



**March 2021**

## **On the Front Lines of the COVID-19 Pandemic**

*One full year. The staff in our Office of Global Policy and Strategy has been coping with the challenges of living and working in the midst of a pandemic now for one full year. Throughout these trying times, our staff has repeatedly risen to the occasion to advance the public health. In some cases, that meant enduring personal challenges and unexpected privations. Here are just a few of their stories.*



### **Kellia Hicks – Consumer Safety Officer, OGPS’ India Office**

“You are literally the ONLY person in the world right now who is qualified and available to conduct this inspection. Will you do it?” The answer was a resounding “yes” from the Office of Global Policy and Strategy’s (OGPS) Consumer Safety Officer, Kellia Hicks, stationed in New Delhi, India.

Investigator Hicks’ agreement to assist came shortly after the beginning of the pandemic when Indian visas were no longer being issued to foreigners, all international flights were suspended preventing anyone traveling from the U.S., and the cancellation

of domestic flights was looming. The ability to inspect the drug production facility that manufactures a possible COVID-19 treatment underscored the importance of having a foreign post located in a country where 30% of the pharmaceutical exports are destined for the United States. Having boots on foreign ground is essential to OGPS being able to accomplish the FDA's mission-critical inspections and investigations at a moment's notice.

Hicks' adventure was fraught with personal challenges. It wasn't easy getting to the remote city, but after making it back to the hotel after Day One of the inspection, she found out the city would be imposing a strict curfew the next morning making it impossible to go out of the hotel to continue the inspection. This was followed that evening by the Prime Minister of India announcing a 21-day nation-wide lockdown effective at midnight — stranding her in a remote area of India, alone, without easy access to safe food, and 34 driving hours away from her home in New Delhi.

After a week, Hicks received a pass that allowed her to travel via private driver to the larger city of Hyderabad. After a harrowing 12-hour drive, she beat the evening curfew but still wound up stranded for an additional four weeks in a hotel room there until FDA, U.S. Department of State, and U.S. Embassy personnel — with much effort — were able to secure a charter repatriation flight back to New Delhi.

Investigator Hicks notes that she often visits remote areas that may not have quick access to clean food and water, A/C or heat, or useable toilets or toilet paper. Although the job may be challenging, she went on to comment, "at the same time 1.5 billion people have managed to learn how to live and work here, so that motivates me to do so, too."

### **Jonathan Chapman – Consumer Safety Officer, and the staff of OGPS' China Office**

At the beginning of February 2020, during the height of China's biggest holiday when businesses tend to be closed, the U.S. State Department ordered departure of all non-emergency Mission China employees, so our China Office employees were forced to scramble to book return flights for their families and find long-term sitters for their pets. Several employees were on vacation outside of China at this time; they were required to report directly back to the U.S., returning with only what they had packed for their vacation. For Jonathan Chapman, that meant leaving a tropical getaway and landing in the frigid Washington D.C. winter wearing shorts and running dangerously low on essential medications.

China Office employees found themselves scattered and hunkered-down at homes or hotels across the U.S., and in telework mode like most of the FDA workforce. The returned employees were given assignments to utilize their knowledge: medical device experts advised on importation of personal protective equipment from China, others performed temporary program and policy assignments for the various FDA centers.

One important task for the China office during the first six months of the pandemic was to assist the Office of Regulatory Affairs' (ORA) Health Fraud Branch in identifying and

researching fraudulent COVID-19 claims related to FDA-regulated products; work that included undercover research of social media platforms and web communications.

Throughout this time, our seven locally employed staff members continued to support the work of the China Office. Their dedication enabled the U.S. direct hires to seamlessly return to post and resume normal operations when, by late summer 2020, some stateside employees were able to return to Beijing due to China's improvement in COVID-19 case numbers. But the logistics of travel back to China were much more difficult and time-consuming than before the pandemic: 46 hours versus the usual 12.5 hours. In addition to outbound antibody and virus testing by U.S. authorities, returning employees were also subject to the Chinese government's mandatory 14-day quarantine, twice-daily temperature reporting, and COVID-19 testing before being allowed to return to regular duties. First order of business for the returning staff was to draft procedures for conducting inspections during the pandemic and begin to schedule those inspections.



### **Janete Guardia – Consumer Safety Officer, OGPS' India Office**

When the government of India declared a nation-wide lockdown and issued stay-at-home orders on March 22 — which included suspension of incoming and outgoing commercial flights — many American citizens were left stranded and wondering how to return home. This prompted a huge influx of calls to the U.S. Embassy in New Delhi. But the consular office (whose job it is to respond to U.S. citizens' inquiries) was already operating with limited staff and service due to many consular officers already having been evacuated nearly a week before.

An all hands-on-deck approach was needed from those remaining at post to assist with repatriation efforts. Since OGPS's India Office is part of the embassy, Investigator Janete Guardia and her FDA colleagues volunteered hundreds of hours over a seven-week period to help 6,170 American citizens and legal permanent residents return home to the United States. The FDA employees assisted with late night airport runs, 12-hour shifts answering consular calls, switchboard operations, and other repatriation efforts.

