October 22, 2019

Office of Science and Technology Policy (OSTP)
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Re: Request for Information on the Bioeconomy

On behalf of BioNJ's 400 research-based life sciences companies, academic institutions, and other stakeholder Members, thank you for the opportunity to comment on the request for information (RFI) on the bioeconomy.

BioNJ is New Jersey's life sciences trade association, representing our state's premier biopharmaceutical firms as well as emerging companies, Patient advocacy organizations, academic research institutions, and those that support them. Delivering access to groundbreaking and lifesaving Patient therapies is the mission of our membership – Because Patients Can't Wait®.

Each and every day our Members are working tirelessly to develop tomorrow's cures. And New Jersey is a global leader in biopharmaceutical research and development where many of the world's greatest scientific discoveries happen. New Jersey is home to nearly 3,300 life sciences establishments, and from 2015-2017, nearly one-third of all FDA-approved drugs – 29 percent – were developed by biopharmaceutical companies with a footprint in New Jersey. That number was nearly 50 percent in 2017 alone. In short, the long-term health of the bioeconomy goes hand in hand with the success of our State.

Treatments developed in New Jersey and around the world continue to make a difference in the lives of Patients and their caregivers around the world, improving quality of life and providing value to the overall health care system. The numbers bear out the importance of continued support for the life sciences sector. For example, Hepatitis C has become curable for millions of Americans, resulting in billions in saved health care costs. The death rate from cancer has continued to decline, and childhood vaccinations are savings millions of lives each year. The life sciences sector is an American asset that should be supported to ensure that innovation continues in delivering lifesavings treatments to Patients around the world.

Yet America's continued success and leadership are not guaranteed. Many countries have great scientists; what has set the U.S. biotech sector apart has been thoughtful, bipartisan public policy approaches that create a favorable climate in which to undertake the lengthy and risky job of investing in and developing the next biotech breakthroughs. Today, foreign countries are taking overt steps to streamline regulatory systems and speed pathways to market, often with direct government support as part of national bioeconomy strategies. America cannot rest on our laurels and must not take our global leadership for granted. The U.S. bio-based economy depends on preservation of those incentives that facilitate robust and steady private investments.

BioNJ encourages the Administration to continue pursuing policies that help spur innovation in our sector. And we appreciate that OSTP is actively seeking information on ways the federal government can keep the American bioeconomy robust. For instance, BioNJ supports continued efforts providing for basic research at the National Institutes for Health and other federal agencies. In addition, given the capital-intensive nature of drug discovery and development, we would encourage the Administration to support policies aimed at ensuring small and emerging life sciences companies have access to the capital necessary for research and development activities. This could include policy items such as an improved Orphan Drug Tax Credit to help spur innovation for the millions of American Patients with a rare disease diagnosis.

We would also encourage the Administration to reexamine several policies under consideration that we believe could significantly harm growth and innovation in the life sciences and other tech sectors.

First, the Department of Health and Human Services has proposed through an advanced notice of proposed rulemaking (ANPRM) an International Pricing Model (IPI) that would address Medicare Part B drug costs by linking Medicare Part B drug prices to international prices, creating new private sector venders to administer the program and reducing reimbursement for provider administration of Part B drugs and biologics. The IPI model would establish a five-year demonstration project using foreign countries as a reference price for Part B administered drugs and biologics. BioNJ believes the IPI model would not only have a negative impact on Patient access to new and novel therapies, but IPI would also directly impact innovation in the life sciences sector.

With a significant proportion of new treatments launched in the United States, our Patients have access to new therapies more quickly than Patients in any other country. Importing these foreign reference prices could have the effect of driving these new treatments to other markets while reducing the early stage investment serving as the lifeblood of emerging biotechnology companies. For all of these reasons, we would encourage the withdrawal of any proposal to implement the IPI model to prevent the erosion of the American biotechnology industry.

A second Administration proposal with a possible negative impact on innovation in the life sciences industry is a recent Section 382 Internal Revenue Service (IRS) proposal. In a proposed rule, the IRS has stated its intention to eliminate the section 338 approach to mergers, acquisitions, and capital financing that has been allowed since 2003. The IRS has been helpful to companies that spend significantly in research and development with the hope that research might generate future revenue. The section 338 approach has allowed life sciences and other technology companies to increase net operating losses (NOL) utilization that otherwise could have gone unused or expired due to a time period utilization.

The elimination of the section 338 approach will drastically and negatively impact the New Jersey life sciences industry. Life sciences companies are frequently active in both mergers and raising capital where ownership changes may occur. Section 382 was created to stop "loss trafficking." Yet, in a merger, acquisition, or an investment infusion resulting in an ownership change, the company's NOLs are not being trafficked. Instead, these NOLs represent research and development activities of the company that could be directly tied to possible future income. Without the section 338 approach, these financial activities may be curtailed as companies look to avoid future tax liabilities on NOLs. As raising capital is paramount to the success of a life sciences company, the removal of this approach could result in reduced investment in the sector. We would encourage the Administration to reconsider this change based on its negative impact on the bioeconomy.

BioNJ strongly believes that a thriving bioeconomy is fundamental to the discoveries of tomorrow in the life sciences as well as other technological developments. We would urge the Administration consider the policy recommendations listed above in order to better provide an environment where life sciences and other technology companies can succeed.

Thank you again for the opportunity to comment on the bioeconomy RFI. Please do not hesitate to contact me at DHart@BioNJ.org or 609.890.3185 should you have any questions.

Sincerely,

Debbie Hart
President and CEO