

FOCUS



August 2018



| | |
|----------------------|---|
| From the Board Chair | 1 |
| Policy Updates | 2 |
| MPO Summit | 5 |
| Events & New Members | 6 |

Hello, friends of CBSA,

You've likely already noticed a few changes in the Focus monthly newsletter, including that this letter is coming from the Board Chair rather than the President and CEO. As most already know, April Giles left CBSA as of August 31 and will be starting her new role at the Fitzsimons Innovation Community in October. As the search for April's successor continues, Vice Chair, Ginny Orndorff, and I will share leadership duties with CBSA Vice President Jennifer Jones.

We are fortunate that April built a strong team. They are extremely professional and well qualified to keep the organization running smoothly. I'm confident you won't notice any diminished service while we continue our search for a new President and CEO.



April leaves an impressive legacy. When she joined CBSA twelve years ago, she was one of five staff. Since then it has grown to meet the expanding needs of the membership and the Colorado Bioscience Institute was established as a separate nonprofit entity. During April's tenure, CBSA's annual revenue grew from \$956,588 in 2006 to more than \$1.5 million (2018 projection).

Our Search Committee recognizes the challenge in finding someone who can build on the momentum April and the team have generated. The search process started less than a month ago, and we have already seen some outstanding résumés. Anyone interested in learning more should view the posting on the [CBSA website](#). We hope to be in a position to announce the name of the successor at our Awards Dinner in November.

You're also seeing a new look for the newsletter. CBSA serves an industry whose very foundation is built upon innovation. To accurately represent you, we make an ongoing effort to keep our image contemporary and relevant.

To further acknowledge the groundbreaking work in our state, we invite you to join us for the [Colorado Life Science Innovation Forum](#). It is the state's largest gathering of bioscience decision-makers and national thought leaders. We have an impressive schedule of speakers, panelists, and networking opportunities for the day. I hope to see you there.

Regards,

A handwritten signature in black ink, appearing to read "Scott Larson".

Scott Larson
Board Chair, Colorado Bioscience Association
Senior Vice President, Legal and General Counsel
Terumo BCT



by Jennifer Jones, CBSA Vice President

MEDICAL DEVICE EXCISE 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 applaud the U.S. House of Representatives who passed H.R. 184, to permanently repeal the medical device excise tax. Thank you to Congressman Buck, Congressman Coffman, Congressman Lamborn, Congressman Polis, and Congressman Tipton who all supported and/or joined on as co-sponsors of important piece of legislation. Now we ask the Senate to do the same when they return from the holiday weekend.



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. To learn more about repealing medical device excise tax, view AdvaMed's [infographic](#). 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](#). And if you are interested in getting engaged, please contact CBSA Vice President [Jennifer Jones](#).

FDA RECEIVES FUNDING IN SENATE PASSED APPROPRIATIONS BILL

The U.S. Senate overwhelmingly passed a \$154.2 billion spending bill that includes more than \$3 billion for the FDA. When industry fees are included, the FDA would have \$5.49 billion in total funding next year.

Now where will the funding go? Nearly a third of the FDA funding—about \$1.721 billion—will go to the Center for Drug Evaluation and Research. The Center for Biologics Evaluation and Research will receive about \$369.9 million. The Center for Devices and Radiological Health will get nearly \$496 million and the National Center of Toxicological Research will get more than \$65.5 million.

Other FDA allocations in the bill include:

- \$70 million for the agency to carry out its responsibilities under the 21st Century Cures Act
- \$20 million to advance telemedicine and distance learning services to help address the nation's opioid epidemic.
- Additional money dedicated for modernizing generic drug development and review and to FDA's oncology center of excellence and rare disease work.

A bulk of the funding for the FDA originates from user fees. Under the bill, the agency is authorized to spend:

- nearly \$960.6 million in prescription drug fees,
- about \$501.4 million in generic drug fees,
- more than \$40.9 million in biosimilar fees and
- nearly \$196.7 million in medical device fees.



Although the bill passed in the Senate, we must wait until the House returns from their Labor Day recess to approve the Senate funding additions which include funding for the FDA. Once the House approves the Senate's version, the bill will go to the President for signature.

For more details on these programs and how the Senate bill compares to what House laid out for FDA, [see this breakdown here](#).

FDA RELEASES NEW DRAFT GUIDANCE TO ADVANCE AND MODERNIZE ONCOLOGY DRUG TRIALS

In the ongoing effort to modernize and create a more efficient approval process, the FDA released their draft guidance to advance and modernize oncology drug trials, "[Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics](#)".

“CBSA commends Commissioner Scott Gottlieb and the FDA for the release of this guidance. We see this as a great approach to help efficiently evaluate drugs, lower costs and ultimately get lifesaving innovations to our patients most in need.”

