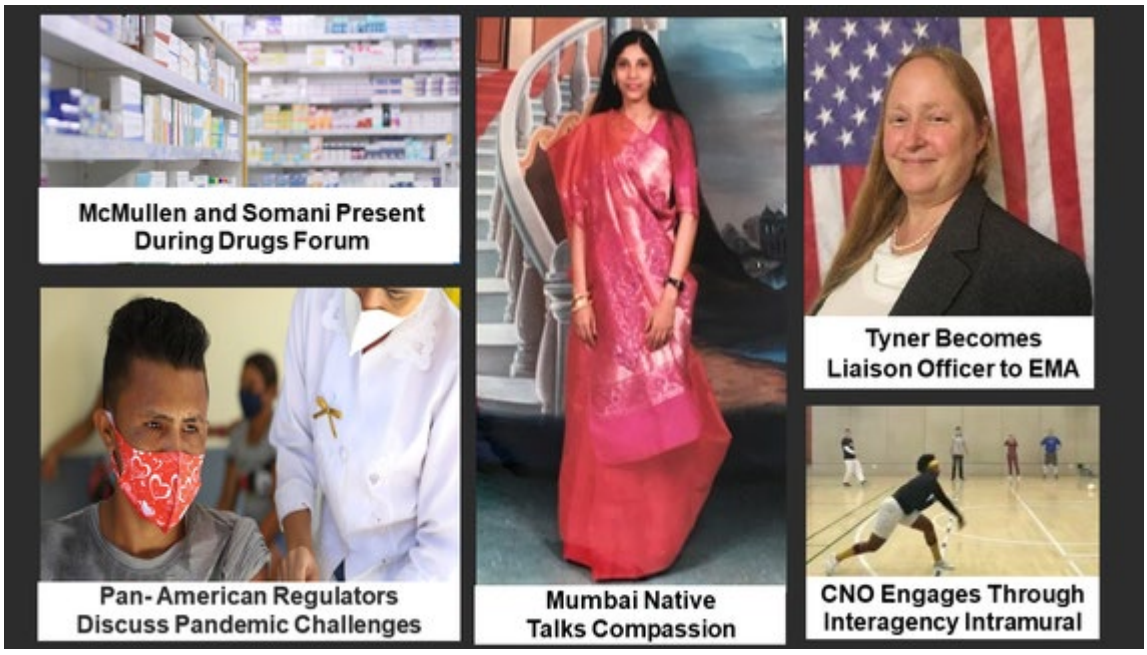
January 2022

Read past issues of the *Global Update* here.

In this issue we salute staff members old and new, and recap recent collaborations



Pan- American Regulators Discuss Pandemic Challenges

How regulators from across the Americas are responding to the challenges posed by the COVID-19 pandemic and what lessons can be learned from this experience were the primary topics during the recent 10th Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH). The three-day conference took place December 6-10 via Zoom and was sponsored by the Pan American Health Organization (PAHO) — the World Health Organization's regional office for the Americas.

