The Senate was in session this week. The House was in recess and will return on May 16.

In this issue:

- Attention on Health Care Reform Turns to Senate
- FDA Commissioner Confirmed
- Senate HELP Committee Advances FDA User Fee Bill
- Center for Consumer Information and Insurance Oversight (CCIIO) Has New Director
- Additional Co-sponsors for EMTALA Liability Bill

Attention on Health Care Reform Turns to Senate
As reported last week, the House approved its controversial health care reform bill, the American Health Care Act (AHCA) on May 4. ACEP opposed the legislation because it erodes the guaranteed coverage of emergency medical care by insurance plans, does not fully protect individuals with pre-existing health conditions, and is projected to cause millions of Americans to lose insurance coverage.

Senate leaders indicated this week that they will not take up the House bill as written and will be starting from scratch on their own bill. Senate Majority Leader Mitch McConnell (R-KY) named a 13-member working group to begin the process although later in the week he indicated that all 52 members of the Senate would be welcome to engage in the negotiations. Senators also are waiting for the House bill to be scored by the Congressional Budget Office (CBO) before they can dive in. Under budget reconciliation, the process Senate Republicans are using to pass a bill with just 51 votes, they must have an estimate of how much the AHCA will cost before they can commit ideas to paper for their own plan. The official score from the CBO will be released on May 22 which could further complicate negotiations and possibly bolster opposition to the House bill. The score is expected to announce even higher rates of uninsured -- more than the 24 million in the assessment of the original bill before final changes were made that weakened Essential Health Benefits like emergency medical care and pre-existing conditions provisions.

ACEP will continue to advocate for our "Emergency Medicine Health Care Reform Principles" in the Senate and will work with that chamber to reestablish key patient protections, such as guaranteed coverage of the Essential Health Benefits. ACEP leaders and staff are initiating a series of meetings with the thirteen lawmakers appointed to the Senate
task force and other key senators who will be vital to the discussion, but who were not formally included in the panel.

ACEP participated in a meeting this week with Senator Orrin Hatch (R-UT), chair of the Senate Finance Committee, who encouraged stakeholders to be engaged in the process and asked for ideas from the physician specialty groups at the table.

Majority Leader Mitch McConnell (R-KY) pledged to remain focused on health care reform, but Democrats have threatened to slow business down in an effort to force the appointment of a special prosecutor to take up the FBI-led investigation into Russia’s interference in last year’s election. The Democrats’ power to do so appears limited to short-term delays, however.

**FDA Commissioner Confirmed**

On Tuesday, the Senate voted 57 to 42 to confirm Dr. Scott Gottlieb as the next Commissioner to the U.S. Food and Drug Administration (FDA). Dr. Gottlieb is a practicing physician and a resident fellow at the American Enterprise Institute. The selection will make him responsible for regulating companies within the pharmaceutical industry, including some with which he has been closely involved in recent years. During Gottlieb’s initial confirmation process, concerns were raised regarding his close ties with the pharmaceutical industry. He has stated that he would remove himself from participating in all FDA decisions involving more than 20 companies for a full calendar year. In President George W. Bush’s administration, Dr. Gottleib served as both deputy FDA commissioner and a high-ranking official at the Centers for Medicare and Medicaid Services (CMS).

**Senate HELP Committee Advances FDA User Fee Bill**

On Thursday, the Senate Health, Education, Labor and Pensions (HELP) Committee voted 21 to 2 to approve the FDA medical device and drug user fee reauthorization bill. These programs are scheduled to expire on Sept. 30 without Congressional action. The four different user fees that are included in the bill are the prescription drug user fee act (PDUFA), the medical device user fee amendments (MDUFA), the generic drug user fee amendments (GDUFA), and the biosimilar user fee act (BsUFA).

The committee agreed by voice vote to add two amendments, including a provision from Sens. Susan Collins (R-ME) and Al Franken (D-MN) requiring the FDA to review generic drug applications in about eight months if at least three versions of the treatment are not already on the market. The panel also agreed by voice vote to a bipartisan amendment led by Sen. Orrin Hatch (R-UT) that would expand clinical trial criteria to allow sicker patients to participate. It would also make it easier for patients to use an FDA program to receive unapproved drugs when they don't qualify for trials. The committee voted 13 to 10 to table an amendment by Sen. Bernie Sanders (I-VT) that would have allowed drug importation from Canada. Sens. Sanders and Rand Paul (R-KY) were the only members who voted against the bill.

**Center for Consumer Information and Insurance Oversight (CCIIO) Has New Director**

It was announced this week that Randy Pate will become the new head of CCIIO, which is
tasked with overseeing the Obamacare insurance exchange marketplaces. He previously served as vice president of public policy for Health Care Service Corporation, which operates Blue Cross Blue Shield plans in five states, including Texas and Illinois. Prior to that, Pate was a health policy fellow at the conservative Heritage Foundation. He replaces Jeff Wu, who had been serving as acting director during the Trump Administration transition.

**Additional Cosponsors Added to EMTALA Liability Bill**
The "Health Care Safety Net Enhancement Act" (H.R. 548/S. 527), re-introduced in this Congress by Rep. Charlie Dent (R-PA) and Senator Roy Blunt (R-MO), has garnered additional support in the House since last reported. The ACEP-supported bill addresses the growing crisis in access to emergency care by providing emergency and on-call physicians who perform EMTALA-related services with temporary protections under the Federal Tort Claims Act. The most recent cosponsors are Reps. Bill Johnson (R-OH), Kenny Marchant (R-TX), Gus Bilirakis (R-FL) and Senator Bill Cassidy (R-LA).