In April, the India Office's efforts were acknowledged by then Secretary of State Michael Pompeo, who expressed his appreciation for the India Mission's "...success in assisting large numbers of American citizens in getting home, supporting the sourcing of key pharmaceuticals and medical supplies, assisting firms critical to the U.S. economy with their back-office operations in India, and supporting India's efforts to combat COVID-19."

### **LCDR Shannon Thor, Pharm.D. – International Policy Analyst, OGPS' Europe Office**

During the COVID-19 pandemic, Public Health Service (PHS) officers have deployed early and often to assist with clinical care, testing, contact tracing, public education, vaccination, and more. LCDR Shannon Thor has twice deployed in the past year for month-long assignments supporting COVID-19 missions. In the summer of 2020, she deployed to Commissioned Corps Headquarters, where she provided 24/7 support to teams of officers deployed around the country. She was in charge of monitoring the deployed teams' safety, including adequate safety training before and during their deployments, ensuring their supply of personal protective equipment, responding to any illness or injury, and monitoring for potential environmental hazards. Then in February 2021, PHS headquarters called and asked LCDR Thor to be ready to deploy on a vaccination mission; 48 hours later she was traveling to the southwestern United States. She is currently working at a mass vaccination site, administering between 100 and 200 vaccines per day to an underserved population. As a pharmacist credentialed in the provision of vaccines, LCDR Thor is thrilled to use her clinical skills to help fight the pandemic. "I am so proud to have the opportunity to play a meaningful role in the national vaccination effort," she says. "Though I'm away from FDA, the experience of vaccinating patients with the vaccines that we have authorized over these past months feels like a true public health victory with every shot I give."

### **Patty Pineda – International Regulatory Analyst, OGPS' Latin America Office**

As the pandemic grew in proportion, the increased demand for hand sanitizers became of paramount importance. Companies from the U.S., China, Korea, and Mexico stepped up — and sprang up — to meet the United States' great demand. With this surge in new suppliers came reports to the FDA of negative effects and deaths from ingesting alcohol-based hand sanitizers. Most of the Mexican samples tested by the FDA from April through December 2020 were found non-compliant with FDA requirements, including methanol and/or 1-propanol contamination at dangerous levels, or were found to be sub-potent. Patty Pineda and the staff from OGPS' Latin America Office (LAO) in Mexico City worked closely with Mexican regulatory officials in COFEPRIS (the Spanish

acronym for Federal Committee for Protection from Sanitary Risks) to identify the source of the contaminants and to take measures to quickly alert the public.

Pineda gathered public information on in-country sources of ethanol and methanol, kept in close contact with COFEPRIS about their inspections and regulatory actions, and shared their findings with the FDA's Center for Drug Evaluation and Research (CDER) and FDA's Office of Regulatory Affairs to aid in the FDA's high-level decision-making. Furthermore, Pineda team kept COFEPRIS apprised of any U.S. import refusals of hand sanitizer shipments, in case they were exported back to Mexico, to prevent them from being distributed within Mexico or offered for import back to the U.S. through a different port.

While all this was happening, COFEPRIS was also in the midst of senior staff changes. Pineda noted that it was "not easy to build a working relationship remotely in the middle of a pandemic, with local internet services overwhelmed, and a culture accustomed to in-person meetings." But the experience turned out to be a great opportunity that strengthened collaboration in the region. She went on to remark, "The collaboration with COFEPRIS prompted them to conduct their own investigation and issue safety alerts for Mexican consumers, raising awareness in their population. These tangible results are the ones that make all those long hours and hectic days, worth it," she said.

Helped by LAO's findings, FDA has identified hundreds of hand sanitizers that should not be used by consumers and ultimately decided to issue a country-wide import alert for all alcohol based hand-sanitizers made in Mexico.

*These are just a few stories of the pandemic. Over the last year everyone in OGPS has experienced unexpected challenges and privations, both large and small. Tragically, some have even lost friends or family members to the pandemic. And yet the staff has repeatedly stepped up to make a difference for public health. To our way of thinking, we are all COVID Heroes of OGPS.*

## **Destroying Records Nets \$50 Million Fine for Indian Drug Manufacturer**

The sharp eyes of an FDA investigator during a 2013 inspection of a cancer drug manufacturing plant in India has now led to \$50 million in fines and forfeitures for the company.

The U.S. Department of Justice (DOJ) announced last month that it was assessing drug manufacturer Fresenius Kabi Oncology Limited (FKOL) in Kalyani, West Bengal, India, fines and forfeitures because the company had concealed and destroyed records prior to the 2013 inspection. The fines were assessed in 2021 because it

typically takes years for DOJ to compile evidence and then shepherd the case through the legal system.

