Federal Health Update

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EXECUTIVE AND CONGRESSIONAL NEWS

- On Feb. 26, 2017, Mr. Philip Bilden has withdrew himself from consideration to be secretary of the Navy. Bilden cited privacy concerns and significant challenges he faced in separating himself from his business interests.

- On March 2, 2017, House Appropriations Chairman Rodney Frelinghuysen today named the vice chairs for the Appropriations subcommittees for the 115th Congress.

  The vice chairs for health-, military- or veterans-relevant subcommittees are:
  - **Defense Subcommittee**: Rep. Ken Calvert (CA)
  - **Labor, Health and Human Services Subcommittee**: Rep. Steve Womack (AR)
  - **Military Construction and Veterans Affairs Subcommittee**: Rep. Jeff Fortenberry (NE)

- The House Appropriations Committee introduced the final version of the fiscal year 2017 Defense Appropriations bill, which will be considered on the House floor next week.

  In total, the bill provides $577.9 billion, an increase of $5.2 billion over the fiscal year 2016 enacted level and $1.6 billion more than the Obama Administration’s request. This includes $516.1 billion in base discretionary funding – an increase of $2 billion above current levels – and
$61.8 billion in Overseas Contingency Operations (OCO)/Global War on Terrorism (GWOT) funding – $3.2 billion above current levels. When combined with the $5.8 billion in supplemental funding enacted in the Continuing Resolution that passed in December, the total Defense funding for fiscal year 2017 is $583.7 billion, an increase of $10.9 billion over fiscal year 2016.

**Bill Highlights:**

**Military Personnel and Pay** – The agreement includes $132.1 billion – $128.7 billion for base requirements and $3.4 billion for OCO/GWOT requirements – to provide for 1,305,900 active-duty troops and 813,200 Guard and Reserve troops. The agreement includes $1.6 billion above the request for increased end strength, to include military personnel and operational support costs. The agreement denies the troop reductions proposed in the previous Administration’s fiscal year 2017 budget request. The agreement also fully funds the authorized 2.1 percent pay raise for the military, instead of 1.6 percent as requested by the previous Administration.

**Defense Health and Military Family Programs** – The agreement contains $34.1 billion for base and GWOT requirements – $1.5 billion above the fiscal year 2016 enacted level and $314 million above the previous Administration’s request – for the Defense Health Program to provide care for our troops, military families, and retirees. The agreement provides $312 million for cancer research, $125 million for traumatic brain injury and psychological health research, and $296 million for sexual assault prevention and response. All of these funding levels represent increases above the budget request for these programs.

For text of the legislation, please visit: https://appropriations.house.gov/UploadedFiles/03.02.17_Defense_-__FY_2017_Appropriations_Bill.pdf

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**MILITARY HEALTH CARE NEWS**

- **TRICARE** provided guidelines to help military families protect their children from traumatic brain injury (TBI).

  TBI is caused by an external force, such as blows to the head, gunshot wounds, or the head being shaken violently. Concussion, also called mild TBI, is the most common type of brain injury and can sometimes be difficult to diagnose because a person may or may not become unconscious and the damage may or may not show up on a diagnostic imaging test, such as a CAT scan. A contusion, or a bruise on your brain, can result from a direct blow to the head and can also cause TBI.

  According to the Centers for Disease Control and Prevention, the leading cause of traumatic brain injury is falls. Because the brain is soft and jello-like in consistency and “floats” in cerebral-spinal fluid in our skulls, when the head is struck or shaken violently it can cause brain injury.

  TRICARE suggests that its beneficiaries can help prevent your child from getting a TBI by always using age and size-appropriate car seats, and by making sure they are properly installed. Also, beneficiaries should ensure children always wear the right helmet for activities such as riding a bicycle or playing sports and make sure it fits right. Wearing a helmet is a must to help lower the risk of serious brain injury and skull fracture. While helmets promote safety, please know that there’s no such thing as a “concussion-proof” helmet.

  For families with toddlers TRICARE recommends that families install gates at the top and bottom of stairs to prevent them from falling. TRICARE also suggests families ensure there is soft material under the play equipment, like mulch or sand rather than grass or dirt.

  TRICARE offers TBI treatment through a robust rehabilitation benefit that includes occupational therapy (OT), physical therapy (PT), speech therapy and behavioral health services when ordered by a physician as part of a comprehensive individual rehabilitation treatment plan. Though TRICARE does not cover Cognitive Rehabilitation Therapy as a stand-alone therapy,
many physical therapists, occupational therapists and speech therapists use CRT techniques in their covered therapies and treatments for TBI.

