2022 CBSA Policy + Advocacy Report

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

Colorado Life Sciences Ecosystem:

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

In 2022, CBSA collaborated with partners and policymakers to promote and champion state and federal legislation that would advance Colorado's health innovation ecosystem. Throughout the year, the Policy + Advocacy team built coalitions to support policies that would make a meaningful impact on patients and also counter legislation that would make it harder for life sciences companies to advance new technologies and treatments for patients.

CBSA could not lead this work without our members, Board of Directors, the Policy Committee, and the lobbying team of 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.

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Colorado BioScience Association

2022 Colorado Legislative Session – End-of-Session Report

The Second Regular Session of the 73rd General Assembly marked the fourth 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 2022 legislative session was no exception.

During the 2022 legislative session, Colorado BioScience Association (CBSA) weighed and supported three bills; opposed two bills; and reviewed, discussed, and worked on countless more. This report provides an overview of several areas of engagement focused on CBSA's Policy Priorities:

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

Renewing and Expanding the Advanced Industries Investment Tax Credit (HB22-1149)

The Advanced Industries Investment Tax Credit (HB22-1149) supports access to capital for companies in Colorado's designated Advanced Industries, including life sciences. CBSA proudly led advocacy efforts on its reauthorization. CBSA's Policy + Advocacy team worked closely with the Office of Economic Development and International Trade (OEDIT), advanced industries partners, and bill sponsors on HB22-1149. The legislation:

- Reauthorized the Advanced Industries Investment Tax Credit for four years
- Increased the funds available from $750,000 to $4 million, a 433% increase
- Raised the investment cap from $50,000 per investor to $100,000 per investor, a 100% increase.

The program delivers ROI to the state by supporting growth companies developing life-saving technologies. Through the Advanced Industries Investment Tax Credit Program, 24 bioscience companies have received $7,164,075 in investments.

CBSA position and engagement: CBSA led the work to reauthorize and expand the tax credit, in partnership with the Office of Economic Development and International Trade (OEDIT) and Advanced Industry Partners throughout the entire bill process.

Outcome: HB22-1149 passed and was signed by Governor Polis on June 3, 2022. This reauthorization is a win for the advanced industries in Colorado. The program demonstrates a significant return on investment, delivering value back to the state through company creation and high-paying jobs. The program is critical to CBSA's life sciences community because it generates new investment in growth companies working to save and change lives around the world.

Expansion of Experiential Learning (SB22-140)

CBSA supported SB22-140, which impacts businesses, workers, and learners, and aligns the talent development ecosystem to maximize economic impact. For businesses, the bill is designed to reduce barriers to the adoption of quality work-based learning models and shore up their talent pipeline, including apprenticeship programs for adults and youth through the establishment of a $3 million state-run fund. For learners and workers, the bill addresses systemic barriers to accessing quality work-

based learning and employment through the creation of programs that close the digital divide and eliminate language barriers.

CBSA position and engagement: CBSA supported SB22-140 and workforce development initiatives to create a talent pipeline for the growing life sciences ecosystem.

Outcome: SB22-140 passed and was signed by the Governor on June 3, 2022.

Colorado Rare Disease Advisory Council (SB22-186)

SB22-186 created the Colorado Rare Disease Advisory Council. The Advisory Council informs state agencies, the public, and the legislature about rare diseases and makes recommendations concerning the needs of Coloradans living with rare diseases and their medical providers and caregivers. The council's 12 voting members include, in part, a researcher, a geneticist, a physician, a pharmacist, a person living with a rare disease, and a representative from the biotechnology or pharmaceutical industry.

CBSA position and engagement: CBSA supported SB22-186. The Advisory Council includes a representative from the biotechnology or pharmaceutical industry, who helps ensure that the industry has a voice and perspective on a range of policy decisions made within the state that are impactful to manufacturers of therapies developed to treat rare diseases.

Outcome: SB22-186 passed and was signed by Governor Polis on June 8, 2022. CBSA solicited recommendations from our membership for candidates for the biotechnology or pharmaceutical industry representative and submitted a letter endorsing and recommending two candidates to the bill sponsors. Ultimately, one candidate CBSA submitted was selected for the Advisory Council.

Consumer Right to Repair Powered Wheelchairs (HB22-1031)

HB22-1031 requires a manufacturer to provide parts, embedded software, firmware, tools, or documentation, such as diagnostic, maintenance, or repair manuals, diagrams, or similar information, to independent repair providers and owners of the manufacturer's powered wheelchairs to allow an independent repair provider or owner to conduct diagnostic, maintenance, or repair services on the owner's powered wheelchair. A manufacturer's failure to comply with the requirement is a deceptive trade practice. In complying with the requirement to provide these resources, a manufacturer need not divulge any trade secrets to independent repair providers and owners.