“By hiding and deleting manufacturing records, FKOL sought to obstruct the FDA’s regulatory authority and prevent the FDA from doing its job of ensuring the purity and potency of drugs intended for U.S. consumers,” said Acting Assistant Attorney General Brian Boynton of the Justice Department’s Civil Division.



FDA investigators are highly trained and know what to look for, with the instincts to know when something is not right, even when things appear normal. During the 2013 inspection, the investigator noticed the FKOL production manager quickly remove some “scratch” paper from a binder the inspector was preparing to review, and surreptitiously conceal the paper in his pocket. The investigator requested to see the crumpled papers and found them to contain, among other things, notations related to concealed leaks in equipment and holes in the walls of the facility. The investigator subsequently found concealed failed API purity test results that had been deleted from a computer.

The United States charged FKOL with violating the Federal Food, Drug and Cosmetic Act (the FD&C Act) in a criminal information filed in federal court in the District of Nevada.

"This a huge success story for the India Office and an example of the advantage of having FDA investigators conduct onsite inspections," said Bruce Ross, director of the

Office of Global Operations, the sub-unit of the Office of Global Policy and Strategy that oversees the foreign offices.

FKOL's actions put vulnerable patients at risk. "Pharmaceutical companies that obstruct FDA inspections jeopardize patient safety," said U.S. Attorney Nicholas A. Trutanich for the District of Nevada. "Maintaining the integrity of records and data is a critical part of drug manufacturing, and our office will continue prosecuting those that obstruct FDA inspections by destroying records or other means."

FKOL, located in multiple cities in India, is a subsidiary of Fresenius Kabi AG, one of the four business segments of the global health care company Fresenius, headquartered in Bad Homburg, Germany. FKOL manufactures active pharmaceutical ingredients (API) used in sterile injectable oncology pharmaceutical products sold throughout the United States through Fresenius Kabi USA, headquartered in Lake Zurich, Illinois.

Its Kalyani facility manufactures active pharmaceutical ingredients (API) used in various cancer drugs distributed to the U.S. The DOJ alleges that prior to the January 2013 inspection of the facility, FKOL plant management directed employees to remove certain records from the premises and delete other records from computers that would have revealed FKOL was manufacturing drug ingredients in violation of FDA requirements.

As part of a criminal resolution, FKOL agreed to plead guilty to the misdemeanor offense, pay a criminal fine of \$30 million, and forfeit an additional \$20 million. FKOL also agreed to implement a compliance and ethics program designed to prevent, detect, and correct violations of the FD&C Act.

FKOL's non-compliance with the FD&C Act for manufacturing drugs for terminally ill patients was ongoing. Parent company Fresenius Kabi AG was issued an FDA warning letter in December 2017 for FKOL's Kalyani plant. The warning letter ([WL 320-18-12](#)) noted current good manufacturing practice (CGMP) violations involving inadequate investigation of out-of-specification results, and the plant's failure to ensure that each API product stage conformed to established standards of purity and quality and that the test procedures to do so were scientifically sound. Similar deviations were cited in a previous 2013 warning letter ([WL 320-13-20](#)), indicating that the facility's oversight and control over the drug manufacturing process were inadequate.

The Central Bureau of Investigation in India provided invaluable assistance to U.S. authorities in the investigation of this matter. "FDA inspections of pharmaceutical manufacturing facilities help ensure the strength, quality, and purity of our medicines. Any attempt to obstruct or interfere with these inspections threatens the public health," said Judy McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs of the FDA. "We will continue to aggressively investigate and present any such obstruction for prosecution."



## Robinson Culminates Federal Service at FDA



The Office of Global Policy and Strategy (OGPS) will bid farewell to [India Office](#) (INO) Country Director Capt. Letitia Robinson, Ph.D., RN, at the end of the month. Robinson, who is set to retire from the Commissioned Corps of the United States Public Health Service (USPHS), deployed in 2018 to the U.S. Embassy New Delhi post - her first FDA position.

How Robinson managed to assume a high-profile FDA position with little knowledge of the agency is a story of family tradition, an impressive background in global public health working with the HIV/AIDS community, and a lifelong quest for learning and growing.

### Making Her Mark in the Military

Having a father who chose a career with the Navy made for an effortless decision to join its ranks. Upon graduation from Hampton University on a Reserve Officers' Training Corps (ROTC) scholarship, Robinson was sworn in as a commissioned officer in the U.S. Navy. For nearly a decade, she was assigned to the Navy Nurse Corps, providing direct care to Navy and Marine Corps service members and their families in the areas of psychiatry, medical-surgical, labor and delivery, and maternal child nursing – specializing in the latter two for her clinical practice.

While on assignment at the National Naval Medical Center (now the Walter Reed National Military Medical Center) Robinson discovered the USPHS, finding its career paths intriguing. Soon after, she leveraged her capabilities and requested an [interservice transfer](#) from the Navy to the USPHS.



