Global Monthly Update

February 2020

Status Update: OGPS China Staff "Safe Haven" Amidst COVID-19

Our FDA colleagues at the FDA China office in Beijing have returned to the United States after receiving an authorized departure (AD) from the State Department on Jan. 29 "due to restricted transportation options and limited availability of appropriate health care" related to the outbreak of the novel coronavirus, now known as COVID-19. Our colleagues are currently practicing self-quarantine, per CDC guidance.

Photo courtesy of CDC, 2020.

The AD was instituted for those U.S. government personnel, including our CNO colleagues, who are stationed at the Embassy in Beijing (as well as those U.S. government personnel who are stationed at the Consulates General in Chengdu, Guangzhou, Shanghai and Shenyang).

This is the first time that FDA has been affected by an AD, which allows for the voluntary departure of all non-emergency U.S. government employees and their family members. Employees granted an AD are permitted to leave the country and return to a safe haven at their respective agency's or department's headquarters in the United States. FDA requested and received a waiver from the Department of State so China office staff could "safe haven" at their district or home offices or at headquarters.

In a Jan. 31 email, Mark Abdoo, Associate Commissioner for Global Policy and Strategy, asked OGPS staff "to be flexible and ready to assist as necessary in supporting this process."

The coronavirus outbreak "is a somber reminder of the dynamic nature of a global organization like ours," he said. "I'd like to commend the resilience of our staff in China and want you all to know that our team at headquarters is committed to supporting them as we all adjust to the disruptions caused by the outbreak."

The day after the AD was issued, the State Department issued a Do Not Travel to China advisory, prompting FDA Chief Operating Officer Jim Sigg to notify FDA staff that all FDA travel to China is "hereby canceled until further notice."

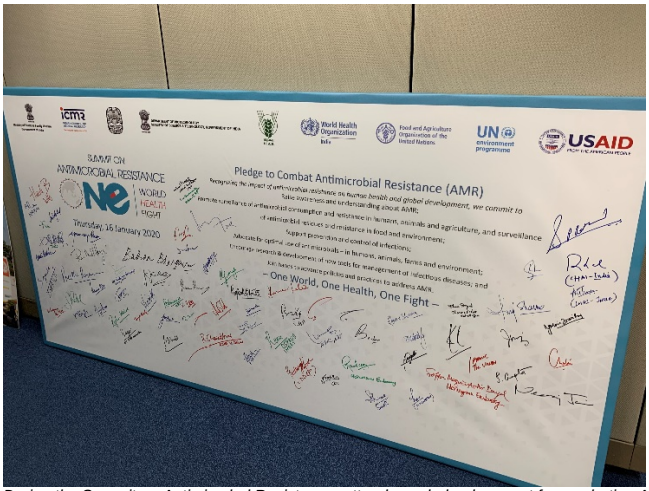
INO Helps Tackle Antimicrobial Resistance

Antimicrobial resistance (AMR)—the ability of a microorganism (bacteria, virus, fungi, parasite) to resist the effects of a drug—is a serious, complex and costly public health problem. In 2019, the UN Ad Hoc Interagency Coordinating Group on Antimicrobial Resistance reported that at least 700,000 people worldwide die each year due to drug-resistant diseases, including 230,000 people who die from multidrug-resistant tuberculosis. If no action is taken, drug-resistant diseases could cause an estimated 10 million deaths each year by 2050.

The FDA proactively engages with domestic and international partners on the complex challenges associated with the growing threat of AMR.

Chris Priddy (far left, rear) attends the FSSAI Workshop.
Photo credit: Food Safety and Standards Authority of India

India, highlighted by the Indian Council for Research on International Economic Relations (ICRIER) as being at a "severely high risk of becoming the AMR capital of the world," provides the FDA with important opportunities for dialogue with food and pharmaceutical sector government and industry stakeholders. Last month, INO officials attended the "Antimicrobial Resistance: World Health Fight" Conference organized by the Government of India, US Agency for International Development (USAID), the World Health Organization (WHO), and the UN Food and Agriculture Organization (FAO). Most recently, INO International Relations Specialist Chris Priddy attended the Food Safety and Standards Workshop "Safe Use of Antibiotics in the Poultry Value Chain."



