

## Government Affairs Initiatives for 2018



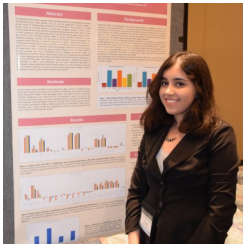
AZBio's policy initiatives in 2018 focus on the path from  
Discovery to Development to Delivery of Life Science Innovations that will  
benefit the people of Arizona today and in the future.

# The Value of Life Saving and Life Changing Innovation



## Improving Lives

Arizona's life science industry is working on finding answers to global health challenges and diseases 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. Innovators across Arizona are creating information technologies to detect and diagnose disease, improve outcomes, and keep us healthy.



## Increasing Economic Vitality

One of Arizona's largest employment sectors, the life science industry includes over 1400 firms, wages significantly higher than the state averages, and an overall economic impact of over \$10 Billion. 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

Value equals benefit minus cost. 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.

## Vision: AZBio is committed to making Arizona a top-tier bioscience state.

**Top Tier Bioscience States** have mastered the 3-D's, 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 tiers.

**Discovery** comes from the exploration of what might be possible. It occurs in our universities, in our private institutes like Barrow, C-Path, IGC, and TGen, 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 final 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 tier bioscience state**, Arizona must master the 3-D's 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.

# AZBio Public Policy Quick List

- ◆ Support the discovery, development, commercialization, delivery and availability of bioscience innovations that support the sustainability of our planet, our people, and our communities.
- ◆ Ensure that patients have access to the life-saving and life-changing innovations our industry creates.
- ◆ Increase access to capital for bioscience and medtech companies so they can grow and create more opportunity and jobs here in Arizona.
- ◆ Grow and attract great bioscience companies by creating a supportive tax and regulatory environment.
- ◆ Support K-12 Education programs that benefit our state as a whole and serve as a magnet to attract and retain a talented and productive workforce.
- ◆ Support Higher Education Funding.
- ◆ Promote University Research Funding and Technology Transfer Activity.
- ◆ Encourage Economic Development Programs that support our overall Business Climate.
- ◆ Serve 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.

## AZBio's Specific 2018 Policy Goals

- ◆ Educate the 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 life saving innovations.
- ◆ Working 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.
- ◆ Ensure that Arizona's Angel Investment and R&D tax Credits are uninterrupted and appropriately funded at levels that support industry growth.
- ◆ Continue investments in University Research and K-12 Education with the next-gen version of Prop. 301 which created Arizona's Technology Research Investment Fund (TRIF).
- ◆ Support creative solutions to improve Arizona's educational systems at all levels including vehicles to provide internship opportunities for our future life science workforce and the educators who train them.

## **AZBio is the unified voice of Arizona's bioscience industry – at the national, statewide and local level.**

Advocacy is a key responsibility of any industry association. The AZBio Public Policy Initiatives provide a framework for the key concepts and initiatives that we, as AZBio, believe are critical to the growth of the bioscience industry in Arizona and nationally. AZBio is represented at the Arizona State Capitol by the Dorn Policy Group, a leading professional public affairs firm serving Arizona and the Western United States. DPG team members provide strategic counsel and issue management. They also sign on behalf of AZBio on key measures affecting our industry as our contract lobbyist. At the national level, AZBio often works in partnership with BIO, AdvaMed, MDMA, PhRMA and patient advocacy organizations.

# AZBio Key Policy Initiatives for 2018



*AZBio's policy initiatives in 2018 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*

## **DISCOVERY:**


### **Leverage Federal Investments by Matching SBIR Grants:**

The Federal **SBIR** and **STTR** programs provide critical funding for life science innovation but the lag time between a Phase I, Phase II or Phase III award can prevent these new technologies from progressing to the Development and Delivery stages. Arizona can help firms and innovators here by extending a 1) **1:1 matching grant** to companies upon successful completion of a Phase I award (feasibility) and application for a Phase 2 (Prototype) SBIR/STTR award; or 2) **.5:1 matching grant** to companies upon successful completion of a Phase II award (Prototype) and application for a Phase III SBIR/STTR award for commercialization. Grant dollars must be specifically applied to 1) employee retention on the project; 2) new hires for the project; or 3) contract employees or consultants to the project located in Arizona. This will not only benefit the life science innovation pipeline but can be extended across all of Arizona's technology innovation sectors.

