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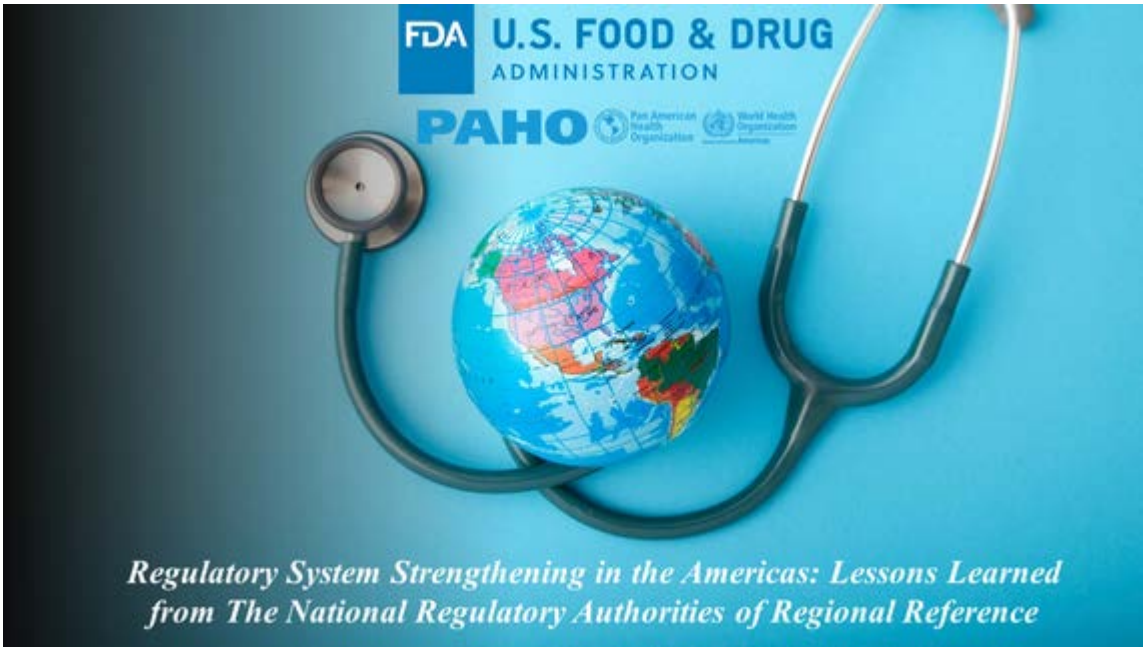
PAHO Releases FDA-Funded Landscaping Report

Regulatory authorities across Latin America and the Caribbean vary greatly in their capacity to evaluate medicines and medical products, according to a report released on April 26 by the Pan American Health Organization (PAHO).

The 134-page landscaping report was produced by PAHO under a grant from the FDA. It provides lessons for improvement by comparing regulatory authorities throughout the region against six National Regulatory Authorities of Regional Reference (NRAr) who have been assessed by PAHO for their competence and efficiency in guaranteeing the safety and quality of medical products. The six NRArs are ANMAT (Argentina), ANVISA (Brazil), ISP (Chile), INVIMA (Colombia), CECMED (Cuba), and COFEPRIS (Mexico). Two other members of PAHO also qualify as NRArs — the FDA and Health Canada — but they weren't used as comparators.

Looking at publicly available data and the results of PAHO assessments over the past decade, the report found that 22 of the 35 PAHO member states have at least some legal and organizational basis for a national regulatory system. In 20% of the PAHO member states these frameworks are limited.



