Gordon Johnston

Vice President of Regulatory Sciences, Generic Pharmaceutical Association

Gordon Johnston is Vice President of Regulatory Sciences at the Generic Pharmaceutical Association. In this role, he serves as the primary industry spokesperson on regulatory matters that impact the generic drug industry.

Johnston has more than 25 years of experience in the pharmaceutical industry, beginning with the U.S. Public Health Service, where he served in a number of pharmacist and health care management positions. In 1987, he was assigned to the Food and Drug Administration (FDA) and in 1994, was promoted to be Deputy Director of the FDA's Office of Generic Drugs (OGD). The OGD is responsible for the review and approval of all generic drugs in the United States. During his tenure at the federal agency, Johnston was a key member of the FDA team that developed and put into practice the regulations implementing the Hatch-Waxman amendments. While at the FDA, Johnston interfaced with a number of foreign governments on generic drug regulatory standards.

Following his retirement from the FDA in 1999, Johnston served as a consultant to the pharmaceutical industry. He also has spoken at numerous national and international meetings on regulatory and technical issues related to generic drugs.

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Suzette Kox is Senior Director Scientific Affairs of the European Generic medicines Association (EGA) and coordinator for the European Biopharmaceuticals Group (EBG), a sector group of the EGA, the EMEA-EGA Working Group and the EGA Safety & Pharmacovigilance Working Group.

Suzette is also Member of the Science Committee of the International Generic Pharmaceutical Alliance (IGPA) and belongs to the visiting faculty of the School for International Training: Department Development Studies and Public Health in Geneva, Switzerland.

Previously she worked for 10 years in regulatory affairs and management for the German generic company ratiopharm and was Chair of the EGA Regulatory & Scientific Affairs Committee and Member of the EGA Board and Executive Committee.

Before joining the generic industry, she followed a hospital and retail pharmacy career. Along with a degree in pharmacy (Paris) she holds a postgraduate diploma in anatomy-pathology.

Dr. Li is a Lead Pharmacologist and Team Leader in the Division of Bioequivalence, Office of Generic Drugs, Center of Drug Evaluation and Research, U.S. Food and Drug Administration (FDA). Her current responsibility is to review drug products submitted in Abbreviated New Drug Applications (ANDAs), to determine the adequacy of the data from bioequivalence studies based on study design, analytical methodology, and statistical analysis. Prior to joining FDA in 2004, she was a research investigator at Bristol-Myer-Squibb where her responsibilities included formulation identification, development and optimization for oral solid dosage form formulations. She received her PhD in Pharmaceutical Sciences from University of Wisconsin at Madison in 2001, and a bachelor degree in Medical Chemistry in 1990 in Beijing Medical University, China.

JUSTINA A. MOLZON, M.S. Pharm., J.D.

Associate Director for International Programs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

CAPT Molzon is a pharmacist and attorney, and a commissioned officer in the U.S Public Health Service. She is currently the Associate Director for International Programs, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration and a member of CDER's senior management team. One of her primary responsibilities is coordination of CDER's efforts related to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In this capacity, she serves as CDER's representative to the ICH Steering Committee. She also coordinates CDER's activities related to the President's Emergency Plan for Aids Relief (PEPFAR) and is involved in technical outreach to the PEPFAR focus countries. She received her B.S. (with honors and distinction) and M.S. in Pharmacy, with a concentration in pharmaceutics and pharmacognosy, from the University of Rhode Island and law degree from the Chicago-Kent College of Law/Illinois Institute of Technology. She is a Fellow in the American Society for Pharmacy Law, serving on its Board of Directors from 1989-1997. Her PHS assignments include serving as a pharmacist on the Navajo Indian Reservation and also the Regional Pharmacist Consultant and Inspector for the Health Care Financing Administration's Survey and Certification Review Branch, in Chicago. Upon leaving the Public Health Service to go to law school, she was a clinical pharmacist in the critical care area of Northwestern University's teaching hospital. After law school, she maintained a private law practice and worked with a pro bono legal program for persons with AIDS. In 1990, she rejoined the Public Health Service to work in FDA's Office of Generic Drugs. In 2008 she was honored with the US Public Health Service Mary Louise Andersen Leadership Award (pharmacist of the year) for extraordinary dedication and leadership in support of global public health. In 2009 she was awarded an exemplary service award by the Surgeon General of the United States for her international efforts. She is very grateful to have the opportunity to work with international drug regulatory authorities in assuring the safety, efficacy and quality of pharmaceuticals worldwide.

