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The O'Neill Institute for National and Global Health Law cordially invites you to

Pathway to Global Product Safety and Quality

with

Jennifer Devine
Deputy Director, Global Regulatory Operations and Policy
U.S. Food and Drug Administration

Thursday, November 8, 2012
1:20 – 3:20 PM
Georgetown University Law Center
Eric E. Hotung Building, Room 2000
600 New Jersey Avenue, NW | Washington, DC 20001

Jennifer Devine joined the U.S. Food and Drug Administration (FDA), Office of Global Regulatory Operations and Policy (also known as the Office of Global Operations or "GO"), as acting Deputy Director in December 2011. In this position, Ms. Devine helps to lead FDA's efforts to transform from a predominantly domestically-focused agency operating in a globalized economy to a public health regulatory agency fully prepared for a complex globalized regulatory environment.

The Office of Global Regulatory Operations and Policy was created in July 2011 and is one of four Directorates at FDA. The Directorate is working on implementing the "Pathway to Global Product Safety and Quality" Report which describes the paradigm shift that FDA must make to face the challenges of globalization today and in the future. The Directorate also facilitates strategic and risk-based global industry oversight. The Directorate includes the Office of Regulatory Affairs (ORA) and the Office of International Programs (OIP). ORA, with a staff of over 4,000 employees across the United States, is responsible for imports, inspections, and enforcement policy for all FDA regulated products. OIP, with a staff of over 80 employees around the world, is responsible for maximizing the impact of FDA's global interactions.

Before working in Global Operations, Ms. Devine worked for several years as Associate and Deputy Director in the Office of Compliance of FDA's Center for Drug Evaluation and Research (CDER). In that role, she led and established a number of public health regulatory efforts including marketed unapproved drugs, compounding, registration and listing, Internet and health fraud drugs, and adverse event reporting. Ms. Devine also led CDER's efforts related to drug supply chain legislation. Ms. Devine spent a year at the Agency for Healthcare Research and Quality. While there, she worked on implementation of the Patient Safety and Quality Improvement Act, a key legislative provision for encouraging the reporting, analysis, and dissemination of information related to adverse events.

Before joining the government, Ms. Devine spent ten years at the United States Pharmacopeia (USP), Office of General Counsel, working on international, patient safety, legislative, and drug information issues. In this role, she helped to lead USP's global strategy and to establish its international offices.

Ms. Devine received her J.D. from Widener University School of Law and her L.L.M in International Law, from Georgetown University Law Center. She has lived in a number of different countries including Chile, Mexico, the Dominican Republic, Venezuela, Argentina, and Italy.

600 NEW JERSEY AVENUE, NW, WASHINGTON, DC 20001
PHONE: (202) 662-9203 **FAX:** (202) 662-4045