treatment can be adjusted as needed.

EPR-3 builds upon comprehensive asthma guidelines issued in 1991 and 1997 and an update on selected topics released in 2002. The guidelines focus on four components of asthma care: measures to assess and monitor asthma, patient education, control of environmental factors and other conditions that can worsen asthma, and medications.

Key features and changes to these four components of asthma care include:

- **Assessment and Monitoring:** EPR-3 takes a new approach to assessing and monitoring asthma by using multiple measures of the patient's level of *current impairment* (frequency

and intensity of symptoms, low lung function, and limitations of daily activities) and *future risk* (risk of exacerbations, progressive loss of lung function, or adverse side effects from medications). The guidelines stress that some patients can still be at high risk for frequent exacerbations even if they have few day-to-day effects of asthma.

- **Patient Education.** EPR-3 confirms the importance of teaching patients skills to self-monitor and manage asthma and to use a written asthma action plan, which should include instructions for daily treatment and ways to recognize and handle worsening asthma. New recommendations encourage expanding educational opportunities to reach patients in a variety of settings, such as pharmacies, schools, community centers, and patients' homes.

A new section addresses the need for clinician education programs to improve communications with patients and to use system-wide approaches to integrate the guidelines into health care practice.

- **Control of environmental factors and other conditions that can affect asthma.** EPR-3 describes new evidence for using multiple approaches to limit exposure to allergens and other substances that can worsen asthma; research shows that single steps are rarely sufficient. EPR-3 also expands the section on other common conditions that asthma patients can have and notes that treating chronic problems such as rhinitis and sinusitis, gastroesophageal reflux, overweight or obesity, obstructive sleep apnea, stress, and depression may help improve asthma control.
- **Medications.** EPR-3 continues the use of a stepwise approach to control asthma, in which medication doses or types are stepped up as needed and stepped down when possible. Treatment is adjusted based on the level of asthma control.

The stepwise asthma management charts are revised and expanded to specify treatment for three age groups: 0-4 years, 5-11 years, and 12 years and older. The 5-11 age group was added (earlier guidelines combined this group with adults) as a result of new evidence on medications for this age group and emerging evidence that suggests that children may respond differently than adults to asthma medications.

Recommendations on medications are updated to reflect the latest evidence on effectiveness and safety. EPR-3 reaffirms that patients with persistent asthma (e.g., patients who have symptoms more than twice a week during the day or more than twice a month at night) need both long-term control medications to control asthma and prevent exacerbations, as well as quick relief medications for symptoms as needed. EPR-3 also reaffirms that inhaled corticosteroids are the most effective long-term control medication across all age groups. EPR-3 includes new recommendations on treatment options, such as leukotriene receptor antagonists and cromolyn for long term control; long acting beta agonists as adjunct therapy with inhaled corticosteroids; omalizumab for severe asthma; and albuterol, levalbuterol, and corticosteroids for acute exacerbations.

EPR-3 also describes areas of current research to improve asthma management, such as new ways for monitoring asthma control (for example, tests using a patient's sputum and exhaled air), and tailoring treatment based on the particular characteristics of a patient's asthma and the patient's genetic makeup.

NAEPP is developing tools and partnerships to improve adoption of the guidelines, including a Summary Report of EPR-3 to be released October 17. An NAEPP-appointed independent panel of experts and guideline end-users is developing an action plan to improve guidelines implementation.

EPR-3 was prepared by a committee of 18 unpaid experts chosen for their scientific and clinical knowledge and experience. The report was reviewed by the NAEPP Coordinating Committee, composed of representatives from 39 medical associations, voluntary health organizations, and federal agencies. A draft was posted on the NHLBI Website for public comment in February to March 2007.

The NAEPP was established in March 1989 to reduce asthma-related illness and death and to enhance the quality of life of people with asthma. The NAEPP also coordinates federal asthma-related activities, as designated by Congress through the Children's Health Act of 2000.

<http://www.nih.gov/news/pr/aug2007/nhbli-29.htm>

- The National Institutes of Health (NIH) has selected the first projects to be funded as part of the Genes, Environment and Health Initiative (GEI), a unique collaboration between geneticists and environmental scientists.