Dr. Viswanathan is currently Associate Director in the Division of Scientific Investigations, Office of Compliance, Center for Drugs & Evaluation Research, FDA. He has policy oversight in the scientific and regulatory administration of GLP and Bioequivalence Inspectional programs.

He received a M.S. in Chemistry from Marquette University, Milwaukee, a second M.S. in Pharmacology and Ph.D in Pharmacokinectics from the University of Wisconsin, Madison. Following post-doctoral research at the University of Georgia and the University of Washington, Seattle, he joined the FDA.

In FDA, Dr.Viswanathan has served as clinical pharmacology reviewer, followed by, as the Chief of Pharmacokinetics Branch and the acting Director of the Division of Biopharmaceutics (currently clinical pharmacology) prior to joining the Office of Compliance.

He has represented the Food and Drug Administration in numerous national and international meetings and has authored several research publications. He has taught Pharmacology, Drug metabolism, Pharmacokinetics and Biopharmaceutics at the University of Wisconsin, University of Montreal, FDA Staff College and NIH Graduate School . He has served on numerous committees in FDA , NIH, PhRMA, SQA, BSAT and AAPS. He is a past Chair of the Regulatory Sciences section of AAPS. He is a Fellow of the American Association of Pharmaceutical Sciences and the recipient of numerous FDA awards. Dr.Viswanthan is the Chair of the FDA GLP Modernization Working Group and represents all Centers of the Agency in OECD for GLP.

Keith Webber, Ph.D.

Deputy Director, Office of Pharmaceutical Science, Food and Drug Administration

Dr. Keith Webber is Deputy Director of the Office of Pharmaceutical Science in the Center for Drug Evaluation and Research (CDER) at the FDA. The Office of Pharmaceutical Science oversees the regulation of product quality of innovative and generic drugs produced synthetically or via biotechnology.

He holds a Bachelor of Science degree in Chemistry from the University of Denver, Colorado and a Doctorate in Biological Chemistry from the University of Michigan.

He has been with the FDA since 1995 and has served as Director of the Division of Monoclonal Antibodies in the Center for Biologics Research and Review and Acting Director of the Office of Biotechnology Products at CDER. In addition to his current role as Deputy Director of the Office of Pharmaceutical Science, he is also serving as the Acting Director of the Office of Generic Drugs.

Dr. Ling Ye received her BS in general chemistry and MS in physical chemistry in Tsinghua University in Beijing, China. After working for two years in the Institute of Photographic Chemistry, Chinese Academy of Sciences, she came to the US and earned her Ph.D. in bioanalytical chemistry in the University of Texas at Austin. She worked at Bayer Corporation from 1993 to 1998, developing glucose self testing device for diabetes management. She joined Abbott Laboratories' Hospira Product Division as a Sr. Research Scientist, working on generic pharmaceutical product development, and plant and marketed product support. She is currently the Manager for Global R&D Collaborations in the Early Stage Development, Hospira, Inc., responsible for concept initiation, development and assessment for new and improved pharmaceutical products and programs, and seeking and managing external collaborations and out-sourcing projects. From 2005 to 2009, she represented the US Generic Pharmaceutical Association (GPhA) participating in JCCT's (US-China Joint Commission on Commerce and Trade) Pharmaceutical and Medical Device Task Force meetings between the US DOC (Department of Commerce) and various Chinese governmental agencies, especially with SFDA. She is an appointed adjunct professor in Beijing University, teaching generic drug development and manufacturing. Dr. Ye is a Board Director and immediate past Chair of the Board of Chinese-American Chemical Society.