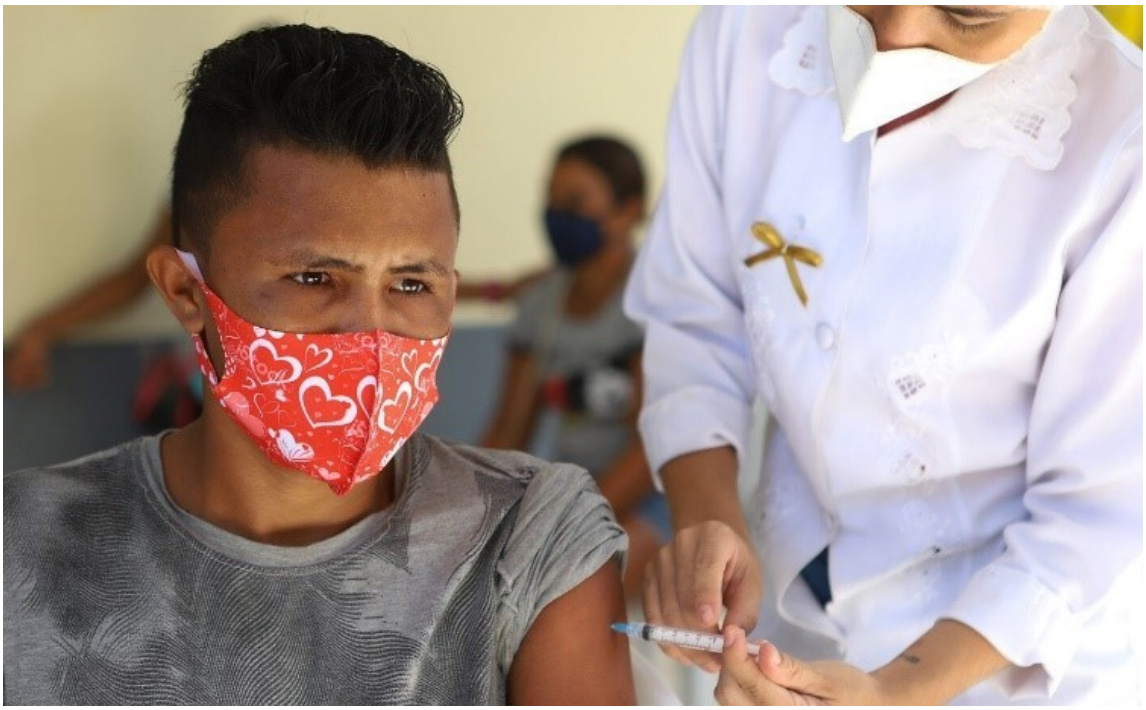


Image courtesy of PAHO

Elizabeth Hillebrenner, Associate Director for Scientific and Regulatory Programs at the Center for Devices and Radiological Health (CDRH), was the keynote speaker in advance of a panel discussion on what the regional regulatory systems had done in response to the COVID-19 pandemic. She focused on the role of the FDA's Emergency Use Authorization (EUA) Authority in the CDRH's intensive review of thousands of medical devices during the pandemic.

By law, FDA may authorize unapproved medical products or unapproved uses of approved medical products to diagnose, treat, or prevent serious or life-threatening diseases or conditions during emergencies when certain criteria are met, including when there are no adequate, approved, and available alternatives.

Image courtesy of PAHO

Hillebrenner described the balancing act involved in CDRH's evaluation of COVID-19 diagnostic and antibody tests, face masks, respirators, decontamination systems, and other products related to the pandemic. In a standard premarket review for a medical device, the FDA evaluators look at whether a product is safe and effective, whereas in the EUA process they look at whether the product may be effective. Other factors are considered too, she explained, such as whether an adequate approved or available alternative to the product exists.

"You're looking at less data than what you would see in a normal pathway," said Hillebrenner. "The trade-off is you can bring products to market faster when they're urgently needed, but you're relying on less evidence."

Engagement with industry stakeholders was also crucial, she said, as many of them were new to the FDA and unfamiliar with the agency's processes. The combination of the ability to interact with product developers and help guide them, and the ability to continually adapt through regulatory flexibility, constituted the 'secret sauce' that allowed CDRH to bring over 1,900 new devices for COVID-19 to the U.S., Hillebrenner said.

Other meeting highlights included:

- A panel discussion with regulators from Canada, the Caribbean Community, Chile, and Cuba and two representatives from the Latin American Association of Pharmaceutical Industries on how the region's regulatory systems evolved from 2010-2020. The panelists discussed the need to increase production of drugs and health technologies

during pandemics and agreed that it was important for regulators and industry to collaborate.

- A keynote by Jarbas Barbosa, M.D., the Assistant Director of PAHO, who kicked off a discussion of regulatory systems in the post-COVID-19 era. The panel discussion, which included regulators from Argentina, Brazil, the European Medicines Agency, and Honduras, centered on developing global regulatory approaches, creating regional networks to monitor safety, authorizing vaccines and other therapeutics, and other salient issues.

PANDRH was created in 1999 under the auspices of PAHO with the active participation of the FDA. Over the years, PANDRH has produced guidance aligned with PAHO resolutions and the needs of the countries of the Americas, supported regional technical cooperation initiatives designed to strengthen national regulatory competencies in science and good regulatory practice and served as a conduit for national regulatory agencies to exchange information.

PANDRH participants include not only regulators but also academics, regional professional organizations, and regional trade organizations.

The three-day conference is available for viewing on PAHO's YouTube channel.

