2023 CBSA Policy + Advocacy Report

A Letter from Amy Goodman, Colorado BioScience Association Vice President and Counsel for Policy + Advocacy

Colorado Life Sciences Ecosystem:

Colorado BioScience Association (CBSA) leads Policy + Advocacy to support a collaborative, pro-innovation environment for life sciences in Colorado. We work in collaboration with partners and policymakers to advance state and federal policies that support the companies in our ecosystem and the patients they serve.

In 2023, the Policy + Advocacy team built coalitions to support policies that would make a meaningful impact on patients and counter legislation that would make it harder for life sciences companies to advance new technologies and treatments for patients.

During the 2023 Colorado legislative session, CBSA reviewed, analyzed, and discussed thirty-eight bills. Of those, CBSA supported six bills and opposed two bills, actively engaging throughout the legislative process. CBSA supported bills related to grant programs, industry incentives, workforce and education, and insurance coverage for needed therapies and technologies. CBSA opposed bills related to regulation of employers and price caps on critical medicines.

CBSA also advocated for the life sciences ecosystem and the patients it serves throughout the regulatory process to implement several key bills passed in prior years, including, most notably, the Prescription Drug Affordability Board (PDAB) and the implementation of a toxic air contaminant monitoring program that could impact the utilization of Ethylene Oxide (EtO) for the sterilization of medical devices and other medical products.

In addition, CBSA worked to promote and champion federal legislation that would advance Colorado's health innovation ecosystem. CBSA collaborated with leading national organizations that work on behalf of life sciences innovators in Colorado and around the country to advocate for shared policy objectives and ensure elected officials hear the collective voice of Colorado's ecosystem.

CBSA could not lead this work without our members, Board of Directors, the Policy Committee, and the lobbying team at Colorado Legislative Strategies. Thank you to everyone who dedicates their time to advocate for our life sciences community and educate legislators on the impacts and unintended consequences of policy decisions.

Amy Goodman, JD, MBE
Vice President and Counsel for Policy + Advocacy
Colorado BioScience Association

2023 CBSA Policy + Advocacy: Summary of Engagement

2023 Colorado Legislative Session			
Bill #	**Bill Title**	**CBSA's Position**	**Outcome**
SB23-066	Advanced Industry Acceleration Programs	Support	Passed
HB23-1260	Advanced Industry and Semiconductor Manufacturing Incentives	Support	Passed
HB23-1130	Drug Coverage for Serious Mental Illness	Support	Passed
HB23-1136	Prosthetic Devices for Recreational Activity	Support	Passed
HB23-1198	Teacher Externship Program for STEM Disciplines	Support	Passed
HB23-1110	Healthcare Coverage for Biomarker Testing	Support	Died
HB23-1118	Fair Workweek Employment Standards	Oppose	Killed
HB 23-1225	Extend And Modify Prescription Drug Affordability Board	Oppose	Passed

2023 Colorado Regulatory Engagement	
Topic	**CBSA's Position**
Prescription Drug Affordability Board (PDAB)	Oppose
Ethylene Oxide (EtO) and Colorado's Toxic Air Contaminants Monitoring Program	Oppose
Drug Importation Program	Oppose

2023 Federal Policy Engagement	
Bill Title or Topic	**CBSA's Position**
R&D Tax Credit Expansion Act	Support
R&D Expensing Fix	Support
Pandemic and All-Hazards Preparedness Act (PAHPA) Reauthorization	Support
Verifying Accurate Leading-edge IVCT Development (VALID) Act	Support
Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act	Support
Transitional Coverage for Emerging Technologies (TCET) and the Ensuring Patient Access to Critical Breakthrough Products Act	Support
Multi-Cancer Early Detection (MCED) Screening Coverage Act	Support
Help Ensure Lower Patient (HELP) Copays Act	Support
PBM Reform	Support
Optimizing Research Progress Hope and New Cures Act (ORPHAN Cures Act)	TBD
Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement Waiver Expansion	Oppose
Medicaid Drug Rebate Program Proposed Rule	Oppose
New Approach to Mergers & Acquisitions (M&A)	Oppose

COLORADO BIOSCIENCE ASSOCIATION

2023 Colorado Legislative Session

The First Regular Session of the 74th General Assembly marked the fifth year of Democratic control of state government. Governor Polis and the Democratic majorities in the House and Senate have largely passed their agenda, and the 2023 legislative session was no exception. Throughout the session, CBSA's policy and advocacy engagement aligned with our state Policy Priorities:

- Protect Patient Access to Health Innovation
- Strengthen Incentives for Innovation
- Increase Capital and Growth
- Promote a Favorable Tax and Regulatory Environment
- Cultivate an Educated Workforce
- Promote Strategies to Improve Public Health
- Advance Ecosystem Priorities Within the Colorado State Budget

During the 2023 legislative session, CBSA reviewed, analyzed, and discussed thirty-eight bills. Of those, CBSA supported six bills and opposed two bills, actively engaging throughout the legislative process. CBSA's engagement on these bills included contacting and meeting with legislators, submitting letters to individual legislators and to committees, testifying during committee hearings, and coordinating the engagement of CBSA members, as well as keeping CBSA members apprised every step of the way. CBSA successfully recommended bill amendments to improve the benefits of bills we supported and to minimize harmful provisions in bills we opposed.

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Advanced Industry Acceleration Programs (SB23-066)

CBSA's Position: Support | Outcome: Passed

Advanced Industry Acceleration Programs (SB23-066) was CBSA's priority bill for the year. The bill sought to reauthorize the Advanced Industries Accelerator Grant Programs, run by Colorado's Office of Economic Development and International Trade (OEDIT).

The programs were created to promote growth and sustainability in seven research-intensive industries by driving innovation, commercialization, and public-private partnerships. The programs increase access to critical, non-dilutive, early-stage capital and create a strong infrastructure that enhances Colorado's capacity to be globally competitive.

The grant programs deliver ROI for Colorado through company creation, high-paying jobs, and follow-on capital. According to OEDIT, the state has awarded $128 Million in the form of 714 awards across all advanced industries. Results include:

- Over 4,400 New Jobs Created and 4,500 Jobs Retained
- 124 New Companies Created
- 624 Patents Filed
- $2.5 Billion in Follow-On Capital

Sponsors: Sen. Cleave Simpson, Sen. Chris Hansen, Rep. Shannon Bird, Rep. Mike Lynch

CBSA position and engagement: CBSA proudly led advocacy efforts to reauthorize the Advanced Industries Accelerator Grant Programs for another ten years (until 2034), working with our advanced industries partners and OEDIT. The bill received broad, bipartisan support throughout the legislative process.