CURRICULUM VITAE
Mr. Yasunori YOSHIDA
Personal details
Date of birth: September 29, 1964
Education
1988 Graduated from the University of Tokyo
Bachelor of Pharmaceutical Science
1990 Received the Master degree at the University of Tokyo
Master of Science (Pharmaceutical Science)
Business Experience
1990 Entered Ministry of Health and Welfare (MHW) of the Japanese government
1990-1993 New Drugs Division, Pharmaceutical Affairs Bureau, MHW
1993-1995 Evaluation and Licensing Division, Pharmaceutical Affairs Bureau, MHW
1995-1997 Chief, Livestock health Division, Livestock Bureau, Ministry of Agriculture, Forestry and Fisheries
1997-1998 Deputy Director, Medical Economics Division, Health Insurance Bureau, MHW
1998-2001 Consul, Consulate general of Japan, Melbourne, Ministry of Foreign Affairs
2001-2003 Deputy Director, Standards Division, Food Safety Department, Ministry of Health, Labour and Welfare(MHLW)
2003-2006 Director, Pharmaceutical Policy Division, Health and Welfare Department, Toyama prefecture
2006-2006 Deputy Director, Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, MHLW
2006-2008 Deputy Director, General Affairs Division, Pharmaceutical and Food Safety Bureau, MHLW
2008-present **Office Director, Office of OTC/Generic Drugs,**
Pharmaceuticals and Medical Devices Agency (PMDA)

Lawrence X. Yu, Ph.D.
Director for Science and Chemistry, Office of Generic Drugs, Food and Drug Administration

Dr. Lawrence X. Yu is the Deputy Director for Science and Chemistry at the Office of Generic Drugs, Food and Drug Administration. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan. Prior to joining the FDA, Dr. Yu had worked at Pfizer (Upjohn) and GlaxoWellcome for 8 years. Dr. Yu joined the FDA in 1999 and has served as Team Leader, Deputy Division Director, and Division Director. Dr. Yu's research interests have centered on the prediction of oral drug delivery and the development of pharmaceutical Quality by Design. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUS™ and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the past Physical Pharmacy and Biopharmaceutics Section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the *AAPS Journal*. Dr. Yu has authored/co-authored over 200 papers, book chapters, and abstracts, and given over 120 invited presentations. He is a co-editor of the book entitled "*Biopharmaceutics Applications in Drug Development"*. Dr. Yu is the winner of numerous awards including the American Foundation for Pharmaceutical Education Fellowship, AAPS Excellent Graduate Research, Department of Health and Human Service Outstanding Leadership Award, FDA Commissioner's Special Citation, Outstanding Achievement, Group Recognition, Regulatory Science, and Team Excellence awards, Upjohn special recognition award, and Naigai Foundation Japan Tokyo Distinguished Lectureship. Dr. Yu received his B. S. in Chemical Engineering from Zhejiang Institute of Technology, his M. S. in Chemical Engineering from Zhejiang University, his M. S. in Pharmaceutics from the University of Cincinnati, and his Ph.D. in Pharmaceutics from the University of Michigan.

Brenda Uratani, Ph.D.
Assistant Country Director
Brenda Uratani serves as Assistant Country Director for FDA's China Office, and holds responsibility as FDA's primary senior technical expert on issues related to drugs and pharmaceuticals. Before joining FDA's China Office, Dr. Uratani served as the Senior Compliance Officer in the Office of Compliance within FDA's Center for Drug Evaluation and Research (CDER). Before her time with FDA, Dr. Uratani worked as a research scientist for a number of years in the field of molecular genetics and biotechnology, at the National Institutes of Health, and later at a biotech firm. Dr. Uratani has extensive working experience in both CMC (Chemistry, Manufacturing, and Control) reviews and GMP (current Good Manufacturing Practice) inspection and compliance review. She served as the Branch Chief in the CDER Biotech Manufacturing Group in 2007. She is a member of the FDA Foreign Inspection Cadre. During her time with FDA/CDER, she played a key role in developing drug CGMP regulations, guidances, and compliance policies. Dr. Uratani is the sterile drug and biotech drug expert in CDER. Among the recent FDA publications, she was central in the drafting and publication of the FDA Guidance for Sterile Drugs processed by Aseptic Processing, the new CGMP regulations for Positron Emission Tomography and guidance, and the Phase 1 IND Guidance. Dr. Uratani is a member of the FDA PAT team, and the PQRI working group. She is active in outreach, and represented FDA frequently in industry training. She received her Ph.D. degree from Brown University.

