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

Sponsored by:

[Image]

Additional Sponsorship Opportunities Available.

Please contact Kate Theroux if you are interested in supporting this service.

ktheroux@federalhealthcarenews.com

EXECUTIVE AND CONGRESSIONAL NEWS


  More than 300 amendments—offered by both Republican and Democratic members—were considered and adopted. The Senate Armed Services Committee voted overwhelmingly, 25-2, to advance this important legislation to the Senate floor. The bill authorizes $716 billion in fiscal year 2019 for national defense. The bill directs $32.5 billion for the Defense Health Program.


- On May 30, 2018, President Trump signed into law S. 204, the “Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017.” This legislation authorizes certain patients to seek access to certain unapproved investigational drugs directly from a drug sponsor or manufacturer; limits the use of clinical outcomes and liability arising from the provision of such drugs; and provides reporting requirements for the use and outcomes of the new authority.
**MILITARY HEALTH CARE NEWS**

- According to *Law360*, Humana Military filed a reverse Freedom of Information Act suit against the Defense Health Agency’s decision a federal agency to disclose proprietary commercial and technical information used in Humana’s bid for the TRICARE contract.

  Humana Military won a contract worth more than $40 billion in 2016 to serve TRICARE beneficiaries in the East Region.

  The Freedom of Information Act is a federal law dictating how and what documents the government can disclose to the public. A reverse FOIA aims to block the release of these records.

- NASA announced it has assigned Lt. Col. (Dr.) Andrew Morgan, a NASA astronaut and emergency physician credentialed at Brooke Army Medical Center, to Expedition 60/61, which is set to launch to the International Space Station in July 2019.

  Morgan became the first Army Medical Corps officer selected as an astronaut after an arduous selection process in 2013. After five years of training, the officer will make his first voyage to the space station next year on a Russian Soyuz rocket and spacecraft alongside an Italian astronaut and a Russian cosmonaut. Once on board the ISS, he will join American astronaut Christina Koch and her Russian cosmonaut crewmate who will launch to the ISS in April 2019.

  Morgan served in the Joint Special Operations Command at Fort Bragg, and went on to become the battalion surgeon for the 1st Battalion, 3rd Special Forces Group. He then embarked on a special operations assignment in Washington, D.C., before completing his sports medicine fellowship.

  In 2011, Morgan saw an announcement that NASA was selecting another astronaut class. “I had always been interested in space exploration, but figured I didn’t have the right background,” he explained. “But I decided to give it a shot anyway.”

  The selection process took more than 18 months and involved extensive interviews, medical testing and language aptitude testing. Over the two years following his selection, Morgan’s training transported him from physician to astronaut. Candidate training included flight training, Russian language proficiency, extra-vehicular activity (space walking), robotics and space station systems and maintenance.

  After candidate training, Morgan focused his attention on spacesuit development and researching injuries caused by spacesuits. Now assigned to a flight, he will undergo in depth refresher training over the next year to prep him for his upcoming trip.

  BAMC Commanding General Brig. Gen. (Dr.) George N. Appenzeller, a fellow emergency medicine physician, is also aware of Morgan’s stellar reputation. “Drew’s service and leadership is always about the team.....his patients, colleagues, and their Families. We are looking forward to his leadership from space next year.”

**VETERANS AFFAIRS NEWS**

- The U.S. Department of Veterans Affairs (VA) announced that the White House has approved an interagency plan to implement President Trump’s executive order supporting veterans with mental health care and suicide-prevention resources during their transition from uniformed service to civilian life.

  Signed by the president in January 2018, the executive order directs VA, the Department of Defense (DoD), and the Department of Homeland Security (DHS) to collaborate to provide, to
the extent consistent with law, seamless access to mental health care and suicide prevention resources for veterans, with a focus on the first year after separation from military service.

Research has shown that service members in transition to Veteran status are at higher risk of mental health challenges and suicide. The president acted to ensure that new Veterans will receive access to VA mental health care and other services to the extent they are eligible.

Implementation of the Joint Action Plan by the three departments includes 16 important services. Below are three examples:

- Expanding peer community outreach and group sessions in the VA Whole Health initiative from 18 Whole Health Flagship facilities to all facilities. Whole Health includes wellness and establishing individual health goals.
- Extending DoD’s “Be There Peer Support Call and Outreach Center” services to provide peer support for Veterans in the year after separation from the uniformed services.
- Expanding DoD’s Military One Source, which offers resources to active-duty members, to include support to separating service members up to one year after separation.

