



by Jennifer Jones, CBSA Vice President

## GET OUT AND VOTE – A GUIDE FROM THE COLORADO BIOSCIENCE ASSOCIATION

We know elections are important and that they shape the outcomes of our State, the economy and they ultimately impact our industry, bioscience. The Election takes place on Tuesday, November 6, 2018. We encourage you to get out and vote. The Colorado Bioscience Association has taken a position on four key statewide ballot measures that we see ultimately having an impact on our industry, business, the economy and our ability to attracting great companies and talent to our great State. To learn more about the initiatives CBSA has weighed in on [click here](#) to view the Association's ballot guide.



To learn more about the election process, all the statewide and local measures and races [click here](#).



photo by Dwight Burdette

## FEDERAL

This month, President Trump signed two bills ([Patient Right to Know Drug Prices Act](#) and [Know the Lowest Price Act](#)) into law that ban gag clauses that were called for in the [American Patients First](#) blueprint back in May. These clauses can be included in contracts insurers have with pharmacies — preventing pharmacies from telling customers they can save money on a drug if they pay with cash instead of using their health insurance.

These bills are similar to [HB18-1284](#) which was signed into law this past legislative session in Colorado by Governor Hickenlooper. CBSA continues to be supportive of [HB18-1284](#) as we see it as a way to provide direct out of pocket cost savings for patients in need. At CBSA we are dedicated to patients, ensuring people live longer, healthier lives. We see this as a way to ensure patients receive the needed treatments and cures. We work every day to create an innovation-friendly business environment ensuring that as an industry we deliver value to patient.



To learn more about CBSA's support of [HB18-1284](#) [click here](#) and to learn more about what is happening at the federal level [click here](#).



### FDA – PRE-CERTIFICATION PROGRAM

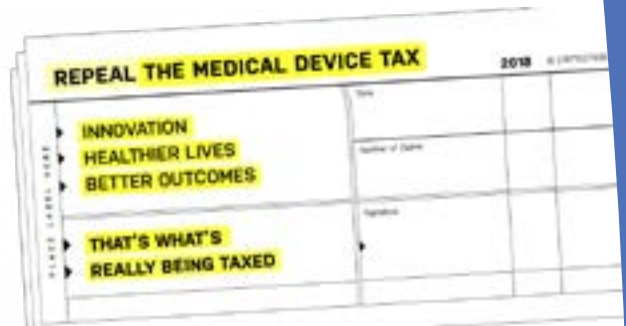
The FDA has recently released a statement on their efforts to work with technology industry to spur innovation in digital health. The FDA has proposed to create a Center of Excellence for Digital Health which shows the FDA's commitment to advancing and modernizing the regulatory approach to help the digital industry grow while protecting patients.

This Center of Excellence would help establish more efficient regulatory paradigms, consider building new capacity to evaluate and recognize third-party certifiers, and support a cybersecurity unit to complement the advances in software-based devices. The FDA believes that with the creation of a Center of Excellence, the FDA could commit additional resources to helping developers create innovative products that can benefit patients.

To learn about the Center of Excellence, the precertification program and a recent statement from FDA Commissioner Scott Gottlieb [click here](#).

### ADVOCATING FOR FULL REPEAL OF THE MEDICAL DEVICE TAX

Repealing the medical device excise tax continues to be a top priority for CBSA and Colorado's medtech innovators. CBSA is engaged in ongoing advocacy for the full repeal before the end of the year. We look forward to working closely with Senator Bennet and Senator Gardner to quickly take up this measure and ensure the medical technology industry continues to bring innovation to patient care. We will continue to keep you updated on our advocacy efforts. To thank Congress and your Representative for voting to repeal the medical device excise tax [click here](#).



*The President signed into law this month an \$854 billion spending bill to keep the federal government open through Dec. 7... It includes a boost in funding for the Department of Health and Human Services, including an additional 5% in funding for the National Institutes of Health.*

### FDA RECEIVES FUNDING IN SENATE PASSED APPROPRIATIONS BILL

The President **signed into law** this month an \$854 billion spending bill to keep the federal government open through Dec. 7. The spending bill was sent to Trump's desk last week. It includes a boost in funding for the Department of Health and Human Services, including an additional 5% in funding for the National Institutes of Health.

The second Fiscal Year 2019 appropriations bill for Health and Human Services (**H.R. 6157**) was supported by Congress overwhelming and in fact, it was the first time in more than two decades that Congress has approved yearlong funding for federal health programs and medical research. Under the new law, HHS receives \$90.5 billion, a \$2.3 billion increase. NIH sees a \$2 billion



increase to \$39 billion for basic research in oncology, and for Alzheimer's and other diseases, according to a [summary released by the House Appropriations Committee](#).

The CDC receives \$7.9 billion for programs to protect against health threats such as pandemics and biological threats, and \$2 billion for biomedical research, acquisition of medical supplies and vaccines, and hospital preparedness grants. Federal programs that help fight, treat and stop substance abuse and those that support access to mental health services receive \$6.7 billion.

The law also includes stopgap funding through Dec. 7 covering the seven other appropriations bills.

## Additional Federal Policy CBSA is Engaged in on Behalf of Industry

[H.R. 184](#) — Protect Medical Innovation Act of 2017/ [S.108](#) — Medical Device Access and Innovation Protection Act

[H.R. 2026](#) — Pharmaceutical Information Exchange Act

[H.R. 5998](#) — Ensuring Patient Access to Critical Breakthrough Products Act. TRID Improvement Act

[S. 204](#) — Trickett Wendler Right to Try Act of 2017/ [H.R.2368](#) — Right to Try Act

[S. 1183](#) — FDA Regulatory Efficiency Act / [H.R. 2483](#) — Quality Systems Certification Act of 2017

[H.R.2569](#) — Transparency in All Health Care Pricing Act of 2017 / [H.R.4808](#) — Transparent Health Care Pricing Act of 2018

[S.1131](#) / [H.R.2439](#) — Fair Accountability and Innovative Research Drug Pricing Act of 2017

[H.R. 4175](#) — Invest in Innovative Small Businesses Act

[S.2419](#) — Support Startup Businesses Act of 2018

[H.R. 5997](#) — President Trump Ensuring Patient Access to Critical Breakthrough Products Act

China Tax Tariffs

Medicare Part D

FY 2019 Agriculture Appropriations bill

FDA Guidances Release:

[“Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers”](#)

[“Medical Product Communications That Are Consistent With the FDA-Required Labeling”](#)

FY 2019 Labor, Health and Human Services, and Education funding bill

Sunshine Act

Cybersecurity