

# Federal Health Update

MARCH 16, 2018

*Welcome to Federal Health Update. This newsletter is a compilation of the latest news in the federal health care sector.*

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## EXECUTIVE AND CONGRESSIONAL NEWS

- **On March 9, 2017, President Trump signed into law H.R.1725, which directs the Secretary of Veterans Affairs to submit certain reports relating to medical evidence submitted in support of claims for benefits under the laws administered by the Secretary.**

## MILITARY HEALTH CARE NEWS

- **The Department of Defense and the U.S. Army has funded research to Banyan Biomarkers to create the first-ever brain trauma blood test.**

On Feb. 14, the [Food and Drug Administration \(FDA\)](#) cleared marketing of the Banyan Biomarkers' Brain Trauma Indicator, or BTI™.

The BTI can identify two brain-specific protein markers, called UCH-L1 (Ubiquitin Carboxy-terminal Hydrolase-L1) and GFAP (Glial Fibrillary Acidic Protein). These proteins rapidly appear in the blood and are elevated 12 hours following an incident where a head injury occurs and can signify if there is bleeding in the brain. The two protein markers won't be elevated if your brain is uninjured or if you have a mild traumatic brain injury (TBI), otherwise known as a concussion.

When these proteins are elevated, there may be blood in the brain. A hematoma, or blood in the brain, may indicate a more serious brain injury has occurred, which could require rapid evacuation for neurosurgery to remove a clot in the brain.

The first thing a doctor tries to rule out with suspected brain injury is the potential for serious complications, like losing consciousness, going into a coma, or death. According to the research results and FDA clearance, the blood test can help medical professionals determine the need for computed tomography (CT) scans in patients suspected of having a concussion. It also can help prevent unnecessary radiation exposure for patients.

Prior to discovering these biological protein markers, medical professionals had to rely on symptom reporting and other more subjective means to evaluate patients with few signals of more serious head injury.

The Department of Defense has been seeking a method for diagnosing and evaluating TBI in service members for over a decade. According to DVVIC, over 375,000 service members have been diagnosed with TBI since 2000. Approximately 82 percent of those TBI cases are classified as a concussion.

Making the machine required to run the blood test smaller and more portable is a work in progress, as currently it's intended for use in a laboratory. Logistical constraints of the BTI device make deployment to the force a challenge.

## VETERANS AFFAIRS NEWS

- **The U.S. Department of Veterans Affairs (VA) announced that Dr. Lynda Davis, chief veterans experience officer, accepted the 2018 Blue Star Families — United Health Foundation Blue Star Award.**

Davis, a U.S. Army veteran and veteran caregiver who leads the department's efforts on improving the veterans experience as well as initiatives affecting veteran caregivers, accepted the award in recognition of VA's leadership in supporting military and veteran caregivers through initiatives such as the veterans' Family, Caregiver and Survivor Advisory Committee and Choose Home.

VA estimates there are more than 5.5 million military and veteran caregivers. In an effort to continually improve VA benefits and services by hearing from caregivers and their advocates directly, VA established the Veterans' Family, Caregiver and Survivor Advisory Committee in 2017.

Chaired by former U.S. Sen. Elizabeth Dole, a noted advocate for military caregivers, the committee will provide advice and recommendations to Secretary Shulkin on ways to improve the experience of veterans' families, caregivers and survivors.

VA is working to improve VA care and benefits case management coordination with caregivers through initiatives such as Choose Home.

VA is identifying evidence-based best practices from military, veteran and faith-based organizations that maximize the effectiveness of all programs in support of family caregivers.

Additional information for Veteran caregivers can be found at <https://www.caregiver.va.gov>.

- **The U.S. Department of Veterans Affairs (VA) announced the Office of Research and Development (ORD) of the Veterans Health Administration (VHA) extended its commitment to reduce future research on canines by initiating a rapid, in-depth internal review of existing canine research projects.**

An external group will review these recommendations and provide VA with guiding principles for future canine research to assure benefits to veterans.

Animal research at VA is strictly controlled and monitored with accountability mechanisms in place that comply with the same regulations and standards that university programs, state, private and military organizations use. In the past 20 years, VA use of canines in research has been reduced significantly and continues to be reduced, as much as possible. It is important to note that of thousands of VA research projects, fewer than 15 currently involve canines.

VA has always required medical relevance and justification for canine use, and in late 2017, VA instituted a policy that no new canine research would begin without approval of both, the Chief Research and Development Officer and the VA Secretary. As a result, new canine studies have not been initiated, and two new studies were required to use alternative models instead of canines. VA is now reviewing existing studies using canines to determine whether the use of canines in these studies should be phased out in advance of their original end dates.

In addition, when canines are the only viable models, VA is proactively contacting the principal investigators leading these studies, requesting they develop plans to establish alternative models. VA intends to fund development of canine alternatives, which will reduce the need for canine research within VA.