Outcome: SB23-066 was passed by the legislature with an amendment that extends the mechanism to fund the advanced industries acceleration cash fund through income tax withholding growth by two years and was signed by Governor Polis on May 17, 2023. Another bill will be needed to extend full funding for the grant programs through 2034.

Advanced Industry and Semiconductor Manufacturing Incentives (HB 23-1260)

CBSA's Position: Support | Outcome: Passed

Advanced Industry and Semiconductor Manufacturing Incentives (HB23-1260), among other things, created an Advanced Industries Task Force to:

- Study the effectiveness of existing financial incentives and development strategies for advanced manufacturing and other STEM companies in Colorado;
- Examine other states' approaches to attracting and promoting the development of advanced manufacturing and other STEM companies; and
- Identify any recommended legislative or regulatory changes to make Colorado's advanced manufacturing and other STEM industries more nationally competitive.

Sponsors: Rep. Matt Soper, Rep. Alex Valdez, Sen. Mark Baisley, Sen. Kevin Priola

CBSA position and engagement: CBSA supported HB23-1260. Conversations between CBSA President & CEO Elyse Blazevich and bill sponsor Representative Matt Soper during the 2022 Bioscience & Cleantech Roadshow in Edinburgh, Scotland, led by Metro Denver Economic Development Corporation, contributed to the inclusion of this task force in this bill. CBSA testified in support of the bill in the House Finance Committee on April 3, 2023.

Outcome: HB23-1260 was passed by the legislature with amendments and signed by the Governor on May 20, 2023. After working closely with OEDIT, Elyse Blazevich was appointed to the Advanced Industries Task Force to represent the best interests of the life sciences ecosystem. The Task Force met during the fall of 2023 and submitted its final report to the Governor and General Assembly on December 1, 2023, with recommendations to make Colorado's advanced manufacturing and other STEM industries more nationally competitive. The Task Force's recommendations were organized into three categories – business support, ecosystem support, and workforce support, and they include:

- Improved communication and marketing of the existing opportunities available to advanced industry companies;
- Improvements to existing and new tax credits;

- Process and partnerships to expedite permitting to support expansions and relocations;
- Increased support for startup companies, Small Business Development Centers, Economic Development Organizations, tech transfer offices, and investment sources (angel investors and venture capitalists);
- Investing in regional advanced industry cooperatives across the state; and
- Support for enhanced partnerships between higher education and businesses focused on producing homegrown talent.

Drug Coverage for Serious Mental Illness (HB23-1130)

CBSA's Position: Support | Outcome: Passed

Drug Coverage for Serious Mental Illness (HB23-1130) aims to help people suffering from a serious mental illness by addressing private payers' step therapy requirements and Medicaid's Preferred Drug List review process. These are both "[b]arriers impeding timely access to cutting-edge and physician-recommended psychiatric treatments," as bill sponsor Representative Dafna Michaelson Jenet explained in an opinion piece in the Denver Post.

The bill prohibits state-regulated insurance plans from requiring more than one alternative drug trial as part of a step therapy protocol before covering a drug prescribed by a provider to treat select mental health conditions. The bill also allows a provider to attest that a prescribed drug is necessary, without undergoing step therapy, and the insurance plan must cover the drug. Lastly, the bill requires the Department of Health Care Policy & Financing (HCPF) to review newly FDA-approved drugs for certain mental health conditions within 90 days for coverage of the drug under Medicaid.

Sponsors: Rep. Dafna Michaelson Jenet, Sen. Robert Rodriguez, Sen. Chris Kolker

CBSA position and engagement: CBSA supported HB23-1130 and worked closely with proponents of the bill, including CBSA members. CBSA testified in the House Health & Insurance Committee on February 21, 2023.

Outcome: HB23-1130 was passed by the legislature with amendments and signed by the Governor on June 6, 2023.

Prosthetic Devices for Recreational Activity (HB23-1136)

CBSA's Position: Support | Outcome: Passed

Prosthetic Devices for Recreational Activity (HB23-1136) requires health insurance plans regulated by the state to provide coverage for an additional prosthetic device deemed necessary by the treating physician for engagement in physical and recreational activities. This bill is part of a movement from the American Orthotic & Prosthetic Association (AOPA). Similar legislation was passed in Maine and in New Mexico to help kids who need prosthetic limbs for activities that are beyond just daily activities.

Sponsors: Rep. David Ortiz, Rep. Anthony Hartsook, Sen. Faith Winter, Sen. Larry Liston

CBSA position and engagement: CBSA supported HB23-1136. CBSA was in communication with the bill's proponents during the legislative session and offered our support.

Outcome: HB23-1136 was passed by the legislature with amendments, including an amendment to make it applicable to people of all ages (not just those under 26), and signed by Governor Polis on May 25, 2023.

Teacher Externship Program for STEM Disciplines (HB23-1198)

CBSA's Position: Support | Outcome: Passed

Teacher Externship Program for Science, Technology, Engineering, and Math (STEM) (HB23-1198) Disciplines requires the Colorado Department of Labor and Employment to establish a teacher externship program to allow K-12 teachers to participate in experiential learning opportunities with employers, outside of the school environment, to gain knowledge and expand their curriculum in the STEM disciplines.

Sponsors: Rep. Brianna Titone, Rep. Meghan Lukens, Sen. Janice Rich

CBSA position and engagement: CBSA supported HB23-1198. CSBA signed onto written testimony from the Colorado STEM Ecosystem and several CBSA member companies provided live testimony.

Outcome: HB23-1198 was passed by the legislature with amendments and signed by the Governor on May 22, 2023. Amendments to the bill shortened the program to a two-year pilot and removed the tax credit in the original bill for costs incurred and paid by the employer for placing and retaining a teacher in an externship.

Healthcare Coverage for Biomarker Testing (HB23-1110)

CBSA's Position: Support | Outcome: Died

Healthcare Coverage for Biomarker Testing (HB23-1110) would have required insurance coverage for biomarker testing supported by nationally recognized clinical practice guidelines for diagnosis, treatment, and disease management. It would have applied to all individual and group health benefit plans regulated by the state as well as to Medicaid.

Biomarker testing is recognized as the key to unlocking precision medicine. Efforts to pass this biomarker testing bill were spearheaded by the American Cancer Society Cancer Action Network (ACS CAN) following the passage of similar bills in Arizona, Illinois, Louisiana, and Rhode Island.

Sponsors: Rep. Dafna Michaelson Jenet, Rep. Anthony Hartsook, Sen. Kyle Mullica, Sen. Janice Rich

CBSA position and engagement: CBSA supported HB23-1110. CBSA engaged with ACS CAN, testified in the House Committee on Health & Insurance on February 21, 2023, and worked with CBSA members to provide support.

