

# 20 YEARS OF IMPACT

Public Policy Guide 2023-2024

## The Arizona **Bioindustry Association**

(AZBio) is the only organization exclusively focused on Arizona's life science and healthcare industry.

### **Our Vision of the Future**

Arizona is a top-10 life science state.

### Our Mission

AZBio supports the needs of Arizona's growing Life Science Ecosystem.

### AZBio Leadership

understands that while focus is important, action is essential. AZBio's leaders identify opportunities and then execute to leverage them.

### AZBio Membership

includes patient advocacy organizations, life science innovators, educators, healthcare partners, communities and leading business organizations.

### **AZBio Programs**

are designed to connect and engage our community, foster collaboration, and to attract and conserve precious resources.

### AZBio Communicates

on AZBio.org, via IN THE LOOP, by maintaining the statewide events calendar, and connects talent to opportunity at the AZBio Career Center.

### **AZBio Creates Bottom Line Impact**

AZBio Members who utilized AZBio's purchasing contracts saved over \$4 Million dollars together in 2022.

### **AZBio Supports Economic Development**

investors, real estate developers, site selectors, economic development agencies and our elected leaders trust AZBio to provide the information they need to retain and grow the industry sector.

### AZBio is active at the state and national level

working to advance innovation and to ensure that the value delivered from life-changing and lifesaving innovation benefits people in Arizona and around the world.

### AZBio is Committed

to making Arizona a Top-10 life science State and we invite you to join us.

Learn more at AZBio.org

### AZBio board members

MARA ASPINALL, Co-Founder and Managing Director of BlueStone Ventures

### KIRAN AVANCHA, PhD, R.Ph, CCRP

Chief Innovation Officer, HonorHealth: Cofounder & CEO, PriZm Therapeutics

### JENNIFER K. BARTON, PhD

Director, BIO5 Institute, The University of Arizona

### PETER BAWIN, MBA

Global VP, Commercial Life Sciences CooperSurgical

### **TONY CALDWEL**

Partner, Snell & Wilmer

#### **CARON DAVIS**

Vice President Business Development, City of Hope Phoenix; Vice President Business Development and Strategic Alliances, TGen

### **DAVID A. DEXTER**

General Manager, Joint Ventures, for the Quest Diagnostics Operations in Arizona; President & CEO, Sonora Quest Laboratories, LLC; President & CEO, Laboratory Sciences of Arizona, LLC

### THOMAS EISIMINGER, JR,

President & CEO Regenesis Biomedical, Inc.

### **BRANDY FLORES**

Senior Manager Alliance Development (AZ, CA, NV), Pfizer

### **RAFAEL FONSECA, MD**

Chief Innovation Officer Consultant, Division of Hematology/ Oncology; Getz Family Professor of Cancer; Distinguished Mayo Investigator, Mayo Clinic

### **RENAE FRANZ**

Principal, Acacia Consultants

### **RENÉE GALÁ**

EVP and Chief Financial Officer, Jazz Pharmaceuticals

### SHANNON GROPPENBACHER

Director Healthcare Policy and Advocacy, Johnson & Johnson Healthcare Systems, Inc.

### **MARYANN GUERRA**

CEO and founder, Aesthetics Biomedical

### **JASON JARDINE**

Partner, Knobbe Martens

### DANIEL J. KASPRZYK

Co-founder, president and CEO, Symple Surgical and co-founder, president and CEO, Poba Medical

### **CATHY LANGHAM**

President & CEO, Langham Logistics

### **JEFF MORTON**

Partner, Procopio, Cory, Hargreaves & Savitch LLP

### **ELLIOTT MUFSON, PhD**

Professor of neurobiology, Barrow Neurological Institute

### STEPHEN MUNK, PhD

Deputy director, Biodesign Institute, Arizona State University

### MARY O'REILLY, PhD

Vice President, Bioscience Research Programs, Flinn Foundation

### **DAVID B. PATIENCE**

Senior Director - Head of Business Development and Corporate Development, Accelerate Diagnostics