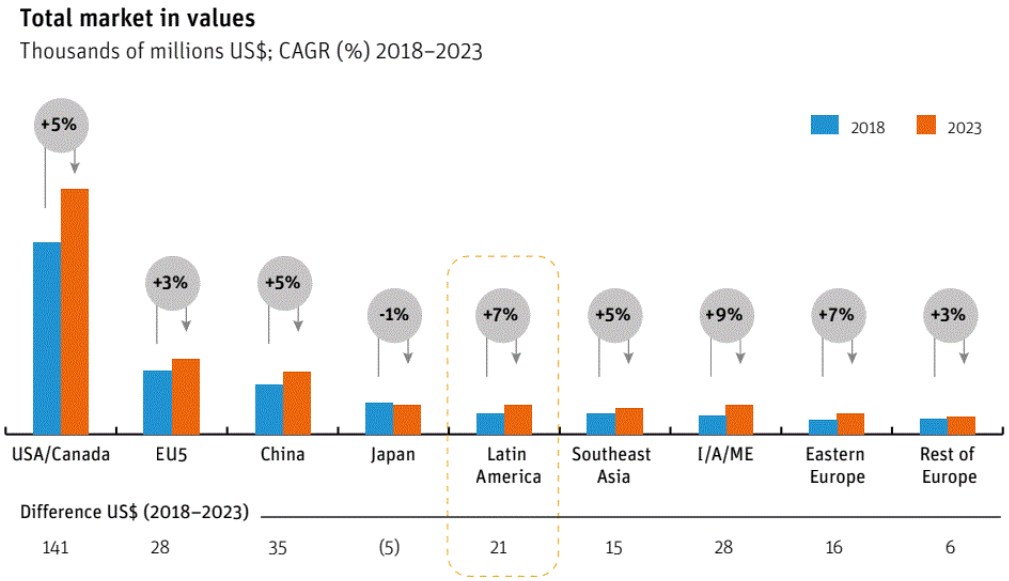
Mark Abdoo, FDA associate commissioner for global policy and strategy, provided opening remarks for PAHO's web-based launch of the report. "As we had hoped, this detailed analysis pulls together current data and information about three areas of key importance," said Abdoo. They include:

The criticality of national regulatory systems

> National regulatory systems promote and protect public health by overseeing the quality and safety of pharmaceuticals, vaccines, medical devices, and other health technologies. The report points to the important role of these systems, especially in globalization, as manufacturing and supply chains "vary in their levels of oversight."

The expanding manufacturing industry in the region

> According to analysis by data science company IQVIA, the collective Latin American NRAr market for pharmaceuticals is predicted to increase by 7% from 2018 to 2023. That makes it the second-fastest growing regional market for these products in the world (next to India, Africa and the Middle East), based on sales in dollars. Latin American NRAr countries aren't just buying medications from overseas: Several have significant domestic pharmaceutical industries, with around two-thirds of units sold in Argentina, Brazil, and Cuba made locally.



Notes: EU5: European Union Five (France, Germany, Italy, Spain, United Kingdom); Latin America: Argentina, Brazil, Chile, Colombia, Mexico, and Peru; Southeast Asia: Australia, Democratic People's Republic of Korea, Indonesia, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Viet Nam; I/A/ME (India, Africa, and the Middle East): Algeria, Bangladesh, Egypt, Kazakhstan, India, Nigeria, Pakistan, South Africa, and United Arab Emirates; Eastern Europe: Czech Republic, Hungary, Poland, Romania, Russian Federation, Slovakia, and Turkey; Rest of Europe: Belgium, Denmark, Finland, Greece, Netherlands, Portugal, Sweden, and Switzerland.

Sources: IQVIA Market Prognosis Issue March 2019, ex-man price. MIDAS, ex-manufacturer price, do not include rebate and discount. Have audited and not audited data. Brazilian. Market Price List non-institutional and institutional markets in second level of price. Growth in constant US$, except Argentina (because of the high inflation rate).

"Regulatory System Strengthening in the Americas. Lessons Learned from the National Regulatory Authorities of Regional Reference." 26 April 2021, p. 25.

> Regulatory authorities can help to further the market entry of generic medicines, the report says. Generics account for 36% or even less of the total market share of prescription drugs sold in the NRAr countries compared to 90% of the market share for generics in the United States. This low penetration for generic medicines indicates opportunities for improving efficiencies and reducing costs without compromising quality of care.

The growing impact of science, technology, and innovation in the regulation of and access to pharmaceutical products

> Countries in Latin America are increasingly interested in and/or manufacturing similar biotherapeutic products (biosimilars under FDA parlance). However, the regulatory work required to evaluate and license these complex products is challenging.

"I am pleased to see so much progress in the region, which implies that the effort FDA, PAHO and others have made to increase the visibility and understanding of the importance of strong regulatory systems has been well spent," Abdoo said.

FDA hopes the report will be useful for regulators particularly in low- and middle-income countries as they seek to enhance their regulatory rigor and enhance their efforts to strengthen their regulatory systems, especially for those who strive to become NRAs.

Related Information

Regulatory System Strengthening in the Americas. Lessons Learned from the National Regulatory Authorities of Regional Reference, produced by PAHO under a cooperative agreement with the FDA, is available in both English and Spanish.

