SPEAKER BIOGRAPHIES

Biosimilars in the U.S.: Current & Emerging Issues

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AMANDA BARTELME is the director of reimbursement at Avalere Health. She provides research and analytical support on reimbursement and policy issues facing pharmaceutical, biotechnology, and medical device manufacturers. Ms. Bartelme is an expert in diabetes reimbursement and has deep understanding of both private and public payer policy for hospital inpatient, outpatient, and clinical laboratory reimbursement. She focuses on reimbursement issues for the current standard of care for diabetes as well as works to help bring new, innovative diabetes treatments to market. In addition, she leads comprehensive reimbursement assessments for new technologies across a broad range of medical conditions and settings of care, with a focus on drug and biologic products, including the emerging US biosimilars market. Ms. Bartelme's work focuses extensively on drug pricing and payment benchmarks, encompassing a deep understanding of the Medicaid Drug Rebate program, Medicare Part B Average Sales Price dynamics, and the 340B Drug Pricing Program. Prior to joining Avalere Health, she worked on issues involving reproductive health and nutrition at the International Center for Research on Women (ICRW) where she focused on women's and children's health in the developing world. Before joining ICRW, Ms. Bartelme worked at NARAL Pro-Choice Maryland where she researched and wrote a guide to reproductive health services for underserved populations in Maryland. Ms. Bartelme holds a B.S. in Sociology from Cornell University.

SALLY HOWARD is the Deputy Commissioner for Policy, Planning, Legislation, and Analysis for the U.S. Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS). In that capacity, she plays a critical role in overseeing the development and implementation of key policy initiatives, the formulation and tracking of strategic priorities, and the Agency's engagement in Congressional activities, and the application of quantitative research and analysis to emerging public health issues. Immediately prior to joining FDA, Ms. Howard was in the Office of the Secretary at HHS, where she served as the Chief of Staff since April 2011. Prior to serving as Chief of Staff, she held other senior positions including Acting General Counsel and Deputy General Counsel. In those positions, she provided legal guidance to leadership across HHS on many issues of critical importance to the department. Before joining HHS, Ms. Howard served as Chief Counsel to the Office of Kansas Governor Mark Parkinson and former Governor Kathleen Sebelius. During her tenure, she provided legal counsel to the Governor on a wide array of issues and policy initiatives and worked with the Kansas Attorney General and executive agencies across the state on significant litigation. She also previously served as Chief Counsel to the Kansas Department of Transportation. In this capacity she provided legal counsel to the Secretary, worked on significant legislation for the department, and managed complex litigation. Prior to her service in government, Ms. Howard was in private practice for 10 years where she provided legal guidance to a number of hospital clients, and handled medical malpractice, general civil, and employment litigation. Ms. Howard received her bachelor's degree from Kansas State University in 1988 and received her law degree from the University of Kansas, School of Law in 1993.

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SUMANT RAMACHANDRA is a senior vice president and the chief scientific officer at Hospira. Dr. Ramachandra brings 20-plus years of healthcare experience and strong leadership abilities to his role as senior vice president and chief scientific officer. Ramachandra has made career leading scientific advancements for some of the industry's largest pharmaceutical companies, including Merck, Pharmacia, Pfizer and Schering-Plough. As an R&D business leader, he set in motion several therapy programs that would benefit patients living with cancer – such as Camptosar® (irinotecan hydrochloride injection) and Aromasin® (exemestane tablets) at Pfizer, and Temodar® (temozolomide capsules) at Schering-Plough. He was responsible for formulating innovative strategies and executing R&D plans that resulted in successful U.S. Food and Drug Administration (FDA) approvals. Dr. Ramachandra's award-winning work is also widely recognized through publications. He has participated in a multitude of scientific studies on tumor cell biology and immunology as well as authoring book chapters about basic cell biology and oncology. He has also filed several product patents for various cancer treatments and the use of antibodies in cancer therapy. In addition, Dr. Ramachandra has appeared in the PharmaVOICE 100, which recognizes top leaders in the health sciences, as well as *Diversity MBA Magazine's* "Top 100 Under 50 Diverse Executive Leaders" and *Crain's Chicago Business'* "40 Under 40." He earned a bachelor's degree in biochemistry from Rutgers University, graduating with high honors. Dr. Ramachandra then pursued a combined M.D./Ph.D. degree from the University of Medicine and Dentistry-New Jersey Medical School, receiving the University's Medal of Excellence and subsequently conducting his residency at the Harvard-affiliated Massachusetts General Hospital. Ramachandra also earned an MBA at Wharton Business School.

GEOFFREY EICH is an executive director at Amgen, Inc. where he leads global external affairs for the company's biosimilars business. He is accountable for policy and external advocacy in support of biosimilars products being developed by Amgen. Mr. Eich comes to this position with a deep experience in biosimilars. His most recent role included corporate leadership for Amgen's strategic planning related to biosimilars where he led the integration of worldwide policy, regulatory, communications and business activities. Previously, he was director of Amgen's regulatory biosimilar group with significant focus on establishment and implementation of the U.S. biosimilar pathway as authorized by Congress in 2010 in the Biologics Price Competition and Innovation Act (BPCIA). Mr. Eich joined Amgen in 2007 and his leadership roles have afforded the opportunity to work in and alongside many business functions including R&D, regulatory, government affairs, communications, manufacturing & quality, commercial operations and law. His teams have spanned Amgen sites in Washington D.C., Colorado, California and Switzerland. He has worked extensively with Amgen's European, Canadian and emerging market affiliates on important biosimilars issues. Mr. Eich has advocated and testified before State, Federal and international government bodies as well as regulatory organizations worldwide. He is a frequent public speaker and a key Amgen spokesperson on the subject of biologic/biosimilar medicines. Mr. Eich holds a Bachelor's of Science degree from the U.S. Naval Academy at Annapolis and a Masters of Business Administration from the University of Maryland. He is also a Paul Harris Fellow.