### STEVE POTTS, PhD, MBA

Founder & CEO, Celerity Biosciences

ALEX TESSMER, MBA, Associate Director, Ideation at BD Peripheral Intervention

### **NATHAN TREMBATH**

General Manager, Phoenix, AZ, Bristol Myers Squibb

### **SANDRA WATSON**

CEO, Arizona Commerce Authority

**KYLE WESLEY, Senior Engineering** Manager, Medtronic

**CLAUDIA WHITEHEAD, Bioscience &** Healthcare Program Manager, City of Phoenix

### **AZBio officers**

### **CHAIRWOMAN:**

Kristen Swingle President & Chief Operating Officer, Critical Path Institute

#### VICE CHAIR:

Kevin Parker

Vice President, Phoenix Business Operations, Exact Sciences

### **IMMEDIATE PAST CHAIR:**

Russ Yelton President, Yelton & Associates Chair, AZAdvances Board of Trustees

### TREASURER:

Jeffrey Singleton Managing Director, Tax, EY

### **SECRETARY:**

Jeff Vallerga Executive Director, Strategic Alliances, VWR, Part of Avantor

### PRESIDENT AND CEO:

Joan Koerber-Walker Arizona Bioindustry Association (AZBio)



# MAKING LIFE BETTER

It's what AZBio members do.
AZBio helps them do it.
AZBio supporters make what we do possible.

**LEGACY LEVEL** 























**CHAIRMAN'S CIRCLE** 







### LEADERSHIP LEVEL

















































### SUSTAINING MEMBERS













































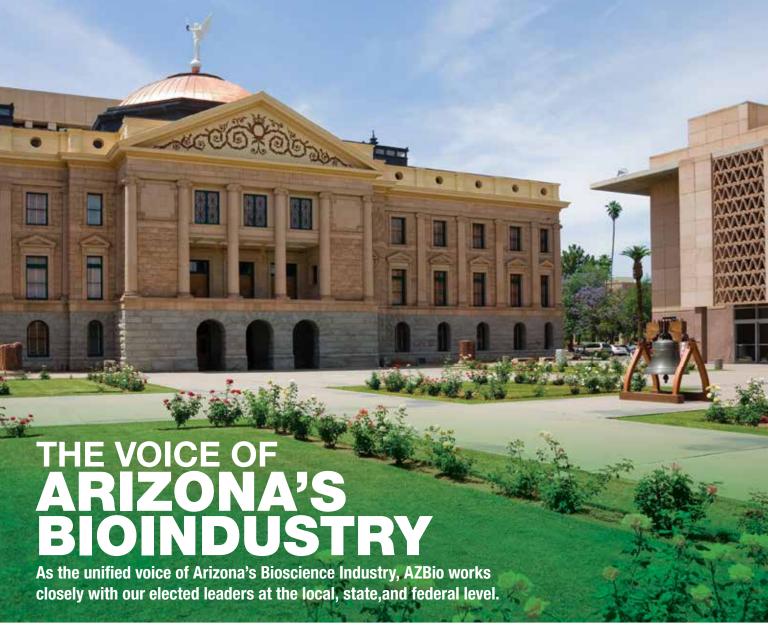












AZBio shares the timely and accurate information our elected leaders need so that they can develop and implement public policies that support the continued growth of our industry and that provide the people of Arizona with access to the life saving and life changing innovations our industry develops, discovers, and delivers, every day.

AZBio is the only organization exclusively focused on supporting the growth of Arizona's life science and healthcare sector. Dorn Policy Group is AZBio's official representative at Arizona's State Capitol. At the federal level, AZBio works with our partners at BIO, PhRMA, AdvaMed, MDMA, and other organizations on the key issues that affect our members and our industry locally, nationally, and internationally.





# PUBLIC POLICY GUIDE



### Improving lives

Arizona's life science industry is working on finding answers to global health challenges and diseases that affect people around the world as well as those that are centered in Arizona like Valley Fever. We are helping people live longer and have a higher quality of life through innovations in diagnostics, medical devices, vaccines, and therapies. And, as medical technology and information technology converge, Arizona innovators are creating solutions that detect and diagnose disease, improve outcomes, and keep us healthy.



### Increasing economic vitality

Goal: Double our economic impact by 2023. One of Arizona's largest employment sectors, the life science industry includes over 2,912 firms, wages significantly higher than state averages, and an overall economic impact of over \$38.54 Billion in 2021. Arizona's bioindustry works with our students, our educators, our innovators and our business partners to ensure that Arizona continues to benefit from the economic vitality this industry can deliver to our state.