The GEI initiative was launched in February 2006 as part of a broader effort across HHS agencies to build on recent advances in genomic science and medicine. NIH received \$40 million in new funding as part of its fiscal year (FY) 2007 budget to support GEI. NIH institutes already planned to spend some \$28 million in FY 2007 on the kinds of studies GEI will conduct. And finally, two institutes chose to add a total of \$9 million in additional funding for targeted studies under the Genes, Environment and Health Initiative.

To identify the genetic risks, researchers will use the rapidly evolving technologies used in genome-wide association studies to focus on common conditions, such as tooth decay, heart disease, cancer and diabetes. This genetic component of GEI uses a strategy which relies on the newfound ability to swiftly identify genetic differences throughout the genome between people with an illness and those who are healthy, leading to an understanding of the underlying genetic contribution to the disease.

The environmental component will begin by developing new technologies that accurately measure personal exposures with small, wearable sensors that can be used to assess environmental agents. The final component of the research strategy is to determine whether the effect of genetic variants that increase disease risk is different in the presence of environmental exposures. In the first year, NIH will fund eight genome-wide association studies, two genotyping centers, a coordinating center and more than 30 environmental technology projects.

The genome-wide association studies will be led by the National Human Genome Research Institute (NHGRI), part of NIH. First-year funding for the studies was contributed by all NIH institutes and centers, including an extra investment by NIH's National Institute of Dental and Craniofacial Research

(NIDCR). For more detailed information, please visit <http://www.nih.gov/news/pr/sep2007/nhgri-04.htm>

- The Director of the National Institutes of Health (NIH), Elias Zerhouni, M.D., has appointed eight new members to the [NIH Peer Review Advisory Committee](#). This committee provides technical and scientific advice on matters related to the procedures and policies governing the scientific and technical evaluation of NIH grant applications. Peer review is the key method NIH uses to ensure that the \$20+ billion it invests in biomedical research grants each year advances the most promising research.

Established by law and charter, the Peer Review Advisory Committee meets 2-3 times a year and advises the NIH Director, the NIH Deputy Director for NIH Extramural Research and the Director of the NIH Center for Scientific Review (CSR). The committee is co-chaired by Toni Scarpa, M.D., Ph.D., Director of CSR; and Jeremy Berg, Ph.D., Director of the National Institute of General Medical Sciences. The committee convened at NIH on August 27, 2007.

Five of the new members will begin their terms immediately:

- R. Lorraine Collins, Ph.D., is a senior research scientist at the research institute on addictions and a research professor in the department of psychology at the University at Buffalo, State University of New York.
- Garret Fitzgerald, M.D., is chair of the department of pharmacology at the University of Pennsylvania in Philadelphia and director of its Institute for Translational Medicine and Therapeutics.
- Heidi Hamm, Ph.D., is chair of the Department of Pharmacology at the Vanderbilt University Medical Center in Nashville, Tennessee.
- Story Landis, Ph.D., is director of the National Institute of Neurological Disorders and Stroke at NIH. Dr. Landis oversees the Institute's annual budget of \$1.5 billion, as well as a staff of more than 900 scientists, physician-scientists, and administrators.
- Jane Steinberg, Ph.D., is the director of the Division of Extramural Activities at NIH's National Institute of Mental Health.

The three other appointed members will begin their terms in January 2008.

- Jill Buyon, M.D., is professor of medicine and associate director of the Division of Rheumatology, Department of Medicine, at the New York University School of Medicine in New York City.
- Paulette Gray, Ph.D., is the director of the Division of Extramural Activities at the NIH National Cancer Institute. Dr. Gray oversees the institute's extramural research policies and procedures, research integrity and portfolio tracking, as well as coordinates its advisory committees.
- Andrew Murray, Ph.D., is the Herchel Smith Professor of Molecular Genetics and director of the Bauer Fellows Program at Harvard University.

- President Bush withdrew his nomination of Charles W. Grim, of Oklahoma, to be Director of the Indian Health Service, Department of Health and Human Services (Reappointment), which was sent to the Senate on May 21, 2007.

- The U.S. Food and Drug Administration approved the first generic versions of Coreg (carvedilol) on Sept. 5, 2007. Coreg is a widely used medication that is FDA-approved to treat high blood pressure, mild to severe chronic heart failure and left ventricular dysfunction following a heart attack.