For more information, visit the Cognitive Rehabilitation Therapy page on the TRICARE website. For specific coverage details, contact your regional contractor.

**VETERANS AFFAIRS NEWS**

- **New Veterans Affairs studies verify the theory that aspirin has cancer-prevention benefits.**

  The studies, led by Dr. Vinod Vijayan at the DeBakey Veterans Affairs (VA) Medical Center in Houston and Dr. Lenard Lichtenberger of the University of Texas Health Sciences Center, found that aspirin blocked the interaction between platelets and cancer cells by shutting down the enzyme COX-1, thereby curbing the number of circulating platelets and their level of activity.

  Some of their experiments used regular aspirin from a local drug store. In another phase, the researchers used a special preparation of aspirin combined with phosphatidylcholine, a type of lipid, or fat molecule. The molecule is a main ingredient in soy lecithin. The product, known as Aspirin-PC/PL2200, is designed to ease the gastrointestinal risk associated with standard aspirin.

  The enhanced aspirin complex was even stronger against cancer than the regular aspirin. Summarizing their findings, the researchers wrote: “These results suggest that aspirin’s chemopreventive effects may be due, in part, to the drug blocking the proneoplastic [supporting new, abnormal growth, as in cancer] action of platelets and [they support] the potential use of Aspirin-PC/PL2200 as an effective and safer chemopreventive agent for colorectal cancer and possibly other cancers.”

  The research study was supported by the National Institutes of Health.

  Lichtenberger is a professor of integrative biology and pharmacology at the University of Texas Health Sciences Center. Vijayan, an expert in platelet biology, is with the Center for Translational Research on Inflammatory Diseases at the DeBakey VA Medical Center. He is also an associate professor at Baylor College of Medicine.

- **Veterans Affairs Secretary David Shulkin announced that Scott Blackburn will be the acting deputy secretary, effective Feb. 26.**

  Blackburn has spent the last two years as the executive director of the MyVA Taskforce. Blackburn served in the Army for four years, achieving the rank of captain.

  At the same time, Bob Snyder, the VA chief of staff, will retire on March 4. Shulkin said Vivieca Wright-Simpson will serve as the interim VA chief of staff starting on Feb. 26. Wright-Simpson previously served as Veterans Health Administration chief of staff and a variety of senior roles both at the VA central office and in the field.

**GENERAL HEALTH CARE NEWS**

- **The Center for Disease Control and Prevention (CDC) announced that the proportion of Zika-affected pregnancies with birth defects is approximately 20-fold higher compared with the proportion of pregnancies seen in 2013-2014, which is before Zika was introduced into the Americas.**

  The types of birth defects—including brain abnormalities and/or microcephaly, neural tube defects and other early brain malformations, eye defects, and other central nervous system
(CNS) problems—were seen in about 3 of every 1,000 births in 2013-2014. In 2016, the proportion of infants with these same types of birth defects born to women with Zika virus infection during pregnancy was about 6% or nearly 60 of every 1,000 completed pregnancies with Zika infections.

The researchers analyzed 2013-2014 data from three birth defects surveillance programs in the United States (Massachusetts, North Carolina, and Georgia) to provide the baseline frequency for Zika-related birth defects. To assess the effect of Zika virus infection during pregnancy, the scientists compared that 2013-2014 baseline number with previously published numbers among pregnancies with Zika virus infection from the US Zika Pregnancy Registry (USZPR) from 2016.

They identified 747 infants and fetuses with one or more of these defects from programs in Massachusetts, North Carolina, and Georgia, from 2013-2014. Brain abnormalities and/or microcephaly were the most frequent conditions reported. Data from the USZPR identified 26 infants and fetuses with these same birth defects among the 442 completed pregnancies of women with possible Zika infection from January through September 2016. These findings demonstrate the importance of having monitoring systems that collect data on birth defects.

CDC continues to recommend that pregnant women not travel to areas with Zika. If a pregnant woman must travel to or lives in an area with Zika, she should talk with her healthcare provider and strictly follow steps to prevent mosquito bites and sexual transmission of Zika virus. Pregnant women with possible exposure to Zika virus should be tested for Zika infection even if they do not have symptoms. For more information, please visit www.cdc.gov/zika/pregnancy/.

- The United States and the European Union (EU) completed an exchange of letters to amend the Pharmaceutical Annex to the 1998 U.S.-EU Mutual Recognition Agreement.

Under this agreement, U.S. and EU regulators will be able to utilize each other’s good manufacturing practice inspections of pharmaceutical manufacturing facilities.