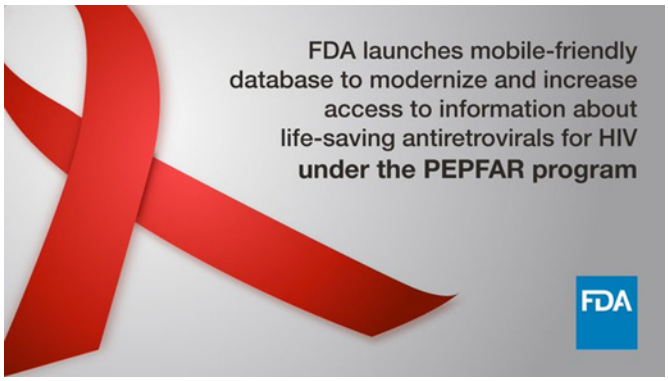
During the Summit on Antimicrobal Resistance, attendees pledged support for combating AMR.

The Government of India has prioritized efforts in addressing AMR concerns and, in April 2017, issued a National Action Plan on AMR with six strategic objectives aligned around increasing AMR awareness and developing appropriate AMR action plans, reducing infection rates, and

promoting appropriate use of antimicrobials. Reflecting India's commitment to its National Action Plan and underscoring a European Congress of Clinical Microbiology and Infectious Diseases abstract that 44% of India food samples contained colistin-resistant bacteria, in 2019 India banned the manufacture, sale and distribution of the antibiotic Colistin and its formulations for food-producing animals, poultry, aquaculture farming, and animal feed supplements.

FDA Launches PEPFAR Database

When the FDA approves a drug for the U.S. market, the approved drug label or prescribing information is posted on Drugs@FDA and the company provides a paper copy of the labeling in the package with the medication. However, such labeling information has not been directly available to health providers and procurers buying antiretrovirals under the President's Emergency Plan for AIDS Relief (PEPFAR) – until now.



That changed on Jan. 29, when the FDA unveiled a greatly enhanced website of the drugs currently available under the PEPFAR program. The revamped database is mobile-friendly, interactive and it includes the drug's prescribing information which can be printed or downloaded from the site.

PEPFAR was created in 2003 to bring together various federal government agencies in providing low-cost, life-saving, treatments for those impacted by HIV epidemic in the hardest-hit countries. It's FDA's role to ensure that the safety, effectiveness and quality of HIV drugs distributed under PEPFAR is the same as for drugs used to treat HIV patients in the U.S. That means these PEPFAR drugs go through the same review process as ARVs intended for the U.S. market and are either approved or tentatively approved if the drugs can't yet be sold here due to existing intellectual property protections. In the 17- year-history of the PEPFAR program, more than 15 million people worldwide have received low-cost, quality-assured antiretroviral treatment drawn from FDA's list of 222 approved or tentatively approved ARV applications (of which 194 are still available for treatment today).

Work on the enhanced website has been a multi-year process, according to Russell Campbell in our Office of Global Diplomacy and Partnerships (OGDP) who serves as the main point of contact for PEPFAR in the agency and represents FDA in interagency PEPFAR discussions. Efforts to update the database began after FDA learned from HHS that PEPFAR country recipients didn't find the agency's PEPFAR list to be very helpful because it provided far less information than is available on Drugs@FDA and other FDA databases. News of that prompted FDA to establish a working group to develop an enhanced website. The group consulted with stakeholders and was told that updates on manufacturing site locations, shelf life, storage conditions, pediatric indications, and the ability to generate metrics easily and export reports were most needed. Moreover, the group was told that patients receiving a product under the PEPFAR program had limited access to FDA approved product labeling – they're typically dispensed a stock bottle containing a one-month supply of medication that contains the name of the medication, the strength, and any additional country-specific messages (e.g., "not for resale"), but receive no further instructions for use. The updated website is intended to address these concerns.

To get the word out about the revamped website, OGPS staff, including Russell Campbell, Karen Riley and Vashti Klein, worked with the Office of Media Affairs and CDER OCOMM on a robust rollout plan that included a statement by FDA Commissioner Stephen M. Hahn, M.D. in English, French and Portuguese that was issued to FDA's media list and distributed by the Foreign Press Center in Washington to overseas reporters who cover Africa.

