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Rie Matsui: has disclosed that she is an employee and stock shareholder of Pfizer.

Gerrit Nijveldt: has disclosed that he is an employee and stock shareholder of Sanofi.

The following have reported no relevant financial relationships to disclose:
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DIA Staff have reported no financial relationships to disclose.

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LCDR Jibril Abdus-Samad
LCDR Jibril Abdus-Samad is the Labeling Reviewer for the Office of Biotechnology Products (OBP), Office of Pharmaceutical Quality/CDER/FDA. Currently, LCDR Abdus-Samad evaluates labeling for all biological products within OBP for compliance with regulations and labeling standards. Prior to OBP, LCDR Abdus-Samad served as a Safety Evaluator within the Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology for 6+ years. He practiced in various pharmacy settings within the Veterans Affairs System and private sector. LCDR Abdus-Samad received his PharmD from the University of the Sciences in Philadelphia and a Graduate Certificate in Patient and Product Safety from the University of Southern California.

Tara Baer
An experienced leader in Medical Device and Pharmaceutical labeling, Tara has worked at such industry leaders as AbbVie, Boston Scientific, Wyeth and Intervet, where she developed a passion for End-to-End Labeling Management, from safety through distribution. An experienced manager, guide and motivator she has led diverse teams of professionals towards collaborative solutions. She specializes in translation management, workflow, content development, artwork management, automated tracking/process integration, and asset management. Tara is the founder of Leaders in Labeling, a group of thought leaders in labeling for regulated products, pharmaceutical, biologics and medical devices.

Steven Bass, PhD
Dr. Bass is President of Bass BioPharm Consulting Group LLC and serves as Vice President, Talent Acquisition for Ruderfer and Associates and executive Biopharmaceutical Search Firm. Dr. Bass retired from Bristol-Myers Squibb as Group Director, Global Labeling. Fujisawa and Fujisawa SmithKline Corporation, Wyeth-Ayerst and Eastman Pharmaceuticals. He received his BS in Pharmacy from Philadelphia College of Pharmacy and Science and his PhD in Pharmacology/Toxicology from Thomas Jefferson University, Graduate School of Biomedical Science. He did a postdoctoral fellowship in Cardiovascular/Pulmonary Pharmacology at the University of Pennsylvania.

Terry Brunone
Terry has been in the pharmaceutical industry since 1993. She has supported Regulatory Affairs and

Product Information areas throughout that time. Since 2003, she has worked with US and Global Labelling in Operations and Compliance areas. Her current role of Labelling Compliance Lead assures that regulatory labelling throughout the local operating companies within GSK are managing their compliance with labelling safety updates. She also leads the Structured Product Labeling Working Group Leadership Team, a group representing manufacturers, vendors, downstream users and the FDA in the varied uses and challenges of SPL.

Dora Cohen
Dora Cohen leads the Regulatory Global Labeling group at Amgen. She has held this position for the last 10 years managing end-to-end labeling documents from Core Data Sheets, Regional Prescribing Information, Instructions for Use, and Package Component Labeling. Dora brings nearly 35 years of pharmaceutical experience and has performed roles in Clinical Trial Management, Regulatory Writing, and Labeling. Dora holds Bachelors of Arts and Master of Science degrees from University of Bridgeport.

Mark Collins
Mark A. Collins is Senior Director, Risk Management & Global Labeling Advisor at Endo Pharmaceuticals Inc. in Malvern, PA. Mark has responsibility for multiple REMS programs, including single and shared systems for brand and generic products. Mark's professional experience includes fifteen years with Wyeth Pharmaceuticals. After starting as a Medicinal Chemist, he spent three years in Project Management and seven years in the Global Labeling Department, and he is now approaching his fifth anniversary as an Endo employee. Mark has participated as a member of the organizing committee for several DIA Labeling and Risk Management conferences, and is a former co-Chair of the DIA Labeling Working Group.

David Dorsey
David Dorsey leads a group at Janssen Research & Development focused on pharmaceutical regulatory policy at the US FDA and in Latin America. Before joining Janssen, David served at the FDA in various roles, including Acting Assistant Commissioner for Policy and Planning, Acting Deputy Commissioner for Policy, Planning, and Budget, and Assistant Chief Counsel. For over 8 years, David was detailed from the FDA to the Senate Health, Education, Labor, and Pensions Committee, where he worked for Senator Edward M. Kennedy on FDA and public health matters, including the Biologics Price Competition and Innovation Act.

Barbara Fanelli, MSc
Barbara Fanelli, MSc. Is the retired Associate Vice President, Regulatory Affairs at Sanofi-Aventis U.S., LLC and retired Senior Director, Worldwide Product Labeling at Merck and Co. In both companies, Barbara worked in the development and maintenance of corporate, United States and European Union physician and patient labeling for prescription drug products, biologics and OTC products and review of other local labeling. Barbara is currently the Associate Adjunct Professor, Temple University, Master's program for Regulatory Affairs and Quality Assurance.

