

FDA

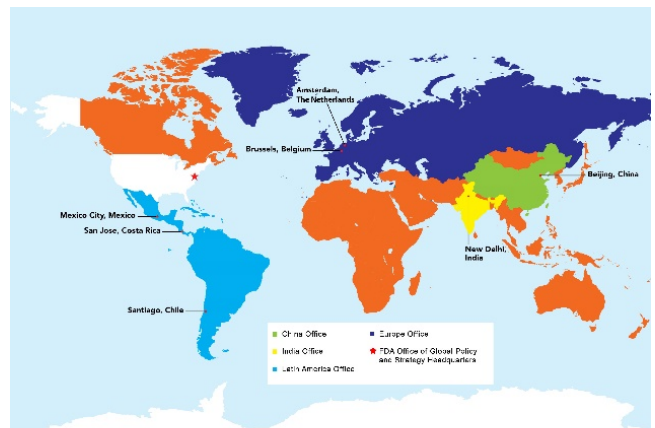
U.S. FOOD & DRUG ADMINISTRATION

**OFFICE OF POLICY, LEGISLATION, AND INTERNATIONAL AFFAIRS
OFFICE OF GLOBAL POLICY AND STRATEGY**

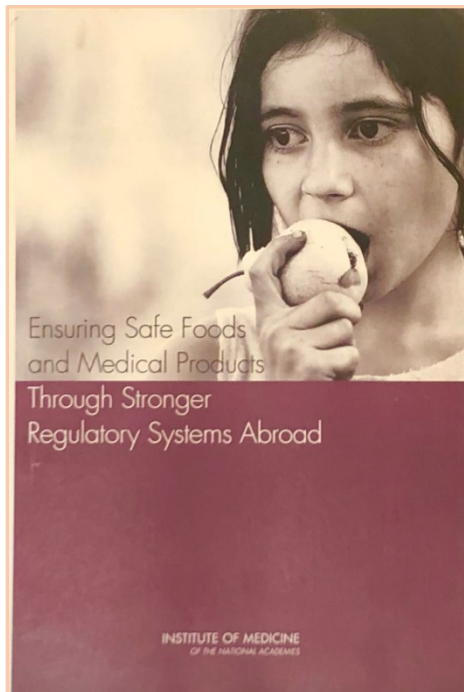
Global Monthly Update

January 2020

Editor's note: Due to the holidays, there was no Update in December. This latest issue covers all events since the November newsletter.



NASEM Provides Update on Global Regulatory Capacity



In today's global economy, with food and medical products trading across borders, weak regulatory systems in low- and middle-income countries can have important public health consequences, not just in those countries but in other, more prosperous countries, such as the United States.

Our international office wisely recognized these interconnections and some 10 years ago commissioned the Institute of Medicine to study the capacity of regulatory systems in emerging economies and determine what, if anything, could be done to strengthen that capacity.

The resulting report was *Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad*, issued in 2012. It called for a risk-based approach that focused on giving more support to surveillance systems in low-and middle-income

countries, providing training to regulators in those countries and taking steps to secure multinational supply chains.