In addition, OGPS sent out a Dear International Colleague to our global stakeholders and the diplomatic community and the Commissioner's statement was amplified on social media, including our OGPS Twitter site, @FDA_Global. The Commissioner also issued a short video as part of his "Commissioner Chat" series to discuss his own work treating patients in Africa and to introduce the new PEPFAR website. So far, we've received a very positive response to the new website.

Improving the Safety of Imported Food Through New Portal

FDA announced it would start taking applications for the Voluntary Qualified Importer Program (VQIP), a voluntary fee-based program that provides expedited review and import entry of human and animal foods into the United States for participating importers.

To participate, importers must meet the eligibility criteria by fully demonstrating the safety of their supply chain and pay a user fee that covers the cost associated with the FDA's administration of the program. Those importers accepted into the program will be able to import their products to the U.S. with greater speed and predictability, avoiding unexpected delays at the point of import entry. Consumers will also benefit from the importer's robust management of the safety and security of their supply chains.

The Feb. 3 announcement focused, in particular, on food importers. FDA will use its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) import screening tool to recognize shipments of food that are part of an approved VQIP application. The screening tool will be programmed to recognize and, in most cases, immediately release the shipment, unless examination and sampling are necessary for specific public health reasons.

Details regarding the program's benefits, eligibility criteria, and application process can be found in FDA's VQIP Guidance: FDA's Voluntary Qualified Importer Program Guidance for Industry.

Planning and Evaluation Team Talks Metrics

During the week of Jan. 6, the Latin America Office in Mexico City hosted our Planning and Evaluation Team, the Financial Management Team, and representatives from our immediate office. The meeting was similar to ones held at other foreign posts. Topics discussed included reporting through narratives, metrics to report for specific activities, preparation and management of spend plans, financial management concerns shared across the posts (e.g., coordination with the embassy systems) and those unique to LAO (e.g., three posts), and drafting of standing operating procedures.

These discussions help standardize OGPS's approach to these critical functions across the posts and HQ, and provide opportunities for the teams to have deeper, more varied conversations than would be possible in hour-long teleconferences. The next such meeting is scheduled for March and will be hosted by the India Office.

Delegation Engages Counterparts in Beijing

On Jan. 14, the FDA China Office met with a delegation from the UK's Medicines and Healthcare Products Regulatory Agency at the British Embassy in Beijing to discuss upcoming plans and ongoing efforts in China for safety monitoring and postmarket surveillance of medical products. These plans include interaction and training of central and provincial regulators on implementation of best practices aligned with applicable International Council for Harmonisation (ICH) efficacy guidelines on pharmacovigilance.

As members of the ICH management committee and with the inclusion of medical product safety monitoring in China's revised Drug Administration Law implemented Dec. 1, 2019, drug safety monitoring is a priority area for Chinese regulators. As experts from MHRA and FDA continue to interact with their regulatory counterparts in China on drug safety monitoring, a greater opportunity exists for a more expansive and robust volume of safety data, providing earlier detection of improved risk signals that will enable regulators to make better informed decisions.

Europe Office Deputy Director Addresses Drug Shortages

During the 19th Regulatory and Scientific Affairs Conference in Amsterdam, Dr. Sandra Kweder provided attendees with an overview of FDA's role in mitigating and preventing drug shortages. She also offered a summary of the FDA Drug Shortage Report, which was issued in October 2019. The key bullets she provided were:

- Most shortages involve older, sterile injectable drugs.
- Companies often discontinue older drugs for business reasons leaving few manufacturers continuing to make them.

- Manufacturing capacity for sterile injectables is limited and multiple drugs are made on the lines with tight production schedules and “just in time” inventory levels.
- Delays and manufacturing quality issues commonly cause shortages.

The report suggests three root causes for drug shortages -
- Lack of incentives for manufacturers to produce less profitable drugs.
- The market does not recognize and reward manufacturers for “mature quality systems” that focus on continuous improvement and early detection of supply chain issues; and
- Logistical and regulatory challenges make it difficult for the market to recover from a disruption.

And, it identified three enduring solutions to address those root causes.
For more information about drug shortages, visit the report site.