Leander Fontaine, MD
Leander Fontaine is the President of Pharmiceutics LLC, a consulting firm based in Pennsylvania, USA. Before founding Pharmiceutics in 2005, Leander served as Vice President and Head of Global Labeling Division and Vice President, International Labeling Liaison, for Wyeth, USA. He started his career in global labeling in 1991 and has served as head of global labeling functions for Hoechst (Germany) and Hoechst Marion Roussel (USA). He has also held positions in clinical development and clinical pharmacology with Behringwerke (Germany). Before joining the pharmaceutical industry, he worked as a physician in internal medicine as well as in anesthesiology, intensive care and emergency medicine.

Michelle Halliez
Michelle has over 18 years of experience in the pharmaceutical industry and has broad experience spanning a variety of roles in labeling, promotion compliance, regulatory operations, and medical information across several therapeutic areas. Michelle has made direct contributions to over 20 new product launches. She has acted as a change catalyst throughout her career with extensive

understanding of change management, process development and optimization, organizational transformation, establishing end-to-end corporate policy, and implementing information management tools.

Paula Hudson
Paula is the Director of the Global Labeling Department at Eli Lilly in Indianapolis, Indiana. She received her B.S. in Pharmacy from Purdue University. She began her career at Lilly with experiences in manufacturing technical services, clinical trial packaging and coordination, and quality assurance. Her first role in regulatory was in 2004 as the Director of Site Regulatory Affairs overseeing the CMC Post-Approval organization. Upon determining Regulatory Affairs would be her home, she took a role in US Advertising and Promotions before arriving in the Global Labeling Department in 2012. In addition to ensuring portfolio needs are met from a labeling perspective, Paula serves as Process Owner for Global Labeling where she has led the improvement of business and governance processes and the implementation of an end to end labeling tracking system.

TamaraJohnson
Dr. Johnson is the Lead Medical Officer for the Maternal Health Team within the FDA/CDER Office of New Drugs (OND) Division of Pediatric and Maternal Health (DPMH). The Maternal Health Team is responsible for evaluating the safe use of drug and biologics products in pregnant and lactating women, and are the Agency experts on the Pregnancy and Lactation Labeling Rule. Dr. Johnson earned her Doctorate in Medicine from Rutgers Robert Wood Johnson Medical School in New Jersey. She completed internship at Georgetown/Providence Hospital Family Medicine program and completed residency training in General Preventive Medicine/Public Health at the University of Maryland Baltimore.

Barbara Lachmann
Barbara Lachmann is an independent Labeling Consultant located in Hofheim, Germany. She provides consultation for pharmaceutical companies and other organizations on labeling requirements worldwide as well as on adequate labeling processes. She also performs labeling services for creation and maintenance of Company Core Data Sheets (including their implementation) and/or EU labeling documents. Previously, she worked for more than 20 years in the Global Labeling departments of several multinational pharmaceutical companies (Hoechst and its successor companies Hoechst-Marion-Roussel and Aventis, as well as Merck KGaA) and was responsible for global and EU labeling strategies and labeling decision-making.

Bruce Leicher, JD
Bruce Leicher is Senior Vice President and General Counsel at Momenta Pharmaceuticals Inc. Bruce has advised biotechnology companies for over 20 of his more than 30 years of legal experience. Bruce is also Vice Chair of the Board of the Biosimilars Council, a Division of GPhA. In private practice, he served as the Co-Chair of the Life Sciences Practice Group at Hill and Barlow, was an attorney at Hale and Dorr and Butler & Binion, and served as a law clerk to the Honorable Thomas F. Hogan in the U.S. District Court for the District of Columbia after receiving his JD from Georgetown University Law Center and his BA from the University of Rochester.

Su-Yueh Lin
As the Senior Director and Head of Regulatory Labeling in Regeneron Pharmaceuticals, Inc. NY, Su manages the processes and operations for labeling activities including CCDSs, country labeling for HA submissions, packaging artworks, and target labeling, for development and marketed products. Su previously worked in Global Labeling with BMS, NJ managing global labeling projects and training BMS regulatory personnel in Europe, Asia Pacific, Latin America, and Canada on global labeling process and the CCDS. Su was also an experienced global labeling compliance auditor while working at Wyeth and a clinical hospital pharmacist. Su is the Co-Chair of the DIA Regulatory Affairs Labeling Community.

Megann Looker
Megann Looker (BA Hons) is the Associate Director of EMEA Regulatory Labelling at Celgene Europe,

based in London. She graduated from the University of Reading in 2001 after studying Classics, English Literature and Sociology, and found her way into Regulatory Affairs whilst planning a career in teaching. Megann joined Celgene in 2009 in Regulatory Intelligence and since 2010 has been responsible for Labelling and Product Information (content development, patient information, tracking and implementation) for the EMEA region. She is a member of the InterAssociation Task Force for IDMP, eLabelling, and DIA SIAC Patient Information.

Gerrit Nijveldt
Gerrit Nijveldt is the Senior Director Global Regulatory Affairs Labeling for the therapeutic area Diabetes and Devices for Sanofi in Bridgewater NJ. He has over 18 years of experience in Global labeling and a broad experience in developing and maintaining Company Core Data Sheets, US Prescribing Information and EU Summary of Product Characterisation, including the labeling for multiple development products. Gerrit has experience with information management tools, SPL, agency inspections and setting up end-to-end labeling process. He earned his MSc in Medical Biology from the Univ. of Utrecht in the Netherlands and started working in the pharmaceutical industry in 1991, in the Netherlands, in Regulatory Affairs and Medical Information dept.

