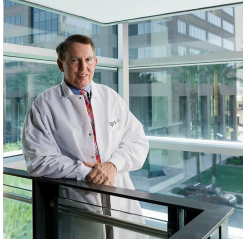


Government Affairs Initiatives for 2019



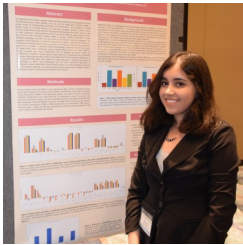
AZBio's policy initiatives in 2019 focus on the path from Discovery to Development to Delivery of Life Science Innovations that will benefit the people of Arizona today and in the future.

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 1300 firms (over 1400 counting our hospitals), wages significantly higher than the state averages, and an overall **economic impact of over \$23.16 Billion in 2016**. 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 providing 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 and protect the vital academic research funding generated under the Technology Research Initiative Fund (TRIF).
- ◆ Develop new policies and programs that support University Technology Transfer Activity; encourage entrepreneurial activity; and foster a going investment base that will create a significant economic impact.
- ◆ Protect 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 2019 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.
- ◆ In 2018, SB 1390 extended the .6 cent transaction privilege tax for education created under Prop 301 through 2041. Essential Prop. 301 allocations including support for our community colleges and the Technology and Research Initiative Fund (TRIF) need to be reaffirmed in the extended statute where they no longer have voter protection.
- ◆ 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 in 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 State Policy Initiatives for 2019



*AZBio's policy initiatives in 2019 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:

University Research Funding

Advance the research enterprise systemwide by working collaboratively with the Arizona Board of Regents. Arizona voters in 2000 approved Proposition 301, which resulted in the investment of hundreds of millions of dollars in research and scientific talent, as well as essential funding for K-20 education. The result was a tremendous improvement in the state's competitive ability to attract and retain valuable private and public investment, commerce, and jobs. In 2018, the Legislature extended the measure for another 20 years. However, the extension is not voter-protected, meaning the Legislature could act to change the funding formula or sweep the funds for another purpose. Attention should be given to sustain this critically important investment and to especially protect the Technology and Research Initiative Fund (TRIF) portion that provides essential biomedical research funding to the three state universities.

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.

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.

DEVELOPMENT & 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 before all qualified requests can be filled. 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 \$10M (\$2.5M/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.

Bridging Arizona's Funding Gap

While the growth of Arizona's bioscience sector has been significant against its baseline measurement in 2002, when compared to states of similar size (5 - 7 million people) we are lagging our peer group in the number of firms and in employee base. A significant contributing factor to this phenomenon is a notable lack of early stage risk capital for commercialization of the life science companies being created in the state. Interest rates are beginning to rise. The time is right to explore the feasibility of using state-sponsored bonds as a funding source for a public-private partnership to support the creation of a steady and sustained stream of early stage capital.

States in our peer group =>	AZ	CO	IN	MD	MA	MN	MO	TN	WA	WI
# of BIO Establishments non hospital (2016)	1,310	2,352	1,730	2,281	2,567	1,780	1,382	1,547	1,744	1,382
BIO Employment (2016)	25,686	29,998	58,018	36,194	93,912	54,414	29,047	33,907	33,564	34,805
State Annualized Avg. Wage \$	48,081	54,879	44,757	55,571	68,082	54,636	46,564	47,618	59,060	45,938
BIO Avg. Wage (2016) \$	77,807	89,002	93,567	107,146	136,941	98,761	75,959	82,768	89,648	77,957
VC BIO Funding \$M (2014-2017)	296.4	1,180.2	241.2	954.8	15,269.5	1,131.6	324.1	292.3	1,993.4	296.5
Est. Economic Impact \$B (U.S. = \$2T) (2016)	23.16	30.95	62.92	44.95	149.06	62.29	25.57	32.53	34.88	31.45

Color Key: Yellow = Lowest in Peer Group Green = Below Peer Group Median



DELIVERY:

TELEHEALTH

Telehealth and its integration into delivery of health care through electronic means should continue to be enabled throughout Arizona. That 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.