### Reducing healthcare costs

Healthy people contribute more to our community and to our economy. By keeping more people healthy and caring for those who are not, we create a benefit that is measured in more than just dollars. Working with our healthcare partners we are committed to better outcomes, early diagnosis and treatment, cost-saving innovations, and a benefit to cost equation that continues to grow value.

## AZBio is committed to making Arizona a top-10 bioscience state.

Top tier bioscience states have mastered the 3-Ds and strike a balance between investments and results across a continuum from Discovery to Development to Delivery. Over the last decade, Arizona has made remarkable progress, but we still have gaps to bridge in order to get to the top-10.



- Discovery comes from the exploration of what might be possible. It occurs in our universities, in our private research institutes, in our private companies, and in the clinical setting. We have attracted top talent and we will need to attract more. That means more investment and support will be required from government, industry and philanthropic partners.
- Development comes next in the form of university tech transfer, translational research, industrial development, or clinical development and trials. None of this happens without capital. Development capital is increasing both from state governments and

private sources. It just is not here in Arizona at needed levels yet. This means innovators must waste time traveling to "follow the money", and sometimes relocate to receive it. Unless Arizona resolves its investment capital crisis in a meaningful way, and at bioscience scale, the benefits of our discovery investments will be realized elsewhere.

• Delivery, taking products to market and gaining market acceptance, is the last step. All the discovery and development in the world will mean little if there is not a final benefit for customers, patients, and investors. Delivery requires still higher levels of investment and a labor force that can support it. Investments in our workforce begin at the K-12 level and extend through our community college and university systems. Having a strong educational system is a prerequisite for attraction and retention of biotech companies and their employees.

To become a top-10 bioscience state, Arizona must master the 3-Ds and support our stated intentions with committed and sustained investments across Arizona's public and private sectors. When we do, we grow. If we do not, Arizona innovations will still emerge; but the benefits of increased employment and tax base will be harvested someplace else.

# INVESTING IN ARIZONA'S FUTURE



### Investing in the future

Arizona has a history of innovative public policy and of making strategic investments designed to improve the lives of Arizonans today and in the future.

20 years ago, Arizonans committed to support TGen. This served as a catalyst for the growth we see today.

In 2003, the Arizona legislature provided \$500 million to the 3 state universities for research infrastructure. In 2017, they added \$1 billion more to maintain and expand this critical resource.

Arizona's FY2022 budget funded the New Economy initiative, making strategic investments at our universities so they can prepare Arizona's workforce for today's jobs, and tomorrow's. An additional \$126 million was included in the FY2023 State Budget.

The Arizona Health Innovation Trust Fund was created in the 2022 legislative session and seeded with an initial \$100 thousand in the FY2023 State Budget. The Trust will be administered by the Arizona State Treasurer's Office (ASTO.) Once the funds in the Trust complete a 5-year maturation process, ASTO will distribute 4% of the 5-year average balance of the fund to a 501c3 nonprofit that is contracted with ASTO and meets the requirements of the statute.

AZAdvances, part of the Opportunity Through Entrepreneurship Foundation, meets these requirements and is contracted by ASTO to serve these needs.

No funding for the trust was appropriated by the Legislature in the FY24 budget cycle. It is critically important that Arizona makes additional investments into the fund in FY25 if we are ultimately to reach the \$200 million goal.

### **AZAdvances**

Based on a multi-year best practices study, AZBio and the Opportunity Through Entrepreneurship Foundation (OTEF) created AZAdvances, a nonprofit model to address the gap in early stage funding that is preventing Arizona's bioscience sector from reaching its full potential.

AZAdvances is designed to be self-supporting after achieving an initial capitalization of \$200 million into the Arizona Health Innovation Trust Fund. Until this level is reached, and has matured, \$10 million per year is needed to bridge the development gap and support moving Arizona discoveries into the commercialization process. AZBio

is seeking support for the AZAdvances initiative from both public funds and private donations.

Public and private investments into the bioscience sector have helped to make Arizona a top emerging bioscience state.

The return on university research investments, as reported by the Arizona Board of Regents, is impressive year after year. The economic impact generated by our Bioscience Industry has grown from \$23.16 billion in 2016 to \$38.54 billion dollars in 2021.

We are growing. However, we are not maximizing our potential. By the most accepted national metrics, Arizona ranks 14th in the number of firms, 22nd in the number of life science employees, and 25th in venture capital invested into bioscience companies in their state.

