2017 BIO Fly-In Policy Priorities

Support Timely Passage of Negotiated FDA User Fee Agreements

- The PDUFA VI agreement will provide FDA with the resources needed to advance modern, patient-focused drug development approaches
- The BsUFA II (biosimilar user fee) agreement will help FDA ensure timely availability of the important new category of biosimilar medicines
- PDUFA and BsuFA must be reauthorized well before their expiration of 9/30/17, to avoid the lay-off of critical FDA employees engaged in review of these medicines

Support Incentives in the Tax Code for Investment in Innovation

- Lower the corporate tax rate and move the U.S. to a territorial tax system to make America's tax code globally competitive
- Go beyond "broadening the base and lowering the rate" by specifically promoting investment in innovation through the tax code
- Support existing tax incentives like the R&D Credit, the Orphan Drug Credit, and the Advanced Biofuel Producer Tax Credit, and expand to cover renewable chemicals and other bio-based products
- Include incentives for investing in R&D-stage companies in any tax reform package, including Section 469 R&D Partnership Structures and Section 382 NOL Reform

Support Full Appropriations for Areas Critical to Discovery & Public Health Security

- NIH spurs key basic discovery in an era of genomic health and personalized medicine, and therefore BIO supports increased resources for NIH and opposes cuts to its budget
- Full appropriations are needed to support BARDA, Project BioShield, & Antimicrobial Resistance programs to spur discovery and development of products designed to battle emerging national and public health security threats

Oppose Changes to the Medicare Part B Drug Program

- Medicare Part B coverage and payment supports access to critical medicines and specialist physicians relied on by the most vulnerable and sickest patients
- Part B's Average Sales Price (ASP) drug reimbursement methodology leverages private market negotiations to keep drug spending as a small fraction of Medicare spending and growing in line with medical inflation
- The ASP system is working well to appropriately reimburse physicians, whether rural or urban, or in a large or small practice; but it's a delicate balance and, if changed, could undermine efforts to keep care in lower-cost community settings rather than more expensive, and less convenient, hospital settings
- As a result of budget sequestration, physicians are currently reimbursed an effective rate of ASP+4.3%, rather than the statutory ASP+6%; any further cuts will harm patient access
- Proposals that would shift drug payment for these drugs into the Part D system would increase beneficiary costs

Oppose Changes to the Medicare Part D Drug Program

- Medicare Part D ensures that seniors have access to a broad choice of retail drugs
- Part D's structure keeps overall costs to beneficiaries and the government down
- Competitive, market-oriented negotiations between plans, PBMs, and manufacturers are critical to this success
- 90% of beneficiaries are satisfied with the program

2017 BIO Fly-In Policy Priorities

Support Federal Policies that Keep the U.S. Competitive in Bio-based Product Innovation

- BIO supports policies that unleash our members' scientific innovative potential to grow the bio-economy
- The Renewable Fuel Standard (RFS) is driving investment and development of advanced biofuels. Advance biofuels replace foreign oil, which lowers the price of fuel at the pump and strengthens our nation's energy security
- The Farm Bill energy title has put home-grown technologies to work converting domestic crops and residues to value-added products, which create high-quality rural jobs, spur economic growth, and improve environmental health

Thank You Congress for Passing a National "GMO" Food Disclosure Solution

- In 2016, Congress passed into law a strong, bipartisan, and national GMO food disclosure solution
- This carefully crafted law provides consumers with consistent, reliable information without stigmatizing the use of biotechnology in food
- Support implementation of the law as Congress intended without changes

Support a Predictable, Risk-Based Biotechnology Regulatory System for Agriculture and Animal Products

- USDA and FDA recently proposed major revisions to regulations governing pre-market use of biotechnology in agriculture
- The USDA proposal contains some promise, but also raises many concerns; the FDA proposal is a significant and unwarranted expansion of regulatory scope
- BIO is working with USDA and FDA to ensure proposed regulatory changes foster a more predictable, risk-based, cost-effective, and legally defensible regulatory system for developers of plant and animal biotechnology products

Support a "One Health" Approach to Problem-Solving that Recognizes the Interconnectedness of Human, Animal, and Environmental Health

- Collaboration among federal agencies responsible for human, animal, and environmental health policy development, research, and innovation is critical in mitigating and adapting to diseases that can easily jump between animals and humans
- Often bureaucratic silos can prevent necessary coordination between human and animal health agencies, such as FDA, USDA, and EPA
- BIO's members operate at the crossroads of One Health, and we support efforts to breakdown these silos and promote coordination to help society better manage serious human, animal, and environmental health challenges