CBSA position and engagement: CBSA opposed and actively engaged on HB22-1031. CBSA opposed the legislation for several reasons, including the precedent-setting nature of the bill, existing federal oversight of medical devices, and patient risk. CBSA's concerns were expressed in a letter that was sent to the bill's primary sponsor, Rep. Brianna Titone.

Outcome: HB22-1031 passed the legislature and was signed by the Governor on June 2, 2022. The final bill included an amendment which stated that manufacturers are not liable for faulty or improper repairs. CBSA advocated for this amendment and was pleased it was ultimately included.

Public Protections from Toxic Air Contaminants (HB22-1244)

HB22-1244 clarified that the Colorado Department of Public Health & Environment (CDPHE) has the authority to regulate air toxins more stringently than the U.S. Environmental Protection Agency (EPA). With this legislation, CDPHE is required to establish a toxic air contaminant monitoring program which will ultimately determine the concentration of contaminants in the state's ambient air using six monitoring stations that would be placed throughout the state.

CBSA position and engagement: CBSA opposed and actively testified against HB22-1244 to express concerns. Ethylene Oxide is already heavily regulated by multiple federal agencies to ensure the chemical is safely used for the sterilization of critical life-saving medical devices and other medical products.

Outcome: HB22-1244 passed and was signed by the Governor on June 2, 2022. The bill ultimately included amendments narrowing its scope and the proponents offered additional conceptual changes. CBSA remains engaged in CDPHE's monitoring and assessment program.

Perfluoroalkyl And Polyfluoroalkyl Chemicals (HB22-1345)

HB22-1345 prohibits the sale or distribution of certain consumer product categories that contain intentionally added perfluoroalkyl and polyfluoroalkyl chemicals (PFAS chemicals), commonly known as "forever chemicals," beginning January 1, 2024. The list of prohibited product categories then expands in 2025 and 2027.

PFAS chemicals are a group of thousands of chemical compounds with varying characteristics, properties, and environmental and safety profiles. One such compound is fluoropolymer, which has applications across the medical device industry. As originally introduced, the bill would have impacted medical products and packaging.

CBSA position and engagement: CBSA took an "amend" position on HB22-1345 and actively worked with bill sponsors on amendments that would exempt all FDA-regulated drugs, medical devices, biologics, or diagnostics and packaging used for these products. An exemption was incorporated based on CBSA's efforts.

Outcome: HB22-1345 passed and was signed by the Governor on June 3, 2022. The final bill included an exemption for "drugs, medical devices, biologics, or diagnostics approved or authorized by the federal Food and Drug Administration or the federal Department of Agriculture."

Pharmacy Benefit Manager Prohibited Practices (HB22-1122)

HB22-1122 created the Colorado 340B Prescription Drug Program Anti-Discrimination Act, which prohibits health insurers, pharmacy benefit managers (PBMs), and other third-party payers from discriminating against entities, including pharmacies, participating in the federal 340B drug pricing program. The bill expanded the definition of a "covered entity" to include contract pharmacies and prohibits PBMs from requiring pharmacies to use a modifier that identifies whether their reimbursement claim is for a 340B drug.

CBSA position and engagement: CBSA took an "amend" position on HB22-1122 due to concerns with the "covered entity" definition and the modifier prohibition. The bill's proponents agreed to changes to the "covered entity" definition but not to the claims modifier prohibition. CBSA submitted a letter expressing its opposition to the claims modifier prohibition.

Outcome: HB22-1122 passed out of the Senate Appropriations Committee with an amendment that entirely removed section one of the bill. Section two, which contains the modifier prohibition, was not impacted. The bill passed on second reading with an amendment to address a transcription error that occurred during the Appropriations hearing. HB22-1122 was ultimately signed by the Governor on June 2, 2022.

Coverage Requirements for Healthcare Products (HB22-1370)

HB22-1370 requires each health insurance carrier that offers an individual or small group health benefit plan to offer at least 25% of its health benefit plans on the Colorado health benefit

exchange and at least 25% of its plans not on the exchange as copayment-only payment structures for all prescription drug cost tiers. Starting in 2024, a carrier or, if a carrier uses a PBM, a PBM is prohibited from modifying or applying a modification to the current prescription drug formulary during the current plan year.