The State of Arizona, our community, and our national partners have an opportunity today and in the future to help Arizona become home to a top-ten health innovation sector. Now is the time as we commence our 3rd Bioscience decade.

	JOBS	FIRMS	AVG WAGE	ECONOMIC IMPACT	VENTURE CAPITAL
Arizona Rank	22	14	22	20	25
Arizona Metric	36,410	2,912	\$99,585	\$38.54B	\$.6B
#10 State	IN	CO	IL	MN	MD
#10 Metric	65,290	3,359	\$124,121	\$78.17B	\$3.4B

## AZBIO PUBLIC POLICY PRINCIPLES

AZBio serves as a reliable and trusted resource to our elected and appointed leaders on issues and opportunities that affect our bioscience industry, our communities, and our state.

### **FOR PATIENTS**

**Educate** community and elected leaders at every level on the VALUE our industry delivers and the importance of ensuring that patients have access to life changing and lifesaving innovations when they need them.

**Work** with elected leaders at all levels to provide the information they need to make good choices as we revise our healthcare policies nationally and at the state level. This includes providing information on the potential unintended consequences of specific policy proposals and proposing workable solutions that support the needs of individual patients and our community as a whole.

### **FOR STUDENTS**

**Education Funding:** In 2018, the State of Arizona extended the .6 percent transaction privilege tax for education, workforce development and university research created under Prop. 301 through 2041. A new ballot initiative is needed to voter-protect this essential funding. Prop. 301 allocations, including support for our community colleges and the Technology and Research Initiative Fund (TRIF), need to be included in any proposed ballot initiative in the same proportions as provided under Prop. 301.

**Internships:** Develop creative solutions to improve Arizona's educational systems at all levels including programs to provide internship opportunities for our current and future life science workforce.

### **FOR GROWTH**

Pursue our vision of Arizona as a top-ten bioscience state.

Research and share information on economic development best practices that can be adopted or adapted in Arizona to fuel future growth.

**Work with public and private funding partners t**o capitalize the Arizona Heath Innovation Trust Fund and support AZAdvances.

**Support programs and public policies** that continue to make Arizona a state that attracts and grows innovative life science and healthcare companies.

Ensure that Arizona's Angel Investment and R&D Tax Credits are uninterrupted and appropriately funded at levels that support industry growth and the creation of high-quality jobs for Arizonans.

Develop programs that encourage real-estate and infrastructure development to house our growing industry.

### FOR ALL OF US

**Build creative solutions** to support diversity, equity and inclusion across our educational systems, workforce, research & clinical trials programs, and healthcare delivery systems.

# AZBIO KEY STATE POLICY INITIATIVES FOR 2024

AZBio's policy initiatives in 2024 focus on the path from Discovery to Development to Delivery of life science innovations that will benefit the people of Arizona today and in the future.

### **FOR PATIENTS**

### **Equitable Access to Testing**

Early detection of a disease or other adverse health condition can save lives, support improved treatment outcomes, AND reduce overall healthcare costs. If a basic screening test for breast cancer, colon cancer or other condition is part of the established standard of care, then follow on tests, as prescribed by a healthcare professional should be covered in the same way, otherwise, for some patients, the ability to pay for additional tests will become a barrier to quality care.

### Multi-cancer screenings and tests

Until recently, early cancer detection tests have focused on screening for one cancer at a time and even these are limited to a small number of cancers. Multi-cancer early detection (MCED) tests utilize advances in genomic science and computing power to, through a simple blood draw, find cancer before it spreads throughout the body. Peer-reviewed research details the effectiveness of these new technologies and the U.S. Food and Drug Administration (FDA) has granted multiple breakthrough device designations. As science moves forward, so must health care policy. Arizona researchers and companies are leaders in the development of innovative diagnostics AND Arizona can be a leader in ensuring that our people do not face unnecessary access barriers to these new

early detection tools. Arizona took a step forward in 2022 but more work is needed at the federal level.

### An Inclusive P&T Committee Process

The AHCCCS Pharmacy & Therapeutics Committee (P&T Committee) advises AHCCCS Administration and is responsible for evaluating scientific evidence of the relative safety, efficacy, effectiveness and clinical appropriateness of prescription drugs. The Committee makes recommendations to the AHCCCS Administration on the development and maintenance of a statewide drug list and prior authorization criteria as appropriate. The Committee may also evaluate individual drugs and therapeutic classes of drugs. Currently P&T Committee meetings are open to public comment but industry-related input or even clarification of data presented in a meeting is restricted. A more inclusive process will better serve the needs of both patients and medical professionals. Patients and their medical professional are in the best position to determine what a patient needs for care. Theirs are the voices that matter most.