## An Illustrious Career Begins

Robinson's first USPHS assignment was as a clinical research nurse at the National Institutes of Health (NIH) where she worked with patients at the [Clinical Center](#) before moving to the Health Resources and Services Administration (HRSA) as a public health analyst. This time she used her background in labor and delivery as a lens to examine the policy implications of providing HIV/AIDS care to perinatal and newborn populations under the Ryan White CARE Act, and thus beginning many years of work relating to HIV/AIDS.

While at HRSA, Robinson was offered the opportunity to join the [Global HIV/AIDS Program](#) overseeing the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in numerous countries throughout Sub-Saharan Africa and the Caribbean. This role required extensive travel abroad, allowing Robinson to see the impact of these programs firsthand – work that supported the health of approximately a half million people. “It’s the kind of thing that fuels you and keeps you going,” she said

Impressively, Robinson was able to complete a Ph.D., while managing her overseas travel schedule. She channeled this into a new position with the National Institutes of Health's [Fogarty International Center](#), where she served as the program officer for Sub-Saharan Africa. Her initial responsibility was to foster scientific exchanges between U.S. and African scientists, with the hope of strengthening research capacity in Africa which led her to develop a program called PEPFAR's [Medical Education Partnership Initiative](#), that provided funding to help foreign institutions develop models of medical education.

## Service Abroad Ensues

Having developed an affinity for Sub-Saharan Africa duty assignments, Robinson moved to the Centers for Disease Control and Prevention (CDC) in [South Africa](#). “I love seeing the impact of HIV programs,” she said. “You are able to see people get well. You see people become advocates. This work is really satisfying because you are able to see the difference.”

Before renewing her tour for another two years Robinson was lured back to HRSA becoming the senior advisor and later acting associate administrator for the Ryan White HIV/AIDS Program. “It was a great opportunity to put leadership into action,” Robinson said of the \$2.3 billion funding program with over 200 staff.

## Limitless Leadership Follows

Robinson describes herself as strategic about her career moves. While still a nurse at heart, her willingness to take on roles with growth potential has served her well throughout the years and was a motivating factor in applying for the foreign office director position at the FDA. She had read the Government Accountability Office’s reports on the foreign offices, which had identified management as a key issue for the offices. Although her government experience had occurred in grant-making institutions and not in a regulatory environment like the FDA, she determined that the agency “needed someone like me.”

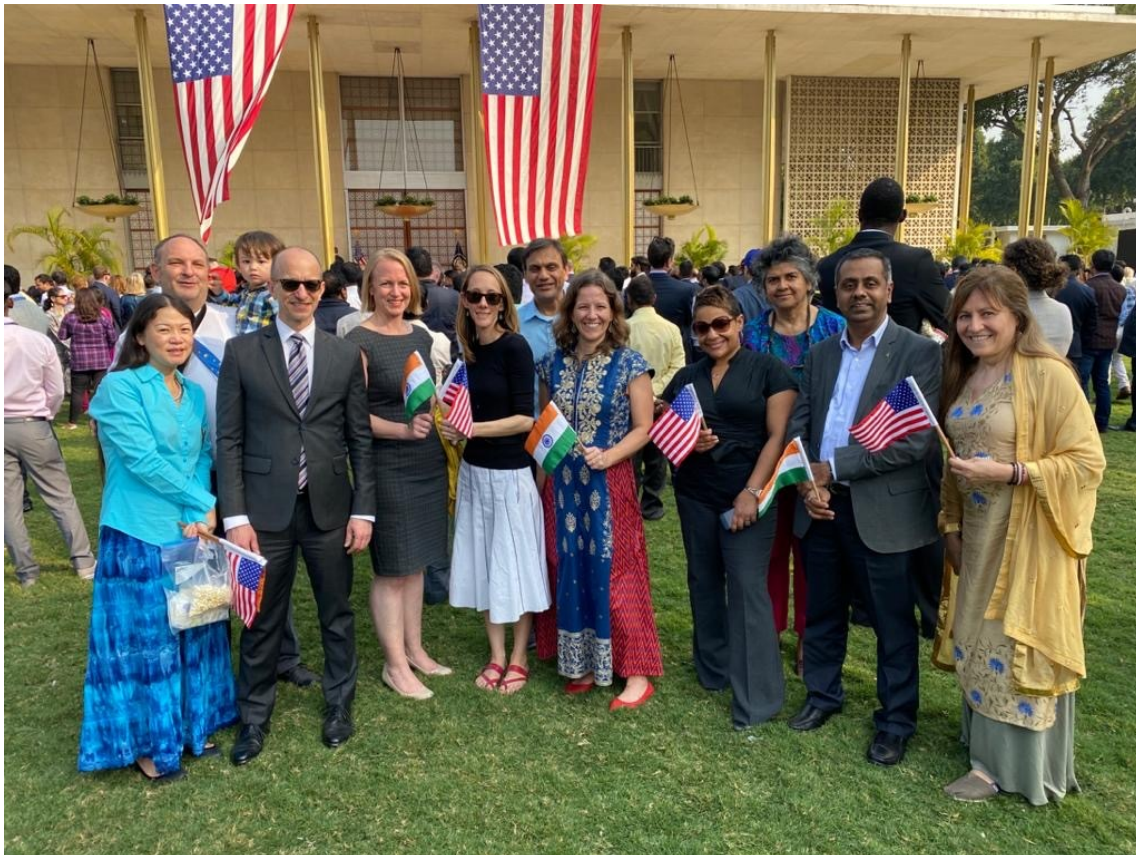


## Exponential Growth Abounds

Nevertheless, there was still a significant learning curve, which she was able to overcome by relying on her leadership and management ability, and through the support of her “very capable and amazing team.”