The bill repealed and reenacted the current requirements for step therapy and requires a carrier to use clinical review criteria to establish the step-therapy protocol. The bill requires the Commissioner of Insurance to promulgate rules to implement prescription drug pass-through requirements for carriers. Each carrier or PBM is required to report annually specified prescription drug rebate information to the Commissioner. Additionally, the bill requires the Colorado Department of Health Care Policy and Financing (HCPF), in collaboration with the administrator of the all-payer claims database (APCD), to conduct an annual analysis of the prescription drug rebates received in the previous calendar year, by carrier and prescription drug tier, and make the analysis available to the public.

CBSA position and engagement: CBSA took an "amend" position on HB22-1370 because it includes several reforms that would improve affordability of and access to prescription medicines, but it falls short of addressing the misaligned incentives in the current rebate system and perpetuates fundamental mis-incentives with respect to plan design.

Outcome: HB22-1370 passed and was signed by the Governor on May 18, 2022.

The State Budget

Due to this year's budget and the state's focus on spending federal stimulus dollars, the Second Regular Session of the 73rd General Assembly created five cash funds and placed the remaining $2.64 billion into those cash funds to be spent in the 2022 or later legislative sessions.

The General Assembly spent about $2.33 billion out of the $2.64 billion available for spending among the five cash funds. Those cash funds include:

- Revenue Loss Restoration Cash Fund ($990 million),
- Economy Recovery and Relief Cash Fund ($697 million),
- Behavioral and Mental Health Cash Fund ($450 million),
- Affordable Housing and Home Ownership Cash Fund ($400 million),
- Workers, Employers, and Workforce Centers Cash Fund ($95 million).

The cashflow continues to give Colorado one of the strongest state budgets to date. CBSA will continue to work with leadership at the State to advocate for important funding of programs and spending.

2022 Federal Policy Engagement

In 2022, CBSA worked tirelessly 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 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, MDMA, BIO, 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.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are critical sources of non-dilutive financing for early-stage life sciences companies in Colorado. The programs fund scientific excellence and technological innovation through the investment of federal research dollars in critical American priorities. They also contribute to a strong economy at the federal and state level. Most importantly, they advance breakthroughs that reinforce America's global leadership in science and technology.

The programs have had a significant impact on Colorado's life sciences growth. Our state has received more than 6,035 awards totaling more than $2.76 billion dollars since the programs began.

CBSA position and engagement: CBSA strongly advocated for the reauthorization of the SBIR and STTR Programs. Earlier in the year, without action by Congress, the programs would have expired on September 30, 2022.

Outcome: As part of a nationwide effort led by our partners at BIO, CBSA worked with a national effort to mobilize Colorado's life sciences community to ensure the SBIR and STTR programs were reauthorized. CBSA celebrated a policy victory for Colorado's life sciences community and America's innovators, scientists, and entrepreneurs when Congress reauthorized these critical SBIR/STTR programs.

User Fee Program Reauthorization

CBSA and our national partners supported the critically important reauthorization of the U.S. Food and Drug Administration's (FDA) prescription drug, generic drug, biosimilar, and medical device user fee agreements. The FDA collects fees from companies that produce certain products, such as drugs and medical devices, and from some other entities, such as certain accreditation and certification bodies. These fees are called "user fees." Federal law authorizes the FDA to collect user fees to supplement the annual funding that Congress provides for the agency. User fees help the FDA fulfill its mission of protecting the public health, and also facilitate timely availability of innovative FDA-regulated products without compromising the agency's commitment to scientific integrity, public health, regulatory standards, patient safety, and transparency. User fees also help the FDA ensure predictable timelines for its review process by providing funding for needed staffing to more expeditiously review products without

compromising the agency's commitment to scientific integrity, public health, regulatory standards, patient safety, and transparency. The fees also directly fund other key activities, including helping ensure the safety of patients enrolled in clinical trials.

For most major user fee programs, the FDA and industry negotiate agreements on user fees every five years. As a part of this process, companies within the regulated industry agree to the collection of fees in exchange for commitments from the FDA to meet certain performance goals. To implement the agreements for the medical product user fees, Congress passes reauthorization legislation that enables the FDA to continue to collect user fees.

CBSA position and engagement: CBSA strongly advocated for the reauthorization of the FDA User Fee Programs. Earlier in the year, without action by Congress, the programs would have expired on September 30, 2022. As part of a nationwide effort led by our partners at BIO, CBSA worked to mobilize Colorado's life sciences community to ensure the FDA User Fee Programs were reauthorized.