### **Non-Medical Switching**

Non-medical switching is the practice of forcing stable patients to switch from their current, effective medications to drugs or biologics that may not be as effective for reasons

unrelated to health. Arizona can honor the decisions made by the prescriber and patient by grandfathering patients who are currently stable on a treatment plan and would be negatively impacted by changes to the insurers' formularies.

### **Opioid alternatives**

Arizona's actions to address the opioid crisis in 2018 were a bipartisan effort. As with many health public health challenges, prevention is the most effective offensive strategy. A number of alternatives to opioids for pain management are either currently available or in development. While the initial cost of opioids is less expensive than these alternatives, the overall cost to the healthcare system, when addiction must be treated, is significantly higher. Arizona has the opportunity to lead the nation in establishing programs that provide incentives to prescribing treatments that are opioid alternatives for both acute and chronic pain management.

### **Telehealth**

Telehealth and its integration into delivery of health care through electronic means should continue to be enabled throughout Arizona. This includes educating and advocating for uniform deployment and enforcement of the new telemedicine laws at state and local levels and facilitating expansion of a robust statewide telehealth ecosystem and improving broadband coverage especially in rural communities.

### **ABRC 2.0**

Ensure funding previously managed by the Arizona Biomedical Research Commission and now administered by AZDHS continues to be applied to bioscience research, health education and innovation specifically designed to benefit the people of Arizona.

### **FOR STUDENTS**

### **Education Funding**

Provide the opportunity for the people of Arizona to voter protect essential education funding with a new ballot initiative including support for our community colleges and the Technology and Research Initiative Fund (TRIF) in the same proportions as originally provided provided under Prop. 301.

### **Internships**

Develop innovative funding sources to support STEM internships to further enrich Arizona's educational environment and attract and retain a highly talented bioscience workforce. This concept has been proven successful in other states and holds the potential to help advance our students in the STEM careers that will provide them greater opportunities.

### FOR GROWTH

### **Bridging Arizona's Funding Gap**

While the growth of Arizona's bioscience sector has been significant, as compared to its baseline measurement in 2002, Arizona is not realizing its full potential. A significant contributing factor to this phenomenon is a notable lack of early-stage risk capital for commercialization of the life science innovations being created in the state.

Early-stage capital investments provide the opportunity for Arizona Life Science companies to build their team and achieve the metrics needed to attract angel or venture capital. The chart below shows Venture Capital invested in life science companies in states with life science sectors similar to Arizona based on the number of life science firms.

The states of Colorado, Maryland, Minnesota, Missouri, Utah, and Washington have increased access to public or private early stage capital. Arizona needs to increase its early stage capital availability to reach its full potential.

AZAdvances has been specifically designed to address this challenge and to provide a steady and sustained stream of early stage capital.

Public support is essential to realize the dual benefit of increased economic development and health innovations and to support the model's nonprofit public charity status.

Arizona can create a new catalyst for the growth of its life science sector by increasing its investments into the Arizona Health Innovation Trust Fund and supporting the current funding need of \$10 million per year until the trust fund matures and its distributions can support this requirement. The sooner the Trust reaches its \$200 million goal, the sooner it begins to mature, and the sooner it can reduce the need for ongoing appropriations.

## **BIO VENTURE CAPITAL 2018-2021**

(\$Millions)

IN WA WI AZ CO MD MN TN UT MO 566.93 531.85 443.76 3.374.60 1,906.00 1,275.10 1.674.20 2.148.50 5.552.10 3.125.40

# NATIONAL ISSUES

### **DISCOVERY**

• Ensuring that our country continues to lead the world in medical innovation through increased funding at the NIH, NSF, DOD, and other federal programs that support both basic research and translational science.

### DEVELOPMENT

- Continuing the work of the 21st Century Cures Initiative and ensuring that the United States maintains its global leadership in life science innovation.
- Working with FDA and CMS on the programs and policies that ensure that our citizens benefit from lifesaving and life changing innovations as soon as they can be safely and effectively delivered.
- Ensuring that our policies and programs encourage the commercialization of the discoveries that can make life better and creates and maintains an environment where private investment in these companies is encouraged and valued.
- Provisions in the Inflation Reduction Act (IRA) will reduce essential investment into our innovative small businesses. Work with policy makers to buffer the impact of this unintended consequence.

