2018 BIO Fly-In Policy Priorities

Health Care

Fight the Opioid Crisis with Innovation

- BIO supports eliminating insurance coverage barriers impeding patients’ access to the most appropriate treatments.
- BIO supports increasing expertise and resources within the FDA to ensure efficient drug development and review processes for innovative treatments for pain and addiction.
- BIO supports enhancing the ability to utilize expedited approval pathways for innovative treatments for pain and addiction.
- BIO supports the creation of an NIH scientific steering committee to coordinate cross-institute research that enhances our understanding of the science underlying pain management and addiction and facilitates the development of novel and safer treatment options.

Reform the 340B Drug Discount Program

- The 340B Program has grown far beyond its original intent. Instead of ensuring that uninsured patients have access to medications they need, it has become a revenue stream for hospitals, with patients and taxpayers paying the price. BIO strongly supports the original intent of the program but wants to curb its abuse and ensure that patients are receiving the benefits.
- **BIO supports H.R. 710, the “340B PAUSE Act” (Reps. Larry Buchon (R-IN) and Scott Peters (D-CA)), which would impose a two-year moratorium on new hospital enrollment and require hospitals to report 340B data similar to what already is required of program grantees.**
- **BIO supports S. 2453, the “Ensuring the Value of the 340B Program Act of 2018” (Sen. Chuck Grassley (R-IA)), which would require hospitals to report acquisition costs for 340B drugs and the total revenues received by the hospital as reimbursement for such drugs.**

Preserve Market-based Reimbursement Structure in Medicare Part B

- Medicare Part B’s drug program provides coverage in the hospital outpatient and physician office settings to the sickest, most vulnerable patients, but accounts for only 4% of total Medicare spending. Budget sequesters over the past several years already have reduced payments to Part B providers.
- **BIO opposes any further changes to Part B drug reimbursement, as they could threaten patient access to needed therapies, especially in rural areas, and could force patients to travel farther to receive care in a potentially higher-cost setting.**
- The competitive reimbursement formula already reflects discounts and rebates negotiated in the commercial marketplace, and this formula has controlled the growth of drug spending to below the rate of medical inflation since 2006.

Changing the Medicare Part D Drug Program can Negatively Impact Patients

- **BIO opposes changing the competitive structure and incentives of the Part D program.**
- Medicare Part D continues to ensure seniors have access to retail pharmacy drugs.
- Part D’s competitive, market-oriented negotiations between plans, PBMs, and manufacturers keeps overall costs low for beneficiaries and the government.
- 90% of beneficiaries are satisfied with the program.

Biodefense

Reauthorization and Robust Appropriations are Essential for Strong Biodefense

- **BIO supports a bipartisan, timely reauthorization of the Pandemic and All-Hazards Preparedness Act this year.** Congress must continue to send a strong signal that it is committed to prioritizing health security by providing resources needed to fully prepare the nation for, and defend against, biological threats.
- BIO requests $710 million for Project BioShield for procuring vital medical countermeasures. We also urge Congress to reinstate multi-year funding for this program.
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- BIO requests $631 million for total Pandemic Influenza funding, which supports R&D, ensures readiness of response capabilities, and maintains adequate vaccine stockpiles of deployment-ready antigens and adjuvants.

**“One Health”**

**Congress Should Create an Innovative, Technology-Driven Framework for the One Health Program**
- **BIO supports S. 2615, the “Advancing Emergency Preparedness Through One Health Act of 2018”** (Senators Tina Smith (D-MN) and Todd Young (R-IN)), which establishes an interagency One Health Program to better safeguard human, animal, and environmental health.

**Agriculture & the Environment**

**Reauthorize the Farm Bill**
- BIO supports reauthorization and dedicated funding of the energy title programs, providing predictable funding to fuel investment in next-generation, biology-based innovations.
- BIO supports changes to permit Renewable Chemical Producers to fully participate in the programs and that incentivize all biotechnology applications.

**Congress Must Promote an Export Regulatory Environment that is Consistent and Predictable**
- **BIO supports H.R. 5379, the “Growing American Food Exports Act of 2018”** (Reps. Neal Dunn (R-FL) and Jimmy Panetta (D-CA)), which updates the USDA Foreign Agricultural Service program to facilitate a stronger export economy for the U.S. and improve relations with key trading partners.

**Protect the Renewable Fuel Standard (RFS)**
- BIO opposes unwarranted legislative or regulatory changes to the RFS Program, which is, as Congress intended, driving investment in more sustainable energy sources and fueling the biobased economy throughout America.
- Congress should encourage EPA to rapidly approve new biofuel technologies and new production facilities.
- Policies that open markets further for new biofuels and fuel blends should be implemented.

**Support Biobased Innovation in the Tax Code**
- **BIO supports S. 1980 / H.R. 3149, the “Renewable Chemicals Act of 2017”** (Sen. Debbie Stabenow (D-MI) and Rep. Bill Pascrell, Jr. (D-NJ)), which would provide tax credits over five years to companies that produce or invest in production capacity for renewable chemicals, similar to other industrial tax credits.
- **BIO supports S. 2005/H.R. 4118, the “Master Limited Partnership Parity Act”** (Sen. Christopher Coons (D-DE) and Rep. Ted Poe (R-TX)), which would enable biofuel, renewable chemical, and carbon capture and utilization projects to use a tax-advantaged ownership structure currently available only to oil and gas exploration partnerships.

**Intellectual Property**

**Reform the Patent System to Promote Innovation and Target Abuses**
- Strong intellectual property protection is the lifeblood of the biotechnology industry.
- Reforming the Inter Partes Review (IPR) process, an administrative patent challenge system, to protect innovators from harassment and abuse is a top priority.
- **BIO supports S. 1390/H.R. 5340, the “STRONGER Patents Act of 2017”** (Sen. Christopher Coons (D-DE) and Rep. Steve Stivers (R-OH)), which cracks down on false or deceptive patent demand letters, ensures urgently-needed fairness and finality in PTO post-grant proceedings, eliminates diversion of PTO user fees, and helps American research-intensive companies protect their investments in innovation.