### **AZBio Strongly Supports the next generation of Prop. 301 and the importance of maintaining TRIF funding at the same proportion of funding as exists in the current statute.**

In 2003, the Arizona State Legislature had the wisdom and vision to approve nearly \$35 million in annual investment over 23 years to service nearly \$500 million in new construction of research facilities at our three state universities. Arizona has seen a tremendous return on that investment, with annual research activity growing over 50% from \$715 million before the new facilities to \$1.1 billion in 2012. In 2017, Arizona doubled that commitment with a new \$1 Billion bonding approval for university research infrastructure.

Research at our universities has generated companies that have helped Arizona grow in industries such as healthcare, biosciences, and technology. These companies create thousands of jobs and millions in economic activity. Our state must continue to mature our economy, which is why the Arizona Board of Regents has set an aggressive goal of almost doubling again the level of research conducted by our universities by 2020 – to \$2 billion annually.



**Leaders understand that to increase production and productivity, investments are required to both maintain current resources and expand capacity so that greater gains can be achieved.**

AZBio thanks the Governor and our Legislators for the 2017 commitment to increased investments by the state allowing our universities to bond \$1 Billion to provide our academic research institutions with the facilities that will be required to discover, develop, and deliver in partnership with industry the life changing innovations that will benefit the people of Arizona today and for generations to come.

As we prepare for the next generation of Prop. 301, Maintaining TRIF funding at the same proportions as exists in Prop. 301 will provide resources at our universities that support life saving and life changing research discoveries and supports the growth of Arizona's talent pipeline and the industry segments that will support Arizona's economy and quality of life.

**Beyond the university system**, our private research institutions are key components in reaching top-tier bioindustry status.

Creative solutions are needed to ensure that Arizona becomes top of mind for both private sector investment and public sector investment in the growth and continued success of Arizona's private research institutions.

## **DEVELOPMENT**

### **Supporting Commercialization:**

#### **Expand Arizona's Refundable R&D Tax Credit**

Where once Arizona was a leader in this area, best practice analysis of the 50 states shows that we are falling behind. In addition, the growth of our industry has resulted in the annual fund being exhausted. The result is that Arizona based companies who make these investments cannot rely on receiving the anticipated state support. It is critically important that both the legislature and the Governor's office work together to keep Arizona attractive and competitive by supporting and expanding this vital program.

#### **Arizona's Angel Investor Tax Credit Program**

In the 2014 legislative session, the Legislature extended the sunset date of the highly successful Angel Investment Tax Credit from 2016 to 2021. In 2017 Arizona committed to \$10 M (\$2.5 M/year) in funding through the end of the program term. Our technology industries rely on Angel Investors to fuel new and continued development of the innovations that create companies and high quality jobs. Those same investors must be able to rely on the state to honor the promised tax credits when they invest in innovation as defined in the statute.

## **DELIVERY:**

### **Ensuring Quality Care: Educating Tomorrow's Physicians**

Work in partnership with Arizona's Universities, Medical Centers, Medical Schools and our National and State leaders to close Arizona's gap of 850 GME (Graduate Medical Education) slots so that as Arizonans are developing the latest in health innovations, we have the healthcare professionals needed to deliver them and keep Arizonans healthy. (In 2010, 1,452 residents were training at Arizona hospitals, which translated to a rate of 21.7 per 100,000 population. The national rate is 35.8 per 100,000. Arizona ranks 37th among the states.) Studies have shown that 75% of physicians will stay to practice in the state where they receive their GME.

Arizona needs to address this challenge today so that we have the doctors Arizonans will need tomorrow.

Without a quality education system, Arizona will not attract, retain or develop the workforce we need to compete in the 21st Century.

Without a 21st Century workforce, Arizona will not be well positioned to attract, retain or develop the industries that create the high-wage jobs and high growth companies that fuel economic growth.