Katherine Tyner Becomes New FDA Liaison Officer to the EMA

Katherine Tyner, Ph.D., has been selected as the new FDA liaison officer to the European Medicines Agency (EMA). Beginning this month, her office will be in Amsterdam.

Tyner possesses a wealth of medical products policy and technical expertise. She joined the FDA in 2007 as a chemist specializing in nanotechnology and has investigated the quality, safety, and efficacy of complex drug products.

In her most recent role within the Center for Drug and Evaluation Research (CDER), Tyner was the associate director for science in the Office of Pharmaceutical Quality (OPQ). There, she led the OPQ Science Staff in coordinating the intersection between science, review, and policy, facilitating interactions among other CDER offices and FDA Centers; and overseeing the OPQ project for developing an advanced manufacturing regulatory framework.

Tyner has participated in numerous bilateral and multilateral discussions involving nanotechnology and other complex drug products. She has served as the FDA representative to various standard-setting organizations, including: the International Pharmaceutical Regulator's Program Nanomedicines Working Group, ASTM E56 (Nanotechnology), and ISO TC 229 (Nanotechnologies), and the United States Pharmacopeia's Joint Subcommittee on Nanotechnology.

In 2015, she was tapped to lead the Nanotechnology Working Group, which produced draft guidance in 2017 on the development of drug products and biologics that contain nanomaterials.

She recently completed a fellowship in the Office of Science and Technology Policy within the Executive Office of the President. While there, Tyner led multiple federal initiatives focused on safe drinking water, sustainable chemistry and how to increase technology transfer across the research, development, and deployment continuum.

Tyner received a bachelor's degree in chemistry from Carleton College, and her Master of Science and Ph.D. degrees in chemistry from Cornell University. She completed a postdoctoral fellowship at the University of Michigan in a joint appointment in the Chemistry Department and the Toxicology Program and is a graduate of the Partnership for Public Service Excellence in Government Fellows Program.

Additional Resources

Draft Guidance for Industry - Drug Products, Including Biological Products, that Contain Nanomaterials

STAFF NEWS

Oehlsen Selected to Lead OGDP

Michael Oehlsen, Ph.D., has been selected as director of the Office of Global Diplomacy and Partnerships (OGDP), the office responsible for providing overall program support, developing strategic plans, and managing international communications in OGPS.

Associate Commissioner Mark Abdoo made the announcement to staff last month, stating, "Michael served as the acting director of OGDP for the past eight months and has successfully developed new and innovative methods of enhancing OGDP's performance, strengthened personnel interactions and communications, and fostered the continuous growth of trust, team building and an esprit de corps."

Oehlsen, a U.S. Air Force veteran, began his FDA career in 2003 as a regulatory review chemist in the Division of Manufacturing Technologies (DMT) at the FDA's Center for Veterinary Medicine (CVM). During his time in the DMT, he reviewed animal drug applications and became an instructor for the FDA's pharmaceutical inspectorate Level III drug certification program. Level III is the highest tier under the pharmaceutical inspectorate.

In 2010, Oehlsen transitioned to CVM's Office of the Director as director of international policy and logistics where he oversaw FDA's Veterinary Mutual Recognition Agreement work both with the European Union Member States and later, with the United Kingdom, following Brexit. He also led several key bilateral and multilateral international working groups to further harmonize global regulatory policies. While at CVM, Oehlsen also established the Center's inaugural Strategic Plan for international programs and was responsible for creating and implementing CVM's international tracking system for monitoring, tracking, and evaluating all international activities, a system that was later adopted FDA-wide.

Oehlsen 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 Virginia Commonwealth University. It was during his Ph.D. program that Oehlsen received initial experience with federal drug and international policy working on a cancer drug that entered into clinical trials.

He describes his career path from a scientist to a policy analyst, and now to an administrator, as a logical progression that "fills a gap" in his professional development.

In his spare time, Oehlsen is also an entrepreneur. He invented and patented a part for riding lawnmowers that is solely manufactured in the United States and sold on the internet, and also oversees a popular catering business in Charles Town, West Virginia.

FDA Alums Launch FDA Foreign Office Network

The FDA Alumni Association's new Foreign Office Alumni Network kicked off its inaugural meeting on December 16 with a panel discussion featuring four current and former FDA employees who have lived overseas and worked at one of the agency's foreign offices.