Outcome and continued engagement: CBSA celebrated a policy victory for Colorado's life sciences community when Congress reauthorized vital prescription and generic drug, biosimilar, and medical device User Fee programs for another five years through the continuing resolution (CR). CBSA supported and advocated for the renewal of the critically important User Fee Agreements, including the Pharmaceutical Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFA).

While CBSA applauded Congress for including the user fee reauthorization in the CR, it is worth noting that the bill lacked many riders supported by the FDA, national partners, and CBSA. These riders include the long-anticipated Verifying Accurate Leading-Edge In Vitro Clinical Tests (IVCTs) Development (VALID) Act, Predetermined Change Control Plans (PCCP), and other important policy riders.

President Biden signed a $1.7 trillion omnibus spending package into law on December 29, 2022, but this bill also left out some of these key riders, including the VALID Act once again. However, the omnibus spending package did include some policies originally considered during User Fee Agreement negotiations: the FDA will be tasked with developing Accelerated Approval (AA) reforms and there are various provisions related to clinical trial modernization and diversity, "platform" technologies for drugs and vaccines, and a new review pathway for designating advanced manufacturing technologies. CBSA will continue to advocate for important riders as Congress evaluates avenues to move them forward in 2023.

Engagement on the WTO TRIPS Waiver

During the World Trade Organization (WTO) 12th Ministerial Conference in June 2022, WTO Member States agreed on a decision to waive certain intellectual property provisions of the Trade-Relations Aspects of Intellectual Property Rights (TRIPS) Agreement, altering aspects of existing rules regarding the ability to issue compulsory licenses on patents covering COVID-19 vaccines. On December 6, 2022, the Office of the U.S. Trade Representative (USTR) announced support for extending the deadline to decide whether the WTO's intellectual property (IP) waiver should be expanded to COVID treatments and diagnostics. The Biden administration will conclude its interagency review of the proposed expanded waiver, including an in-depth analysis from the U.S. International Trade Commission (USITC).

CBSA position and engagement: CBSA opposes the TRIPS waiver and any form of expansion to COVID-19 therapeutics or diagnostics. Expanding the waiver would be ineffective and counterproductive in accelerating the global response to the pandemic.

Outcome and continued engagement: CBSA continues to monitor activity around the TRIPS waiver, including at least one upcoming hearing following the USITC's Federal Register notice to launch its investigation. CBSA will continue to speak out against the TRIPS waiver due to the harmful precedent set

by waiving IP protections for the life sciences sector. Intellectual property is the foundation of our sector. IP protections are essential to the technology transfer process in life sciences that leads from lab invention to life-saving commercial products.

CBSA advocates for a supportive, pro-innovation business climate for life sciences. We support proposals to strengthen the ability of patent owners to defend their inventions and businesses against infringement.

Multi-Cancer Early Detection Screening Coverage Act (MCED)

CBSA supports policies that improve patient access to health innovation. In 2020, Senator Michael Bennet, along with Senators Mike Crapo (R-Idaho), Ben Cardin (D-Maryland), and Tim Scott (R-South Carolina), introduced H.R.1946/S.1873, Medicare Multi-Cancer Early Detection Screening Coverage Act (MCED). The bipartisan 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.

Senator Bennet's MCED legislation continued to gain momentum in 2022 and was co-sponsored by Senator Hickenlooper this June. The bill is co-sponsored by a bipartisan majority in both the Senate, with 54 members of the Senate sponsoring, and an impressive 257 members in the House of Representatives, including Representative Crow, Representative DeGette, Representative Neguse, and Representative Perlmutter.

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. CBSA appreciates the Senator's continued leadership and support of our life sciences ecosystem.

CBSA position and engagement: CBSA is supportive of MCED and has been since its initial introduction in 2020. CBSA applauds Senator Bennet for his leadership on 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.

Outcome and continued engagement: MCED did not make it into the 2023 Omnibus Appropriations Bill signed into law on December 29, 2022, but this legislation continues to be a priority and CBSA and national partners will continue to advocate for it in 2023.

Inflation Reduction Act

On August 16, 2022, President Biden signed the Inflation Reduction Act, a bill aimed at addressing high inflationary costs. The massive bill increases corporate taxes and includes measures designed to reduce greenhouse gas emissions. CBSA and our national partners lobbied against provisions in the new law that allow the federal government to negotiate prescription drug costs.

The sweeping legislation imposes government price setting in Medicare, a decision that could chill investment in next-generation treatments and cures for patients in need. In fact, according to a Vital Transformation study, price setting will impact jobs in our industry, including here in Colorado. Research indicates the legislation will likely lead to the loss of over 590,000 jobs across the country, dealing a devastating blow to our economy and to families everywhere. The legislation could lead to a loss of 1,264 direct biopharma jobs in Colorado and over 6,700 biopharma-supported jobs in our state. That translates to $1,645 million in lost biopharma-supported output.