Education extends across a continuum from early childhood to adulthood. To create a job ready workforce, we must give Arizona students the opportunity to develop the skills and talents that will allow both the individuals and our industries to be globally competitive.

Funding for K - 20 education is essential along with our continued commitment to the *Next Generation Science Standards* that were developed in partnership by 26 states including the State of Arizona.

Establishing the standards was the first step. Ensuring our teachers have the resources to implement them is the next vital step in the implementation process.

Beyond the classroom, we can offer applied learning opportunities to both teachers and students so that theory can be fine-tuned through real world experience by creating a Real-World Training Program to include paid work-study opportunities for STEM educators and paid internships for students aspiring to careers in STEM fields.

By funding STEM internships, we can help to build our 21st Century Workforce without adding additional pressure to a strained State Budget.

## Preparing for the Expiration of Prop. 301 in 2021

Passed by the voters on the 2000 Ballot, Proposition 301 provides for:

1. An increase of six-tenths of one per cent in the rate of state transaction privilege (sales) tax, and an increase of six-tenths of one per cent in the state use tax for twenty years. An increase of six-tenths of one per cent changes the state's current rate from 5.0% to 5.6%. This equates to an increase of 12% to the state's rate. State general fund expenditures began in 2002 with an additional \$94.5 million, increasing annually thereafter. The uses of the Prop. 301 revenue are for the following purposes:

(a) To authorize and pay for issuance of up to \$800 million of new school improvement revenue bonds to correct existing deficiencies in school buildings. At 6% interest total principal and debt service will be approximately \$1.4 billion over the next 20 years. (b) For universities to invest in technology and research-based initiatives. (c) For community college districts to invest in workforce development programs. (d) For community colleges that are owned, operated or chartered by an Indian tribe for workforce development and job training. (e) For distribution to the state department of education for the phase-in of five additional school days and associated teacher salary increases resulting from an increased number of school days. (f) For distribution to the state department of education for school safety and character education. (g) For distribution to the state department of education for: (1) Developing a system to measure school performance based on student achievement, including student performance on the AIMS test. (2) Developing a statewide computerized database of information on individual students including student attendance and academic performance. Data items collected on individual students will be developed at the discretion of the Department of Education. (h) For distribution to the failing schools tutoring fund. (i) For reimbursement of the state general fund for the cost of income tax credits in mitigation of increased transaction privilege and use taxes for families with an annual income of less than \$25,000 and individuals with an annual income of less than \$12,500. (j) For increases in teacher base level compensation, teacher compensation based on performance, and maintenance and operation purposes.

2. Automatic inflation adjustments in the state aid to education base level or other components of a school district's revenue control limit.

3. The inclusion of school district excess utility costs within the revenue control limit, beginning in fiscal year 2009-2010.

4. A limitation on the school district qualifying tax rates and the county equalization assistance for education tax rate.[2]  
[3]

# The Impact of Prop. 301



**Prop. 301, which expires in 2021, has provided essential funding for education, workforce training and research.**

***Without prop. 301, Arizona's Bioscience Industry would not have achieved the success it has today.***

Using Proposition 301 revenue, A.R.S. §15-1648 established the Technology and Research Initiative Fund (TRIF) in the State Treasurer's Office and gives the Arizona Board of Regents (ABOR) the responsibility to administer the fund. The TRIF statute includes a 20 percent limitation on use of TRIF funds for capital projects expenditures.

In FY 2015-16, according to ABOR, TRIF received approximately \$69.7 million in revenue. The revenue for the current 5-year period, FY 2012-2016, is approximately \$376.2 million. Total TRIF revenue received to date since the inception of the program in June 2001 is over \$892 million.

A strong business and educational coalition was a driving force behind the success of Prop. 301 in 2000 and it can be again in coming elections.

**AZBio supports the creation of a joint business, education, and legislative committee that comes together to craft successor solution to Prop. 301 that can be implemented well in advance of its expiration so that we create a clear path for planning purposes and make the commitment to investing in Arizona's future well in advance rather than in the eleventh hour.**



## **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:**

Permanently exempting industry paid user fees at the FDA and USPTO from sequester. Supporting the work of the 21st Century Cures Initiative in ensuring that the United States maintains its position as a global leader in life science innovation and develops the programs and policies that ensure that our citizens benefit from them as soon as they can be safely and effectively delivered.