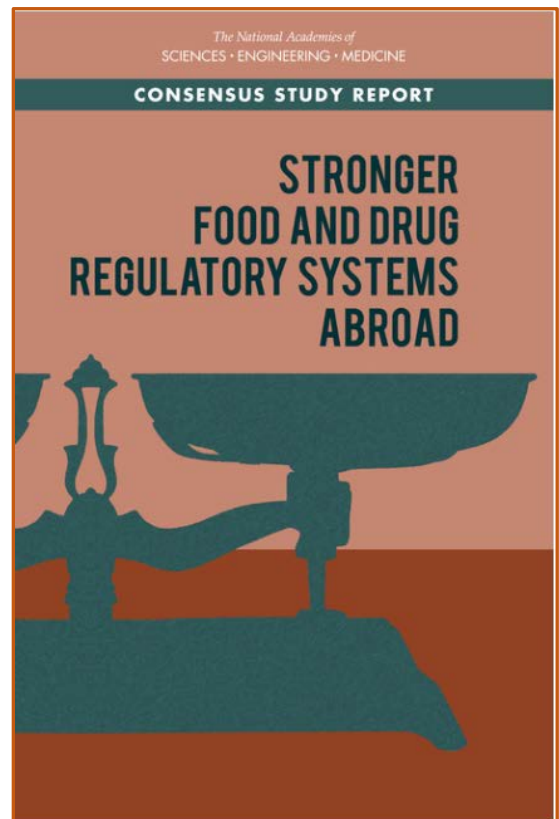
Recently, our office decided it was time to determine how much progress had been made in improving the regulatory capacity of emerging economies and once again commissioned the IOM, now renamed the National Academies of Sciences, Engineering and Medicine, to revisit the topic. On Jan. 15, a NASEM expert panel of food and drug experts issued a report, *Stronger Food and Drug Regulatory Systems Abroad*, informed by four public workshops, including a meeting in Costa Rica organized by our Latin America Office.

In a briefing to FDA staff on Jan. 13, the committee chair, Dr. Catherine Woteki from Iowa State University, said the panel had identified "evolutionary, not revolutionary" changes in global regulatory capacity. Today, she explained, there is a growing recognition of the interconnectedness of regulatory systems; a growing demand for safe food and quality medicines; and notable improvements in health and nutrition as a result of increased attention to health from governments, multilateral and donor organizations and rising prosperity across the globe.

Laced throughout the report are examples of how FDA has served as a key catalyst: in helping to strengthen these regulatory systems, in encouraging the development of standards and in demonstrating the value of multilateral efforts. This can be seen, for example, in our work supporting global efforts to combat and report falsified and substandard medicine, combatting the global burden of foodborne disease and encouraging harmonization efforts in the International Council for Harmonisation and other forums.

Nevertheless, public health challenges remain. Unsafe food still kills over 400,000 people a year and costs the global economy \$110 billion in treatment and lost productivity. Moreover, in sub-Saharan Africa alone, poor-quality medicines cause about 70,000 excess pneumonia deaths and 8,500 to 20,000 excess malaria deaths in children under five.

The report offers a variety of ways to confront these remaining challenges on a multilateral (e.g., the United Nations Food and Agriculture Organization or FAO and the World Health Organization or WHO), national government, and regulatory agency level.



An important theme in this new report is the importance of data collection and, in particular, the need for benchmarking using such tools as the WHO Global Benchmarking Tool (for medical products) and the WHO/FAO Food Control System Assessment Tool. Both of these tools are designed to shed light on a system's relative strengths and weaknesses, to determine what progress has been made over time, and to identify areas where multilateral and donor organizations can maximize efforts and investments.

The 2012 report offered several recommendations that FDA should take to strengthen regulatory systems. This latest report includes only one and is not our action to take alone: it recommends that the National Institutes of Health, in collaboration with the FDA and the U.S. Agency for International Development, establish a network of Global Centers of Excellence in Regulatory Science for research and capacity building to identify and address the challenges of ensuring food and drug safety in low- and middle-income countries.



Associate Commissioner Valdez to Retire

Mary Lou Valdez, FDA Associate Commissioner for Diplomacy and Partnerships, within the Office of Global Policy and Strategy (OGPS), is retiring effective Jan. 31, 2020 after 29 years of service in the U.S. government (USG). The following Monday, she will continue her unwavering dedication to global public health issues by assuming the position of Deputy Director of the Pan American Health Organization, Regional Office of the World Health Organization.

Lou has enjoyed a long and distinguished career at FDA and HHS, beginning in February 1991. When she arrived at FDA in January 2009, the Agency was standing up foreign posts in strategic locations around the globe and through her leadership, FDA successfully advanced these efforts, establishing a strong cadre of experts to serve as the FDA face and voice abroad.