CBSA position and engagement: As part of a nationwide effort led by our partners at BIO, CBSA worked to mobilize Colorado's life sciences community to combat aspects of the Inflation Reduction Act.

Outcome and continued engagement: The legislation passed and while CBSA is disappointed with the outcome, CBSA thanks our community for speaking out against government price setting on prescription drugs. We will continue to advocate for policies that protect patient access and medical innovation.

Transitional Coverage for Emerging Technologies (TCET)

The Centers for Medicare & Medicaid Services (CMS) are currently working to develop a new rule that could provide Medicare patients faster access to innovative, lifesaving, and life-enhancing medical devices and diagnostics. This CMS initiative is called the Transitional Coverage for Emerging Technologies (TCET) rule. It would modernize Medicare for patients and create an alternative, expedited pathway to provide coverage and payment for emerging devices and diagnostics. Transitional coverage for these technologies would give Medicare patients more healthcare options and would support health innovators here in Colorado and across the U.S.

CBSA position and engagement: CBSA urges CMS to adopt this rule. It balances access to innovative technologies with patient protection, while also guaranteeing coverage is flexible, predictable, and evidence-based. This is an important opportunity for our industry and CMS to modernize the coverage process, allowing swifter access to innovative, lifesaving technologies and therapies for Medicare beneficiaries. A recent survey led by the Stanford Byers Center for Biodesign identified the current lag time is anywhere from two-and-one-half years to nearly eight years before full patient access to new technologies, due to adoption of applicable coding, coverage, and payment changes. This rule would help speed up this timeline.

Outcome and continued engagement: While there is no final outcome to report yet, CBSA is working with national partners at Advanced Medical Technology Association (AdvaMed) and Medical Device Manufacturers Association (MDMA) to express our support for CMS to issue a proposed rule.

CBSA encourages CMS to move quickly to help improve the lives of patients by issuing the TCET proposed rule in 2023.

The PASTEUR Act

The Pioneering Antimicrobial Subscriptions to End Up-Surging Resistance Act (PASTEUR Act) would establish an outcomes and value-based alternative payment model where the federal government pays companies set amounts for critical-need antimicrobials based on the treatment's value to public health. This model would be designed to provide a predictable return for companies, enabling them to continue innovating, while incentivizing investments to support a more robust R&D pipeline.

The legislation, introduced by Senator Michael Bennet and Senator Todd Young [R-Indiana], gained significant momentum in 2022, obtaining 70 bipartisan co-sponsors across the House and Senate bills, including Senator Hickenlooper (who signed on in mid-December) and Representative DeGette. In fact, its principles are supported by Health and Human Services (HHS) Secretary Xavier Becerra.

The passage of the PASTEUR Act would create new incentives through a subscription reimbursement model where the federal government would enter a subscription contract with a drug developer if the developer received a 'critical need antimicrobial' designation.

CBSA position and engagement: CBSA supports the PASTEUR Act and urged Congress to pass this important legislation during the "lame-duck" session. CBSA applauds Colorado U.S. Senator Michael Bennet for serving as the sponsor of this key legislation in the Senate and thanks CO U.S. Representative Diana DeGette for co-sponsoring in the House. CBSA's outreach to date has included:

- Partnering with national partners on outreach.
- Urging the Colorado Congressional Delegation to engage and join on as a co-sponsor on this important legislation.

- Offering support and feedback to Senator Bennet's office with a comment letter that provided recommendations on areas of improvement to enhance the critical legislation.

Outcome and continued engagement: The PASTEUR Act did not make it into the 2023 Omnibus Appropriations Bill signed into law on December 29, 2022, but the omnibus bill did include several provisions related to antimicrobial resistance (AMR): Antifungal Research and Development (commonly known as the FORWARD Act), Advancing Qualified Infectious Disease Product Innovation (from the PREVENT Pandemics Act), and CDC Laboratory Capacity. 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.

Looking Ahead to 2023

As CBSA's Policy + Advocacy team prepares for the 2023 Colorado legislative session, we plan to continue our collaborations with partners and policymakers focused around CBSA's Policy Priorities. Following CBSA's successful efforts to reauthorize and expand the Advanced Industries Investment Tax Credit Program, CBSA will turn its attention to extending the Advanced Industries Accelerator Grant Program, which is a critical source of non-dilutive funding for Colorado life sciences companies. 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 118th Congress.