As director, she has led a team of consumer safety officers, international relations specialists, and product safety coordinators, as well as program analysts, public health specialists, and administrative staff.

Relationship-building has been an essential component of running the office. When staff work overseas, the team at post necessarily becomes your family and friends and the office director is not only responsible for how the team performs at work but for the staff’s well-being even outside of the office. Staff would hold bi-weekly breakfasts, visit each other’s homes for dinner on the weekend, and participate in India holidays and festivals like Diwali. And should staff have to go to the hospital, it might be the director who takes them and stays with them, she said.



Robinson is proud of the fact that the office experienced a 500% growth in staff during her tenure. She cites several factors for her success: encouraging people to come to

India on detail -which invariably led to their deciding to stay full time after experiencing the positive environment in India; her willingness to talk to anyone who inquired about working at the INO as well as changes made at headquarters, including establishing a continuous open announcement for CSOs. Moreover, once staff were hired, they wanted to stay because they have felt "supported, engaged, and part of a cohesive group," she said.

One of the highlights of Robinson's tour was upgrading the *Statement of Intent* on medical products between the FDA and the Ministry of Health and Family Welfare of the Republic of India to a [Memorandum of Understanding](#), (MOU) in record time in February 2020. MOUs are important because they support cooperation and information sharing between regulatory counterparts. The MOU with the India's Central Drugs Standard Control Organization (CDSCO) supported the continuance of FDA and CDSCO cooperation in regulatory, scientific and technical matters, and public health protection of medical products.

Throughout her tenure, Robinson worked to build strong relationships with counterparts in India, efforts that proved all the more important in the midst of the COVID-19 pandemic.



## **A Climactic Finale Materializes**

Dubbing herself a transparent and approachable leader who listens to her staff, Robinson thinks there are a few keys to her success:

- *Don't be afraid to do things that no one else wants to do. Sometimes to get your foot in the door, you should take the job that no one else wants.*
- *Figure out what you want to do and be strategic about getting there. Gauge the bigger picture during each step of your career.*
- *Don't limit yourself by boxing yourself in to a single ideal.*

Taking her own advice, Robinson is not planning to limit herself after retirement. She is thinking of going back to HIV/AIDS work. Whatever her path, we trust she will be prosperous. Her last day with the FDA is April 1. INO Deputy Director Sarah McMullen, Ph.D., is currently leading FDA's activities at post until a new director is selected.

## Using AI to Target Violative Seafood Shipments

The second phase of the [FDA's Artificial Intelligence \(AI\) Imported Seafood Pilot](#) program is now underway. The program, which will run through the end of July, is designed to enhance and improve the FDA's ability to quickly and efficiently identify possible issues with imported seafood products which may pose a threat to public health.



In 2019, the agency launched the first phase of the pilot, an analytical proof of concept, to examine the use of a Machine Learning (ML) screening tool to target violative seafood shipments. Machine learning is a type of AI that makes it possible to rapidly analyze data, automatically identifying connections and patterns in data that people or even the agency's current rules-based screening system cannot see. During this first phase, the FDA used years of retrospective data from past seafood shipments that were refused entry or subjected to additional scrutiny, such as a field exam, label exam, or laboratory analysis of a sample. This gave us an idea of how much our surveillance efforts might be improved using these technologies. The analysis demonstrated AI's potential.

Using AI is one of the priorities of the FDA's [Technology Modernization Action Plan](#) (TMAP) and reflects the [New Era of Smarter Food Safety Blueprint](#) which outlines how the agency plans to leverage new technologies and approaches to create a more digital, traceable, and safer food system.

Seafood was chosen for the pilot because nearly 94 percent of the seafood consumed in the U.S. is imported.

## **CDRH Calls Out Bogus Registration Certificates**

On March 3, the FDA sent letters to 25 companies asking them to stop producing and issuing official-looking "[FDA registration certificates](#)" that sometimes even used the FDA's logo. The problem is, they're bogus documents. FDA doesn't issue a registration certificate to medical device manufacturers after they use our Establishment Registration & Device Listing system to register their manufacturing facilities and list what devices they manufacture. And yet, some third-party companies do issue these certificates and many in the device supply chain attribute erroneous meaning and value to them.