Much of the discussion focused on the unique personal and professional development opportunities that foreign service can offer. Sarah McMullen, Director of the FDA's India Office, called her time abroad "a growth accelerator" and described an intensive learning process that helped her gain a better understanding of the regulatory landscape faced by her Indian counterparts.

"We always think other governments should do it the way we do it," said McMullen. "One of the perspective changes has been how to leverage FDA resources — figuring out how to walk alongside our counterparts and help them identify and utilize their resources, because in a lot of cases it's different or less than what we have."

FDA recognized the need for foreign offices in strategic locations 13 years ago after confronting a series of public health tragedies that stemmed mostly from FDA-regulated imports from China, explained Mark Abdoo, FDA Associate Commissioner for Global Policy and Strategy, who moderated the discussion. Beijing and New Delhi were the first foreign posts, both established in late 2008.

Since then, the FDA's international presence has grown and now includes an office in Brussels with liaison postings to the European Medicines Agency in Amsterdam, and posts in three Latin American capitals — Mexico City; Santiago, Chile; and San Jose, Costa Rica. Abdoo pointed out that employees working overseas are able to develop relationships that can't be built from afar and can act as "eyes and ears" to improve the agency's information-gathering ability within the host countries.

Working abroad can also be personally beneficial.

From October 2011 to July 2015 Mike Rogers was Director of the FDA's Latin America Office, which oversees 44 countries and territories. Rogers took advantage of language training programs before going overseas, and he and his family became proficient in Spanish during their tour.

“My oldest son actually minored in Spanish in college,” said Rogers, who is now Assistant Commissioner for Human and Animal Food in the Office of Regulatory Affairs. “Both of us continue to take Spanish courses to this day because we didn’t want our language skills to decline after coming back to the United States. It’s a skill we plan to carry with us for the rest of our lives.”

Panelist Irene Chan, who was the Assistant and Deputy Director of the FDA China Office from 2009 to 2013, stressed the importance of having broadened her view of the agency’s global oversight. Part of the original FDA cadre that was posted overseas, she later returned to the China office in 2017 for a two-year tour as Deputy Director. Chan, who came from a policy background, was excited to have opportunities to interact closely with investigators and even occasionally join them on inspections.

As a result of her two tours and exposure to the more than 50 U.S. agencies working at Mission China, she has gained a sense of interagency camaraderie, as well as a recognition that everything that the FDA does from both a policy and regulatory perspective has a global impact and a resultant effect on commerce. “Now, in my new capacity in the industry, this becomes all the more relevant,” said Chan, who has since left the FDA and is currently the Deputy Director of Pharmaceutical Research and Manufacturers of America.

Sandy Kweder, the Deputy Director of the Europe Office and liaison to the European Medicines Agency in Amsterdam, continues to experience foreign service that differs in key aspects from that of the other panelists. Her European counterparts are working in more mature regulatory systems and tend to share information, she explained, though the exchange can be “frank in some areas, not as much in others.”

Additionally, Kweder faced a challenge in the form of the Brexit decision, which occurred only months after she had begun her initial assignment in London. She decided to view the event as a learning opportunity. “I wanted to see how this organization that I was embedded in responded to such a massive change,” said Kweder. “At the same time, I knew it was extraordinarily traumatic for them.”

After being posted overseas, Kweder also found her life enriched in an unexpected way: she no longer needed a personal vehicle. “I’m delighted to say I have not had a car for five, almost six years, and it’s phenomenal!” said Kweder.

FDAAA International Committee Chair Nancy Bradish Myers, who opened the meeting, credited the initial conception of the network to Leigh Verbois, Ph.D., Director of FDA’s Office of Drug Security, Integrity, and Response, former FDA China Office Director and former Acting Assistant Commissioner for International Programs. According to Myers, the new virtual community will serve its members by connecting FDA employees around the world while encouraging alumni to mentor new foreign staff.

For information on how to join the Foreign Office Alumni Network, please contact Leigh Verbois at Leigh.Verbois@fda.hhs.gov.

To view the Zoom recording of the meeting, visit: https://www.youtube.com/watch?v=kJrowr4bxlA.

