

John C. Balzano Partner, Covington & Burling LLP

John Balzano represents companies and business associations on U.S. and China regulatory and policy matters related to food, drugs, medical devices, cosmetics, and other regulated products.

Mr. Balzano has over a decade of experience with legal and regulatory issues related to China, particularly with regard to products regulated by the State Administration for Market Regulation, the National Medical Products Administration (NMPA), and other agriculture, animal and healthcare (including digital health) products and services. He assists clients with developing strategies to obtain premarket approvals for these products in China, including clinical development, understanding relevant pricing and reimbursement policies, and reviewing distribution and promotional plans.

He also advises on regulatory compliance, due diligence, and enforcement matters for China operations, including drafting and revising and integrating China and global standard operating procedures, assessing the functions of regulatory departments in China, responding to inspection results and enforcement inquiries, and implementing product recalls. Mr. Balzano also has significant experience designing strategies to handle professional consumer litigation for food and cosmetic companies operating in China and working with local counsel.

He advises companies and industry associations on their advocacy strategies, including the notice and comment process before NMPA and other regulatory agencies.

Mr. Balzano has particular experience in the U.S. advising on the requirements for the acquisition and transfer of biospecimens for research purposes.

Mr. Balzano has not previously testified before the Commission.