Regulatory system strengthening in the Americas (AUDIO ORIGINAL) - YouTube

FDA's Decade-Long Participation in the U.S.-Canada Regulatory Cooperation Council

Ten years ago, the U.S. and Canada established the United States-Canada Regulatory Cooperation Council (RCC), composed of senior regulatory, trade, and foreign affairs officials from both governments — knowing that creating a vehicle for open dialogue is critical to continued economic success for our two countries. It was a recognition that the U.S. and Canada have uniquely connected economies that together generate billions of dollars a day.

The RCC's mission (on top of already established diplomatic and cooperative activities between the two countries) is to work toward closer regulatory harmonization, provide a forum for stakeholders to discuss regulatory barriers, and work with regulators to identify opportunities for cooperation between the two governments. The RCC initially focused on an Action Plan that listed 29 U.S. government-wide initiatives covering a broad range of regulatory work, with many involving the FDA's initiatives in the areas of food safety, pharmaceuticals, and medical devices. Soon after, regulators established department-to-department commitments, and by 2018, the RCC principles were reaffirmed by OMB's Office of Information and Regulatory Affairs in a Memorandum of Understanding with Canada.

The FDA, Health Canada, and the Canadian Food Inspection Agency (CFIA), all have embraced the RCC concept that “regulators must lead the way to create and sustain change; they are the ones doing the work.” Within the FDA, the Office of Global Policy and Strategy’s (OGPS) Global Engagements Team (GET) coordinates the FDA’s RCC work and has negotiated bilateral commitments and work plans with our Canadian counterparts on behalf of the FDA product centers.

Highlighted RCC successes over the years include:

- The establishment of joint use of the Common Electronic Submission Gateway to allow for simultaneous online submission of new drug applications to both the FDA and Health Canada.
- The signing of a Food Safety Systems Recognition Arrangement between the FDA, CFIA, and Health Canada, which recognized each other’s food safety systems as comparable.
- The implementation of simultaneous reviews of new animal drug applications and improvement of internal review mechanisms.

Looking forward, the FDA and Health Canada aim to expand veterinary drug review cooperation to generics and establish an online single-portal submission gateway. Additionally, the agencies continue to work toward the establishment of a Medical Device Single Review Program to allow manufacturers the opportunity for a single premarket review (for eligible devices). OGPS’ Global Engagements Teams in conjunction with the FDA product centers will continue to pursue the FDA’s international harmonization goals. For more on this topic, read the full article on our blog, From a Global Perspective.

On the Road in China to Ensure Safe Food Import Facilities

Today, U.S. consumers insist on a wide variety of foods at attractive prices, and don’t want their cravings to be deterred by the season. Food facilities throughout the world help to meet this demand. One of the important ways in which FDA ensures that this food is safe and of high quality is to send Consumer Safety Officers (CSOs) to inspect those foreign food facilities that import foods to the U.S.

That’s where Jennifer Mathern’s job comes in, as a Supervisory CSO for OGPS' China Office (CNO).

FDA first began conducting international inspections in 1955; but for decades the agency’s oversight of food facilities was limited only to "hazard to health" inspections of

low-acid canned food facilities and manufacturers making infant formula. That began to change in 1992 when the Office of Seafood, the Center for Food Safety and Applied Nutrition (CFSAN), and the Office of Regulatory Affairs (ORA) started inspections of foreign seafood facilities in response to increased global diversity of the U.S. food supply chain. Today, FDA investigators work all over the world to inspect a wide array of food facilities. Over her six-year career in China, Mathern has inspected and supervised inspections of food facilities that produce canned fruits, canned seafood, frozen vegetables, ready-to-eat foods, and dietary ingredients.

The Nature of the Work

CNO staff are based in Beijing. Since there are few food facilities in Beijing, FDA investigators have to travel out of the city to inspect food facilities. For Mathern that meant she wound up traveling throughout mainland China. One of her furthest inspections occurred in Yunnan, the most southwestern province in China near the border with Myanmar. Since there is no direct flight from Beijing to Yunnan province, she had to endure several stops along the 1,300-mile trip – which added up to a full day of travel. “One thing that is hard here is traveling,” she said. “Food inspectors see more remote parts of the country.” Often, there are occasions when inspectors must locate a hotel which will approve their stay, as many establishments will only accept guests who are Chinese citizens. Subsequently, CSOs can find themselves commuting two hours each way, each day, from an international chain to the facility they are assigned to inspect.