Carvedilol tablets in four strengths (3.125 milligrams, 6.25 milligrams, 12.5 milligrams and 25 milligrams) are manufactured by multiple generic drug companies. The following company's applications were approved: Actavis Elizabeth LLC; Apotex Inc.; Aurobindo Pharma Limited; Caraco Pharmaceutical Laboratories Limited; Dr. Reddy's Laboratories; Glenmark Pharmaceuticals Limited; Lupin Limited; Mylan Pharmaceuticals Inc.; Ranbaxy Laboratories Ltd.; Sandoz Inc.; Taro Pharmaceutical Industries Ltd.; TEVA Pharmaceuticals USA; Watson Laboratories Inc.; and Zydus Pharmaceuticals USA Inc.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01695.html>

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Reserve/Guard

- The total number of Guard and Reserve currently on active duty has **increased** by 55 from the last report to 96,363. The totals for each service are Army National Guard and Army Reserve, 78,172; Navy Reserve, 5,608; Air National Guard and Air Force Reserve, 6,366; Marine Corps Reserve, 5,910; and the Coast Guard Reserve, 307. www.defenselink.mil

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Contracts/Procurements

- The Office of the Secretary of Defense, TRICARE Management Activity (TMA), published a special notice on Aug. 29, 2007, to advise interested parties that the Department of Defense (DoD), TMA plans for the follow-on procurement of its current TRICARE Quality Monitoring Contract (TQMC) which concludes in April 2009. TMA has developed requirements and has prepared a [draft solicitation](#), which is available electronically on the TMA Industry forum Web site.

The contractor shall provide the government with an independent, impartial evaluation of the care provided to Military Health System (MHS) beneficiaries. The TQMC shall review care provided by the Designated Providers (DP) under the Uniformed Services Family Health Plan (USFHP), or managed under the Managed Care Support Contracts (MCSC). The TQMC is part of TRICARE's Quality and Utilization Review Peer Review Organization Program, in accordance with 32 CFR 199.15. The solicitation will be issued as a Request for Proposal (RFP). The cut off date for information and comments regarding this solicitation will be on or about September 28, 2007. It is anticipated that the solicitation will be issued on or about October 22, 2007, and the date of receipt of proposals is anticipated to be December 7, 2007. The contract action will result in a Firm- Fixed Price contract. The selected contractor shall be registered in the Central Contractor Registration (www.ccr.gov) before award can be made. The period of performance includes the base period and five one-year option periods. Questions regarding the solicitation must be submitted using E-Mail Questions to the Contracting Officer option on the TRICARE Web site. <http://www.fbo.gov/spg/ODA/OSD/TRICAREMA/>

Reports/Policies

- The Institute of Medicine (IOM) published “*Cancer-Related Genetic Testing and Counseling: Workshop Proceedings*,” on Aug. 24, 2007. The report is the result of the IOM’s National Cancer Policy Forum workshop. The workshop focused on the fact that genetic testing and counseling are becoming more complex and important for informing patients and families of the risks and benefits of certain courses of action, but at the same time organized expert programs are in short supply. The workshop covered the scientific and clinical aspects of genetic testing and counseling as well as workforce and reimbursement issues, among others. <http://www.iom.edu/CMS/26765/45319.aspx>
- The GAO issued *Military Base Realignments and Closures: Observations Related to the 2005 Round*,” (GAO-07-1203R) on Sept. 6, 2007. <http://www.gao.gov/new.items/d071203r.pdf>

Legislation

- **S.RES.307** (introduced Sept. 5, 2007): A resolution supporting efforts to increase childhood cancer awareness, treatment, and research was referred to the Committee on Health, Education, Labor, and Pensions.
Sponsor: Senator Johnny Isakson [GA]
- **S.AMDT.2661 to H.R.2642** (introduced Sept. 4, 2007): To require a report from the Comptroller General on the adequacy of mental health care services provided by the Department of Veterans Affairs and the Department of Defense to female members of the Armed Forces and female veterans was agreed to in Senate by Voice Vote.
Sponsor: Senator Russell D. Feingold [WI]
- **S.AMDT.2677 to H.R.2642** (introduced Sept. 5, 2007): To authorize the Secretary of Veterans Affairs to transfer funds to the Secretary of Health and Human Services to train psychologists was agreed to in Senate by Voice Vote.
Sponsor: Senator Patty Murray [WA]
- **S.AMDT.2681 to H.R.2642** (introduced Sept. 5, 2007): To provide that the Secretary of Veterans Affairs may carry out a major medical facility lease in fiscal year 2008 in an amount not to exceed \$12,000,000 to implement the recommendations outlined in the August, 2007 Study of South Texas Veterans’ Inpatient and Specialty Outpatient Health Care Needs was agreed to in Senate by Voice Vote.

