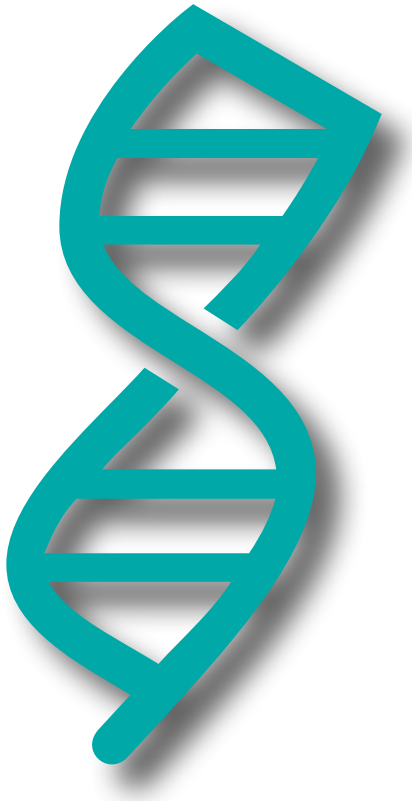
2019 Federal Priorities

BioNJ Background

BioNJ is New Jersey's largest life sciences trade association, representing 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. From 2015-2017, nearly one-third of all FDA-approved drugs – 29 percent – were developed by biopharmaceutical companies headquartered in New Jersey. That number was nearly 50 percent in 2017 and 25% in 2018 alone. New Jersey's life sciences community has nearly 400,000 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 therapies and medicines.

Step Therapy/Protected Classes

Commercial health plans have employed a strategy known as "step therapy" in the commercial health marketplace. Step therapy, known to many as "fail first," is a utilization strategy where Patients are required to use the least expensive treatment in a class before accessing a more expensive treatment, regardless of Patient needs or physician orders. Step therapy unnecessarily and inappropriately places an intermediary – an insurance provider – between the Patient and their healthcare provider. Most importantly, step therapy can result in barriers to accessing the treatment that best fits a Patient's needs.

Unfortunately, the Centers for Medicare and Medicaid Services (CMS) have recently proposed fail first for Part B drugs furnished through Medicare Advantage as well as Part D protected class drugs that all plans must include in their formularies. Traditionally, Part D plans require sponsors to include six categories or classes of drugs on all formularies. The CMS proposal would instead create exceptions to these protected classes by allowing Part D sponsors to more broadly deploy prior authorization and step therapy, exclude a protected class drug from a formulary if the drug represents a new formulation of an existing drug or biologic, and exclude a protected class drug from a formulary if the price of a product increases over an arbitrary threshold over a given period of time. Moreover, the proposed rule would reaffirm CMS guidance related to step therapy for Part B drugs.

BioNJ is concerned that these proposed changes would have a deleterious impact on the ability of Patients to access the right treatment at the right time. Step therapy inappropriately interferes with the provider-Patient relationship, and we encourage members of the New Jersey federal delegation to oppose these CMS proposals.

International Pricing Index

The Trump Administration has also announced its intention to propose in spring 2019 rulemaking 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. 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 both foster innovation while enhancing Patient access to new and novel treatments.

BioNJ believes implementing IPI could undermine these principles and have the consequence of reducing innovation in New Jersey and around the nation. A recent study estimated that 117 fewer medicines would have been produced for worldwide use from 1986-2014 if European-style drug and biologic pricing had been in effect in the United States. Further studies show that a 50 percent drop in prices could lead to a 14-24 percent decrease in the number of drugs and biologics in the development pipeline, thereby reducing the number of drugs and therapies getting to the Patients who need them. New Jersey's life sciences ecosystem is working collaboratively each and every day to discover tomorrow's cures; the IPI could negatively impact the innovative spirit that is the hallmark of our State's biopharmaceutical sector.

The IPI is problematic in a number of other areas. For instance, the IPI model will create a new class of Medicare vendors specific to products distributed under the IPI model. This additional layer of complexity could cause disruptions and delays in treatment delivery and hinder provider and Patient access to lifesaving treatments. The IPI also runs contrary to the CMS Innovation Center's stated purpose of testing "innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care. The IPI model fails 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.

The most important consideration is the IPI's potential impact on Patients. Unfortunately, Patient access is perhaps the IPI model's greatest failure. BioNJ is concerned that the IPI's impact on innovation could lead to less Patient access to new and novel treatments. Life sciences innovation is developing therapies never before thought possible, curing the incurable and giving new life to Patients with previously terminal illnesses. We believe that IPI will keep these treatments from Patients. Indeed, 92 percent of all new medicines are launched in the United States, and 95 percent of the 74 cancer drugs launched between 2011 and 2018 are available in the United States. Seventy four percent of these new cancer treatments are available in the United Kingdom, 49 percent in Japan and only eight percent in Greece.

BioNJ has significant concerns with the ANPRM outline of the IPI model. We believe this model could have significant impacts on Patient access to critical treatments, and we encourage the New Jersey delegation to voice their concerns with CMS on the IPI proposal.

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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