Outcome: HB23-1110 passed out of the House Committee on Health & Insurance by a vote of 10-1, where amendments were added to the bill clarifying that biomarker testing "is inclusive of diagnostic, monitoring, prognostic, pharmacogenomic, and predictive tests" and that biomarker testing "does not include direct-to-consumer genetic tests." Unfortunately, though, the Chair of the House Appropriations Committee informed the bill sponsors on April 17th that the bill could not move forward without first undergoing the SB22-040 actuarial review process for new insurance mandates over the summer and fall of 2023, so the bill died on the calendar this year. The bill is going through that actuarial review process and we expect it to be introduced again in 2024.

Fair Workweek Employment Standards (HB23-1118)

CBSA's Position: Oppose | Outcome: Killed

Fair Workweek Employment Standards (HB23-1118), which was arguably one of the most restrictive employment bills in the country, would have required certain employers in Colorado to follow strict rules related to employee scheduling. The broad, inflexible new regulations and restrictions on how employers manage employee workweek schedules and pay would have included a requirement that employers

release all work schedules at least two weeks in advance and provide predictability pay and retention pay to workers.

Sponsors: Rep. Emily Sirota, Rep. Serena Gonzales-Gutierrez, Sen. Julie Gonzales, Sen. Faith Winter

CBSA position and engagement: CBSA joined a coalition of diverse business and industry groups in opposition to HB23-1118 organized by the Colorado Chamber of Commerce due to concerns that the proposal would drive businesses out of the state and hurt Colorado's economic competitiveness.

Outcome: HB23-1118 was postponed indefinitely (killed) by the House Business Affairs & Labor Committee on March 2, 2023. The coalition that CBSA participated in was instrumental in successfully killing the bill.

Extend And Modify Prescription Drug Affordability Board (HB 23-1225)

CBSA's Position: Oppose | Outcome: Passed

Colorado's Prescription Drug Affordability Board (PDAB or Board) was established in 2021 by HB21-175. The PDAB, a Type-1 Board within the Division of Insurance, has the authority to review prescription drug costs and evaluate their impact on Coloradans through affordability reviews of prescription drugs. The Board may then recommend ways to address those costs and may set an upper payment limit (UPL) for certain prescription drugs.

Extend And Modify Prescription Drug Affordability Board (HB23-1225) extends and expands the PDAB by pushing back the repeal date from 2026 to 2031, expanding the eligibility criteria for affordability reviews, and increasing the twelve-drug limit on upper payment limits (UPLs) that can be set by the PDAB. When determining which drugs are eligible for an affordability review, the PDAB must now identify any prescription drug that has:

- A wholesale acquisition cost (WAC) of $3,000 or more;
- An increase of $300 or more above the WAC for the drug in the previous 12 months;
- An increase of 200% or more above the WAC for the drug in the preceding 12 months; or
- A current WAC for an average course of treatment per person per year of $30,000 or more.

In addition, any biosimilar drug with an initial WAC that is not at least 15% lower than the WAC of the corresponding biological product is eligible for an affordability review. The PDAB is now required to issue a report summarizing data considered in determining whether a drug is affordable, and this report shall be available on its public webpage.

Sponsors: Rep. Chris deGruy Kennedy, Rep. Ruby Dickson, Sen. Sonya Jaquez Lewis, Sen. Janet Buckner

CBSA position and engagement: CBSA opposed HB23-1225. Through CBSA's intensive member engagement work, collaboration with our partners at PhRMA and BIO, and advocacy with bill sponsors, we were able to negotiate important amendments to this bill.

Outcome: HB23-1225 was passed by the legislature with amendments that removed some of the most harmful provisions and was signed by the Governor on May 10, 2023. Although we remained opposed to the final version of the bill, the mitigating amendments we secured were an important win. CBSA, PhRMA, and BIO were successful in reaching a deal with the bill sponsors and getting an amendment in the House on March 20, 2023, which secured:

- Removal of the "catch-all" eligibility criteria provision that would have allowed essentially any drug to be referred to the PDAB;

- A delay of the implementation of the rest of the changes to the eligibility criteria triggers to January 1, 2025; and
- A mutual agreement with the bill sponsors not to seek additional amendments in the Senate, which protected us from any additional harmful amendments.

In addition, a favorable amendment passed in the Senate Health & Human Services Committee on April 19, 2023, which backed away from an unlimited number of UPLs by reinstating the twelve-UPL limit, but allowed the PDAB to set up to eighteen UPLs if there is a need to do so and if it has the staff support to do so, and allowing one "prescription drug" to include multiple National Drug Codes (NDCs) that are indicated for the drug.

Implementation of the PDAB also moved forward throughout 2023. Please see the next section for a discussion of that work.

2023 Colorado Regulatory Engagement

In 2023, CBSA continued to engage throughout the implementation process for several bills passed in previous years. Most notably, CBSA was heavily engaged in the implementation process for Colorado's Prescription Drug Affordability Board (PDAB).

2023 Colorado Regulatory Engagement	
Topic	**CBSA's Position**
Prescription Drug Affordability Board (PDAB)	Oppose
Ethylene Oxide (EtO) and Colorado's Toxic Air Contaminants Monitoring Program	Oppose
Drug Importation Program	Oppose

Prescription Drug Affordability Board (PDAB)

CBSA's Position: Oppose

In 2023, implementation of the Prescription Drug Affordability Board (PDAB or Board) established in 2021 by SB21-175 (and modified in 2023 by HB23-1225), continued to ramp up. After finalizing the regulations and policies to guide its work, the PDAB compiled a list of drugs eligible for an affordability review, selected five drugs for an affordability review from that list, began conducting affordability reviews on the first set of drugs, and made an affordability decision for the first drug up for review.

CBSA position and engagement: CBSA continues to oppose the setting of upper payment limits (UPLs) by the PDAB and has serious concerns about the PDAB's process. CBSA has closely monitored all PDAB meetings and Prescription Drug Affordability Advisory Council (PDAAC) meetings, provided public comment during meetings, submitted comment letters, coordinated comment letters from CBSA members, communicated informally with PDAB staff to seek process clarifications, and submitted a letter to Governor Jared Polis. CBSA also put out a digital and print ad campaign with the message that drug price caps are the wrong solution for patients. CBSA has been working closely with our members and our national partners at BIO and PhRMA to proactively engage and advocate every step of the way.

