

Government Affairs Initiatives for 2017



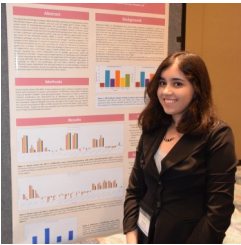
AZBio's policy initiatives in 2017 focus on the path from Discovery to Development to Delivery of Life Science Innovations that will benefit the people of Arizona today and in the future.

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 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 Key Policy Initiatives for 2017

*AZBio's policy initiatives in 2017 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 Investment in Arizona Universities and Research Centers As Reflected in the Governor's Budget Proposal.

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. Despite the downturn in the economy since then, 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.

Research at our universities has generated companies that have helped Arizona grow in industries such as healthcare, biosciences, and technology. Those 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 supports increased investments by the state 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.

Investment in innovation resources at our universities is Arizona's opportunity to grow our 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

In 2013, the Arizona Legislature passed HB2342 amending section 41-1507, Arizona Revised Statutes; relating to tax credit refunds for research and development. The bill was then vetoed by Governor Brewer. 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 successfully expanding this vital program in 2018.

Recapitalization of the 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. Though the bill extended the life of the program, there were no added funds allocated to the program. 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.

AZBio stands with the Arizona Technology Council and the innovation community in recommending that the program be funded at the level of \$10 million for the life of the program.

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.

EDUCATION

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]

Source: AZ Legislative Counsel Summary

The Impact of Prop.301

Prop. 301, which expires in 2021, has provided essential funding for education, work-force 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 during the 2018 budget/election cycle 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.

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 reauthorization the SBIR/STTR.

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 are negotiated between industry and the FDA and approved by Congress 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 renewal of the User Fee Agreements.