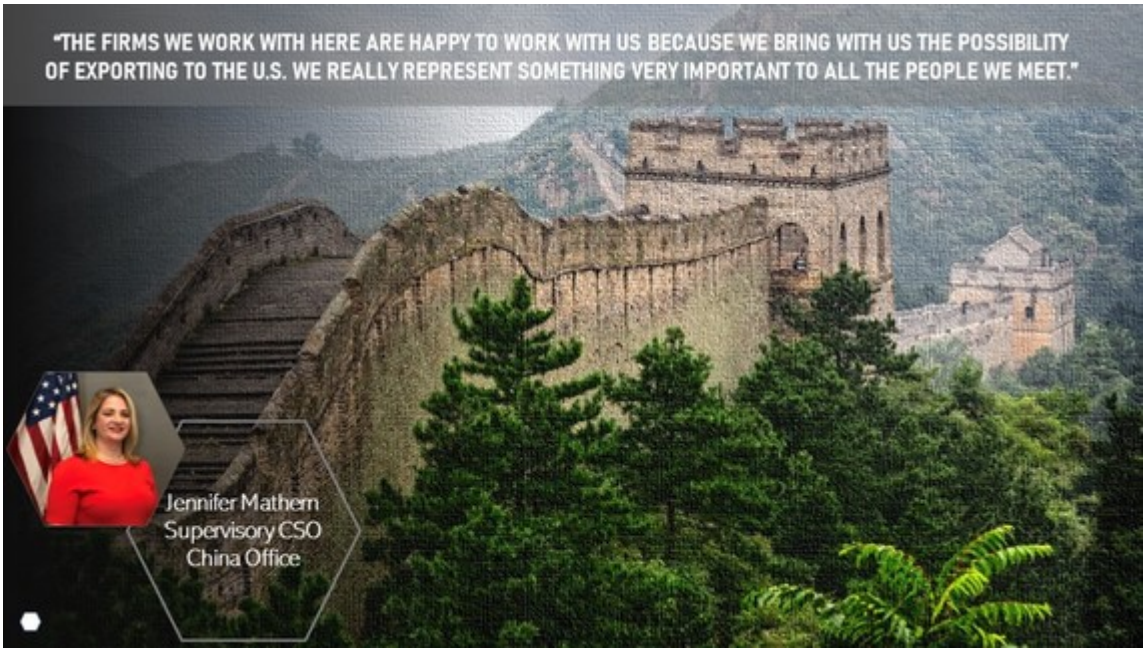
For the first four years of her posting in China, Mathern was on the road to conduct an inspection every third week, with a two-week break in between. For the past two years, she has been a Supervisory CSO for the Foods CSO team, so her travel has been limited to accompanying CSOs on inspections to audit their work and attending food safety conferences/meetings.

FDA investigators are required to stay abreast of FDA laws and regulations, including the rules that implemented the landmark 2011 Food Safety Modernization Act (FSMA), such as the Final Rule for Preventive Controls for Human Food and Hazard Analysis and Critical Control Point (HACCP) inspections for seafood.

Mathern believes that investigators in China must “educate while we regulate,” and playing a teaching role so that facilities not only understand the rules and regulations but also the science behind the regulations, to help them comply. Facilities appreciate this consideration and training. “In every aspect of our work, from training to inspections, you’re acting as an ambassador, not just for the FDA but of America, too. The firms we work with here are happy to work with us because we bring with us the possibility of exporting to the U.S. We really represent something very important to all the people we meet,” Mathern said.

During her inspections, Mathern collects evidence which can be in the form of documentation, photographs taken by CSOs, food samples, or regulatory notes. Regulatory notes are used to report important details of a sample collection, inspection, and/or investigation, and are recorded in an inspection diary. The contents of a diary are

used to draft the report and are considered official documentation which can be used in a court of law.



What it Takes

The FDA seeks experienced CSOs for their overseas deployments. Currently, all applicants for foreign posts must submit a Level I Investigator Certification. Mathern's journey to China began as a CSO inspecting domestic facilities, first in the Minneapolis District Office in 2008, then Denver in 2010, where she became a Food Specialist four years later. China isn't her first foreign inspection experience. She was sent to conduct foreign inspections in Poland and Belgium while based in Denver. Before coming to work at the FDA, Mathern worked for the Minnesota Department of Agriculture as a food inspector.