Lou also has led the Agency in our engagement with multilateral organizations, including the WHO and its Regional Committees, the World Bank and the Inter-American Institute for Cooperation on Agriculture in such areas as regulatory system strengthening, food safety, substandard and falsified medical products, regulatory landscaping, and innovative methods of training in support of FSMA implementation. During her tenure at HHS within the HHS Office of Global Health Affairs, Lou led a range of complex policy issues involving multilateral organizations such as WHO,

PAHO, UNICEF and World Health Assemblies. She coordinated the development of a USG report submission to the United Nations Special Session (2002), a whole-of-government report on progress made since the World Summit for Children in health, education, and child development; the USG policy efforts for the WHO global strategy on diet, nutrition and physical activity (2004); HHS work to establish the U.S.-Mexico Border Health Commission (2006) led by the Secretary of Health and Human Services and the Secretary of Health of Mexico; and HHS efforts at the Rabia Balkhi Women's Hospital in Kabul, Afghanistan bringing together experts from the Centers for Disease Control and Prevention, Indian Health Service and Health Resources and Services Administration to assist health providers in the delivery of safe emergency obstetrical and neonatal care.

In an email to colleagues outside FDA, Lou said: "It has truly been a privilege and blessing" to spend a career in public service and for global health. "I've been lucky to have the opportunity to engage on a diverse range of initiatives and efforts which have brought me in contact with such incredible colleagues, public health champions and experts such as you," she said.

We in OGPS have gained so much from Lou. We will miss her broad and deep institutional knowledge of global health issues, her close and thoughtful reading of documents and her generosity in mentoring staff.

JAMA Article on PEPFAR

The President's Emergency Plan for AIDS Relief (PEPFAR) was launched in 2004 to provide low-cost, life-saving anti-retroviral drugs to people in more than 50 low-resourced nations. Since then, PEPFAR has provided ARVs to more than 15 million people with HIV/AIDS.

It is FDA's responsibility to promptly review submissions of new single entity, fixed-dose combination and co-packaged versions of previously approved ARVs from sponsors worldwide. To speed up approval, FDA uses its existing processes, including expedited review, while ensuring that these products meet the same stringent standards as similar products intended for the U.S. market. ARVs that would otherwise receive a full approval from the FDA, but for patents or other intellectual property rights, receive tentative approval from the FDA rather than full approval.

In the study, the authors noted that under PEPFAR, the FDA has authorized 216 (now 222) applications for 272 antiretroviral drugs, including 26% for pediatric use. Thirty-seven percent of the applications received rejection letters, primarily for deficiencies in manufacturing processes.



FDA staff recently took a look at its PEPFAR program in a study published in JAMA Network Open. Mary Lou Valdez and Karen Riley were among the co-authors of the study, [*An Evaluation of U.S. Food and Drug Administration's Program to Register HIV Drugs for Use in Resource-constrained Settings.*](#)

The authors concluded that while the FDA's efforts have made many HIV drugs available for use globally, more pediatric-specific therapies are needed, and the quality of applications needs to improve.

FDA Joins GMP Pilot

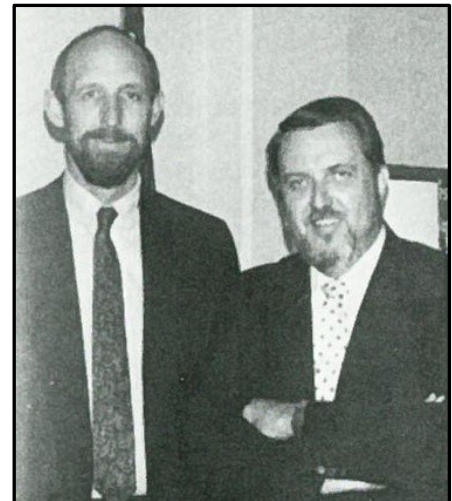
This year, regulators across the EU, U.S., Australia, Canada, Japan and the WHO will embark upon a new international pilot program to share information from the good manufacturing practice (GMP) inspections of manufacturers of sterile medicines for human use. The new initiative is built on the success of, and the experience gained, from a similar collaboration, the international active pharmaceutical ingredients inspection program.