CBSA's engagement and advocacy have focused on a number of key issues or themes: concerns about the data that informed the initial selection of drugs; concerns about inconsistency and lack of transparency in the PDAB's process; and opposition to the setting of UPLs due to concerns that it would not lower patients' out-of-pocket costs, concerns that it could impact patients' access to critical medicines, and concerns about the impact on Colorado's innovation ecosystem. To learn more, please see the following blog posts, letters, and articles:

- 8/7/23: Weekly Policy Blog: PDAB Selects Drugs for Affordability Reviews
    - 6/23/23 letter from CBSA and BIO to the PDAB
    - 7/21/23 dashboard Inquiry
    - 7/31/23 letter from CBSA and BIO to the PDAAC
    - 8/4/23 letter from CBSA and BIO to the PDAB
- 8/14/23: Weekly Policy Blog: PDAB Releases Stakeholder Engagement Guide on Affordability Review Process
- 9/5/23: Weekly Policy Blog: CMS Announces Drugs Subject to Price Controls Under the IRA
- 9/18/23: CBSA Opinion Piece: Efforts to Control Prescription Drug Pricing Harm Collaborative Work to Advance Patient Care with Health Innovations
- 9/28/23: CBSA letter to Governor Polis
- 10/30/23: Weekly Policy Blog: CBSA Has Concerns About Inconsistency of Preliminary Data Review Process for Drugs Under Affordability Review by PDAB
    - 10/26/23 sign-on letter from CBSA and members to the PDAB (setting UPLs)
    - 10/27/23 letter from CBSA to the PDAB (inconsistency of preliminary data review process)
- 12/1/23: Colorado Chamber of Commerce - The Sum & Substance: Coming vote on prescription drug affordability holds major consequences (quotes CBSA)
- 12/4/23: Weekly Policy Blog: CBSA Talks PDAB at CSBA Summit; PDAB Ad Campaign & Media Highlight
    - Sample print ad that links to Elyse Blazevich's first-person opinion piece
- 12/8/23: Colorado Chamber of Commerce - The Sum & Substance: Colorado board casts unanimous vote on first drug whose affordability it considers (quotes CBSA)
- 12/11/23: Weekly Policy Blog: PDAB Deems Trikafta "Not Unaffordable" in First Affordability Decision

Outcome: On December 8, 2023, the PDAB completed its first affordability review and unanimously voted that the selected drug, a cystic fibrosis drug called Trikafta, is "not unaffordable for Colorado consumers." Trikafta is therefore not eligible for the imposition of a UPL by the Board. The PDAB also reviewed preliminary data presented by staff on the next two drugs under review, Genvoya (for HIV) and Enbrel (for autoimmune diseases), and plans to vote on their affordability, and then potentially on whether to set an upper payment limit, in February 2024.

Ethylene Oxide (EtO) and Colorado's Toxic Air Contaminants Monitoring Program

CBSA's Position: Oppose

In 2022, the Colorado General Assembly passed HB22-1244, which created a new program in the Colorado Department of Public Health and Environment (CDPHE) to regulate toxic air contaminants (or TACs) based on adverse health effects, and clarified that CDPHE has the authority to regulate air toxins *more* stringently than the EPA.

The bill requires certain sources to submit annual toxic emissions reports and creates a TAC monitoring program, which will ultimately determine the concentration of contaminants in the state's ambient air using monitoring stations placed throughout the state. It also requires the Air Quality Control Commission (AQCC) to identify priority TACs, establish health-based standards, and adopt emission control regulations.

CBSA position and engagement: CBSA opposed HB22-1244 due to concerns around CDPHE regulating air toxins more stringently than the EPA and potential unintended consequences of CDPHE establishing a toxic air contaminant monitoring program that could impact the utilization and availability of Ethylene Oxide (EtO) for the sterilization of medical devices and other medical products. While we understand the need for appropriate, reasonable regulations, caution must be taken to not jeopardize the medical product supply chain through unnecessary regulatory action based on inaccurate information.

Outcome: After HB22-1244 was signed into law, CBSA and AdvaMed met with CDPHE regarding the process and timing for implementation of the TAC monitoring program and other aspects of the legislation. CBSA and AdvaMed have continued to engage with CDPHE and CBSA members on the implementation of this bill, including stakeholder meetings held in late 2023.

CBSA, in collaboration with AdvaMed, will continue to be in communication with CDPHE, work with stakeholders to help ensure CDPHE and the public have accurate information about scientific evidence and risk levels, and fully engage with the upcoming rulemaking process.

Drug Importation Program

CBSA's Position: Oppose

In 2019, the Colorado General Assembly passed SB19-005, which authorized HCPF to seek approval from the federal government to create a Canadian drug importation program in Colorado. HCPF submitted its Section 804 Importation Program (SIP) application to the U.S. Food and Drug Administration (FDA) in December of 2022 and is still awaiting federal approval. In 2023, HCPF attempted "to engage with drug manufacturers to secure drug supply for [the] program," since "all drugs imported through Colorado's program will be done so with express permission of the drug's manufacturer."

CBSA position and engagement: CBSA continues to oppose prescription drug importation. We believe it will jeopardize patient safety and do little to lower out-of-pocket costs for Coloradans. The resources required to ensure the safety and efficacy of imported drugs would far outweigh any potential savings for Colorado consumers.

Outcome: The Colorado Drug Importation Program submitted its 2023 annual report to the legislature on December 1, 2023. A Washington Post article, *Colorado Says Drug Industry Blocked Its Canada Dreams – And Biden Hasn't Helped*, discusses how, since federal regulators have yet to green light Colorado's program and drug companies have not agreed to participate, the program has not moved forward.

A Colorado spokesperson has indicated the state is working on an amendment that will likely be submitted to the FDA in early 2024. CBSA will continue to monitor any developments with the state's implementation of the Drug Importation Program and provide regular updates to our community.

2023 Federal Policy Engagement

In 2023, CBSA worked to promote and champion federal legislation that would advance Colorado's health innovation ecosystem. The Policy + Advocacy team worked to drive global health innovations, products, and services that improve and save lives. CBSA's federal policy priorities include:

- Protect Patient Access to Health Innovation
- Increase Research Funding
- Improve the Regulatory Review and Approval Process
- Strengthen Incentives for Innovation
- Promote the Development of Agricultural Biotechnology Products
- Advance the Role of Digital Health Technologies in Improving Care

CBSA collaborated with leading national organizations (AdvaMed, BIO, MDMA, and PhRMA) that work on behalf of life sciences innovators in Colorado and around the country. Together, we advocate for shared policy objectives to ensure elected officials hear the collective voice of Colorado's ecosystem and understand the ways we save and change lives. Since political divisions, lack of leadership, and disagreements over border control, international affairs, and how to continue funding the

government have subsumed Congress for much of the year, Congress has not yet passed any of the key bills CBSA advocated for in 2023. We will continue to engage with Colorado's Congressional delegation and advocate for our priorities in 2024.

