Alliance of Specialty Medicine

Sound Policy. Quality Care.

May 1, 2019

RE: HR 2113, the "Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act of 2019"

Dear Member of Congress:

The undersigned organizations of the Alliance of Specialty Medicine (the "Alliance") write to express our concern about provisions in H.R. 2113, the "Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act of 2019" that could impact patient access to samples of drugs and devices. The Alliance represents more than 100,000 specialty physicians from thirteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

As you may know, the House Ways and Means Committee reported out the STAR Act on April 9, 2019. We are concerned that Section 3 of the legislation, entitled "Requirement for Manufacturers of Certain Drugs, Devices, Biologicals, and Medical Supplies to Report on Product Samples Provided to Certain Health Care Providers," will have a chilling effect on the provision of such samples to patients by manufacturers.

As specialists, we often treat patients in need of expensive medicines and devices. In recent years, out-of-pocket burdens have increased sharply for patients, all while utilization management restrictions have made it more difficult than ever for them to access needed treatments. Because of the delays imposed by insurers and pharmacy benefit managers, physicians often must rely on samples to begin treatment for conditions such as rheumatoid arthritis, for which time is of the essence. Insurers may take weeks or even months to approve treatment, but some conditions do not afford patients with that much time to wait.

The STAR Act would require manufacturers to report, as part of their other sunshine reporting requirements, the value of the samples they provided to physicians during the reporting period. Underlying this new requirement is the flawed premise that these samples are of value to the physician. Additionally, such a reporting requirement may lessen companies' willingness to provide samples. As noted above, with today's aggressive utilization restrictions, physicians must sometimes rely on these samples to begin treatment. If the Congress must move forward with

this new reporting requirement, we urge you to simultaneously reform insurers' ability to delay treatment through step therapy, prior authorization, and other utilization management tools.

On behalf of our patients in need of expensive treatments, we urge you not to advance the STAR Act until these concerns are addressed. Please do not hesitate to contact any of the undersigned organizations, should you have questions or require additional information.

Sincerely,

American College of Osteopathic Surgeons
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Plastic Surgeons
American Society of Retina Specialists
American Society of Cataract and Refractive Surgery
American Urological Association
Coalition of State Rheumatology Organizations