### **Delivery:**

Protecting the delicate balance of payments under Medicare Part D. When programs work, operate under budget and carry a 90% approval rating, changing them is unwise.

Preserving the ASP+6 provider payment structure under Medicaid Part B so that our sickest patients have access to the treatments they need close to home.

Repealing IPAB. A component of the Affordable Care Act, IPAB is a board appointed by the President, with the sole authority and responsibility to cut Medicare. If costs in Medicare rise above a certain level of inflation, cuts to bring those costs have to be made and implemented in one year. The law also says that if the President does not appoint this Board, then the Secretary of Health and Human Services has the sole discretion to make these cuts. Neither IPAB nor the Secretary of HHS is accountable to the voters. Given the importance of Medicare and the potential impact, our elected representatives should be involved in making this kind of major decision about Medicare.

# NATIONAL ISSUES:

## Permanently Repealing the Medical Device Excise Tax

The U.S. leads the world in medical technology, but the device tax threatens that leadership. Suspended in 2016 and 2017, it is time permanently repeal this tax.

Advocating with CMS for review and correction in the reimbursement schedule for diagnostic tests to ensure patient access and ongoing investment in these crucial innovations.

## Overall Tax Reform

Addressing disparities in the U.S. Code that are increasingly putting our industry in a position that is globally uncompetitive and is driving innovator companies off-shore. Advocating for a reasonable and responsible pathway for repatriation of off-shore that incentivizes reinvestment in research, development and manufacturing facilities and jobs here in the United States.

## Patent Reform

Ensuring that patent reform legislation is fair and balanced across industries to support and promote BOTH innovation and investment. Address the issues that have evolved out of the inter-parties review process (IPR) to address abuses of this process by non-industry participants.

## Reauthorizations:

### SBIR/STTR Programs:

The SBIR/STTR Programs are a critical component of the national technology ecosystem and provide funding for innovation across multiple agencies and innovation sectors. AZBio Supports permanent authorization the SBIR/STTR programs.

### User Fee Agreements:

The User Fee programs help the Food and Drug Administration (FDA) to fulfill its mission of protecting the public health and accelerating innovation in the industry.

The User Fee Agreements that were negotiated between industry and the FDA and reauthorized by Congress in 2017 define both the Agency service levels for review of new products and the supporting fee structure paid by industry for this service.

**AZBio will work with its members and its industry partners to provide the necessary input and comments required to support the successful and timely implementation of the FDA Reauthorization Act of 2017 (FDARA), which includes the User Fee Agreements.**

# NATIONAL ISSUES:

**“The path to Cures has been a multi-year journey that has always been about putting patients first. Hand-in-hand with that goal is to advance Cures this year, legislation that will bring hope to families all across the country,”**

-- House Energy & Commerce Chairman Fred Upton (R-MI) and Rep. Diana DeGette (D-CO), original co-sponsors of the bill, together with Ranking Member Frank Pallone, Jr. (D-NJ), Health Subcommittee Chairman Joseph Pitts (R-PA), and Health Subcommittee Ranking Member Gene Green (D-TX).

**“... I believe we should seize every chance we have to find cures as soon as possible. When it's your family, hope can't come soon enough.”**

---President Barack Obama



## **What is in 21st Century Cures?**

This landmark legislation provides \$4.8 billion for the three signature research programs over the next 10 years: Vice President Joe Biden's cancer moonshot, the BRAIN Initiative, and the Precision Medicine Initiative. It would also give states \$1 billion to fight the opioid crisis, and deliver an additional \$500 million to the FDA.

### **21st Century Cures includes:**

- New funding for research and development in the fight against debilitating diseases.
- Expedited pathways at the FDA for Drugs, biologics and medical devices
- Funding to help people and families affected by opioid addiction
- Mental and behavioral health funding

**AZBio will work with its members and its industry partners to provide the necessary input and comments required to support the successful and timely implementation of 21st Century Cures.**