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Bill Title or Topic	**CBSA's Position**
R&D Tax Credit Expansion Act	Support
R&D Expensing Fix	Support
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Verifying Accurate Leading-edge IVCT Development (VALID) Act	Support
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R&D Tax Credit Expansion Act

CBSA's Position: Support

Representative Joe Neguse (D-CO-2) introduced the Research and Development (R&D) Tax Credit Expansion Act of 2023 (H.R.6685) on December 7, 2023. The bill would expand the R&D Tax Credit for small and new businesses. The R&D Tax Credit allows companies to expense certain R&D costs or provides a credit for certain expenses related to R&D. Companies that are under five years old and have less than $5 million in gross receipts may use these tax incentives to help support these small, young startups that face a large financial impact at the beginning of their creation. The R&D Tax Credit Expansion Act of 2023 would:

- Modify the refundable research tax credit for new and small businesses to be adjusted for inflation. It is currently at a limit of $500,000.
- Allow new and small businesses to cover all unemployment payroll taxes.
- Extend the eligibility for the credit to small businesses with less than $10 million in gross receipts. The current limit is less than $5 million. Small businesses would also be able to claim the tax credit for up to ten years after accruing $25,000 in gross receipts, instead of for five years after the first penny is received.
- Expand the Alternative Simplified Credit so small and new businesses can more easily utilize the R&D tax credit.

Colorado Sponsor: Rep. Joe Neguse (D-CO-2)

CBSA position and engagement: CBSA supports and is officially endorsing the R&D Tax Credit Expansion Act. CBSA discussed the draft bill with Congressman Neguse's staff before the bill was introduced and provided a quote for the press release, which has not yet been released:

"Life sciences companies in Colorado and around the nation develop breakthroughs that save and change lives around the world. They also face significant hurdles to bringing innovative health technologies and therapies to market," said Amy Goodman, Colorado BioScience Association Vice President and Counsel for Policy + Advocacy. "We applaud Congressman Joe Neguse's leadership in expanding the R&D Tax Credit, which will strengthen Colorado's thriving life sciences ecosystem and its health impact around the world by providing valuable support and incentives for companies working to bring technological and scientific discoveries to patients."

R&D Expensing Fix

CBSA's Position: Support

CBSA has been asking Congress to remove a "tax on innovation" by restoring the immediate expensing of research and development/experimentation expenditures. R&D is critical to the development of innovative breakthroughs, especially in the life sciences, and we must ensure U.S. tax policy enables and encourages investment in this innovation. The American Innovation and R&D Competitiveness Act of 2023 (H.R.2673) and American Innovation and Jobs Act (S.866) would fix the Section 174 R&D tax amortization issue.

Colorado Cosponsors: Rep. Joe Neguse (D-CO-2, original cosponsor), Rep. Brittany Pettersen (D-CO-7), Rep. Jason Crow (D-CO-6), Rep. Yadira Caraveo (D-CO-8)

CBSA position and engagement: CBSA supports efforts to restore the immediate expensing of research and development/experimentation expenditures. CBSA and other members of the Council of State Bioscience Associations (CSBA) submitted a letter to Congressional leadership on March 28, 2023, urging them to pass S. 866. CBSA also reached out to members of the Colorado Congressional delegation about the importance of addressing this issue and encouraged them to sign on as cosponsors of the bill.

Pandemic and All-Hazards Preparedness Act (PAHPA) Reauthorization

CBSA's Position: Support

The Pandemic and All-Hazards Preparedness Act (PAHPA) underpins Department of Health and Human Services (HHS) agencies, programs, and funding authorizations for addressing national health security threats, including pandemics, biothreats, and other public health emergencies. PAHPA created the HHS Assistant Secretary for Preparedness and Response (now the Administration for Strategic Preparedness and Response) and the Biomedical Advanced Research and Development Authority (BARDA) and provides important congressional oversight and direction to federal programs related to early warning, prevention, preparedness, and response.

The House Energy & Commerce Committee marked up two bills reauthorizing PAHPA on July 19, 2023, and the Senate HELP Committee gave bipartisan approval on July 20, 2023, to a proposal for PAHPA reauthorization. The bill's incentives to promote research into Medical Countermeasures (MCMs) included a clean five-year extension of the MCM Priority Review Voucher (PRV) program and measures to support vaccine development and manufacturing, and a helpful amendment was added thanks to Sen. John Hickenlooper (D-CO) that would establish a program for reviewing MCMs for emerging pathogens at the FDA. However, none of those bills moved forward. The overall PAHPA framework expired on September 30, 2023, requiring stopgap, temporary extensions in the continuing resolution that expired on November 17, 2023. Some preparedness efforts were funded into January 2024 with November's stopgap spending measure, but a full PAHPA reauthorization is still needed.

Colorado Cosponsors: Rep. Diana DeGette (D-CO-1, original cosponsor of H.R.4697)

CBSA position and engagement: CBSA supports PAHPA's incentives to spur innovation and the development of new and faster response capabilities, such as the MCM PRV program. CBSA signed onto

a letter, along with more than 100 organizations, circulated by the Johns Hopkins Center for Health Security urging Congress to pass PAHPA submitted to Congressional leadership on November 14, 2023. Advocates are encouraging Congress to include a comprehensive five-year PAHPA reauthorization in the next moving legislative vehicle.

Verifying Accurate Leading-Edge IVCT Development (VALID) Act

CBSA's Position: Support

For years, Congress has been urged by a growing coalition of state life sciences associations, patient groups, and other stakeholders, to enact legislation that will modernize the FDA's regulation of diagnostic tests, giving the agency the authority, the framework and the resources to balance proper oversight with advancement of innovation.

In 2023, lawmakers began pushing again for the creation of a program to modernize FDA regulation of diagnostic tests through the Verifying Accurate Leading-Edge In Vitro Clinical Tests (IVCTs) Development (VALID) Act. The VALID Act of 2023 (H.R.2369), bipartisan legislation introduced in March and cosponsored by Rep. Diana DeGette (D-CO-1), was another opportunity for Congress to act on comprehensive diagnostic regulatory reform that failed to move forward in 2023.

Under this new, modernized framework, the unique characteristics of diagnostic tests would be differentiated from medical devices. Hospitals and laboratories could submit their technologies for electronic review, and diagnostics developed to address an unmet medical need could be expedited, speeding high-quality, reliable, and innovative tests to providers and patients, while providing the FDA with tools to administer effective oversight of these tests.