Latin America Office Meets Secretary Pompeo

Latin America Office staff based in San Jose, Costa Rica, were honored to meet briefly with Secretary of State Mike Pompeo during his visit to the U.S. Embassy there. LAO works to ensure that food and medical products imported to the U.S. from this region are safe, effective and of high quality.

Left to right: Secretary Pompeo with LAO staff Jason Cornell, Katie Serrano, Allan Gonzalez and Nicki Conklin

LAO Supports Produce Safety Rule Training for Chilean Farmers

Our Latin America Office (LAO) continues its efforts to help fresh produce growers feel prepared and ready to comply with the requirements of FDA’s Produce Safety Rule, which applies to both U.S. growers and those international growers who import their produce to the United States. Beginning on Jan. 21, (LAO), in conjunction with the Center for Food Safety and Applied Nutrition’s (CFSAN) - Produce Safety Network (PSN) and Chile’s food safety agencies, conducted an On-Farm Readiness Review (OFRR) four-day tour program in Curicó, Chile.

Participants of the course "OFRR-International Reviewers" representatives of the Ministry of Agriculture (SAG, INDAP, ACHIPIA) and technical advisors linked to INDAP programs, together with experts Diane Ducharme (staff fellow at CFSAN) and Theresa

Klaman (consumer safety officer at CFSAN), Donna Clements, extensionist of Cornell University's "Produce Safety Alliance," and representatives of the FDA's Regional Office for Latin America in Chile, Gonzalo Ibañez and Wendy Fanaselle.

This was the second international OFRR tour program in Chile and the fourth in Latin America since the program was developed by CFSAN-PSN at the LAO in fiscal year 2019.

The four-day tour was hosted by the Chilean Agency for Food Safety and Quality (ACHIPIA), part of the Ministry of Agriculture. OFFRs were conducted at conventional and organic berry farms with active harvesting operations for strawberries, raspberries and blackberries.

The program also included a closeout meeting with farmers, ACHIPIA, and other Chilean food safety agencies to address any observed trends or recommendations. LAO personnel were present throughout the visit to support the program.

The Produce Safety Rule implements provisions of the landmark Food Safety Modernization Act or FSMA, which required that FDA establish science-based, minimum standards for safe growing, harvesting, packing and holding of fresh produce. The Rule sets mandatory minimum standards for employee health and hygiene; soil amendments (compost/ manure); equipment, tools and buildings; and domesticated and wild animals.

LAO Staff and CDRH Host Mini-Symposium

On January 29, LAO, in collaboration with the Center for Devices and Radiological Health (CDRH), co-hosted a Medical Devices "Mini-Symposium" at FDA headquarters in White Oak for regulators from Argentina, Chile, Colombia and Mexico. Chile was invited to attend because it had requested that LAO help support the development of its medical device regulatory system and because it is considered a Regulatory Authorities of Regional Reference, and therefore is considered to have a certain level of leadership/influence in the Americas.

The agenda for the day-long symposium included device nomenclature; adverse events; export certifications; ISO 13485, a global inspectional standard; the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world working on regulatory convergence; and the Medical Device Single Audit Program (MDSAP), which allows a third party auditing organization represented by MDSAP to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

Left to right: Bruce Ross, Michelle Rodriguez, Katie Serrano, Jeff Shuren, Melissa Torres

In opening remarks, CDRH Director Dr. Jeffrey Shuren urged the regulators to consider becoming an MDSAP affiliate, as Argentina's National Administration of Drugs, Foods and Medical Devices recently did. Affiliates can use MDSAP audit reports and/or MDSAP certificates for evaluating a medical device manufacturer's quality management system. Dr. Shuren also told the attendees that regulatory convergence is a priority for CDRH which it is striving to do under the auspices of the IMDRF.

Transitions

Rita K. Kabaso is a Consumer Safety Officer with the India Office, focusing on pharmaceuticals. She previously worked in the Office of Pharmaceutical Quality Operations, Office of Regulatory Affairs, conducting drug inspections. Prior to joining FDA, Rita worked as a Research Technologist in an infectious disease lab. Rita holds a master's degree in biotechnology from Johns Hopkins University and a Bachelor of Science in Biology from McDaniel College.