This latest pilot will enable information-sharing from GMP inspections of manufacturers located in countries that are not participating in the pilot and allow participants to organize joint inspections for manufacturing sites of common interest. The program is expected to last for a minimum of two years, after which the participating authorities will assess the program and determine the next steps of the collaboration.

In Memoriam

This month we honored the lives of John F. Harty Jr. and Patrick J. Pouzar, who died when their small plane crashed in northern Chile in the Andes Mountains on Jan. 13, 1990. The two men had been inspecting Chilean grape fields as a follow-up to a highly-publicized product tampering incident.

Pouzar was director of the investigation branch in FDA's Nashville district office and Harty was director of FDA's international affairs staff. Harty had previously worked in FDA's field offices, and later in drug regulation and regulation policy at FDA headquarters, before joining the international affairs staff as the European desk officer in 1979. A year later, he was named deputy director, and in 1986 he became staff director.



Patrick J. Pouzar and John F. Harty, Jr.

The tragic crash – and the public health crisis that preceded the Chilean trip – was discussed by Anna Abram, FDA's Deputy Commissioner for Policy, Legislation, and International Affairs; Judith A. McMeekin, FDA's Acting Associate Commissioner for Regulatory Affairs; and Vanessa Burrows, an FDA Historian, in [*FDA's Unwavering*](#)

[Commitment to Our Public Health Mission: Reflections on the 30th Anniversary of a Defining Public Health Moment](#), one of our series of occasional thought pieces on global topics that we call From a Global Perspective.

China Office

Tour Creates Impact

FDA recently welcomed delegates from [China's National Medical Products Administration \(NMPA\)](#), formerly known as the China Food and Drug Administration or CFDA, the Chinese agency for regulating drugs and medical devices. In 2018, restructuring removed the agency's oversight of food safety and it is now part of the State Administration for Market Regulation. Today NMPA's responsibilities include drafting laws and regulations for drugs, medical devices, and cosmetics, as well as establishing medical device standards and classification systems.

NMPA was visiting FDA in November as part of a 2-week, "Executive Leadership Training" focusing on drug and medical device regulations and other factors related to regulated medical products. This was NMPA's third annual trip, which is funded by a [public-private partnership](#) called the U.S. – China Healthcare Cooperation Program, initially created in 2011 under the auspices of the U.S. Trade and Development Agency, HHS, the U.S. Commerce Department and China's Ministries of Health and Commerce.

This year, the NMPA group visited the University of California, San Francisco – Stanford Center of Excellence in Regulatory Science and Innovation during their first week and traveled to the Washington-Baltimore area for their second week to visit Johns Hopkins University, the American National Standards Institute, and AdvaMed, the medical device trade organization. The highlight of their second week was a visit to FDA's White Oak campus for a one-day technical exchange on Nov. 21.



During the FDA meeting, NMPA members, led by Wang Zhexiong, director-general of NMPA's Department of Medical Device Supervision, presented an update on the agency's medical device clinical data requirements for studies conducted both inside and outside of China and expressed interest in topic-specific training from FDA SMEs on FDA's [RWD/ RWE](#) activities; [MDR](#); CDRH reorganization – [OPEQ](#) and [TPLC](#); and FDA's medical device inspection program ([Risk Based Model](#)).

Ensuring the success of the meeting required many hours of behind-the-scenes- planning and -executing, made all the more complicated because it had to be coordinated 7,000 miles away. Many thanks to OGPS's Bill Sutton and CDRH's Melissa Torres for their efforts on this project.