### **DELIVERY**

- Ensuring Access to Medicare
   Part B Medications requires
   that community-based infusion
   centers, private clinics, and
   our hospitals have adequate
   reimbursement levels to support
   patient care.
- AZBio strongly supports statutory and regulatory reform to help fix our country's broken rebate system and ensure savings provided by drug makers are passed along to patients.
- Pricing and tax provisions in the IRA, that are intended to be payfors, may ultimately increase overall healthcare costs and delay or prevent the development of treatments and cures that patients are waiting for. Work with our elected leaders on alternate solutions that improve patient care and can reduce healthcare spending.
- Promote Trade Policies that ensure American companies can succeed globally by strengthening international intellectual property protections and avoiding tariff policies that can result in the reduction in our industry's position as a net exporter.
- Fully Support policy that protects biotechnology innovation, including provisions that update intellectual property protections and agricultural market access to 21st century standards.

- Intellectual property protections are essential to a vibrant U.S. technology sector. Oppose the dangerous precedent that TRIPS waivers on vaccines represent.
- Advocating to ensure that the reimbursement schedule for diagnostic tests is fair and reasonable as a way to protect patient access and the ongoing investment in these crucial innovations.
- In 2022, Arizona passed HB2144 which provides mandatory insurance coverage of biomarker tests designed to detect disease and direct the most effective patient care. Arizona's leadership on the plans it has authority to regulate can become a national best practice model for federally regulated healthcare plans.

### BUILDING BALANCED SOLUTIONS FOR COMPLEX ISSUES.

• Ethylene Oxide (EtO) gas is one of the most common ways to sterilize medical devices, a safe, tightly controlled, highly regulated process which is critical for preventing infections and ensuring patients have safe surgeries and medical treatments. Approximately 50 percent of all medical devices are sterilized with EtO, and for many of those it is the only option known to modern science. Hundreds of thousands of medical, hospital, and laboratory processes

rely on EtO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. For the majority of these products, EtO sterilization is the most effective and efficient—and often the only viable—sterilization technology. The gentle yet thorough nature of EtO allows for sterilization of many critical medical technologies and devices that would otherwise be destroyed and rendered unusable by other sterilization methods. Our industry is committed to working with our state and federal partners to ensure EtO is used responsibly and in the most environmentally friendly way while providing the products and services patients need.

 Cyber Security and Al are hot topics at home, in businesses, and in the halls of government. Protecting personal information and insuring that bad actors do not compromise the safety and effectiveness of our medical technologies are a top priority. As these technologies evolve, we need to work collaboratively to ensure we put appropriate safeguards in place but do not create barriers to health innovation and health care delivery.

FOSTER CONSTRUCTIVE
CONVERSATIONS on how to lower
health care costs while continuing
to develop and deliver the health
innovations people need today and
in the future.

- + The needs of Seniors and Endof-Life Care are our greatest cost drivers. Focus on innovations that can improve quality of life while reducing cost including home health, telehealth, enhanced senior living options, and hospice care.
  - + Focus on reducing the total

cost of of patient care rather than singling out individual components like the price of a subset of our most effective medicines.

- + Deconstruct and redesign the current healthcare value chain to enhance price/fee transparency of each component. The current system of wholesale costs and multi-tiered rebates is broken. Each price point or fee should be visible cross the value chain.
- + Revisit the concept of patient copays. The current system results in poor adherance and ultimately higher hospitalizations and healthcare spending.
- + Protect our healthcare delivery system. Shortages of doctors, nurses and other health professions is reaching epidemic proportion. Our nation is seeing the rise of "healthcare deserts" where people do not have access to care.







# Championing Change That Makes Life Better

AZBio makes life better for the people of Arizona by advocating for patients, developing our workforce, supporting health innovators, and working to make Arizona home to a top-ten life science sector.

Working with our elected leaders, AZBio championed the creation of the Arizona Health Innovation Trust Fund, a permanent endowment managed by the Arizona State Treasurer, that will support the development of our workforce and the health innovations created by Arizonans...forever!

We invite YOU to be a champion for change.

Contact us today to explore the ways that you can get involved. Together, we can make Arizona home to a top-ten life science sector.

azbio.org/contact