Living in India's Most Populous City Taught Chaula Shah Compassion

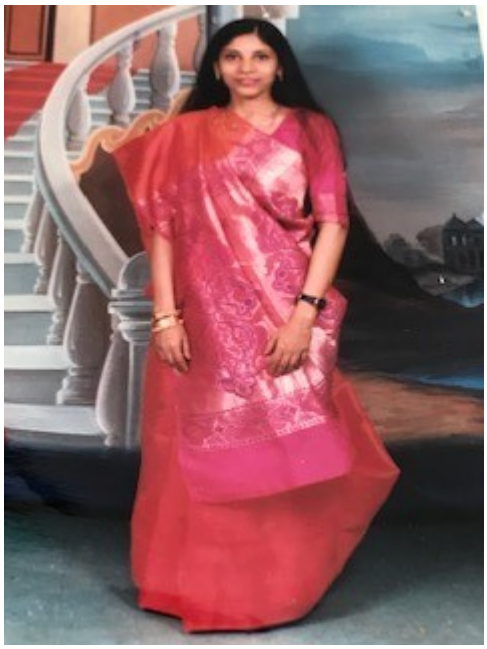
For young Chaula Shah, stepping inside the slums of Mumbai for the first time was like entering an entirely different world. The huts—some made of tin, plastic sheets, duct tape, tarp, and other odd materials—were pieced together by hand and provided minimal shelter, at best, from precipitation and air pollution.

She had passed the area on her way to school many times before and wondered how people could live that way but had only seen the makeshift dwellings from afar. Then her school offered students the opportunity to collect vaccine information as "a foot soldier" for a charity organization. Chaula, then 13, volunteered immediately.

To be a foot soldier in India means going door-to-door to carry out important tasks. Foot soldiers work in-person with their intended population to gather data and information. "Direct personal touch/interaction is involved," Chaula said. "Just sitting in an office or simply conducting computer surveillance is not going reflect what is going on in the field."

She recalls entering a one-room home with a dirt floor and no running water or indoor plumbing. Dressed in her clean, pressed uniform, Chaula approached its owner—a young, very tired-looking woman—and began speaking in the regional language. "When I asked her if [the] kids had [their] polio vaccination, I still remember her look into my eyes. It was like, 'you must be kidding'," said Chaula.

This was the moment Chaula realized that an entire population lived in poverty less than 10 miles away from her upper middle-class home. "These kids were very sweet and all, and playing around and in their own joy but still the basic reality is—which made me realize I have everything I need—here are people who are just living," she said.



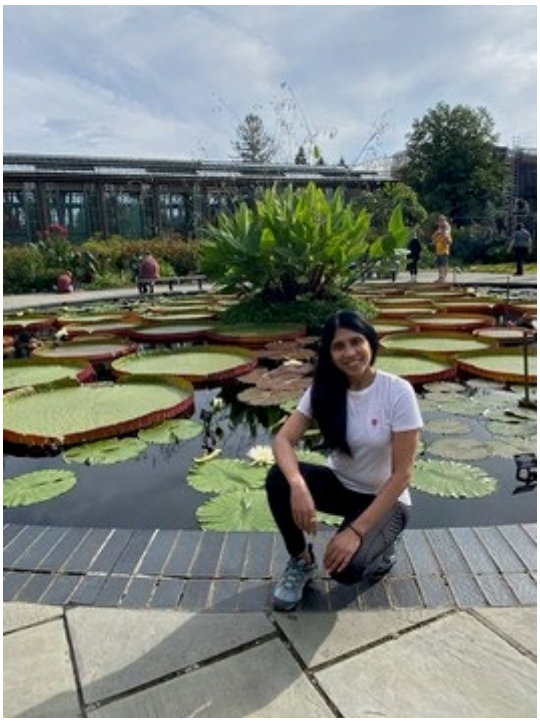
Chaula in a sari

Foundation

Chaula, the fourth daughter of an accountant and English teacher, was born 15 years after the sister before her. She learned many values from her parents and her older sisters, who now work in pharmacy, finance, and computer systems.

“They gave me every opportunity to basically grow as well as keep my feet grounded; not to do any kind of show off of anything and maintaining your self-respect also,” she said. This foundation helped Chaula mature as a foot soldier throughout her life, being of service to many people along the way.

Her maturity was tested before Chaula moved to the United States when she encountered a merchant hitting a child on the street. While reticent to intervene in private matters, Chaula stopped to assist the screaming child. The young boy had stolen just one chocolate, she learned. “Okay, I'm paying you for this chocolate,” she told the merchant. “Leave him alone. You cannot be hitting a child!”