Europe Office



Conference Delivers Controls Against Animal Diseases

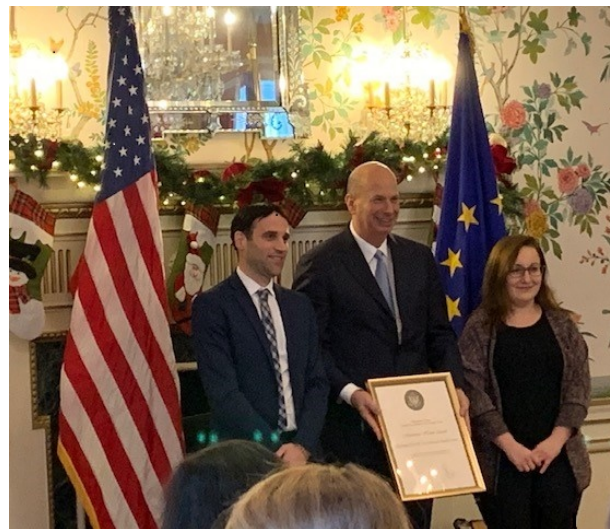
Ritu Nalubola, Ph.D., Director of FDA's Europe Office, was one of the speakers at the day-long conference, "Smarter Rules for Safer Food and Plant Health," organized by the European Commission on Dec. 13 in Brussels. The aim was to share best practices and increase awareness and preparedness among EU countries, interested parties and trading partners.

Dr. Nalubola's panel addressed the topic of official controls and global trade. After the conference, new controls were put in place, through the EU Official Controls Regulation that are intended to modernize protections against animal diseases and plant pests as well as improve food safety.

EO Staff Acknowledged

Alessandro Fiorelli, Lucy Gherasa, and Claudia Louati from the Europe Office, Brussels, received the Group Meritorious Honor Award for exemplary collaboration and teamwork in planning and implementing the first global workshop on plant and animal biotechnology innovation. They were recognized by U.S. Ambassador to the European Union Gordon David Sondland at a ceremony at the U.S. Mission to the European Union on Dec. 3, 2019.

The Meritorious Honor Award is presented to groups or individuals in recognition of a special act or service or sustained outstanding performance.



Alessandro Fiorelli, Ambassador Sondland and Lucy Gherasa

India Office

State Regulatory Meetings

November was a busy month for INO, with a flurry of meetings, including quarterly meetings with two state regulators. India's oversight of food and drugs is decentralized, meaning that primary enforcement occurs at the state level in India. Each of its 29 states and seven union territories have their own FDA. That inevitably means lots of meetings with state regulators. On Nov. 13, INO held its quarterly meeting with **Gujarat Food and Drug Control Administration** at the U.S. Embassy in New Delhi to discuss food and medical product regulatory updates. The state of Gujarat has one entity for both food and drug enforcement. The quarterly meeting centered around food and medical product regulatory updates. Mark Abdoo and visiting subject matter experts from ORA and CDER also attended the meeting.



The following week INO held a quarterly meeting in Hyderabad with another state regulator, the **Telangana Drugs Control Administration**. Unlike Gujarat, Telangana has separate entities for overseeing food and drug activities within its borders. The meeting, which centered around medical product regulatory updates, was attended by INO staff and visiting SMEs from ORA.



National Regulatory Meetings

INO also participated in some important meetings with India's National Regulatory Authority, the Central Drugs Standard Control Organization (CDSCO). CDSCO is responsible for the standards and approval of drugs and the integrity of clinical trials, among other regulatory duties. It establishes federal laws and policies for medical products in India that are then implemented by state FDAs.



Mark Abdo greets CDSCO's Joint Drugs Controller Dr. S. Eswara Reddy

On Nov. 14, CDSCO hosted its 3rd Annual Regulatory Forum Workshop, attended by more than 50 CDSCO staff, OGPS leadership and state inspectors. The workshop was facilitated by six experts from ORA and CDER.