Telemedicine Bill Refinements – Support expanded telemedicine parity, licensure and electronic establishment of doctor/patient relationship laws that are driving Arizona telemedicine adoption and enhancing access to health care. Additional refinements include amending existing policies and rules for implementing the new telemedicine laws. Patients and health care providers are benefitting from initial policy and rule implementations. However, still lacking is uniform understanding of the new telemedicine parity and licensure laws that expanded service coverage and removed statutory and regulatory barriers. This lack of awareness, understanding and enforcement of the new telemedicine laws has resulted in a lag in provider participation, which negates providers' ability to reach their potential. We need to educate and advocate for uniform deployment and enforcement of the new laws at state and local levels.

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 are 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.

EDUCATION & WORKFORCE:

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 using all of our available resources including K-12, our Community Colleges, and our Universities.

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.

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.

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.



Credit: AZBio

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.
- ◆ Permanently exempting industry paid user fees at the FDA and USPTO as well as Medicare Part B reimbursements from sequester.
- ◆ 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.

Delivery:

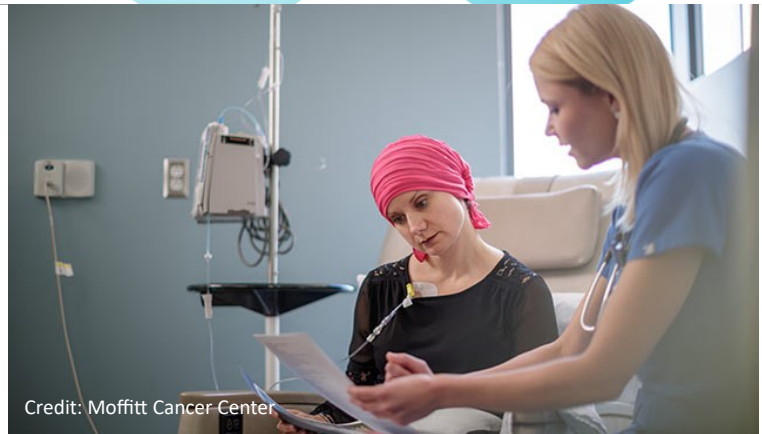
- ◆ Ensuring Access to **Medicare Part B** Medications requires that community based infusion centers, private clinics, and our hospitals have adequate reimbursement levels to support patient care.
- ◆ Protecting the delicate balance of payments under **Medicare Part D** is essential. When programs work, operate under budget and carry a 90% approval rating, changing them is unwise.
- ◆ 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.
- ◆ 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.

Permanently Repealing the Medical Device Excise Tax

The U.S. leads the world in medical technology, but the device tax threatens that leadership. Suspended for 2016 - 2017 and again for 2018-2019, permanently repealing the device tax will provide medical technology innovators with the long-term certainty necessary to support future job growth and sustainable, cutting-edge R&D that will ultimately lead to the next generation of breakthroughs in patient care and treatment.

NATIONAL ISSUES:

Medicare Part B: Understanding how changes can negatively impact our most challenged patients.



Medicare Part B covers beneficiary care provided in physicians' offices and in hospital outpatient departments, including prescription medicines administered by your physician or under their supervision (e.g., therapies that need to be injected or infused). Part B-covered medicines are often those that treat serious, chronic conditions like cancer, rheumatoid arthritis, and many rare diseases.

Among other healthcare services, Medicare Part B provides critical access to needed medicines for some of the sickest, most vulnerable Medicare beneficiaries, like those with cancer. Medicare reimburses physicians for their purchase and administration of these life-saving medicines at the Average Sales Price (ASP) of the drug plus six percent ("ASP+6%"), a formula that has worked well to ensure all patients can get access to these drugs, regardless of where they live.

Some policymakers have called for changing this formula to lower drug spending. But the ASP methodology already ensures that Medicare is getting a good, competitive price on such drugs, because it reflects the net price of the drug after all marketplace rebates and discounts have been factored in.

As a result, this reimbursement formula has been successful in keeping Part B spending on prescription drugs below the annual growth in medical inflation for the last 10 years, and is predicted to continue to do so in the future. And that is why Part B spending on prescription medicines is only a tiny fraction of overall Medicare spending each year.

Protecting Patient Access

The Medicare Modernization Act of 2003 established the ASP+6% rate for payment of Medicare Part B drugs. However, this percentage was affected by the sequester beginning on April 1, 2013. A 2% cut is being applied to Part B drug reimbursement. The sequester is taken off the top of the 80% paid by Medicare, bringing a drop in the ASP from 6% to 4.3%. For example, there has been a 28.4% drop in reimbursement for cancer medications (chemotherapy, immunotherapy, and supportive intravenous drugs) under Part B reimbursement. This has been a strong contributing factor in the closure of non-hospital community cancer centers and private infusion centers. This has resulted in fewer care options for patients especially in rural communities.