Colorado Cosponsors: Rep. Diana DeGette (D-CO-1, original cosponsor)

CBSA position and engagement: CBSA supports the VALID Act and continues to strongly advocate for it along with our national partners. Modernization of the regulation of all LDTs and IVDs under a single, predictable, diagnostic-specific, and risk-based regulatory framework is needed to foster innovation, embrace scientific advances, ensure consistency in development, accuracy, and reliability of all tests, and advance patient care and public health. CBSA applauds Colorado Congresswoman Diana DeGette for her tireless leadership in working with key stakeholders to shape and champion this important legislation. In October of 2023, the FDA issued a proposed rule that would simply regulate laboratory developed tests (LDTs) as in vitro diagnostics (IVDs) and phase out the FDA's general enforcement discretion approach to LDTs. This proposed rule does not align with the modernized regulatory framework we have been advocating for through the VALID Act.

Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act

CBSA's Position: Support

The Pioneering Antimicrobial Subscriptions to End Up-Surging Resistance (PASTEUR) Act establishes a delinked subscription program to encourage innovative antimicrobial drug development targeting the most threatening infections, to improve the appropriate use of antibiotics, and to ensure domestic availability when needed. The PASTEUR Act of 2023 (S.1355), spearheaded by Senator Michael Bennet (D-CO), and H.R.2940 were both introduced on April 27, 2023,

The antimicrobial resistance (AMR) crisis has been exacerbated by a lack of new drug development by the pharmaceutical industry due to reduced economic incentives and challenging regulatory requirements, creating a severe market failure. The PASTEUR Act seeks to address this market failure and increase public health preparedness by keeping novel antibiotics on the market and improving appropriate use across the health care system. While current reimbursement between the government and drug makers base payment on volume, the PASTEUR Act would be a $6 billion down payment to protect public health and address the growing threat of AMR. The legislation would establish a

subscription-style model which would offer antibiotic developers an upfront payment in exchange for access to their antibiotics, encouraging innovation and ensuring our healthcare system is prepared to treat resistant infections.

Colorado Cosponsors: Sen. Michael Bennet (D-CO, sponsor), Sen. John Hickenlooper (D-CO); Rep. Diana DeGette (D-CO-1), Rep. Joe Neguse (D-CO-2)

CBSA position and engagement: CBSA supports the PASTEUR Act and participated in PASTEUR Advocacy Day in September 2023, joining BIO and other organizations, including Infectious Diseases Society of America, Cystic Fibrosis Foundation, Partnership to Fight Infectious Disease, and The Pew Charitable Trusts, in raising awareness about the public health crisis of AMR. We encouraged policymakers to pass the PASTEUR Act and applauded Senator Michael Bennet for serving as the sponsor of this key legislation, along with applauding the three members of the Colorado Congressional delegation cosponsoring the legislation. CBSA will continue to work with national partners to express our support for passage of the PASTEUR Act, as it could be an effective strategy to promote the development of new antimicrobial medications to fight drug-resistant infections.

Transitional Coverage for Emerging Technologies (TCET) and the Ensuring Patient Access to Critical Breakthrough Products Act

CBSA's Position: Support

Improving access to emerging technologies is a top priority as many Americans continue to struggle to access the newest, most effective technologies because Medicare coverage policies create hurdles for novel products. The Ensuring Patient Access to Critical Breakthrough Products Act was first introduced in 2019. In January 2021, the Centers for Medicare & Medicaid Services (CMS) announced the Medicare Coverage of Innovative Technology (MCIT) rule, which was similar to the "Breakthrough" Act and would have provided four years of automatic coverage for FDA-approved breakthrough-designated products. CMS repealed the MCIT rule that November, a month before it was set to go into effect. After repealing MCIT, CMS announced it would propose a new rule called Transitional Coverage for Emerging Technologies (TCET).

Just weeks ahead of CMS' promised timeline to propose TCET in April 2023, the Ensuring Patient Access to Critical Breakthrough Products Act of 2023 (H.R.1691) was introduced to accelerate safe and effective technologies to Medicare patients. This House bill seeks to provide four years of Medicare coverage for medical devices that receive approval from the FDA under the Breakthrough Devices Program. It would also create a roadmap for additional data collection for CMS to make a permanent coverage decision after the initial four years.

Then, on June 22, 2023, CMS released its notice on the proposed TCET coverage pathway. CMS plans to establish TCET through a procedural notice rather than rulemaking so that it can be implemented more quickly and modified as needed.

Colorado Cosponsors: Rep. Diana DeGette (D-CO-1), Rep. Joe Neguse (D-CO-2), Rep. Brittany Pettersen (D-CO-7), Rep. Yadira Caraveo (D-CO-8), Rep. Jason Crow (D-CO-6)

CBSA position and engagement: CBSA supports the Breakthrough Act and encourages CMS to improve the TCET pathway policy. CBSA urged members of Colorado's Congressional delegation to sign on as cosponsors of the Breakthrough Act and applauds Reps. DeGette, Neguse, Pettersen, Caraveo, and Crow for doing so. In addition, on August 28, 2023, CBSA signed on to a letter responding to the long-awaited proposed TCET pathway offering recommendations to improve the existing TCET proposal. While the TCET notice released in late June is a positive step forward, we believe more can be done to ensure patients have timely access to new technologies soon after they are approved by the FDA. We look forward to working with CMS and Congress to ensure Medicare beneficiaries have coverage for

emerging devices and diagnostics while supporting health innovators here in Colorado and across the U.S.

Multi-Cancer Early Detection (MCED) Screening Coverage Act

CBSA's Position: Support

CBSA supports policies that improve patient access to health innovation. In 2020, Senator Michael Bennet introduced the Medicare Multi-Cancer Early Detection (MCED) Screening Coverage Act. The legislation provides a pathway for Medicare coverage of screening tests that can detect multiple types of cancer before symptoms develop. Early detection saves lives and reduces healthcare system costs.

MCED legislation has continued to gain momentum, but it has not yet made it over the finish line. It was reintroduced in the House in March of 2023 (H.R.2407) and in the Senate in June of 2023 (S.2085). Senator Bennet is once again championing this issue as an original cosponsor of the Senate bill.

The bipartisan legislation has significant impacts and delivers hope to patients. Multi-cancer early detection tests have the potential to be among the most important advances in the War on Cancer in our lifetimes. The legislation helps ensure that Medicare beneficiaries have timely access to these important tests.