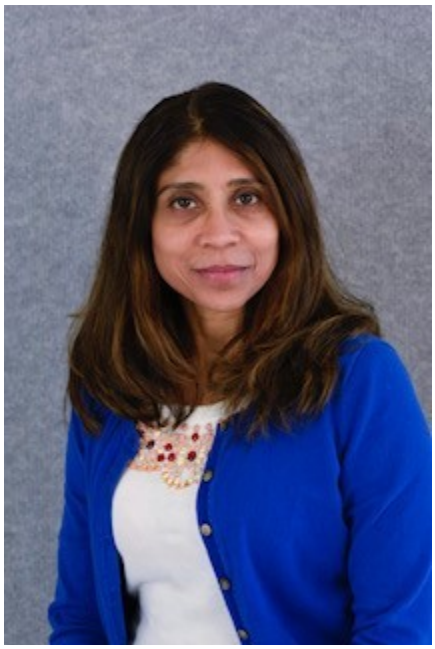


Chaula at Longwood Gardens in Kennett Square, Pennsylvania

Staying grounded in the U.S.

Chaula attended nursing school at the University of Maryland, believing that becoming a nurse would allow her to do work that "helps humankind." After graduation she went straight to work at Washington Hospital Center, a facility that often treats D.C.'s poor. As a cardiac care nurse, Chaula tended to patients in post-surgery recovery. "I was the very odd one in the family. Everybody told me I shouldn't go there," she said. "But I always wanted to work in the inner city."

Prior to discharging a patient, Chaula and other nurses often pitched in to pay for their bus ticket or other needed items. She also stayed past her shift and advocated for patients who did not possess health insurance. "You will have instances in your life where your soul takes over your brain and that soul will guide you," she said.



A foot soldier expands the compassion

Advancing her nursing career took Chaula to Kimbrough Ambulatory Care, a Department of Defense facility on Fort Meade in Maryland. There, she helped active-duty soldiers and family members recover from orthopedic and reconstructive surgeries.

Not long after, in 2014, she joined the Center for Devices and Radiological Health (CDRH) to work in postmarket surveillance as a lead reviewer in the Office of Cardiovascular Devices after learning that the FDA was looking for nurses who had hands-on experience with cardiac medical devices.

There, her focus shifted from direct patient care to coordinating projects involving manufacturers from China and India who were trying to gain approval to market their medical devices in the United States. Her job was to explain the FDA's regulations using an interpreter.

At CDRH, she made recommendations on postmarket surveillance, premarket submissions, device allegations, recalls, investigation reports, and post-approval studies. Her background as a nurse enabled her to provide clinical consultant services to her colleagues on health program policies, quality of care, and evidence-based clinical practices. During this time, she completed her Master's in Public Health focusing on global health from Liberty University in Virginia.

Building upon her experience in the global sphere, Chaula accepted a detail to OGPS as a quality program specialist in 2020, supporting efforts to refine operational processes and develop standard operating procedures and the new Assessment and Corrective and Preventive Action (ACAPA) Portal. She has since

accepted a permanent position supporting the Quality Management System, reporting to Ravi Bharwani, principal policy advisor in the OGPS Immediate Office.

Her experience as a nurse and as public health graduate have aided her transition to her newest role. To Chaula, these new systems are akin to a medical flow chart. They provide tools to guide people step-by-step. “The streamlined process can be compared to a nurse setting up the patient with all their needs and then getting the doctor to sign off on it,” she said.

Above and beyond

With her compassionate heart, Chaula is always looking for ways to do more. She recently volunteered to co-lead the September 1, 2021, through January 15, 2022, Combined Federal Campaign (CFC) for OGPS and the Office of Policy, Legislation, and International Affairs—setting a goal to raise $13,570 through donations to local, national, and international charities. She has volunteered to assist with the CFC in other FDA offices over the years.

Normally around this time, Chaula would be setting up tables for a chili cook-off to support the CFC or going door-to-door for donations with her “foot soldier mentality” but with the FDA teleworking, the group has organized a virtual walk and other activities.

Chaula’s personal cause: health and sanitation.

