Inside PPTA: Health Policy in Action

INTERNATIONAL AFFAIRS

Canada was a major focus for the PPTA International Affairs team in early 2018. In late April, British Columbia banned compensated plasma donation despite PPTA's outreach to members of both parties, including the British Columbia Minister of Health, and outreach by patient advocates. Directly on the heels of the ban, Health Canada's Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada publicly released a report on its findings. PPTA and its members were afforded an opportunity to comment and did so, with positions grounded in science, quality, donor and patient safety, and availability. The yearlong evaluation was focused largely on the merits of compensated plasma donation. Though the report is favorable to the concept of compensated plasma donation, it proposes troubling demand-management strategies, which could restrict access to IG.

We continue to prepare for the second Plasma Protein Industry Summit at the Parenteral Drug Industry Congress. The summit will feature PPTA members and staff, as well as leading experts and Chinese and U.S. regulatory officials, and will focus on areas of possible cooperation. It will also feature discussions of how Chinese industry and PPTA might be able to find common ground on some existing differences.

EUROPE

PPTA's Health Policy staff has continued working on several projects at the European level, such as the new Health Technology Assessment (HTA) Regulation. After its engagement in the Industry Association Stakeholder Pool earlier this year, PPTA recently participated in a meeting of European trade associations with the EU Health Commissioner Vytenis Andriukaitis regarding the current draft HTA Regulation. The meeting's goal was to exchange views and concerns on the production of Joint Clinical Assessments (JCAs) and their governance. PPTA supported the idea of voluntary participation from industry in the JCAs to establish best practice, as well as a mandatory uptake of JCAs by EU Member States. PPTA also highlighted the role of trade associations as stakeholders and the need to clarify issues related to HTA methodologies.

Another current major topic at the European level is the reform of the pharmaceutical incentives by the European Commission. Earlier this year, PPTA provided its comments during the consultation period and, recently, a study on the legal aspects of the Commission's Supplementary Protection Certificates, and has published a proposal for regulation on those certificatesfor medicinal products. Finally, with regard to advocacy at the European institutions level, PPTA reached out to some members of the European Parliament and advocated that they formally put forward a Parliamentary Question (PQ) in support of the need for more plasma in the EU. The answer from Health Commissioner Andriukaitis to the PQ provided fertile ground for PPTA's future advocacy efforts: The discrepancy between current levels of plasma collection in the EU and the growing need for plasma-derived medicinal products (PDMPs) were acknowledged, and the importance of PDMPs for the treatment of EU patients was recognized.

NORTH AMERICA

The upcoming 2018 fall midterm election is one of the most momentous midterms in recent memory, as future control of the House and Senate are both unknown. Republicans previously expected to strengthen their majority in the Senate this midterm due to the 33 seats up for re-election, but when considering historical outcomes of midterm elections, the Democratic party now has an opportunity to regain control of both chambers of Congress. For Democrats to control the Senate, they only need to gain two seats and they now have a potential path to win 24 seats in the House and regain full control of Congress. This would establish a divided government for Trump's final two years of his term, limiting his ability to pass any major legislation through Congress, forcing the White House to consider implementing policy reform via executive orders and other administrative procedures.

Considering this year's midterm election, the priority on Capitol Hill has been on campaigning, rather than on hearings, policy, or legislation. However, health care reform has remained a focus for the Trump Administration, with the publication of the "American Patients First" Blueprint. PPTA responded to the Secretary of Health and Human Services' Request for Information with comments currently posted on the association's website. The comments urged the Secretary not to move reimbursement for plasma protein therapies (PPTs) in Medicare Part B to Part D and objected to the inclusion of PPTs in a flawed Competitive Acquisition Program. PPTA remains committed to its mission to promote the availability of, and access to, safe and effective plasma protein therapies for all patients in the world. •