State and Federal Policy Updates

June 2018

Jennifer Jones CBSA Vice President



ELECTION UPDATE

The Colorado Primary Elections were held on June 26th. Below you'll find the outcomes of some of the key race including the race for the next Colorado State Governor. CBSA will be developing a plan to engage the newly elected officials to talk to them about the bioscience industry and share some of the exciting innovations taking place.

Colorado State Governor Race

Governor — Democratic Party Cary Kennedy — 24.74 percent

Jared Polis — 44.66 percent

Mike Johnston — 23.32 percent

Donna Lynne — 7.28 percent

Governor — Republican Party

Walker Stapleton — 47.90 percent

Greg Lopez — 13.06 percent

Doug Robinson — 8.89 percent

Victor Mitchell — 30.14 percent



U.S. Congress

Representative to the 116th United States Congress

District 1

Democratic Party

Diana DeGette — 70.94 percent

Republican Party

Charles Casper Stockham — 100.00 percent

District 2

Democratic Party

Joe Neguse — 66.00 percent

Republican Party

Peter Yu — 100.00 percent

District 3

Democratic Party

Diane Mitsch Bush — 64.06 percent

Republican Party

Scott R. Tipton — 100.00 percent

District 4 **Democratic Party** Karen McCormick — 64.66 percent

Republican Party Ken Buck — 100.00 percent

District 5 **Democratic Party** Stephany Rose Spaulding — 100.00 percent

Republican Party Doug Lamborn — 52.55 percent

District 6 **Democratic Party** Jason Crow — 66.05 percent

Republican Party Mike Coffman — 100.00 percent

For more information on all the local races and to learn more click here and here. If you have any questions please contact Jennifer Jones.

BIO CONFERENCE

This month CBSA President and CEO April Giles and Vice President Jennifer Jones attended the 2018 BIO International Convention in Boston, Massachusetts. This annual trip provides a venue where we can learn directly from industry leaders and share policy lessons, trends and insights. To learn more about the trip click here.



CBSA Vice President Jennifer Jones, Colorado BioGenius participant Isani Singh, and CBSA President and CEO April Giles together at the BIO International Convention in Boston.

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INVESTMENT, INNOVATION AND JOB CREATION

While in Boston the TEConomy/BIO report, Investment, Innovation and Job Creation in a Growing U.S. Bioscience Industry 2018 was released. The eighth biennial report focuses on the economic progress and footprint of the industry including the performance, positioning and latest trends in the bioscience industry for the nation, states and metropolitan areas. This year's study found that that the U.S. bioscience industry has reached \$2 trillion in annual economic impact while maintaining accelerated venture capital investment and job growth numbers. Among U.S. technology sectors, the bioscience industry has held a leading position as an economic driver and job generator.

Additionally, it finds U.S. bioscience firms directly employ 1.74 million people, a figure that includes more than 273,000 high-paying jobs created since 2001. Specifically, for Colorado, all five-major bioscience industry sub-sectors have increased employment since 2014. Further, Colorado's bioscience sector broke the billion-dollar mark in 2017, with companies raising a record \$1.2 billion. Our state now ranks in the top five for life science VC funding. The NIH has also steadily increased their grant funding in the state since 2014. More good news for our industry is in the report released at the BIO International Convention. To learn more about Colorado Specific data click here.

FEDERAL

This month CBSA congratulated Senator Gardner who received the 2018 Champion of Health Care Innovation Award. STAQ Pharma and We Work for Health Colorado joined CBSA in congratulating the Senator. We are proud to have a great CO Delegation who advocates for innovation and our bioscience industry.

FDA Communications Guidance

The FDA recently announced the release of an important guidances, "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers," and "Medical Product Communications That Are Consistent With the FDA-Required Labeling".

The first guidance answers common questions about companies' communications to payors, including insurance companies, formulary committees and similar entities.

The second guidance provides the FDA's views on manufacturers' communication of information that is not contained in the FDA-required labeling for their products, but that is consistent with that labeling. Both guidances are critical to outline how companies can communicate off-label health care economic information about their products to health plans, hospitals and other drug purchasers.

Our national industry partner, AdvaMed, was a powerful influence in ensuring that the medical device industry was included in the guidances. The initial FDA draft was largely focused on communications from drug companies, which is a vital component. However, it is also crucial that AdvaMed advocated for the inclusion of medical technology. It is important that our entire industry is supported in continuing to foster lifesaving advances and delivering high quality care for our patients most in need.

To learn more about the guidances and to read AdvaMed's press release click here.



Colorado Bioscience Association, STAQ Pharma, We Work for Health CO, CO Business Roundtable, CMS, and the Colorado Gerontological Society present innovation award to Senator Gardner.

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DRUG PRICING NEWS

This month HHS Secretary Alex Azar appeared in front of the Senate Health, Education, Labor and Pensions (HELP) Committee ànd Sénate Finance committee for a hearing on drug pricing. Secretary Azar's prepared testimony in large part summarized President Trump's blue print. For more information on the blueprint click here. To view the full hearing in the Senate HELP committee click here and Senate Finance committee click here.



Azar highlights the

administration's plan to require drug companies to include list prices in television commercials; pivots to a call for getting rid of drug rebates; and suggests a system "where PBMs and drug companies just negotiate fixed-price contracts." Azar also addresses possible changes to drug pricing in Medicare Parts D and B and praises FDA moves intended to increase drug competition.

At CBSA we remain committed that we need to look at the system holistically. We need true transparency. We are dedicated to patients, and we work every day to help people live longer, healthier lives. That's why we support true transparency.

We encourage our CO delegation and our local state legislators to consider:

- Reviewing the influential role insurers, pharmacy benefit managers (PBMs) and others play in deciding how much patients pay for medicines at the pharmacy counter.
- Considering the information patients need to make decisions about out-of-pocket drug costs when selecting their health plans.
- Tackling all areas of health care that drive up prescription costs.

There's a reason why close to 730 bioscience companies call Colorado home. Our state works to create an innovation-friendly environment. Colorado BioScience Association represents tens of thousands of researchers and entrepreneurs who work every day to improve the quality of life for patients.

We look forward to working with our Colorado Delegation in DC, and our local elected officials on creating federal and state policies that support patients and encourage innovation. For more information on the hearings, true transparency and recommendations of ways to look at the system holistically click here.

COLORADO REGENERATIVE MEDICINE ROUNDTABLE

We are convening the Colorado
Regenerative Medicine Roundtable
on August 13th. As a reminder we
host these roundtables with the
University of Colorado Gates
Center for Regenerative Medicine,
regenerative medicine companies
and partners. The goal of this
roundtable is to initiate a process
and define a 'legislative ask' related
to regenerative medicine on behalf
of the Colorado Life Science industry.

For more information or to attend the roundtable please contact

Jennifer Jones.

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