"The Office of Regulatory Programs has alerted firms that produce and issue these certificates that some device manufacturers and distributors are using registration certificates to create the misimpression that the FDA has reviewed, approved, cleared, or authorized their products. The FDA will continue to take appropriate steps to help ensure that the public is not misled about medical devices sold in the U.S.," noted Rear Adm. Sean Boyd, director of the Office of Regulatory Programs at the FDA's Center for Devices and Radiological Health (CDRH).



The FDA does not issue any type of device establishment registration certificate.

This issue has taken on heightened concern since the onset of the COVID-19 pandemic, as the need for imported medical devices, especially personal protective equipment, has grown. Those involved in the medical device supply chain should note well that:

- The FDA does not issue any type of device establishment registration certificate;
- Registration and listing with FDA does not denote approval or clearance of the establishment or its devices.

The use of such certificates is common in China — 16 of the 25 letters were issued to firms in China. The OGPS' China Office plays an important role in monitoring the registration and listing of Chinese companies and is doing what it can to educate Chinese companies that “certification” of FDA device registration is a meaningless concept.

## Translation Widens Reach





The FDA is pleased to announce that the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) is now available in the languages of Chinese and Portuguese. The PSR was previously translated only into Spanish.

Adding Chinese and Portuguese translations of the PSR helps to ensure that this important produce safety regulation is accessible to a broader audience.

The PSR establishes mandatory science-based, minimum standards for the *safe* growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. The translations can be found on the [FSMA website](#).

## Transitions



**Andi Fristedt** comes to the FDA as Deputy Commissioner for Policy, Legislation, and International Affairs from the Senate Committee on Health, Education, Labor, and Pensions (HELP), where she served as deputy health policy director and lead public health staffer to Ranking Member/ Chair Patty Murray (D-WA). She first came to the HELP Committee as staff to Sen. Tom Harkin (D-Iowa).

Prior to joining the Committee staff, Fristedt worked at the Centers for Disease Control and Prevention's Washington Office, completed a Global Health Fellowship at the World Health Organization in Geneva, Switzerland, and served as campaign manager and later chief of staff to an Oregon State Representative. She has a Master of Public Affairs from the Princeton School of Public and International Affairs and a bachelor's degree in Family and Human Services from the University of Oregon.



**Michael Oehlsen** comes to the Office of Global Diplomacy and Partnerships on detail from the FDA's [Center for Veterinary Medicine](#) (CVM), where he has served as director of international policy and logistics since 2010. He has worked on various drug- and food-related activities and directly interacted with many of the FDA's global partners, such as the World Organization for Animal Health (OIE), Codex Alimentarius, and the World Trade Organization.

While at CVM, Oehlsen has led the FDA's efforts to extend the FDA's Mutual Recognition Agreement with European Union member states to include veterinary drugs, thus facilitating the mutual use of inspection data for veterinary medicines, a practice that now exists for human drugs. He has also contributed to and led several key bilateral and multilateral international working groups to further harmonize global regulatory policies. For example, his work on the CVM/EMA (European Medicines Agency) Bilateral Cluster was recently highlighted in the January publication of the International Update News Letter, published by the Office of Global Policy and Strategy's Europe Office. Oehlsen also led ongoing efforts to evaluate the implementation of the Systems Recognition program, an international regulatory system to ensure the safety of exported and imported veterinary foods; was instrumental in developing CVM's International Affairs Strategic Plan; and currently serves as CVM's international focal point for the agency's [One Health Initiative](#), which recognizes the interconnection among people, animals, plants and their shared environment.

Oehlsen is a U.S. Air Force veteran with over 22 years of experience in federal drug regulatory and international policy. He received a bachelor's degree in chemistry and a Ph.D. in metallo-inorganic medicinal chemistry with a concentration in oncological platinum complexes, both from the Virginia Commonwealth University. After obtaining his Ph.D., Oehlsen brought his expertise to CVM as a regulatory review chemist in the Division of Manufacturing Technologies (DMT). During his time in DMT, he served as a key subject matter expert for FDA's Office of Criminal Investigations and later became a certifying instructor for FDA Level III investigators.



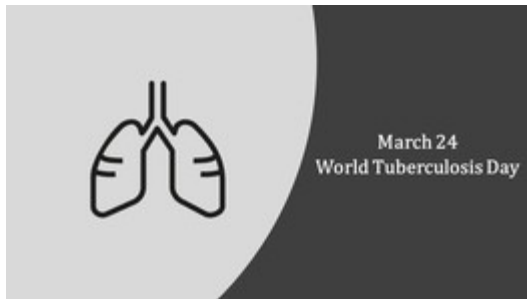
**Kunapuli "Madhu" Madhusudhan** has been selected as a consumer safety officer (CSO) for the India Office. Prior to his current role, Madhusudhan was a CSO stationed in North Carolina. Before joining the FDA in 2015, he taught as an assistant professor of microbiology at the University of Arkansas Medical School.

