2025 Policy & Advocacy Priorities

BioNJ Background

BioNJ is New Jersey's life sciences trade association, representing nearly 400 research-based life sciences companies, academic institutions, Patient advocacy organizations and other stakeholder members. New Jersey's life sciences ecosystem has consistently been a global leader in innovation in biopharmaceutical research, development and manufacturing. The State's life sciences sector is comprised of approximately 4,500 life sciences establishments with more than 1,000 drugs in development. A substantial percentage of all FDA new drug proposals nationwide continue to come from biopharmaceutical firms with a significant presence in New Jersey. New Jersey's life sciences community includes approximately 300,000 direct, indirect, and induced employees in the State — and is a central contributor to the State's economy, bringing new cures and therapeutics to the Patients who need them.

Health Equity in Clinical Trials

BioNJ is devoted to ensuring that Patients have access to the treatments they need when they need them — Because Patients Can't Wait®. Beginning in 2022 and continuing in 2025, BioNJ is working to support more equitable access to clinical trials in communities that continue to be underrepresented amongst the newest innovations in biomedical science. The inception of BioNJ's Health Equity in Clinical Trials initiative represents a manifestation of this priority.

Following the successful execution of an MBA Business Plan Competition which brought forward business plans featuring strategies to increase health equity in diverse Patient settings, BioNJ's Health Equity in Clinical Trials Initiative is currently focused on two primary goals:

- **NJ Baseline:** Understanding the current status of participant demographic representation across clinical trials conducted throughout the State and considering strategies to improve on collection and representation by underrepresented groups
- **Collecting & Connecting the Dots:** Inventorying what innovator companies are doing to improve and expand representation by underrepresented communities in clinical trials, sharing those efforts and best practices across the ecosystem to encourage learning and collaboration across clinical trial sponsors

The goal of our initiative is to produce practicable improvements in equitable access in clinical trials throughout New Jersey that will also be applicable nationwide and internationally. In 2025, BioNJ will provide best practices that can be operationalized by every entity interested in achieving greater equity in clinical trial participation so that every Patient has access to the newest and most effective treatments when they need them.

Protecting New Jersey's Status as "Medicine Chest of the World"

New Jersey has earned the reputation of being a critical nucleus of biopharmaceutical research, development, and manufacturing nationwide following decades of leadership in life sciences innovation. As the "Medicine Chest of the World", entities throughout New Jersey responded early and effectively to confront the COVID-19 pandemic — creating and advancing new diagnostics, therapeutics, and vaccines with unprecedented efficiency. Approximately 50% of FDA drug approvals in 2022 and more than 50% in 2023 were produced by companies with a footprint in New Jersey. The biopharmaceutical and medical technology industries create over 300,000 direct and indirect jobs throughout the State, with New Jersey being the only state in the union where a high degree of life science specialization spans 4 of the 5 major industry subsectors.

While many of the provisions in the Inflation Reduction Act of 2022 were laudable, several are having unfortunate consequences that inhibit the access that Patients have to the medications on which they rely. In particular, the price negotiation provisions penalize the development of small molecule therapeutics by providing diminished time prior to negotiation relative to large molecule therapeutics. As a consequence, this provision results in certain Patient populations who confront medical conditions that can only be treated with small molecules having to face delayed access to innovative new therapies and cures. We are working to ensure that New Jersey's congressional

delegation appreciates this issue and supports increasing the amount of time that the Act provides to small molecules to achieve parity with small molecules.

Further, the Inflation Reduction Act penalizes the pursuit of secondary indications for therapeutics that have been developed to treat rare diseases. Given the opportunities of approved rare disease therapeutics to treat multiple conditions, we are working to convey the unintended consequence of this provision — ensuring that life science innovators can pursue every available opportunity to develop life-changing and life-saving therapeutics for as many Patients as possible.

BioNJ remains committed to working closely with policymakers and regulators throughout our State to promote policies that support Patient access to medicines as rapidly as possible. The Garden State has always been the home of biomedical innovation nationwide, and BioNJ is devoted to advocating for policies that accelerate innovation, avoiding policies that inhibit biomedical progress, and ensuring that Patients have access to a growing and more effective armamentarium of medicines.