Colorado Cosponsors: Sen. Michael Bennet (D-CO, original cosponsor), Sen. John Hickenlooper (D-CO); Rep. Jason Crow (D-CO-6), Rep. Joe Neguse (D-CO-2), Rep. Yadira Caraveo (D-CO-8), Rep. Diana DeGette (D-CO-1), Rep. Brittany Pettersen (D-CO-7)

CBSA position and engagement: CBSA has supported MCED legislation since its initial introduction in 2020. CBSA applauds Senator Bennet for his leadership on this legislation that improves patient access to leading-edge cancer diagnostics developed by America's health innovators and approved by the FDA and has urged Congress to move ahead with this critical legislation. CBSA also applauds Sen. Hickenlooper and Reps. Crow, Neguse, Caraveo, DeGette, and Pettersen for signing on as cosponsors as well. In November of 2023, MCED legislation hit a major milestone by earning the support of a bipartisan majority in both the House and Senate, including the support of the Senate Finance Committee chair, Sen. Ron Wyden (D-OR). MCED legislation continues to be a priority and CBSA and national partners will continue to advocate for it in 2024 so that senior can gain access to the latest cancer detection tools.

Help Ensure Lower Patient (HELP) Copays Act

CBSA's Position: Support

On February 6, 2023, the Help Ensure Lower Patient (HELP) Copays Act (H.R.830) was reintroduced in the U.S. House of Representatives by Representative Earl "Buddy" Carter (R-GA-1) and referred to the House Committee on Energy and Commerce. This bipartisan legislation would require health insurance plans regulated by the federal government to count the value of copay assistance for covered prescription drugs toward patients' cost-sharing obligations (i.e., deductible and out-of-pocket maximum) and would end an insurer and pharmacy benefit manager (PBM) practice classifying certain medications as "non-essential" to avoid out-of-pocket maximums.

Colorado Cosponsors: Rep. Diana DeGette (D-CO-1, original cosponsor), Rep. Joe Neguse (D-CO-2), Rep. Brittany Pettersen (D-CO-7), Rep. Jason Crow (D-CO-6)

CBSA position and engagement: CBSA supports the HELP Copays Act because copay accumulator programs harm patients by negating the longer-term benefits of copay assistance programs, which are designed to help patients by lowering the amount they have to pay out of their own pocket before their insurance benefits kick in. Copay accumulator programs force patients to incur their plans' full out-of-pocket costs later, because, once they have exhausted copay assistance from third parties, patients are

still on the hook for their entire deductible or out-of-pocket maximum before they can access insurance benefits. CBSA has thanked Representative Diana DeGette (D-CO-1) for serving as an original cosponsor of this important bill and discussed the importance of addressing copay accumulator programs with members of Colorado's Congressional delegation.

Following a U.S. District Court for the District of Columbia decision that struck down a rule that allowed health insurers to not count copay assistance towards a beneficiary's out-of-pocket costs, four sponsors/cosponsors of the HELP Copays Act, including Rep. DeGette, circulated a letter expressing disappointment with HHS' decision to appeal the court's decision and urging them to work quickly to issue a notice reaffirming the 2020 final rule that health plans must count copay assistance toward the patient's maximum annual limitation on cost sharing for drugs that do not have a medically appropriate generic equivalent available. Forty-eight members of the U.S. House of Representatives, including Rep. Pettersen and Rep. Crow, signed onto the letter, which was submitted on December 11, 2023.

PBM Reform

CBSA's Position: Support

Pharmacy benefit managers (PBMs) have been described as the "target of the year" on Capitol Hill, with scrutiny of PBMs and PBM reform efforts garnering bipartisan support. When looking at lobbying spending, legislation related to PBMs has been the most heavily lobbied in 2023. That's partly because lawmakers have introduced over thirty separate bills aimed at reforming PBMs so far in the 118th Congress. Many of those bills have been incorporated into broader legislative packages considered by committees in both chambers. The PBM reform bills address spread pricing, delinking, transparency and reporting requirements, and more.

On December 11, 2023, the House passed the Lower Costs, More Transparency Act (H.R.5378) by a bipartisan vote of 320-71. This was the first PBM reform bill to pass a full chamber this Congress. The bill would require PBMs to disclose drug rebates and discounts. The bill is not expected to pass the Senate in its current form, but some provisions and policies could ultimately pass the Senate. Earlier in December, the House Energy & Commerce Committee advanced several PBM-related bills, including the Protecting Patients Against PBM Abuses Act (H.R.2880), which includes PBM transparency requirements, and the Medicare PBM Accountability Act (H.R.5385), which would enhance PBM reporting requirements.

CBSA position and engagement: CBSA supports PBM reform efforts and has spoken to members of Colorado's Congressional delegation about the need to address PBM practices. On July 12, 2023, CBSA sent letters to Senator Michael Bennet and Senator John Hickenlooper encouraging them to cosponsor the Patients Before Middlemen (PBM) Act (S.1967), which would de-link PBM revenues from drug prices for Medicare Part D beneficiaries, eliminate one of the most egregious flaws in the U.S. prescription drug pricing system—the ability of PBMs to favor higher-priced drugs. When CBSA's President & CEO Elyse Blazevich represented the Colorado life sciences community in Washington, D.C. at the 2023 We Work For Health Healthcare Summit, she discussed a number of bills that have been introduced as part of Congress' push to achieve PBM reform. CBSA will continue to advocate for PBM reform legislation that will help fix a broken system and make medications more affordable for patients.

Optimizing Research Progress Hope and New Cures Act (ORPHAN Cures Act)

CBSA's Position: TBD

The Optimizing Research Progress Hope and New Cures Act (ORPHAN Cures Act), which was introduced in the House in September of 2023 (H.R.5539) and in the Senate in October of 2023 (S.3131), is aimed at boosting rare disease drug development to ensure patients have access to innovative therapies. Orphan drugs are drugs that target rare diseases, which are defined as diseases that affect fewer than 200,000 people in the U.S. Because orphan drugs benefit small patient populations, incentives to invest in these treatments are limited due to the inherent risk of such investments.

The Inflation Reduction Act (IRA) that was signed by President Biden in August 2022 currently exempts orphan drugs from government price negotiations/caps – but only if the drugs are approved for a single indication. This ultimately means drug manufacturers are disincentivized to test whether an orphan product can treat other indications. If enacted, the ORPHAN Cures Act would support existing incentives and boost research into new treatments by incentivizing research in follow-on indications, thus bringing hope to the 30 million Americans currently suffering from any of more than 7,000 rare diseases. Additionally, the bill would incentivize critical follow-on investment into rare disease drug development.