The draft guidance outlines how companies can use seamless trial designs to consolidate the traditional three-phase trial approach into one first-in-human study to expedite development of cancer drugs and biologics. CBSA commends Commissioner Scott Gottlieb and the FDA for the release of this guidance. We see this as a great approach to help efficiently evaluate drugs, lower costs and ultimately get lifesaving innovations to our patients most in need. To learn more about the guidance click [here](#).

FDA RELEASES THREE INITIATIVES FOR MEDICAL DEVICE DEVELOPMENT, INNOVATION AND SAFETY

The FDA announced it is taking steps to advance innovation and surveillance for medical devices through the implementation of three initiatives related to the recent user fee re-authorization. CBSA continues to applaud the FDA for efforts to streamline and create more efficient processes.



FDA Commissioner Dr. Scott Gottlieb



The initiatives include the finalized Voluntary Malfunction Summary Reporting Program, a request for public commentary on a proposed list of accessories for which general controls will provide assurance of safety and effectiveness, and draft guidance, [Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices](#).

To learn more about these initiatives read the blog post [here](#) and visit the FDA's website [here](#).

COLORADO REGENERATIVE MEDICINE ROUNDTABLE

This month CBSA and the University of Colorado Gates Center for Regenerative Medicine convened the Colorado Regenerative Medicine Roundtable. We host these roundtables with regenerative medicine companies and partners with a goal of developing a legislative and/or regulatory 'ask' on behalf of the Colorado Life Science industry.

At this month's meeting, the discussion focused around recently issued draft guidance documents for gene therapy, recently finalized guidance documents for tissue products, Biologic Guidance Documents issued by FDA both in Draft and Final format. The team is finalizing the proposed recommendations to bring forward to the FDA and our Congressional Members. For more information please contact [CBSA Vice President Jennifer Jones](#).



*Republican Treasurer
Walker Stapleton*



*Democrat Congressman
Jared Polis*

JOIN CBSA, THE DENVER METRO CHAMBER OF COMMERCE AND BUSINESS PARTNERS FOR THE 2018 GUBERNATORIAL CANDIDATE FORUM ON FRIDAY, OCTOBER 5TH!

This business-focused forum, moderated by the Denver Business Journal, will engage Colorado's major party gubernatorial candidates — Democrat Congressman Jared Polis and Republican Treasurer Walker Stapleton.

Join to hear their plans for ensuring a strong Colorado business climate. For more information the event, the other business partners and to register [click here](#).



MPO SUMMIT 2018

— OCTOBER 11-12 • OMNI INTERLOCKEN RESORT • COLORADO —

Ascending to the Peak of Medtech Innovation

MEDTECH OUTSOURCING'S PREMIER CONFERENCE EVENT

HELPING YOU DO BUSINESS BETTER

For more information, contact: Howard Revitch • 201-880-2243 • hrevitch@rodmanmedia.com • mposummit.com

CBSA & CBSI EVENTS

**R&D Workshop: Medical Device
Cybersecurity-Manufacturer Approaches**

Thursday, September 6, 2018 5:30pm-7:30pm
NITA Training Center
1685 38th Street Suite 200 Boulder, CO

THE INSTITUTE
COLORADO BIOSCIENCE

Foundations of Leadership

Thursday, September 13
Thursday, September 27
Thursday, October 11 8:00am-5:00pm
University of Colorado
3415 Colorado Avenue Boulder, CO

THE INSTITUTE
COLORADO BIOSCIENCE

Colorado Life Science Innovation Forum

Friday, September 14, 2018 7:00am-6:00pm
Westin Westminster
10600 Westminster Blvd. Westminster, CO

Regulatory Affairs Symposium

Thursday, October 4, 2018 1:30-5:00pm
St. Julien Hotel
900 Walnut Street Boulder, CO

Colorado Life Science Night

Tuesday, October 16, 2018 5:00-7:00pm
Fitzsimons Innovation Community
12635 E Montview Blvd Aurora, CO

15th Annual Awards Dinner

Thursday, November 8, 2018 5:00-8:30pm
Hyatt Regency Denver
650 15th Street | Capitol Ballroom Denver, CO

Colorado Life Science
Innovation Forum

**Friday, September 14, 2018
Westin Westminster
Westminster, CO**

This full day conference includes discussion sessions, keynotes and C-Level interviews on topics shaping the future of the industry with opportunities for networking and collaboration. This will be the largest gathering for a one day conference that includes Colorado life science executives and business leaders with 350 expected to attend.

**Full Information, Agenda,
and Registration**

CBSA STAFF

Jennifer Jones
Vice President
jjones@cobioscience.com

Tracey Nilson
Director of Partnerships
tnilson@cobioscience.com

Steve Ambriz
Director of
Administrative Services
sambriz@cobioscience.com

Daniela Blagoeva
Events Coordinator
dblagoeva@cobioscience.com

Benn Stebleton
Communications & Marketing Manager
bstebleton@cobioscience.com

**WELCOME OUR NEW
AUGUST MEMBERS**

AxImmune

InVitria