The amended agreement represents the culmination of nearly three years of U.S. Food and Drug Administration and EU cooperation as part of the Mutual Reliance Initiative and will allow the FDA and EU drug inspectors to rely upon information from drug inspections conducted within each other’s borders. Ultimately, this will enable the FDA and EU to avoid the duplication of drug inspections, lower inspection costs and enable regulators to devote more resources to other parts of the world where there may be greater risk.

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act, which gave the FDA authority to enter into agreements to recognize drug inspections conducted by foreign regulatory authorities if the FDA determined those authorities are capable of conducting inspections that met U.S. requirements. Since May 2014, the FDA and the EU have been collaborating to evaluate the way they each inspect drug manufacturers and assessing the risk and benefits of mutual recognition of drug inspections. The FDA was invited to observe the EU’s Joint Audit Programme, in which two EU nations audit the inspectorate – the regulatory authority – of another EU country.

The FDA first observed the audit of Sweden’s inspectorate by auditors from the United Kingdom and Norway. Since then, the FDA has observed 13 additional audits of drug inspectorates across the EU with more audit observations planned through 2017.

REPORTS/POLICIES

- The GAO published “Antibiotics: FDA Has Encouraged Development, but Needs to Clarify the Role of Draft Guidance and Develop Qualified Infectious Disease Product Guidance,” (GAO-17-189) on March 2, 2017. This report examines steps FDA has taken to encourage the development of antibiotics since GAIN, and drug sponsors’ perspectives on FDA’s efforts.
The GAO published “VA Health Care: Actions Needed to Ensure Medical Facilities' Controlled Substance Programs Meet Requirements,” (GAO-17-442T) on Feb. 27, 2017. This report summarizes the testimony regarding information contained in GAO's February 2017 report, entitled VA Health Care: Actions Needed to Ensure Medical Facility Controlled Substance Inspection Programs Meet Agency Requirements. http://www.gao.gov/assets/690/683049.pdf

HILL HEARINGS

- The Senate and House Veterans Affairs Committees will hold joint hearings on March 9 and 22, 2017, to examine the legislative presentations of multiple veterans service organizations.

LEGISLATION

- **S.476** (introduced Feb. 28, 2017): A bill to exempt health insurance of residents of United States territories from the annual fee on health insurance providers was referred to the Committee on Finance. Sponsor: Senator Marco. Rubio [R-FL]
- **H.R.1275** introduced March 1, 2017): To eliminate the individual and employer health coverage mandates under the Patient Protection and Affordable Care Act, to expand beyond that Act the choices in obtaining and financing affordable health insurance coverage, and for other purposes was referred to House Education and the Workforce. Sponsor: Representative Pete. Sessions [R-TX-32]
- **H.R.1246** (introduced Feb. 28, 2017): To exempt health insurance of residents of United States territories from the annual fee on health insurance providers was referred to House Energy and Commerce. Sponsor: Representative Carlos Curbelo [R-FL-26]
- **S.465** (introduced Feb. 28, 2017): A bill to provide for an independent outside audit of the Indian Health Service was referred to the Committee on Indian Affairs. Sponsor: Senator Mike Rounds [R-SD]
- **S.445** (introduced Feb. 27, 2017): A bill to amend title XVIII of the Social Security Act to ensure more timely access to home health services for Medicare beneficiaries under the Medicare program was referred to the Committee on Finance. Sponsor: Senator Susan M. Collins [R-ME]
- **H.R.1279** (introduced March 1, 2017): To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to establish within the Department of Veterans Affairs a center of excellence in the prevention, diagnosis, mitigation, treatment, and rehabilitation of health conditions relating to exposure to burn pits was referred to House Armed Services. Sponsor: Rep. Elizabeth H. Esty [D-CT-5]
- **H.R.1290** (introduced March 1, 2017): To amend title XVIII of the Social Security Act to improve access to mental health services under the Medicare program was referred to House Ways and Means. Sponsor: Representative Barbara Lee [D-CA-13]
- **H.R.1280** (introduced March 1, 2017): To amend the Internal Revenue Code of 1986 to increase the maximum contribution limit for health savings accounts, and for other purposes was referred to the House Committee on Ways and Means. Sponsor: Representative Jeff Fortenberry [R-NE-1]
MEETINGS

- The Heroes of Military Medicine Awards will be held on **May 4, 2017**, in Washington, DC.
  [http://www.hjfcp3.org](http://www.hjfcp3.org)
- The 7th Annual Traumatic Brain Injury Conference will be held **May 24-25, 2017**, in Washington DC.

If you need further information on any item in the *Federal Health Update*, please contact Kate Theroux at (703) 447-3257 or by e-mail at katheroux@federalhealthcarenews.com.