In 2013, Mathern saw a job posting for a CSO in China and mentioned it to her husband. He was surprisingly supportive, so she applied. During 2013 and 2014, Mathern was able to perform temporary duty travel to China to conduct food inspections and a year later secured a full-time position allowing her to move there with her family.

Mathern (center in red) sits on a panel in China

In addition to her CSO work, Mathern has provided subject matter expertise to the World Bank for the China Food Safety Improvement Project on traceability, seafood HACCP requirements, food safety risk analysis and hazards, and capacity-building.

Life in China

When new hires arrive in China, the embassy's Social Sponsors program links new families with families who have been in-country for a while — to help with the transition. Their houses are ready to live in and their first meal is in the refrigerator waiting for them. Sponsors can be a resource to assist in connecting with the community and other families; everyday tasks like obtaining a bank account; and getting settled into overseas life.

Mathern (front, second from left) and her husband with the "Stars and Stripes" softball team

There are even sports leagues, and since she arrived with years of experience playing softball, Mathern and her husband joined the embassy's softball team, *Stars and Stripes*. The players have two seasons: one in the spring and one in the fall. There are 10 teams in the league, comprised of mostly other expatriates working in Beijing. "From being on this team I have gotten to know many good friends that are here in Beijing working for various reasons," said Mathern.

Mathern and her husband in China

The embassy's Community Liaison Office helps organize events for U.S. government workers and regularly sets up tours and sightseeing trips in Beijing and across China. Mathern's husband and daughter were able to accompany her on a trip where they visited Dandong, Liaoning Province, a town along the China-North Korea border. There, they saw an inscription stone marking the border with a view of North Korea in the distance.

Mathern's tour ends this June. "It's a great place to be. If I could stay, I would," she said. When she first arrived in China, Mathern had set a personal goal of visiting each of the country's 23 provinces, four municipalities, and four autonomous regions (excluding Tibet). She has come close. So far, she has visited all but two provinces.

Mathern at the Great Wall

Related Information

Living and Working Abroad for FDA

Consumer Safety Officer factsheet

Current openings:

https://www.usajobs.gov/GetJob/ViewDetails/589485300

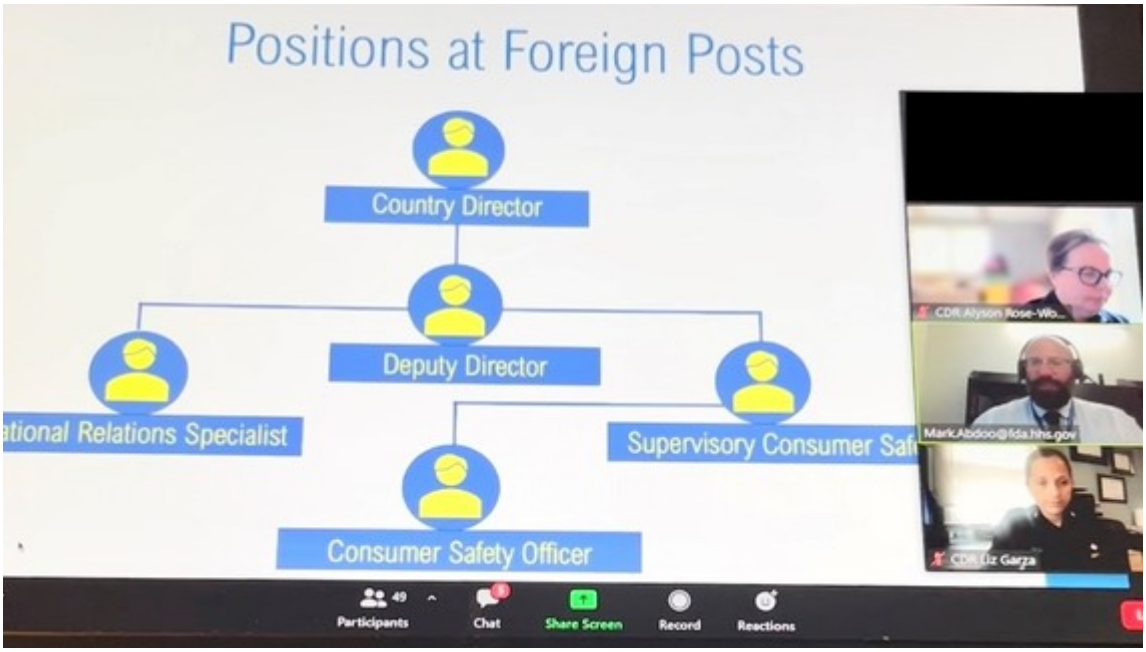
https://www.usajobs.gov/GetJob/ViewDetails/589516500

Abdoo Provides PHS Officers an Inside View of OGPS Foreign Work

On April 9, a group of Commissioned Corps officers of the U.S. Public Health Service received a comprehensive briefing about the Office of Global Policy and Strategy's public health responsibilities, including the work it does across the federal government and with our many global regulatory partners and industry stakeholders.