## GENERAL HEALTH CARE NEWS

- **On March 6, 2018, UnitedHealthcare announced it will expand pharmacy discounts to millions of its plan participants when they fill prescriptions through retail pharmacies or home delivery.**

The new program will apply to over 7 million people enrolled in UnitedHealthcare fully insured commercial group benefit plans, lowering out-of-pocket costs by directly providing consumers with savings from pharmacy manufacturer rebates at the time of purchase.

Beginning Jan. 1, 2019, and on plan renewal thereafter, people enrolled in fully insured group health benefit plans will have discounts applied to their medication cost at the point of sale. The savings will apply to plan participants who are filling a prescription for a drug where the manufacturer provides a rebate. UnitedHealthcare will apply savings from rebates upfront, at the time of sale, to ensure people are paying the lowest amount possible under their plan. Rebates are currently used to keep premiums lower for the benefit of all members and customers, rather than distributed to individual consumers.

In addition to expanding discounts to all fully insured group plan participants, UnitedHealthcare currently supports self-insured customers who choose to implement similar expanded discounts for their employees. OptumRx's stand-alone point of sale solution is also currently available to clients who do not receive their pharmacy benefits through UnitedHealthcare.

- **On March 15, 2018, The Food and Drug Administration Commissioner Scott Gottlieb announced the agency would take action to lower the nicotine levels in tobacco products.**

FDA-funded analysis finds that reducing nicotine levels to 0.04 milligrams per gram of tobacco filler could lower the adult smoking rate from 15 percent to 1.4 percent. As a result, the FDA estimates that 8 million fewer tobacco-related deaths through the end of the century.

The Federal Register [notice](#), will be published on March 16, 2018 and will be open for public comment until June 14, 2018

The nicotine notice will be open for public comment for 90 days. FDA officials are seeking input on what the maximum nicotine level in cigarettes should be and whether such a limit should be

implemented all at once or gradually. FDA officials will also consider the potential of a black market in high-nicotine cigarettes this rule would create. After the comment period ends, officials will decide whether to move forward with a formal proposal.

The 2009 Tobacco Control Act gave the FDA the power to regulate tobacco, though not to ban it.

Gottlieb also announced the FDA plans to issue notices on the role that flavors, including menthol, play in use of tobacco products; and on the regulation of premium cigars.

## REPORTS/POLICIES

- **The National Academies of Sciences, Engineering, and Medicine published “Achieving Rural Health Equity and Well-Being: Proceedings of a Workshop,” on March 14, 2018.** This report outlines the initiatives and approaches to improve health outcomes in rural areas, which were showcased at the workshop to meeting the particular challenges and opportunities in improving health in rural communities. <http://nationalacademies.org/hmd/reports/2018/achieving-rural-health-equity-and-well-being-proceedings.aspx>

## HILL HEARINGS

- The House Armed Services Subcommittee on Military Personnel will hold a hearing on **March 21, 2018**, to examine Military Personnel Posture: FY 2019.
- The Senate Veterans Affairs will hold a hearing on **March 21, 2018**, to examine the president's proposed budget request for fiscal year 2019 for veterans' programs and fiscal year 2020 advance appropriations requests.

## LEGISLATION

- **S.2533** (introduced March 12, 2018): A bill to amend title III of the Public Health Service Act to allow National Health Service Corps members to provide obligated service as behavioral and mental health professionals at schools, other community-based settings, or patient homes, and for other purposes was referred to the Committee on Health, Education, Labor, and Pensions. Sponsor: Senator Tina. Smith [D-MN]
- **S.2554** (introduced March 14, 2018): A bill to ensure that health insurance issuers and group health plans do not prohibit pharmacy providers from providing certain information to enrollees was referred to the Committee on Health, Education, Labor, and Pensions. Sponsor: Senator Susan M. Collins [R-ME]:
- **H.R.5254** (introduced March 14, 2018): A bill to direct the Secretary of Health and Human Services to conduct a study on the feasibility of expanding eligibility for enrollment in Medicare Advantage plans to individuals enrolled under the Medicaid program or enrolled under a group health plan was referred to the Committee on Ways and Means. Sponsor: Representative Ted. Budd [R-NC-13]
- **S.2553** (introduced March 14, 2018): A bill to amend title XVIII of the Social Security Act to prohibit health plans and pharmacy benefit managers from restricting pharmacies from informing individuals regarding the prices for certain drugs and biologicals was referred to the Committee on Finance. Sponsor: Senator Debbie. Stabenow [D-MI]
- **S.2548** (introduced March 14, 2018): A bill to amend title 38, United States Code, to direct the Secretary of Veterans Affairs to furnish mental health care to certain former members of the

Armed Forces who are not otherwise eligible to receive such care, and for other purposes was referred to the Committee on Veterans' Affairs. Sponsor: Senator Dean Heller [R-NV]

## MEETINGS

- 2018 Heroes of Military Medicine Awards Dinner will be held on **May 3, 2018**, in Washington, DC. <http://www.hjfc3.org/heroes-dinner/>
- The 8th Annual Traumatic Brain Injury Conference will be held on **May 16-17, 2018**, in Washington DC. <http://tbiconference.com/home/>

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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 [katetheroux@federalhealthcarenews.com](mailto:katetheroux@federalhealthcarenews.com).