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December 31, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM)

Dear Administrator Verma:

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 advanced notice of proposed rulemaking (ANPRM) proposing the International Pricing Index demonstration for Medicare Part B drugs (RIN 0938-AT91).

BioNJ is New Jersey's largest 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 cures 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. Unfortunately, we believe the IPI proposal as drafted could have a devastating impact on the ability of our members to continue these efforts in researching and developing new and novel treatments in oncology, gene therapy, and other rare diseases. For these reasons, BioNJ strongly opposes the IPI proposal and urges CMS to withdraw this proposal entirely.

New Jersey is a global leader in biopharmaceutical research and development, and many of the world's greatest scientific discoveries happened here in our State. 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. Nationally, the United States is responsible for more life sciences research and development than the rest of the world combined. Implementing IPI could 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 were in effect in the United States. Further studies show that a 50 percent drop in prices could lead to a 14-24 percent drop 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.

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Unfortunately, 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 eight percent in Greece. Given this evidence that systems using reference pricing typically offer Patients less access to new and groundbreaking therapies, we strongly urge CMS against importing foreign price controls.

In addition, the IPI model creates a new class of Medicare vendors specific to products distributed under the guise of the model through the authority of the Competitive Acquisition Program (CAP). This additional layer of complexity could cause disruptions in treatment delivery and hinder provider and Patient access to critical, lifesaving medicines. We would encourage CMS to instead work with stakeholders in the provider community to develop smaller scale reforms that could more accurately model impacts on both quality and cost of care.

Finally, we believe the IPI model runs contrary to the goal of the CMS Innovation Center to test care models that better align payment systems to lower costs and improve Patient-centered care. Instead, the IPI model fails to address a defined population for which there are identified deficits in care leading to poor outcomes or unnecessary health care costs. Moreover, it is unclear how the IPI model will preserve or enhance quality of care for Medicare beneficiaries served under the model. Ironically, the model could instead reduce Patient access to lifesaving treatments while adding additional complexity in the drug delivery system that could lead to shortages and diversion.

BioNJ reiterates our significant concerns with the ANPRM outline of the IPI model. We believe this model, if implemented, could have significant impacts on Patient access to critical prescription treatments. We encourage CMS to work with stakeholders to instead develop solutions that encourage further health care innovation while protecting Patient access to the right treatment at the right time.

Thank you again, Administrator Verma, for the opportunity to comment on the ANPRM. 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