REGULATING STEP THERAPY

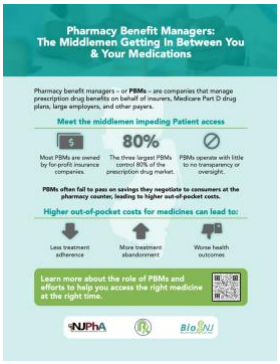
Health plans continue to utilize tools that can result in slowed Patient access to treatments when they're needed most. The use of step therapy is a continuing and deeply concerning trend in health coverage and the implementation of capricious and onerous prior authorization policies interferes with the decisions that Patients make with their physicians.

Step therapy — also known as "fail first" — is a utilization management tool and type of prior authorization that requires Patients to try and fail with one or more treatments before gaining access to the treatment initially prescribed by the Patient's clinician. Interfering with the treatment decisions of a clinician and Patient can result in dire and unnecessary consequences that would have been avoided had third parties never intervened.

Further, prior authorization policies more broadly can result in sudden changes in covered medications, disrupting the lives and well-being of Patients who have relied on medications for years to sustain healthy lives. Additionally, physicians regularly confront overly burdensome administrative work to navigate these policies and advocate on behalf of Patients. Enacting reasonable guidelines on prior authorization practices is critical to ensure that Patients and their physicians are not shocked or burdened with the decisions of third parties that ultimately determine which medications are available.

BioNJ believes that, in many instances, step therapy results in delaying Patient access to necessary and lifesaving therapies. Studies show that over 50 percent of Patients are required to try two or more treatments before receiving authorization to get the treatment originally prescribed by their physician. Other states around the country have developed statutory guardrails for the appropriate use of step therapy. These guardrails are motivated by clinical evidence and developed by independent experts who have relevant biomedical expertise, rather than maximizing insurer profitability.

At the end of the last legislative session, a bill was signed that applies guardrails to some applications of prior authorization. While this is a welcome improvement in healthcare policy from the perspective of Patients, there is still a meaningful opportunity to ensure that Patients aren't prevented from accessing the medications that they and their physicians decide are best for them. Fortunately, a bill that would more effectively address step therapy practices has made progress in the Legislature. A1825 (Conaway/Verrelli), a bill with 23 co-sponsors, has moved through the Assembly Health Committee with considerable support. We hope to see this bill continue to make progress.



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Finally, BioNJ will continue to guide educational efforts to support increased public healthcare literacy — particularly helping to illuminate the role that Pharmacy Benefit Managers (PBMs) play in driving healthcare costs. There is no reason that Patients should have to worry about whether they understand the nation's complicated healthcare landscape when they are navigating the choices that they make in partnership with their clinicians.

We look forward to working with coalition partners amongst Patient advocates, physicians, and pharmacists to produce a resource on which every Patient can rely in these critical moments. We are partnering with a coalition to provide educational materials right at pharmacy counters to help Patients connect with resources that exist within the State to ensure that they are able to access every resource available that will ensure they have.

Increase Angel Investor Tax Credit Incentives

New Jersey's Angel Investor Tax Credit (AITC) has been extremely beneficial to the innovation ecosystem throughout the Garden State. This program establishes tax credits against corporation business or gross income taxes based on qualified investments in the State's emerging technology businesses. Given the success of the program to date, BioNJ will work to support an increase in the incentives associated with the AITC to ensure that New Jersey continues to represent an ideal home of innovation as life sciences companies consider potential homes for their work.

Engage Policymakers on the Emergence of Cell & Gene Therapies, Precision Medicine, and Regenerative Medicine

As life sciences companies have continued to invent and produce new and more effective medicines, a new generation of therapeutics is emerging that is likely to transform the wellbeing of Patients, rendering what are currently chronic or fatal conditions into curable maladies. This new biomedical paradigm will require innovation at the policy level to ensure that these novel therapeutics continue to be invented and are available to every Patient who needs them. Accordingly, BioNJ intends to engage policymakers at both the state and federal levels, connecting the companies who are forging this new phase of biomedical science with the policymakers who will have to implement innovative and novel policy approaches. If cures to diseases are able to be created, we must and will do all that we can to ensure that New Jersey's policy landscape facilitates this progress — Because Patients Can't Wait®.

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