Dr. Marijo Kambere is on a 60-day detail as the CNO Supervisory CSO for Medical Products, effective January 6, 2020. Marijo joined CNO as a pharmaceutical investigator in 2015. She started her career with FDA in 2010 as an Investigator for the Seattle District Office and specialized in pharmaceutical and bioresearch monitoring inspections and assumed the Drug Registration Monitor position in 2014. Marijo earned a B.S./M.S. degree in Industrial Engineering in Belgium and a Ph.D. in Molecular Biology and Biochemistry from Wesleyan University.

Solomon Yimam is serving a detail within the India office as an international relations specialist, bioresearch monitoring program (BIMO). He has over 25 years of public health experience in evaluating practices and products to ensure compliance with clinical laboratory, GCP, and GMP regulations. Previously, he served as a policy analyst in India and as a Bioresearch Monitoring Program reviewer in CBER. Solomon holds a bachelor's degree in Laboratory Medicine from University of Kentucky and is Board Certified by the American Society of Clinical Pathologists.

Farewell to Lou Valdez

Friends and colleagues of **Mary Lou Valdez** gathered on January 27, for her farewell retirement party in Building 2. There was food, music, anecdotes, a slide show and many memories, capped by the reading of this letter –

On behalf of the Department of Health and Human Services, I want to I want to thank you for your decades of exceptional service to the American people. You have shown remarkable dedication in your thirty years of service at HHS. As deputy director of the Office of Global Health Affairs, associate commissioner of International Programs now associate commissioner of Diplomacy and Partnerships, your tenure with the Department has been marked with distinction. Your extensive involvement in leadership on international health diplomacy efforts has allowed the HHS to influence a range of complex policy issues for the U.S. Government in several multilateral organizations and with various governance. You can be proud of your time with the Food and Drug Administration as you have been instrumental in the establishment of the FDA's international presence in several countries and the agency's engagements with

multilateral organizations in areas of regulatory systems strengthening, food safety, substandard and falsified medical products, regulatory landscaping, and innovative methods of training in support of FSMA implementation. Your dedication to global health with HHS is acknowledged and valued. Your leadership during your tenure with the Department has been marked with numerous accomplishments and accolades and has earned you the highest respect of those who had the pleasure of working with you. Congratulations on your retirement. You have my sincere gratitude and appreciation for all of your contributions over the last thirty years. I wish you all the very best.

Alex Azar
United States Secretary of Health and Human Services

Deputy Commissioner for Policy, Legislation, and International Affairs Anna Abram, who read the letter, then gave a toast to Lou: “for her incredible contributions to public health over the past thirty years and to wish her the very, very best as she takes on new endeavors in pursuit of public health.”

International Day of Women and Girls in Science

As OGPS builds up an online and social media presence, we look for opportunities to highlight the important work of our staff. To that end, we took advantage of Feb. 11, the International Day of Women and Girls in Science, to recognize Europe Office Director Ritu Nalubola, Ph.D., for both her work leading FDA's nanotechnology policy activities and the agency's efforts to modernize the regulatory system for biotechnology products.

The UN General Assembly established this International Day in 2015, in recognition that women and girls play a critical role in science and technology communities and their participation should be strengthened. At present, less than 30 per cent of researchers worldwide are women. According to UNESCO data (2014 - 2016), only around 30 per cent of all female students select STEM-related fields in higher education.

We know that many women in STEM work in OGPS and on Feb. 11, 2021 we will celebrate more of our staff.

Upcoming Activities

2/25 OGPS members of the *Technical Barriers to Trade* committee (Joseph Rieras and Jade Pham) will participate in discussions: *Good Regulatory Practice* and *Conformity Assessment Procedures* during the World Trade Organization's February thematic session.

2/29 FDA will join the global observance of Rare Disease Day, which was created to raise awareness about the 7,000 known rare diseases, many of which have no treatment.

3/17 DIA Europe 2020
EO plans to participate in multiple activities during this 3-day meeting in Brussels. EO Deputy Director Sandra Kweder will lead the session, "Lessons Learned in the Opioid Epidemic," and Matt Scherer will present, "Progress with the U.S.-EU Good Manufacturing Process (GMP) Mutual Recognition Agreement (MRA). The EO will also host a booth on the exhibit floor to engage with stakeholders and share information about FDA and EO activities and priorities.

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