SPEAKER BIOGRAPHIES

Biosimilars in the United States: Next Steps

Monday, June 20th, 2016

Sean Cavanaugh is the deputy administrator and director of the Center for Medicare at the Centers for Medicare & Medicaid Services (CMS). He is responsible for overseeing the regulation and payment of Medicare fee-for service providers, privately-administered Medicare health plans, and the Medicare prescription drug program. Medicare provides health coverage to 50 million elderly and disabled Americans, with an annual budget of over $550 billion. Prior to assuming his current role, Sean was the deputy director for programs and policy in the Center for Medicare and Medicaid Innovation (CMMI). In that capacity, he was responsible for overseeing the development and testing of new payment and service delivery models, including accountable care organizations and medical homes. Previously, Mr. Cavanaugh was director of health care finance at the United Hospital Fund in New York City. He has also served in senior positions at Lutheran Healthcare (Brooklyn, NY), the New York City Mayor's Office of Health Insurance Access, and the Maryland Health Services Cost Review Commission. He started his career on Capitol Hill working for a member of the Ways and Means Subcommittee on Health. He attended the University of Pennsylvania and the Johns Hopkins School of Hygiene and Public Health.

Leah Christl is the associate director for therapeutic biologics in the Office of New Drugs (OND) in the FDA's Center for Drug Evaluation and Research. Dr. Christl leads the Therapeutic Biologics and Biosimilars Staff (TBBS) in OND. TBBS is responsible for ensuring consistency in the scientific and regulatory approach and guidance to sponsors regarding development programs for proposed biosimilar biological products and related issues regarding development programs for therapeutic biologics. TBBS is also responsible for developing scientific and regulatory policy as it relates to the review and approval of biosimilar products. In addition, TBBS is responsible for developing the procedures and staff training necessary to implement the Biologics Price Competition and Innovation Act of 2009 and the Biosimilar User Fee Agreements in a consistent manner across all OND review divisions, and for managing the CDER Biosimilar Review Committee. Dr. Christl represents OND as a technical and scientific expert within CDER and other Centers within FDA and represents FDA with other Federal, State and local agencies, academia, and regulated industry with regard to biosimilar products, follow-on versions of complex protein products, follow-on versions of other complex products, and biological products through participation on and coordination of committees, working groups, panels, meetings, and conferences. Dr. Christl also represents FDA with international regulatory agencies and international trade and industry organizations for activities related to biosimilars. She is the Center's principal advisor for all international activities related to biosimilars, including serving as FDA lead for the FDA-EMA-Health Canada-PMDA biosimilars cluster and other international working groups. Prior to joining the FDA, Dr. Christl received her Ph.D. in Molecular and Cellular Biology and Pathobiology – Marine Biomedicine and Environmental Science from the Medical University of South Carolina in Charleston. She also spent 2 years at the University of South Carolina as an associate research professor.

Barbara Finck is a board certified rheumatologist with more than 20 years of preclinical and clinical drug development experience in academic and biopharmaceutical settings. She received her rheumatology training at University of California, San Francisco, where she studied the effects of CTLA4-Ig (subsequently developed and marketed as Orencia®) in a murine lupus nephritis model. Dr. Finck, whose drug development activities have spanned multiple therapeutic areas, started her pharmaceutical career at ALZA as medical director for early clinical development of Ditropan-XL®, to treat spasms of the bladder. She subsequently held senior level positions at a half-dozen innovative biopharmaceutical companies. At Immunex (later acquired by Amgen) she was lead medical director for the Phase III clinical development of Enbrel® in rheumatoid arthritis and juvenile idiopathic arthritis. At Eos Biotechology, she was vice

(over)

president for clinical development. In addition, she was on the executive teams at PDL Biopharma, Osprey Pharmaceuticals USA, Inc., and NKT Therapeutics, Inc. Throughout her career in pharmaceutical development, Dr. Finck has demonstrated the ability to build effective teams and alliances, as well as a personal passion for developing therapeutics to treat diseases where there is significant unmet medical need. Dr. Finck joined Coherus Biosciences, a pure play biosimilars company, in 2012 and has served as Chief Medical Officer for Coherus since 2013.

Brian Lehman is manager of pharmacy benefits and policy at the Ohio Public Employees Retirement System (OPERS), the 11th largest public retirement system in the United States. Lehman focuses on managing programs, services and plan design aspects of the retiree prescription drug program. He also focuses on influencing pharmacy policy and regulations impacting the retiree prescription drug program. Lehman has been involved with legislative and regulatory efforts to improve patient access to affordable medications such as generics and biosimilars. Lehman has more than 18 years of pharmacy plan management and retail pharmacy management experience, including activities in specialty drug management, pharmacy policy, consulting, formulary and utilization management, development and implementation of clinical programs, teaching, development of business plans and leadership. Prior to joining OPERS, he was employed by The Ohio State University as director of pharmacy benefits at the OSU Health Plan and at Target Pharmacy as an executive pharmacy team leader. During his career Lehman has spoken at various events on topics such as biosimilars, value based purchasing of drugs, comparative effectiveness research and value based insurance design. He has served as a clinical assistant professor at The Ohio State University College of Pharmacy and is currently serving as an adjunct professor teaching students on managed care pharmacy and policy. He has been an active member with the Academy of Managed Care Pharmacy and is currently serving on the Public Policy Committee. Lehman received his Bachelor of Science degree in Chemistry from Otterbein University and a Bachelor of Science Degree in Pharmacy from The Ohio State University. He also earned his Masters of Business Administration from Franklin University and Masters in Health Administration from The Ohio State University.

Leigh Purvis is the director of health services research in AARP's Public Policy Institute. She leads a team of policy analysts and researchers who work on health care issues that are relevant to the 50+ population. In addition, Ms. Purvis heads the Institute's work on prescription drug and mental health issues. Her primary areas of expertise are prescription drug pricing, biologic drugs, and prescription drug coverage. She is a coauthor of the Public Policy Institute's annual Rx Price Watch reports, which track price trends for prescription drugs widely used by older Americans. Ms. Purvis joined AARP in 2005 as a senior policy research analyst. Prior to her tenure at AARP, she worked for the American Psychological Association. Ms. Purvis is a recognized expert on prescription drug issues and frequently speaks with the press. Ms. Purvis has a MPA with a concentration in health administration and policy from George Mason University and a BS in psychology from the University of Mary Washington. She also holds a certificate in gerontology from the University of Washington.

Angus Worthing, MD, FACR, FACP, is a practicing rheumatologist at Arthritis & Rheumatism Associates, a large single-specialty rheumatology group in the Washington, DC metro area. He is a Clinical Assistant Professor of Medicine at Georgetown University Medical Center. Dr. Worthing is a member of American College of Rheumatology's Government Affairs Committee and previously was chair of the ACR's Affiliate Society Council, made up of local and state rheumatology societies focusing on issues of independent clinical practice and management. He is a director of the Medical Society of the District of Columbia. He chairs the Public Policy Education Committee of the Rheumatism Society of the District of Columbia, for which he also served as president in 2010. He has spoken on a range of health policy issues related to access to rheumatology care in a variety of settings including Capitol Hill briefings, FDA public meetings, state rheumatology societies, and the DC City Council. Dr. Worthing is a graduate of Princeton University and the University of Minnesota Medical School.