



2020 Federal 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 nearly 3,300 life sciences establishments with more than 1,000 drugs in development. More than 50 percent of all FDA new drug approvals in 2019 were developed by firms with a New Jersey presence. New Jersey's life sciences community has nearly 430,000 direct, indirect and induced employees in the State and is a critical cog to the State's economy as well as to bringing new therapies and cures to the Patients who need them.

Focus: Protect Patient Access to Health Care Innovation

BioNJ strongly supports measures that enhance Patient access to innovations in health care. We believe that Patients should have access to the right treatments at the right time – Because Patients Can't Wait®. As groundbreaking and lifesaving cures are developed, timely Patient access to these treatments is critically important. Unfortunately, several recent policy concepts discussed in Washington could have a negative impact on Patient access to innovative treatments.

H.R. 3: The Wrong Prescription for Patient Access

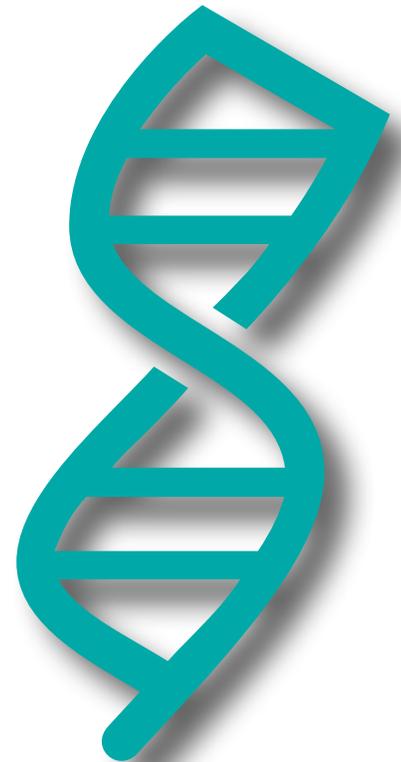
H.R. 3, passed by the House in early December, would lead to devastating consequences for both New Jersey life sciences companies and the Patients we serve around the globe. The legislation would eschew Patient access in favor of draconian “negotiation” tactics that would reduce innovative therapies coming to the marketplace by as many as 100 according to one estimate. Moreover, the proposal would cause significant economic and employee disruptions here in the Garden State – as much as 54,000 lost jobs – and billions in reduced economic output.

We must do better. BioNJ supports proposals to reduce Patient out-of-pocket costs – such as proposals to reduce Part D beneficiary cost-sharing – while promoting continued life sciences innovation. Let's work together to ensure Patients continue to have access to tomorrow's lifesaving cures AND that New Jersey remains a globally recognized life sciences ecosystem.

Importation

The Trump Administration in 2019 introduced its “Importation Action Plan” to provide for a framework for the importation of certain prescription treatments meant for sale in foreign markets. The administration followed with a December proposed rule and draft guidance to implement the Action Plan. The proposed rule would allow states and other non-federal government entities to petition the FDA for approval of importation program proposals from Canada. The rule proposes that certain products – such as biologics or treatments with a REMS strategy – be excluded from importation programs. Meanwhile, the draft guidance describes how a manufacturer might obtain a National Drug Code (NDC) for certain prescription treatments -- including biologics -- that were manufactured for distribution in a country other than the United States.

BioNJ believes importation is the wrong way to address the price Patients pay at the pharmacy counter. Importation could jeopardize our nation's drug supply as well as the health and well-being of the Patients relying on the effectiveness of treatments. Drugs coming to the United States through Canada could have originated anywhere in the world. Moreover, the cost savings as well as feasibility of drug importation are unproven, with possible savings being gobbled up by middlemen rather than being passed along to the Patient. In short, importation is dangerous to Patients and will not achieve the intended savings to the overall health care system.



International Pricing Index

The Trump Administration announced in late 2018 its intention to propose a rule creating a demonstration project – the International Pricing Index (IPI) – for 50 percent of Part B drugs and biologics to be reimbursed through international “reference” prices. The IPI model could resurface in 2020. Studies have shown changes in reimbursement can have a positive impact on life sciences research and development funding. For example, Part D’s 2003 creation paved the way for significant investment in new and novel treatments for Medicare Patients. BioNJ supports policies that foster innovation while enhancing Patient access to new and novel treatments.

With an anticipated release of a proposed rule in 2020, we continue to believe implementing IPI could have the consequence of reducing Patient access to therapies as well as stifling biopharma innovation in New Jersey and around the nation. Our State’s life sciences ecosystem is creating therapies previously thought impossible, developing cures in oncology and other disease states. The IPI could significantly impact the development pipeline through its use of reference prices, reducing the availability of therapies getting to the Patients who desperately need them. Patient access remains a serious concern in countries that the IPI model would reference. For example, 92 percent of all new medicines are launched in the United States, and 95 percent of the 74 new cancer treatments launched since 2011 are available in the United States. Meanwhile, only 74 percent of these new cancer treatments are available in the United Kingdom, 49 percent in Japan, and only eight percent in Greece.

The IPI model would chill innovation and reduce Patient access to new and lifesaving cures. New Jersey’s federal delegation should oppose this model.

CMMI Guardrails

Among the Affordable Care Act’s many provisions aimed at health care quality improvement was the creation of the “Innovation Center” at the Centers for Medicare and Medicaid Services. The Innovation Center was designed to “test” new models of care seeking to lower costs and improve outcomes. However, an alarming trend has come to the fore at the Innovation Center where demonstrations and payment models become mandatory for participants. Examples of this include models focused on joint replacement as well as a proposed cardiac care model. The IPI model is also an example of this, failing to address a defined population for which care quality has been questioned or outcomes have been poor. In addition, it remains unclear how the proposal would preserve or enhance quality of care for those Medicare beneficiaries served under the model.

Legislative proposals have emerged to enact guidelines for the models the Innovation Center is testing. BioNJ supports efforts to ensure the Innovation Center is using its authority to seek solutions to improve care quality rather than enact policy changes that could subvert congressional intent. We would encourage our federal delegation to consider supporting legislative proposals to ensure the Innovation Center’s work focuses on voluntary models focused on improving Patient care and outcomes.

Promote Innovation, Protect Patients

BioNJ is proud to represent the entirety of New Jersey’s life sciences industry. We stand committed to working with our federal delegation to promote policies that both protect Patient access to biopharmaceuticals and continue to spur innovation in new and novel treatments.

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