The workshop's dual focus was strategic collaboration and the drug inspection life cycle. The following day, on Nov. 15, INO and other FDA representatives, including Associate Commissioner Mark Abdo, held an annual bilateral with CDSCO to discuss emerging policy areas and ways to collaborate in 2020.



LCDR Connie Jung in New Delhi

An ongoing issue for both FDA and CDSCO has been how best to protect the drug supply from counterfeit or substandard drugs and how to improve the detection and removal of potentially dangerous drugs once they enter the supply chain. Title II of the Drug Quality and Security Act (DQSA) passed by the U.S. Congress in 2013 is the Drug Supply Chain Security Act (DSCSA), which outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

In November, Associate Director for Policy and Communications (Acting) Connie Jung, in the Office of Drug Security, Integrity and Recalls (ODSIR) at CDER, traveled to New Delhi to brief regulators about DSCSA requirements and present at the GS1 Global Healthcare Conference. Held twice a year, the Global GS1 Healthcare Conference is a catalyst for information-sharing to the GS1 Healthcare community.



INO's Important Work on ARBs

Collaborating with FDA's regulatory counterparts is an important part of INO's work, especially when public health issues arise, as occurred in recent months with the findings of potentially cancer-causing nitrosamine contamination in various [drugs](#), including the blood pressure and heart failure medicines called Angiotensin II Receptor Blockers (ARBs).

INO aided in the global investigation of nitrosamine impurities in ARBs by identifying that the recycling of solvents used in [drug manufacturing](#) was a potential source for these impurities.

In November, INO collaborated with the European Medicines Agency and European Directorate for Quality of Medicine and Healthcare on two workshops with the Government of Gujarat Food and Drug Controls Administration where nitrosamine contamination in drugs was discussed, as well as Current [Good Manufacturing Practice Regulations](#). Also in attendance, were 200 representatives from 60 companies and 30 central/state regulators.

Staff Synergy Wins



Modeling in a fashion show was INO's creative way to educate others about FDA's important responsibilities. They modeled traditional clothing of India, accessorized by FDA-regulated commodities such as shrimp, drugs, lipstick, canned food, toothbrushes and cigarettes at the U.S. Embassy Diwali Fashion Show - and won an award. Diwali is the Hindu festival of lights. It usually lasts five days and occurs between mid-October and mid-November each year. INO decided to participate this year as part of a team-building exercise.

Latin America Office

Course Trains Trainers

LAO staff are engaged in an innovative program designed to rapidly increase the number of international produce exporters who are trained in how to comply with FDA's [Produce Safety Rule](#) for the growing, harvesting, packing and holding of produce for human consumption. The Rule implements a major provision of the landmark [Food Safety and Modernization Act \(FSMA\) of 2011](#). It is intended to minimize the presence of potentially dangerous contamination that could cause serious adverse health consequences.



Since approximately 200-plus countries or territories and roughly 125,000 food facilities and farms supply about 32 percent of the fresh vegetables, 55 percent of the fresh fruit, and 94 percent of the seafood we eat in the U.S., it is critical for foreign farms to understand how to comply with the requirements of the rule.



Nicki Conklin of LAO (center left, second row, in yellow) pictured with personnel from the Mexican State Agricultural Committees who were selected to attend the course along with course instructors: Sergio Nieto Montenegro (front left blue jacket) and Noemí Zúñiga (center, right of Nicki), Jim Rushing of JIFSAN (front row, second from left) Ana Cordero of IICA (front row, far right), Dr. Ofelia Rodríguez of the University of Guadalajara (front row, second from right).

Last year, FDA awarded the Inter-American Institute for Cooperation on Agriculture (IICA) an initial grant of \$750,000 to develop “new tools, digital platforms and alternative technologies” to provide Latin America and Caribbean food producers with training on FSMA. One main goal of this training is to instill the importance of food safety in all that farmers do.