BIOGRAPHY
JEFFREY L. GREN, DIRECTOR
OFFICE OF HEALTH AND CONSUMER GOODS, U. S. DEPARTMENT OF COMMERCE

Jeffrey L. Gren has been Director of the Office of Health and Consumer Goods (OHCG) within the U.S. Department of Commerce since August 2004. OHCG's mission is to help U.S. health and consumer goods firms to compete in world markets by fostering export opportunities, providing support for trade negotiations, performing industry analysis, working with foreign governments to reduce regulatory and other trade barriers, and developing industry-led joint government/industry initiatives. Prior to being OHCG Director, Mr. Gren has been Director of the Office of Microelectronics, Medical Equipment and Instrumentation (OMMI) from 1991 to 2004 - also within the U.S. Department of Commerce.

Examples of major accomplishments as Director of OHCG and OMMI include: leading numerous trade and policy missions to promote U.S. health and microelectronic products; developing programs to promote U.S. health industry products in major global markets; organizing global anti-counterfeit medical product seminars and activities, and serving in a leadership role in the U.S. - China Pharmaceuticals and Medical Devices Subgroup. Mr. Gren works with major health industry associations, USFDA and other global regulatory agencies to improve the global regulatory environment for the U.S. medical industry. Mr. Gren also represents the Department of Commerce on the Medical Devices Global Harmonization Task Force (GHTF). Mr. Gren has also organized and developed numerous health regulatory training programs for regulators and firms from countries with developing revised regulatory regimes, such as China, Russia, Ukraine, Asia and Latin America.

Mr. Gren completed the DOC Senior Executive Service (SES) Candidate Development Program. This is a two-year program that included training, teamwork, and a four-month developmental assignment. Mr. Gren completed his four-month developmental assignment at U.S. Pharmacopoeia (USP) in Rockville, Maryland. USP is an official standards setting body for the U.S. pharmaceutical, biotechnology and dietary supplement industries. While at USP, Mr. Gren helped USP expand their international activities.

Prior to working as the Office Director for OHCG and OMMI, Mr. Gren was Senior Policy Advisor to the Deputy Assistant Secretary for Basic Industries, also within the U.S. Department of Commerce. In this position Mr. Gren coordinated a variety of activities related to the metals, chemicals, pharmaceuticals, biotechnology, wood products, construction and energy industries. From 1976 through 1990, Mr. Gren was Deputy Director of the U. S. Department of Commerce Trade Adjustment Technical Assistance Program. The Trade Adjustment Technical Assistance Program helps firms and industries injured by foreign trade.

Before joining the Department of Commerce, Mr. Gren worked for the Massachusetts Department of Community Affairs, Office of Program Development, where he served as Deputy Director and a Senior Policy Analyst. In these positions, Mr. Gren was responsible for developing housing and community development programs and managing statewide housing planning.

Mr. Gren received a Masters of Arts in Economics from Northeastern University, Boston, Massachusetts in 1972, and a Bachelor of Science in Business Administration from Northeastern University in 1971. In 2007, 2003, 1999, and 1997 Mr. Gren received the International Trade Administration Bronze Award (ITA's highest medal award), in 2010, 2009, 2000 and 1996 he received the Department of Commerce Silver Award (DOC's second highest medal award) and in 2006 and 2005 he received Under Secretary for International Trade Quarterly Stars Awards. In 2004 Mr. Gren received the prestigious "Kite and Key Award" from the National Electrical Manufacturers Association (NEMA).