New and Innovative Part B Drugs - Impact of the CMS Proposal to reduce WAC based reimbursement to 3%

While many Part B drug payments are based on ASP+6%, some Part B drug payments are based on wholesale acquisition cost (WAC) such as single-source drugs without ASP data. WAC-based payment rates typically exceed rates based on ASP amounts. CMS has proposed reducing the 6% add-on for WAC-based Part B drug payments to 3% to address cost of innovative new products that may be more expensive on a line item basis. The proposed rule seeks to reduce WAC-based payments for new Part B drugs during the period first quarter of sales when ASP is unavailable. Factoring in the sequester, the effective rate is estimated to be 1.35%. This may further restrict patients having timely access to breakthrough medicines including new cancer drugs and other specialty therapies for the first six months they are on the market. If the current effective rate of 4.3% is limiting the number of locations able to operate under Part B, this further reduction is likely have an even greater impact on the business decisions these care centers must make.

ARIZONA

By the numbers: Medicare Part D



Source: Medicare Today

915,596

Medicare Part D beneficiaries in Arizona in 2018¹

408,800

Beneficiaries enrolled in Medicare Advantage prescription drug plans in 2017²

75

Number of Medicare Advantage plans available in 2018³

27%

Beneficiaries receiving Part D's Extra Help in 2018³

17%

Medicare beneficiaries as a percent of state population in 2015⁵

434,290

Beneficiaries enrolled in stand-alone prescription drug plans in 2017⁴

23

Number of Part D Plans available in 2018³

\$12.70

Lowest monthly premium for a prescription drug plan in 2018³

79%

Beneficiaries with access to Part D plan with lower premium than what they paid in 2017³

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

According to Medicare Today, total Part D costs were 45%, or \$349 billion, less than initial projections for 2004-2013. Additionally, Part D drug spending was just 13.6% of total Medicare spending in 2018. CBO changed its scoring methodology to reflect evidence that increased prescription drug use leads to offsetting reductions in Medicare spending for other medical services. Part D helped expand drug coverage and improve adherence to medicines; gaining Medicare Part D prescription drug coverage was tied to an 8% decrease in hospital admissions for seniors overall, with higher reductions for certain conditions.

The changes made to Part D in the Bipartisan Budget Act (BBA) that passed in February threaten the program's successful competitive structure. While these changes closed the donut hole a year early, a boon to seniors, they went much further by lowering insurers' payment responsibility to just five percent of costs in the donut hole for brand medications.

This undermines Part D's market-based structure by reducing insurance plans' stake in the program and therefore reducing their incentive to manage program costs, while also creating a significant imbalance in payment responsibility. Beginning in 2019, seniors will be paying five times more than their insurers for coverage of brand drugs in the donut hole.

In April of 2018, CMS expressed specific concerns in their Part D call letter about the BBA changes and their potential negative impact on the program, stating "... we have significant concerns about the impact these changes will have on drug costs under Part D in 2019 and future years, particularly as plan liability in the gap significantly decreases for brand name drugs beginning in 2019."

By cost shifting 70% of the former "Donut Hole" costs to manufacturers, we have circumvented the market based structure that has historically been successful. The change also artificially reduces the insurance risk calculation that is a key element of the Part D program. This limits the incentives for insurers to bargain effectively to lower the cost of drugs. This has the potential to limit the overall benefit to our seniors over time.

Drug Importation: Why Importing Drugs will NOT Lower Costs, and Risks Patient Safety



Efforts in Congress to force the Secretary of HHS to allow mass importation of prescription medicines from Canada and potentially 30 other countries will create serious risks to the safety of patients across the United States without meaningfully lowering the cost of drugs.

The most recent effort, the “Affordable and Safe Prescription Drug Importation Act” (S. 469, H.R. 1245), is no exception. For many years the Secretary of HHS has had the ability to allow for importation of drugs from Canada, so long as it poses no additional risk to the public health or safety and will result cost savings to U.S. consumers. To date, the Secretary has not permitted such importation because both Republican- and Democratic-appointed Secretaries and FDA Commissioners have refused to certify that it can pass the safety and savings tests.