In December, LAO staff conducted a Train the Trainer (TTT) course with the University of Guadalajara using The Produce Safety Alliance (PSA) curriculum. Dr. Ofelia Rodríguez García, a professor from the University of Guadalajara Center for Exact Sciences and Engineering helped with recruitment of participants. The course is designed to develop trainers who become qualified to deliver the curriculum to fruit and vegetable growers.

During a previous LAO-conducted TTT event in September 2018, one of the participants became a strong lead trainer, and qualified with PSA to try out as a Trainer of Trainers (ToT) at the December course. Noemí Zúñiga Thimeos will be the first PSA ToT resulting from FDA intervention in Latin America!

Talks Spur Teamwork

FDA is making progress in setting up a cooperative partnership on food safety with Mexico’s two food safety authorities, Service for the National Health for Food Safety and Food Quality (SENASICA) and Federal Commission for Protection against Sanitary Risk (COFEPRIS).

LAO staff, along with leadership from ORA and CFSAN, met with SENASICA and COFEPRIS for talks on Nov. 5-6 to share information related to recent outbreaks involving papayas, cilantro, and basil and to identify work under the proposed collaborative partnership.



Webinar

Don't miss a free virtual training opportunity on the FSMA Produce Safety Rule, Thursday, January 30, at 8:30 a.m. (Central Standard Time).

Webinar

Don't miss a free [virtual training](#) opportunity on the FSMA Produce Safety Rule, Thursday, January 30, at 8:30 a.m. (Central Standard Time).

LAO and IICA will host this fourth of seven webinars covering Produce Safety rule standards.



FDA

Agricultural Health,
Safety and Food Quality

IICA

Webinar

FSMA Produce Safety Rule: Subpart F. Biological soil amendments of animal origin and human waste, Subpart I. Domesticated and wild animals, Subpart K. Growing, harvesting, packing, and holding activities

To participate access here

More information:
Ana Marisa Cordero
Email: ana.cordero@iica.int
Phone: (+506) 2216-0403

Thursday
January 30
8:30 a.m.
(Costa Rica Time)

Transitions

OGPS welcomes Bruce Ross for a 60-day detail, as the Director of the Office of Global Operations. Bruce comes from FDA's Office of Human and Animal Food Operations in ORA, where he serves as a Senior Advisor.

Bruce was the Deputy Regional Director for FDA's Latin America Region based in Mexico from 2013-2015, where he served as the agency's principal liaison for a variety of bilateral issues with Mexico's regulatory government agencies and the exporting food industry. From 2009 to 2013, Bruce was FDA's Country Director in India, helping to establish FDA's presence there while interacting and collaborating with government and industry counterparts.



Bruce first joined FDA in 2008 to serve as Acting Director of the Asia, Africa, and Capacity-building Office before his assignment to India. Earlier he was the HHS Health Attaché in Beijing from 2006-2008; and Associate Director for Operations with the CDC, first in Kampala, Uganda, from 2000-2002, and later in Bangkok, Thailand, from 2002-2006.



Kirsten Byerts accepted a new position in CDER's Office of Regulatory Policy as a Regulatory Counsel. Kirsten previously served as the lead for the OCPC Policy Team, now the OGDG Communications Team, where she oversaw responses to GAO, OIG, Congressional and media queries and Congressional Budget Justifications and managed the OGPS Executive Secretariat, the Weekly Forecast and the OGPS website.

Kirsten also served as the acting lead for the Planning and Evaluation Team during the OGPS transition process. Karen Riley in the OGPS inner office is currently detailed to lead the OGDG Communications Team.

Dr. Natalie Mickelsen has been serving as the India Office (INO) Acting Supervisory Consumer Safety Officer across all commodities (drugs, the Bioresearch Monitoring Program, and food) since October 27. Natalie is a Consumer Safety Officer focusing on food products. Prior to joining INO and since 2013, Natalie was an ORA Consumer Safety Officer and conducted food facility inspections.



Don't Forget

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