The White House will closely monitor the outcomes of the Joint Action Plan.

- The White House named Peter O’Rourke as acting secretary of the U.S. Department of Veterans Affairs. O’Rourke previously served as VA Chief of Staff and prior to that as executive director of VA’s Office of Accountability and Whistleblower Protection.

  O’Rourke succeeds former acting secretary Robert Wilkie, whom the president has selected for nomination as VA Secretary. Wilkie has returned to his prior position at the Department of Defense, where he serves as Under Secretary of Defense for Personnel and Readiness.

  Jacquelyn Hayes-Byrd will serve as VA acting chief of staff while O’Rourke serves as acting secretary. She previously was VA deputy chief of staff.

  In addition, VA Deputy Secretary Thomas G. Bowman is re-entering retirement effective June 15, 2018. Bowman continue to support the VA as an expert consultant to the acting secretary. His VA experience spanned more than a decade, including assignment as chief of staff to two previous VA secretaries.

GENERAL HEALTH CARE NEWS

- The Substance Abuse and Mental Health Services Administration (SAMHSA), is now accepting applications for $196 million to treat opioid use disorder through its Targeted Capacity Expansion: Medication Assisted Treatment-Prescription Drug Opioid Addiction grant program.

  The new funding will expand access to medication-assisted treatment and recovery support services to people with opioid use disorder. Eligibility is limited to the states, political subdivisions within states, and public and private nonprofit organizations in states with the highest rates of primary treatment admissions for heroin and prescription opioids per capita and includes those with the most dramatic increases for heroin and prescription opioids, as identified by SAMHSA’s 2015 Treatment Episode Data Set.

  Tribes and tribal organizations across the United States are also eligible to receive funding. The desired outcomes of this grant program include an increase in the number of people receiving medication-assisted treatment for their opioid use disorder, leading to a decrease in heroin use and prescription opioid misuse.

  By funding treatment in states with the greatest need for additional treatment resources, HHS
and SAMHSA aim to reduce the number of deaths related to opioid use. The funding opportunity announcement contains a list of the 35 eligible states; tribes and tribal organizations from anywhere in the United States are eligible.

- The U.S. Food and Drug Administration approved the first stand-alone prosthetic iris in the United States, a surgically implanted device to treat adults and children whose iris (the colored part of the eye around the pupil) is missing or damaged due to a congenital condition called aniridia or other damage to the eye.

Congenital aniridia is a rare genetic disorder in which the iris is completely or partially absent. It affects approximately 1 in 50,000 to 100,000 people in the U.S. The iris controls the amount of light entering the eye, and those with aniridia have sensitivity to light and other severe vision problems. In addition to congenital aniridia, the CustomFlex Artificial Iris is indicated to treat iris defects due to other reasons or conditions, such as albinism, traumatic injury or surgical removal due to melanoma.

The CustomFlex Artificial Iris is made of thin, foldable medical-grade silicone and is custom-sized and colored for each individual patient. A surgeon makes a small incision, inserts the device under the incision, unfolds it and smooths out the edges using surgical instruments. The prosthetic iris is held in place by the anatomical structures of the eye or, if needed, by sutures.

The CustomFlex Artificial Iris was approved through a premarket approval application (PMA), which is the most stringent type of device marketing application and generally required for high-risk devices. A PMA approval is primarily based on a determination by the FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended uses.

CustomFlex Artificial Iris was granted Breakthrough Device designation, meaning the FDA provided intensive interaction and guidance to the company on efficient device development, to expedite evidence generation and the agency’s review of the device. To qualify for such designation, a device must provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition. It must also meet one of the following criteria: the device must represent a breakthrough technology; there must be no approved or cleared alternatives; the device must offer significant advantages over existing approved or cleared alternatives; or the availability of the device is in the best interest of patients.

The FDA granted approval of the CustomFlex Artificial Iris to Clinical Research Consultants, Inc.

REPORTS/POLICIES


HILL HEARINGS

- The Senate Committee on Health, Education, Labor, and Pensions will hold a hearing on June 12, 2018, to examine the cost of prescription drugs, focusing on examining the President's blueprint 'American Patients First' to lower drug prices.

LEGISLATION

- There was no health-related legislation introduced this week.

MEETINGS

- The 2018 AMSUS Annual Continuing Education Meeting will be held on Nov. 26-30, 2018, at the Gaylord National Harbor, Md. [http://www.amsusmeetings.org/home-2/](http://www.amsusmeetings.org/home-2/)

---

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.