In March of 2017, four former FDA Commissioners (Robert M. Califf, MD; Margaret B. Hamburg, MD; Mark B. McClellan, MD, PhD; and Andrew Von Eschenbach, MD) sent an open letter to Congress expressing their concerns over the recent proposal. These concerns include:

- ◆ **Serious risks to patients and consumers as drugs purchased from foreign countries may be substandard, unsafe, adulterated, or fake.**
- ◆ **The FDA lacks the resources needed to oversee a major importation program.**
- ◆ **The global drug supply system will limit improvements in access.** Drugs are distributed to countries in allotments that are based on the needs of their respective populations, so only a limited supply of drugs would be available for importation, at best. For this reason, importation is unlikely to achieve real impact on the supply to the U.S. market, and could even exacerbate problems by increasing the likelihood of counterfeit or unsafe products.
- ◆ **Any improved access and cost savings resulting from importation are likely to be minimal.** Studies examining this issue have estimated that importation would likely have only a small, incremental effect on cost and access for drugs in the U.S. market; further, these small savings might not be passed on to patients, even if consumers are able to obtain a legitimate imported drug.

To view the full letter visit:

<https://www.bio.org/sites/default/files/FDA%20Commissioners%20importation%20letter.pdf>

Addressing the Rising Cost of Healthcare



According to the National Health Expenditure Data (NHE):

- ◆ Under current law, national health spending is projected to grow at an average rate of 5.5 percent per year for 2017-26 and to reach \$5.7 trillion by 2026. While this projected average annual growth rate is more modest than that of 7.3 percent observed over the longer-term history prior to the recession (1990-2007), it is more rapid than has been experienced 2008-16 (4.2 percent).
- ◆ Health spending is projected to grow 1.0 percentage point faster than Gross Domestic Product (GDP) per year over the 2017-26 period; as a result, the health share of GDP is expected to rise from 17.9 percent in 2016 to 19.7 percent by 2026.
- ◆ Projected national health spending and enrollment growth over the next decade is largely driven by fundamental economic and demographic factors: changes in projected income growth, increases in prices for medical goods and services, and enrollment shifts from private health insurance to Medicare related to the aging of the population.
- ◆ Among the major payers for health care, growth in spending for Medicare (7.4 percent per year) and Medicaid (5.8 percent per year) are both substantial contributors to the rate of national health expenditure growth for the projection period. Both trends reflect the impact of an aging population, but in different ways. For Medicare, projected enrollment growth is a primary driver; for Medicaid, it is an increasing projected share of aged and disabled enrollees.

Healthcare Innovation is the only hope we have of slowing the rising costs

The population factors that are driving these trends are not something we can change. There are other levers that can be, and must be, used if we are to bend the healthcare cost curve.

- ◆ **Prevention:** From advocating for healthy behaviors to educating on ways to prevent disease, we can lower its instance. This includes continually educating the public on the critical importance and safety of vaccines.
- ◆ **Early Detection:** When we detect disease early, we have a better chance of treating it effectively and often at a significantly lower cost. Policies to promote testing, including investments in test development and reasonable reimbursement levels for both the innovators and the patients, is an essential component.
- ◆ **Better Disease Management:** The instance of chronic diseases increase as we age and is a significant driver in the current trend. Innovative diagnostics, medical devices, and therapeutics are already reducing chronic disease costs. Providing patients with access to these options and incentives to use them could be a successful strategy. Hospitalizations are our single largest expense. Every hospitalization avoided is a win on cost saving.
- ◆ **Investing in Innovation:** The US leads the world in public and private investment in health innovations. Our greatest gap is at the stage where the NIH and other agencies stop and where private investment steps in. New models of public/private partnerships may be a way to close this gap and get cost saving innovations to market. Our polices need to incentivize investing in innovation not restrict it by limiting the incentives for innovators and investors who are investing.
- ◆ **Managing Costs Holistically:** Pointing fingers at individual components of the Healthcare Value Chain will not solve this problem. Cost shifting from one side of the continuum to the other simply masks it. Putting list prices on TV ads, when they do not reflect actual pricing, likely won't change behavior either. Our best chance to bend the cost curve will come from the innovations that support the best possible patient outcomes with the lowest possible overall cost to the system. That's where we need to focus.