Sponsor: Senator Kay Bailey Hutchison [TX]

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Hill Hearings

- The Senate Budget Committee will hold a hearing on **Sept. 11, 2007**, to examine health care and the federal budget, focusing on options for achieving universal health coverage.
- The House Veterans Affairs Committee will hold an oversight hearing on **Sept. 18, 2007**, to examine the State of the Department of Veterans Affairs.
- The Senate Veterans Affairs Committee will hold an oversight hearing on **Sept. 19, 2007**, to examine information technology.
- The House Veterans Affairs Committee will hold an oversight hearing on **Sept. 19, 2007**, to examine the findings of the President's Commission on Care for America's Returning Wounded Warriors.
- 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.
- The Senate Veterans Affairs Committee will hold an oversight hearing on **Sept. 25, 2007**, to examine the Persian Gulf War research.
- The Senate Veterans Affairs Committee will hold an oversight hearing on **Sept. 27, 2007**, to examine the nomination of Paul J. Hutter, of Virginia, to be General Counsel, Department of Veterans Affairs.

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Meetings / Conferences

- The Defense and Veterans Brain Injury Center will hold a conference on Traumatic Brain Injury: Training for Military Health Care Providers on **Sept. 9-20, 2007**, in College Park, Md. www.hjf.org/events
- A Defense Forum: "*Keeping Faith With Those Who Serve: How Can We Provide the Healthcare Our Military and Veterans Need—and Deserve?*" will be held on **Sept. 18, 2007**, in Washington DC. <https://www.usni.org/conferences/registration/register.asp> or http://www.moaa.org/controller.asp?pagename=serv_prof_forum
- The First AHRQ Annual Meeting "Improving Health Care Quality," will be held **Sept. 26-28, 2007**, in

Bethesda, Md. <http://www.blsmmeetings.net/2007ahrqannual/index.cfm>

- The 44th Annual Meeting of the Association of Reproductive Health Professionals (ARHP) will hold the *Reproductive Health 2007 Conference* on **Sept. 26-29, 2007**, in Minneapolis, Minn. www.arhp.org/rh2007/
- The American Academy of Family Physicians (AAFP) will host a meeting for family physicians on **Oct. 3-6, 2007**, in Chicago, Ill. www.aafp.org/online/en/home/cme/aafpcourses/conferences.html
- The 14th Annual Meeting of the ACP Navy Chapter will be held on **Oct. 4-6, 2007**, in Portsmouth, Va. www.hjf.org/events
- The 20th Annual Infectious Diseases in Children Symposium will be held on **Oct. 20-21, 2007**, in New York City, N.Y. <http://www.vindicomed.com/meetings/idc/ny/default.htm>
- The American Association for Clinical Chemistry (AACC) and the National Academy of Clinical Biochemistry (NACB) will hold a one-day conference: "*Making the Case for the New Cancer Diagnostics*," on **Nov. 2, 2007**, in St. Louis, Mo. <http://www.aacc.org/AACC/events/meetings/NewCancerDetectionTechnologies.htm>
- The 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. <http://www.aamc.org/meetings/annual/2007/start.htm>
- The American Public Health Association 135th Annual Meeting will be held on **Nov. 3-7, 2007**, in Washington, D.C. <http://apha.confex.com/apha/135am/techprogram/>
- The FDA's conference: "*Anthrax Vaccines -- Bridging Correlates of Protection in Animals to Immunogenicity in Humans*," will be held on Nov. 8-9, 2007, in Gaithersburg Md. <http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-11613.htm>
- The AMSUS 113th Annual Meeting will be held Nov. 11-16, 2007, in Salt Lake City, Utah. <http://www.amsus.org/convention/>
- The 27th AMEDD Neurology Meeting will be held on **Nov. 14-16, 2007**, in Washington, D.C. www.hjf.org/events
- The 2007 meeting of the Army and Air Force Chapters of the ACP will be held on **Nov. 14-18, 2007**, in San Antonio, Texas. www.hjf.org/events

- The 13th International Congress on Infectious Diseases will be held **June 19-22, 2008**, in Kuala Lumpur, Malaysia. http://www.isid.org/13th_icid/

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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.