Given the increasingly complex environment for FDA-regulated products, both here and abroad, FDA must maintain a dedicated global focus to fulfill our mission of protecting and promoting the public health of Americans, said Associate Commissioner Mark Abdoo, who gave the hour-long presentation.

Today, OGPS oversees the work of our staff in seven foreign posts, who function as the FDA's eyes and ears in the country or region where they are located. In addition, OGPS serves as the focal point for FDA-wide coordination and information sharing on international policy, as a point of access to multilateral organizations, and as the lead for addressing issues related to international trade of regulated products.



Abdoo presents to PHS officers

The 41 officers who participated in the webinar are members of the Global Health track of the Education, Training, and Mentorship subcommittee, a subgroup of the Health Services Officer Professional Advisory Committee. The track helps provide global health resources and professional development opportunities to PHS officers in order to increase the capacity of the Corps in global health.

The participating PHS officers wanted to learn more about working for OGPS, the types of jobs involved, and how to qualify for these jobs. Staff who work domestically have a

variety of backgrounds, Abdoo said. Some are lawyers, some are policy analysts, some are scientists, some are communicators and others are data analysts.

Besides supervisory roles, there are two categories of jobs in the foreign offices: International Relations Specialists (IRS) or Consumer Safety Officers (CROs). IRS' develop and implement FDA policy initiatives and priorities; participate in engagement and information sharing with our regulatory counterparts and regulated industry; conduct commodity strategic planning and operational reporting; and take the lead for our outreach activities in these countries. Consumer Safety Officers (CSO) conduct inspections and typically specialize in commodity areas.

A Level I Investigator commodity-specific certification is required to be considered for a CSO position within OGPS along with foreign inspection experience.

The Pros and the Cons

There are many pros and some cons to consider when working and living abroad for the FDA, Abdoo said. PHS officers are eligible to receive a cost-of-living adjustment and funded environmental and morale leave. The government also provides furnished housing and covers international school fees for accompanying children.

Before deployment several prerequisites must be completed: Security Overseas Training (SOS), Foreign Affairs Counter Threat (FACT) training, and Working in an Embassy training. Selectees are also required to obtain both a medical clearance (for self and family), and a security clearance. Those interested in working abroad for FDA, should watch for periodic vacancy announcements. Those who are outside of FDA can request to be added to periodic email distributions by entering their email address and selecting "international news."

Related Information

Living and Working Abroad for FDA

Current openings:

https://www.usajobs.gov/GetJob/ViewDetails/589485300

https://www.usajobs.gov/GetJob/ViewDetails/589516500

OGPS Staffers Assisting in Humanitarian Crisis at Border

Health and Human Services Secretary Xavier Becerra sent employees a department-wide call to action on March 25, asking for volunteers to assist with the influx

of unaccompanied children and youth who are entering the United States without immigration status at our Southern Border.

“These children are alone, scared, separated from family, and currently being housed by U.S. Customs & Border Protection (CBP) in holding areas that were not meant for children beyond a short period of time," he said. “To solve this problem, it will take us at the Department of Health and Human Services (HHS) banding together to look out for these children and youths as if they were our own.”

The Secretary’s request was echoed in an FDA-wide email to staff from Acting Commissioner Janet Woodcock and in a message to OGPS from Associate Commissioner Mark Abdoo. “As HHS and FDA and our nation face continuing crises, we are truly all in this together and I’d like to thank everyone for their continued professionalism and service to the American public,” said Abdoo.

Two staffers from OGPS – **Mimi Sharkey and Christine Lim** - answered the call and began serving 120-day details early last week.