Madhusudhan worked on animal vaccines as a microbiologist at the Animal and Plant Health Inspection Service (APHIS) Center for Veterinary Biologics at the U.S. Department of Agriculture. He has also served as a chief scientist and program manager for over seven years at Clean Earth Technologies quality control and biosciences laboratories. Madhusudhan holds a Bachelor of Science in Agriculture from Agricultural University, Hyderabad, India, and earned both a master's degree in food technology and a Ph.D. in protein chemistry, from the University of Mysore in India.



**Gabrielle Lamourelle** departs OGPS after completing a 120-day detail as director of the [Office of Global Diplomacy and Partnerships](#). She returns to her role as the deputy director for multilateral relations within the HHS Office of Global Affairs (OGA) where she has served since 2016, leading U.S. negotiations at the World Health Assembly, the United Nations General Assembly, and other key forums on health matters; managing special projects, such as drafting the HHS Global Strategy; and serving as OGA's focal point on noncommunicable diseases (NCDs) and injuries.

**World Tuberculosis Day is March 24**



World Tuberculosis Day is recognized each year on March 24, commemorating the the date in 1882 when Dr. Robert Koch announced his discovery of [Mycobacterium tuberculosis](#), the bacteria that causes tuberculosis (TB).

TB is one of the world's most damaging infectious diseases, primarily targeting the lungs. It can also attack other parts of the body including the kidney, spine, and brain.

While TB is preventable, the Centers for Disease Control and Prevention estimates that up to 13 million people in the United States alone are living with [latent tuberculosis infection](#). This means that although the bacteria may be present, the infection is not.

World TB Day is a day to raise awareness and educate the public about the social and economic consequences of TB and its impact around the world. This year's theme is [The Clock is Ticking](#). Global efforts to end the TB epidemic have saved millions of lives, but there is more work still to be done.

## INO Staff Supports Black History



For Black History Month, the U.S. Embassy New Delhi [commemorated](#) the achievement of Blacks through a series of video messages. Two members of OGP S's India Office (INO) provided video comments.

Consumer Safety Officer Kellia Hicks shared [fun facts](#) about historically black colleges and universities in video messages for the embassy and the [American Center New Delhi](#), the embassy's cultural center which offers art exhibits, book launches, film screenings, discussions, lectures, and cultural programs. Consumer Safety Officer Rita Kabaso was also featured in the videos discussing the contributions of Blacks in the areas of science, technology, engineering, and math (STEM).

## US Mission Europe Highlights Nalubola



In observance of Women's History Month, the U.S. Mission to the European Union is launching a [social media campaign](#) to spotlight its section heads led by women.

Included in the campaign is OGPS' Europe Office Director Ritu Nalubola. The official recognition, which runs from March 1 through March 31, commemorates and encourages the study, observance, and celebration of the vital role of women in American history.

## Middendorf Talks Inspections at IPA Forum

In-person, mission-critical drug inspections have resumed in India again after being suspended in March 2020 for several months due to the COVID-19 pandemic, India Office International Relations Affairs Specialist Chris Middendorf, reported recently.



Middendorf told participants at the virtual 6th India Pharmaceutical Forum (IPF) hosted by the [Indian Pharmaceutical Alliance](#) (IPA) that FDA investigators began conducting mission critical inspections in January while still following strict protocols to protect against exposure to infection. How mission-critical is defined is set by the Center for Drug Evaluation (CDER) and Research but it has included COVID-related therapies in short supply.

The Forum brought together global regulators and industry experts who covered topics relating to this year's theme, *Patient Centricity: New Paradigm in Quality Management*.

Middendorf was joined by CDER staff: Office of Pharmaceutical Quality Director [Michael Kopcha](#), Ph.D., R.Ph.; Associate Director for Strategic Initiatives [Theresa M.](#)

[Mullin](#) Ph.D.; and Director of the Office of Manufacturing Quality Office of Compliance Francis Godwin.

Even though COVID19 is a “once-in-a-century event,” he said, “industry should ask itself if it is prepared for situations like these.”



Mullin echoed Middendorf’s points. “The COVID-19 pandemic has put a spotlight on the pressing need for manufacturers to rapidly learn to adjust manufacturing processes to suit new situations, guidelines, and regulations.” With patients at the receiving end of any drug quality or shortage problems, “it is crucial, therefore, for the pharma industry to maintain high levels of quality in products and processes.”

[Drug shortage](#) mitigation is continually at the forefront for FDA, and all the more important during the pandemic. The Drug Shortage Staff within CDER has asked manufacturers to evaluate their entire supply chain, including active pharmaceutical ingredients, finished dosage form, and any components that may be impacted in any area of the supply chain due to the COVID-19 outbreak.

Middendorf was quoted in the Indian financial web portal [Money Control](#).