Colorado Cosponsors: None

CBSA position and engagement: CBSA has significant concerns about the IRA's impact on patient access and medical innovation, and has repeatedly spoken to members of Colorado's Congressional delegation about those concerns, but CBSA has not yet taken a position on the ORPHAN Cures Act.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement Waiver Expansion

CBSA's Position: Oppose

The World Trade Organization (WTO) is considering expanding a Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver put in place in June of 2022 during the COVID-19 public health emergency that allowed for COVID-19 vaccines to be manufactured and exported under a compulsory license exclusively to serve the needs of developing countries. The Biden administration requested an interagency review of the proposal to expand the waiver to COVID-19 treatments and diagnostics, including an in-depth analysis from the U.S. International Trade Commission (USITC) of COVID-19 diagnostics and therapeutics to "provide information on market dynamics to help inform the discussion around supply and demand, price points, the relationship between testing and treating, and production and access."

As part of its investigation, the USITC held an all-day public hearing on March 29, 2023, and interviewed representatives from more than 120 entities through virtual meetings and fieldwork. On October 17, 2023, the USITC released a 497-page report on the proposal entitled "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities." The report delved into issues related to demand for COVID-19 diagnostics and therapeutics, delivery challenges in different countries, and the pros and cons of voluntary licenses (VLs) as opposed to compulsory licenses (CLs). Although the report stopped short of making any recommendations, BIO's Chief Policy Officer stated: "This report reiterates our stance that there is no credible evidence supporting the need for an expanded TRIPs waiver — or other expansions that would hinder critical intellectual property protections within the biomedical field — to increase global access to COVID-19 diagnostics and therapeutics." At the end of the day, though, the backdrop for the report is that the waning of the COVID-19 pandemic has meant that demand for the COVID-19 diagnostics and therapeutics at issue has also declined.

CBSA position and engagement: CBSA opposes the TRIPS waiver and any expansion of it that further erodes IP protections for life sciences innovations. CBSA has spoken to members of Colorado's Congressional delegation about how expanding the waiver would be ineffective and counterproductive in accelerating the global response to the COVID-19 pandemic and would perpetuate a harmful precedent set by waiving IP protections for the life sciences sector. IP is the foundation of our ecosystem; IP protections are essential to the technology transfer process in life sciences that leads from lab invention to life-saving commercial products.

CBSA applauds Representative Brittany Pettersen (D-CO-7) for signing onto a letter on December 20, 2023, along with eighteen other House Democrats, urging the U.S. Trade Representative to oppose efforts by the WTO to expand the IP waiver for COVID-19 vaccines to also include diagnostics and therapeutics because it could stifle domestic biomedical innovation.

Medicaid Drug Rebate Program Proposed Rule

CBSA's Position: Oppose

On May 23, 2023, CMS issued a proposed rule entitled *Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program*. The proposed rule seeks to reinterpret the Medicaid "Best Price" calculation for the Medicaid Drug Rebate Program (MDRP), drastically altering the program. The proposal would make manufacturers aggregate, or "stack," all discounts and rebates received throughout their supply chain when determining the "Best Price," which establishes what state Medicaid programs pay for drugs. CMS' proposed modifications to the MDRP also include changes to the definition of "Covered Outpatient Drug" (subject to the rebate program) and a new survey authority requiring manufacturers to disclose significant quantities of information. CMS has indicated that it plans to finalize the MDRP rule in June 2024.

CBSA position and engagement: CBSA opposes this proposed rule and, along with other members of the Council of State Bioscience Associations (CSBA), submitted a letter to CMS on October 19, 2023, expressing our deep concerns with it. We are concerned that this proposed rule would place a substantial burden on biotechnology manufacturers and negatively impact patients, healthcare programs such as the 340B program, and the commercial market, leading to increased healthcare expenses and out-of-pocket costs for patients.

On October 27, 2023, Senate Finance Committee Ranking Member Mike Crapo (R-ID) and ten other Republican members of the Senate Finance Committee sent a letter to CMS echoing many of our concerns. The press release highlights that the Senators urge CMS "to abandon proposals that risk patient access to cutting-edge prescription drugs." The Senators' letter emphasizes that the rule change is unworkable, faces "legal headwinds," risks disrupting patient care, and would not achieve desired savings on drug coverage.

New Approach to Mergers & Acquisitions (M&A)

CBSA's Position: Oppose

The Federal Trade Commission (FTC) and Department of Justice (DOJ) have outlined a new approach to antitrust enforcement for mergers & acquisitions (M&A) that represents a drastic shift in U.S. competition policy, which will directly undermine the life sciences ecosystem responsible for groundbreaking cures. The FTC and DOJ released draft Merger Guidelines on July 19, 2023, and then finalized new 2023 Merger Guidelines on December 18, 2023. In addition, the FTC released new rules for premerger disclosures and review on June 29, 2023.

The agencies' guidelines and recent approach toward M&A broadly suggest that even theoretical and speculative impacts on competition could be enough to deem a life science deal unlawful – an unprecedented expansion of authority that extends beyond the agencies' remit.

CBSA position and engagement: CBSA opposes this new approach to M&A and joined a newly-formed coalition called the Partnership for U.S. Life Science Ecosystem (PULSE), dedicated to raising awareness about the unique life sciences ecosystem and the importance of M&A in leveraging efficiency and experience across companies of all sizes, that was formed in the fall of 2023 and publicly launched on October 3, 2023. PULSE is helping to advance a national dialogue focused on fostering innovation across the life sciences while supporting a competitive U.S. market that advances next generation treatments and cures for patients.

Following the release of the finalized 2023 Merger Guidelines on December 18, 2023, PULSE put out a statement expressing significant concerns about the agencies' antitrust agenda and the implications for pro-innovation M&A that are designed to bring new treatments and cures to market with speed and precision. The latest guidelines introduce unclear standards of competition that create uncertainty, inconsistent application, and potential impediments to pro-innovation mergers.

PULSE is continuing to urge the FTC and DOJ to take a balanced, bipartisan approach to M&A that allows life sciences companies of all sizes to deliver new treatments and cures more effectively and efficiently, acknowledging the unique and differentiated market dynamics that drive the life science ecosystem.

Looking Ahead to 2024

As CBSA's Policy + Advocacy team prepares for the 2024 Colorado legislative session, we plan to continue our collaborations with partners and policymakers focused around CBSA's Policy Priorities. The Colorado legislature and Polis administration continue to show that they're not afraid to lead the country on issues that affect the life sciences ecosystem and the patients it serves, so CBSA's role as the voice of Colorado's life sciences ecosystem is more important than ever. Following the passage of SB23-066 reauthorizing the Advanced Industries Accelerator Grant Programs, CBSA plans to bring a follow-up bill in 2024 to extend full funding for these critically important grant programs until 2034. In addition, CBSA will continue to advance its federal Policy Priorities by working with national partners to build on the momentum generated by this year's progress going into the second half of the 118th Congress.