Mimi Sharkey, a licensed certified social worker, (who had been on detail to the Planning and Evaluation Team from of the Office of Regulatory Affairs Leadership Development Program), is uniquely sensitive to the needs and concerns of vulnerable children and immigrants. Before joining the federal government, she served as a substitute teacher, child protection social worker, and crisis line volunteer. Her own father escaped communism when he fled Hungary during the Hungarian Revolution in 1956, ultimately immigrating to Canada. Additionally, her mother immigrated to Canada from Mexico. An immigrant herself, Sharkey came to the U.S. from Canada, and she has children who were born in both countries.

Christine Lim, special assistant to the director of OGPS' Office of Global Diplomacy and Partnerships, has been dispatched to a new intake facility in Albion, Michigan, along with 32 other people, half of them from the FDA. She's promising to tell more when she returns.

The Office of Refugee Resettlement (ORR), an office within HHS' Agency for Children and Families, is tasked with the care and custody of unaccompanied children while they are awaiting immigration proceedings. ORR provides a continuum of care for children, including placements in emergency intake sites, influx care facilities, ORR foster care, and funding residential care providers that provide state-licensed, temporary housing and other services to unaccompanied children in ORR custody.

Transitions

Dennis Cantellops has joined the China Office as a consumer safety officer. His career with the FDA began in 1983 as an analytical chemist in the Southeast Regional Laboratory in Atlanta. He has also worked at the Atlanta Center for Nutrient Analysis, which allowed him to gain experience in all areas of analysis and later as a laboratory manager.

Cantellops started performing drug inspections in 1996 and has continued this work ever since; most recently as a drug inspector for the Generic Drug User Fee program. He received an associate degree in chemical engineering from the Puerto Rico Institute of Technology, Rio Piedras, and a Bachelor of Science degree in chemistry from the Interamerican University, San German, Puerto Rico.

Letitia Robinson, Ph.D., retired as director of the OGPS' India Office, and from the U.S. Public Health Service Commissioned Corps on April 1. She worked to build strong relationships with counterparts in India, accomplished many important milestones, and enjoyed a career with many highlights. Robinson now works as a senior care and treatment advisor for HIV/AIDS with the South Africa | US Agency for International Development - USAID.

FDA Voices Spotlights Renewed Partnership

FDA Voices offers insights from FDA leadership and experts into the agency's work in specific topic areas. On March 17, the Voices published an article authored by Associate Commissioner for Imported Food Safety within the Office of Food Policy and Response Donald Prater, D.V.M.; Director of the International Affairs Staff in the Center for Food Safety and Applied Nutrition Julie Moss, Ph.D., R.D.; and Director of OGPS' Latin America Office (LAO) Katherine Serrano.

FDA's Partnership with Mexico's Regulators Strengthens Food Safety Protections offers readers an in-depth view of the longstanding relationship between the FDA and food regulators in Mexico. The collaboration helps implement innovative ways to enhance food safety protection. Since the LAO, part of OGPS, was established in 2009, the staff there have been paramount in building the FDA's relationship with counterparts in the Federal Commission for the Protection from Sanitary Risks (COFEPRIS) and the National Service of Agro-Alimentary Health, Safety and Quality (SENASICA) – facilitating successful collaborations on food safety across the food industry. LAO's successful relationship building, as well as cultural expertise, have been integral in strengthening the mutual trust that is evident in our partnership with Mexico.

The authors further delve into broadening partnerships through the FDA-Mexico Food Safety Partnership (FSP); implementing the FDA Food Safety Modernization Act (FSMA); committing to ensure safe papayas are imported from Mexico; and minimizing the risk of *Cyclospora cayetanensis* infections associated with fresh basil grown in Mexico. The *Voices* article also looks toward the future as shared data generated by laboratories all over the world is linked through the GenomeTrakr network, a global database which can be accessed by researchers and public health officials for real-time comparison and analysis that promises to speed foodborne illness outbreak investigations.

DIA Europe Features FDA Townhall

The recent 2021 DIA Conference held on March 15, featured a session with FDA experts discussing current and relevant issues in the regulatory space. DIA is a global association that mobilizes life science professionals from across all areas of expertise to engage with patients, peers and thought leaders in a neutral environment on the issues of today and the possibilities for tomorrow.

During the FDA Townhall, moderated by OGPS Europe Office (EO) Deputy Director Sandra Kweder, M.D., panelists discussed their various FDA roles, and work during the COVID-19 pandemic. Europe Office Director Ritu Nalubola, Ph.D., provided a bird's eye view of the work they do, discussing EO's engagements with the European Union, medical devices, digital health, and the Mutual Recognition Agreement (MRA).