## ***Update Magazine Publishes Rieras Article***



The Food and Drug Law Institute (FDLI) has republished an article that initially appeared in [December](#) in our publication [From a Global Perspective](#), OGPS' series of occasional thought pieces on international topics. The article, on Australia's plain packaging regulations by Joseph Rieras, a senior advisor in the Office of Trade, Mutual Recognition, and International Arrangements, appears in the Spring 2021 issue of the FDLI's *Update Magazine*.

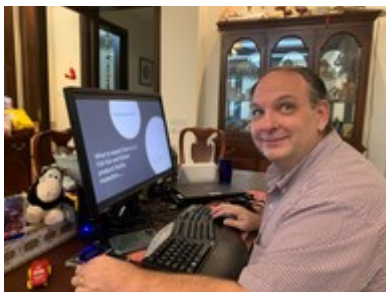
In the article, Rieras delved into a significant public health ruling by the World Trade Organization's Appellate Body in June 2020 that affirmed Australia's Plain Packaging Measures requiring that brand images, display logos and promotional text be removed from cigarette packages - doing away with the use of attractive colors, eye-catching designs, and engaging characters on tobacco packages that public health experts argued made smoking more appealing, and attracted new customers, especially teens.



"OGPS staff are encouraged to follow Joseph's example and consider how they might repurpose their external presentations and written work for publication elsewhere. That way you'll achieve the widest possible reach for what you have to say," said Karen Riley, acting supervisor of the OGPS Communications Team. The CT stands ready to help OGPS staff if they are considering possible venues for their written materials.

The *Update* releases its issues quarterly: Spring, Summer, Fall, and Winter.

## ***Getting to Know Your Food with INO Staff***



Last month, [India Office](#) Consumer Safety Officer for Food Eric Milstead and Food Safety Coordinator Pankaja Panda presented, *Getting to Know Your Food* for Embassy Health Month. Their presentation covered FDA and India's labeling laws, allergens, how to read the labels, gluten, [GMOs](#), and organics.

Also in February, Milstead gave a presentation, *What to Expect from a U.S. FDA Fish and Fishery Products Facility Inspection* to the Indian government and industry. He covered what food facilities in India can expect during an FDA seafood [Hazard Analysis](#)

[Critical Control Point](#) (HACCP) inspection; the applicable regulations; and common issues FDA food investigators encounter on seafood HACCP inspections.

His presentation was one of six for industry and embassy staff on preparing for an inspection to coincide with Health Month at the embassy. The series was the brainchild of Consumer Safety Officer Denise Connelly, of the FDA's Office of Regulatory Affairs, and India Office Supervisory Consumer Safety Officer Natalie Mickelsen, D.V.M. Although Connelly returned to the U.S. before the project began, Milstead and Mickelsen carried on with the project. The embassy had asked for a few topics to consider. Milstead provided some suggestions, and the embassy requested all of them.

So far Mickelsen has given two of the presentations, Milstead has given three. He will wrap up the series in April.

## **INO Staff Bids “Bon Voyage” to Director**

Staff of the [India Office](#) gathered in late January to say, “bon voyage” to their director, Dr. Letitia B. Robinson. Letitia arrived at post in July 2018 (working as director since 2017) and left post February 3, 2021 to return to Washington, D.C., for her retirement from the U.S. Public Health Service.

The staff enjoyed hearing about some of the accomplishments achieved under Dr. Robinson's leadership, including:

- The FDA India Office went from 70% vacant to 70% staffed.
- Most eligible deployed staff renewed their tours.
- Robust relationships with our central government counterparts in India including: [CDSCO](#), [EIC](#), [FSSAI](#), [MPEDA](#), [APEDA](#), and [Spices Board](#) were established and maintained.
- Working relationships with two state regulatory bodies (states of Gujarat and Telangana) were established.
- Meaningful and high-profile inspectional work were solicited, planned, and executed with more than a dozen warning letters, exclusion of study data, and several import alert additions due to our inspectional work.
- Fruitful relationships with our internal stakeholders were nurtured and grown.
- Relationships with other national regulatory authorities including [WHO](#), [EU](#), [EDQM](#), [EMA](#), [TGA](#) (Australia) were established and leveraged.



- Important outreach to industry in both foods (PCQI: Preventive Controls Qualified Individual Lead Instructor training; increasing the number of qualified individuals in India from two to over 100) and medical products (developed and led workshop with four other regulatory authorities on Active Pharmaceutical Ingredients, also known as API's) were developed and executed.
- Collaborative efforts were undertaken with other USG agencies here at post (including [NIH](#), [CDC](#), [USDA](#), [DEA](#)) on health-related initiatives.
- [Memorandum of Understanding \(MOU\) between FDA and CDSCO](#) on the safety of medical products was signed (February 2020).
- Diplomatic facilitation of critical medical products supply chain was conducted during the COVID-19 pandemic and assistance was provided for stranded Americans returning to the U.S. during the lockdown.



In a moment of hilarity, Letitia was gifted with the office microwave which has caused her much grief over the past two years. This was followed by the real gift; a commemorative photo and plaque set, marking her time as INO director.



April 7

[World Health Day](#)

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