Michelle Remillard
Michelle Remillard is a Senior Policy Analyst with the Therapeutic Products Directorate, Health Products and Food Branch at Health Canada. Michelle holds a Bachelor of Science, Honours degree in Biology from the University of Guelph. She began her career with Health Canada 22 years ago, in the virology laboratories and today leads policy initiatives involving labelling. She is project lead on the Product Monograph file. Michelle led the revisions to Part III: Patient Medication Information, of the Product Monograph Guidance, released in 2014, and she has just completed revisions to Part I: Health Professional Information, and Part II: Scientific Information.

Julie Retzinger
Julie is the Senior Director of CCDS- Labeling for Astellas Pharma Inc. She provides expertise in the authoring and management of Company Core Data Sheets, early labeling development and life cycle management of labeling. Julie has over 20 years of experience dedicated to global labeling and CCDS. Her past experience included phase 3-4 research and development, management of phase IV registries for anesthesia and sedation therapeutics. Prior to entering the pharmaceutical industry, she provided nursing care as an RN in the Critical Care and Cardiac Care Units. Julie holds a BS in Biology from Truman State University, an RN degree from St. Francis Hospital School of Nursing and a MBA from Lake Forest Graduate School of Management.

Ann Robards
As the global regulatory affairs labeling consultant, Ann is responsible for creating global and affiliate medical device labeling, including labeling for Mobile Medical Applications. She partners with a cross-functional group of device and software engineers to collaboratively develop content for the user interface of Lilly's digital device initiatives to align with US FDA regulations and patient labeling guidelines. She has worked for Lilly over 11 years with prior experience in pharmaceutical sales and clinical research. Ann holds a BS in Animal Science and a MS in Animal Nutrition. Ann recently completed a Certification in Health Literacy and Communication for Health Professionals with the University of Nebraska Medical Center.

Tracy D. Rockney JD
Tracy Rockney is a respected regulatory leader with more than 20 years of experience in the pharmaceutical industry. She is the Co-founder and Managing Partner at OneSource Regulatory, a consulting firm specializing in Regulatory Advertising & Promotion, Medical Review, Labeling Development and Healthcare Compliance. Tracy received her JD from Washburn University School of Law, and her BA from the University at Albany, SUNY, Rockefeller College of Public Affairs & Policy. Tracy is a board advisor and Regulatory Officer in Residence for Doctor Evidence, a specialty software platform and services company that transforms clinical studies, drug labeling and epidemiological

databases into reusable dynamic relational databases.

Dave Thatcher
Dave Thatcher has been in the biopharma industry for over 20 yrs. His career has included Filling/ Packaging equipment selection, installation and commissioning, secondary packaging design and qualification and for the last 8 years commercial artwork processing.

Joseph P. Thomas
Dr. Thomas is Chair of the Life Sciences Group and Co-chair of the Litigation Department at Ulmer & Berne LLP. He has extensive experience in scientifically complex litigation, and often serves as national counsel to a broad range of pharmaceutical clients. He holds undergraduate and doctorate degrees in pharmacy, has conducted clinical research, and has published in the scientific literature. He also is a member of the patent bar. His experience includes class actions, MDL litigation, mass torts, and catastrophic-injury litigation. He represented PLIVA in the *Mensing* case and Mutual Pharmaceutical

LT Morgan Walker, MBA, PharmD
LT Morgan Walker is a Patient Labeling Reviewer for the Division of Medical Policy Programs (DMPP), Office of Medical Policy Initiatives/OMP/CDER/FDA. Currently, LT Walker evaluates patient labeling for several divisions within the Office of New Drugs for compliance with regulations and patient labeling standards. Prior to DMPP, LT Walker served as a Safety Evaluator within the Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology. LT Walker received her PharmD from Howard University, completed a 2 year Health-Systems Pharmacy Administration Residency at Johns Hopkins Hospital and received her MBA at Johns Hopkins University.

Elisabeth Walther
Elisabeth Walther is a health scientist policy analyst at the US Food and Drug Administration where she currently leads regulatory policy development related to patient prescription drug product information. She also continues to practice as a community pharmacist. She holds a Doctor of Pharmacy and Juris Doctor from Drake University.

Veronica Yip
Veronica Yip has over 13 years of Canadian pharmaceutical regulatory experience. As the Manager of the Labelling Division in the Therapeutic Products Directorate (TPD), she is currently responsible for advancing TPD's current and future drug label review mandate and delivery objectives. Ms. Yip previously worked as a Labelling Reviewer for three years with the Bureau of Pharmaceutical Sciences. She has also served as Acting Manager of the Regulatory Project Management Division in TPD; and Senior Regulatory Manager for various review bureau. She holds an Honors Bachelor of Science in Human Biology from the University of Toronto and a Post-Diploma in Regulatory Affairs and Quality Operations.