"It was a great session" with robust discussion and questions from the audience," she said. When Nalubola was asked about what EO was doing to increase regulatory cooperation with the EU she cited, as examples, the FDA/EMA scientific clusters and the Parallel Scientific Advice (PSA) program. The PSA provides a mechanism for EMA assessors and FDA reviewers to concurrently exchange with sponsors their views on scientific issues during the development phase of new medicinal products (i.e., new human drugs and biologics).

Co-panelists were Lynne Yao, M.D., director for the Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research (CDER); Kerry Jo Lee, M.D., acting associate director for Rare Diseases Division of Rare Diseases and Medical Genetics at CDER; and Bakul Patel, MBA, director of the Digital Health Center of Excellence at the Center for Devices and Radiological Health.

Nalubola also participated in the WHO session on mutual reliance which included various regulators and representatives from the Bill and Melinda Gates Foundation. She talked about the FDA-sponsored NASEM report, MRA, and the International Medical Device Regulators Forum, a voluntary forum of medical device regulators from around the world (including FDA) who have come together to accelerate international medical device regulatory harmonization and convergence.

McMullen Presents INO Activities During International Conference

Sarah McMullen, Ph.D., acting director of the OGPS' India Office, provided an update on the FDA's pharmaceutical regulatory activities during the 6th edition of the International Conference on Pharmaceutical & Medical Device. Also known as India Pharma 2021 & India Medical Device 2021, this year's conference was held virtually from February 25-26 and March 1-2.

India has the largest number of FDA-registered drug manufacturing facilities outside of the United States, is one of the largest exporters of drug products to the U.S., and also leads other countries in the submission of abbreviated drug applications which are submissions seeking pre-market approval for generic drugs.

During her presentation, McMullen discussed the FDA's recent drug and biologic approvals and Emergency Use Authorizations (EUAs). She also discussed the agency's COVID-19 response, which features a commitment to providing timely recommendations, regulatory information, guidance and technical assistance during the pandemic.

Finally, Dr. McMullen discussed the agency's use of remote regulatory assessments during the pandemic, leveraging of section 704(a)(4) of the FD&C Act which allows the agency to request and review records in advance or in lieu of an inspection.

Abdoo to Speak During Upcoming FDLI Annual Conference

Associate Commissioner for Global Policy and Strategy Mark Abdoo has been invited to speak during the Food and Drug Law Institute's Annual Conference. On May 19, Abdoo will participate in a panel entitled, *Supply Chains in a Post-Pandemic World*.

Other panelists include Winston S. Kirton, a partner at Winston & Strawn, LLP., and Peter V. Lindsay, a partner at Paul Hastings.

The panel will be moderated by Howard Sklamberg, a partner at Arnold & Porter. Sklamberg was once a senior official at the FDA, where he played a central role in coordinating global agency operations.

The Food and Drug Law Institute (FDLI) Annual Conference is an event bringing together an array of experts from the federal government, industry, the private bar, non-profits, patient and consumer advocates, and academia to participate in discussions on the latest trends and updates in complex legal, regulatory, compliance, and policy issues currently impacting all facets of FDA-regulated industry.

This year, the three-day conference will be held virtually, which will allow participants and attendees to be as safe as possible. The theme is: *Exploring Advanced Topics in Food and Drug Law.* From May 18 through May 20, attendees will hear the FDA's strategic priorities from the acting FDA commissioner, chief counsel, center directors, and other key leaders within the agency.

Dear International Colleague

The Dear International Colleague Letter (DICL) is a letter sent via email to a list-serve of about 20,000 subscribers – both DC-based embassies and international stakeholders. The DICL is intended to inform these stakeholders of any FDA announcements that are relevant to an audience with international interests. Here are the most recent DICLs:

Manufacturers of OTC Drugs for U.S. Market: User Fees Released

Midwestern Pet Foods Voluntarily Recall Due to Possible Salmonella Health Risk

FDA Releases Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies, Young Children

FDA extends time for food facilities to submit DUNS

Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine

FDA Issues Guidance on Remote Interactive Evaluations of Drug Manufacturing/Bioresearch Monitoring Facilities

Generic Drugs Forum 2021: Lifecycle of a Generic Drug

FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab

FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use

Upcoming events

April 24-30	World Immunization Week
May 18-20	2021 FDLI Annual Conference
May 21	DIA China
May 24- June 1	World Health Assembly
May 26-27	The FDA Science Forum | FDA

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