Patient groups want tighter regulation for biosimilar drugs

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion and analysis.

Twenty-three patient groups have sent a letter to the House Energy and Commerce Committee asking for hearings on biosimilar drugs and patient safety as the FDA creates regulations to implement the biosimilars approval pathway.

The groups, all members of the Patients for Biologics Safety & Access (PBSA), said they are requesting the hearings “to assure that patient safety is being fully protected as” the Food and Drug Administration implements the Biologics Price Competition and Innovation Act. The BPCIA, part of the Affordable Care Act, created a pathway for the FDA to approve follow-on biologic drugs, or biosimilars. Thus far, the FDA has approved one biosimilar under that law.

The groups said, “While our communities are eager for new and affordable treatments, patients with rare and chronic diseases are keenly aware of the possible risks associated with biologics and biosimilars, including immunogenicity and the lack of long-term safety data for new treatments.” The groups include the Arthritis Foundation and the Crohn’s & Colitis Foundation of America.

The FDA has accepted eight biosimilar applications and approved one biosimilar drug, but hasn’t yet issued final guidance on “crucial patient safety issues such as naming, labeling, interchangeability standards, and indication extrapolation,” the letter said. “We would like to see those guidances issued and finalized with full input from those who will take and prescribe biosimilars—patients and their health professionals.”

Read full, original post: Groups Want House Panel to Hold Biosimilar Hearings