

Biologics Law Committee Mission

The purpose of the Biologics Law Committee is, in part, to keep the biologics and biosimilars industry and legal practitioners up to date and provide practical advice concerning issues that are of interest to the industry. Such issues involve the U.S. Food and Drug Administration's regulation of biological products, including its implementation of the Biologics Price Competition and Innovation Act (BPCIA) and related reimbursement and substitution rules, interactions with the Food and Drug Administration, Federal Trade Commission, and state agencies, and legislative developments. The Committee will also follow the recent trends in litigation involving consumer class actions, labeling claims, biosimilars "patent dance", among others.

The Committee will also seek to engage members in programming and activities to contribute to the development of sound laws, policies, and regulations concerning the biologics industry, including biosimilars. These activities will provide members with opportunities to network with colleagues on the committee and with relevant external organizations and individuals.