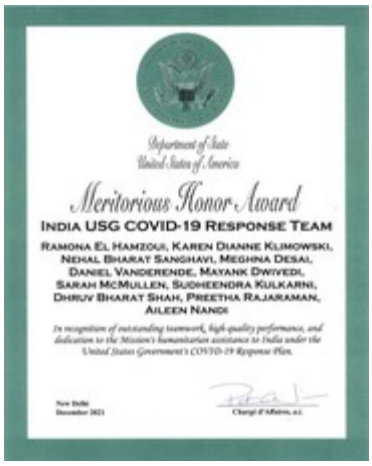
She is reminded of that hut in the slums that has left a mark on her life. “I am the same person as the 13-year-old girl who saw that lack of such a basic thing. You cannot begin to talk about health without sanitation.”

When asked about her hope for her home, Mumbai, her answer was simple. “I want them to achieve, at a minimum, the basic food, water, and shelter recommended by the World Health Organization.”

For now, she says, “together we strive towards compassion and respect for each other.”

INO Staff Recognized for Second Wave Work

Three India Office staffers were among those who received the State Department’s Meritorious Honor Award in December for their efforts as part of the 11-person India USG COVID-19 Response Team in New Delhi. The Team worked to receive, plan, and distribute $80 million in medical equipment and supplies, as well as lifesaving treatments, that arrived on seven flights from the United States in seven days during India’s second wave of COVID-19 cases that began in April 2021.


Department of State
United States of America

Meritorious Honor Award

INDIA USG COVID-19 RESPONSE TEAM

RAMONA EL HAMZOUI, KAREN DIANNE KLIMOWSKI, NEHAL BHARAT SANGHAVI, MEGHNA DESAI, DANIEL VANDERENDE, MAYANK DWIVEDI, SARAH MCMULLEN, SUDHEENDRA KULKARNI, DHRUV BHARAT SHAH, PREETHA RAJARAMAN, AILEEN NANDI

In recognition of outstanding teamwork, high quality performance, and dedication to the Mission's humanitarian assistance to India under the United States Government's COVID-19 Response Plan.

"This hard work and commitment during the second wave of the COVID-19 crisis was instrumental in providing emergency supplies to an overtaxed health system and allowing healthcare workers to effectively manage cases and provide lifesaving treatment," said Chief of Mission Patricia A. Lacina in announcing the award.

The INO recipients included:

INO Office Director Sarah McMullen, Ph.D., who chaired the interagency Specs team, which evaluated Government of India (GOI) needs and requests and worked through specification and regulatory concerns to ensure that USG donations could be utilized in India and that GOI regulatory barriers to donation were addressed and satisfied.

Sudheendra Kulkarni, Ph.D., a product safety director for drugs and locally-employed staffer, who assisted in helping to communicate the regulatory hurdles for USG donations to other U.S. government office; and,

Dhruv Bharat Shah, a public health specialist and locally-employed staffer, who also assisted with communications with our GOI counterparts and, in particular, explaining the regulatory requirements for medical products, including oxygen.

Sarah McMullen memorably recapped INO's work during the Second Wave in our OGPS blog, *From a Global Perspective*.

Additional Resources

Doing the Needful During India's "Second Wave"

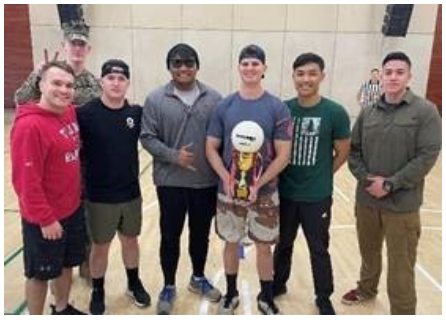
Building Morale and Interagency Relationships Through Dodgeball

With so much going on recently due to the pandemic, employees at the U.S. Embassy in Beijing needed help *dodging* these blues.

- In-country COVID restrictions interrupting official and personal travel plans.
- Another holiday season away from loved ones.
- A recently canceled Marine Corps Ball.
- Work stress.

The CNO Employee Engagement Team put on their thinking sweatbands and decided to dodge the naysayers, duck under the Grinch's radar, dip into their pocketbooks, divert attention from the news and…ditch any holiday waistline expansion by organizing an embassy-wide dodgeball tournament.

We realize old habits are hard to break. Save yourself another yearly round of coal in your stocking from Santa by recognizing these five style faux pas. Embrace change to improve your writing in 2022.

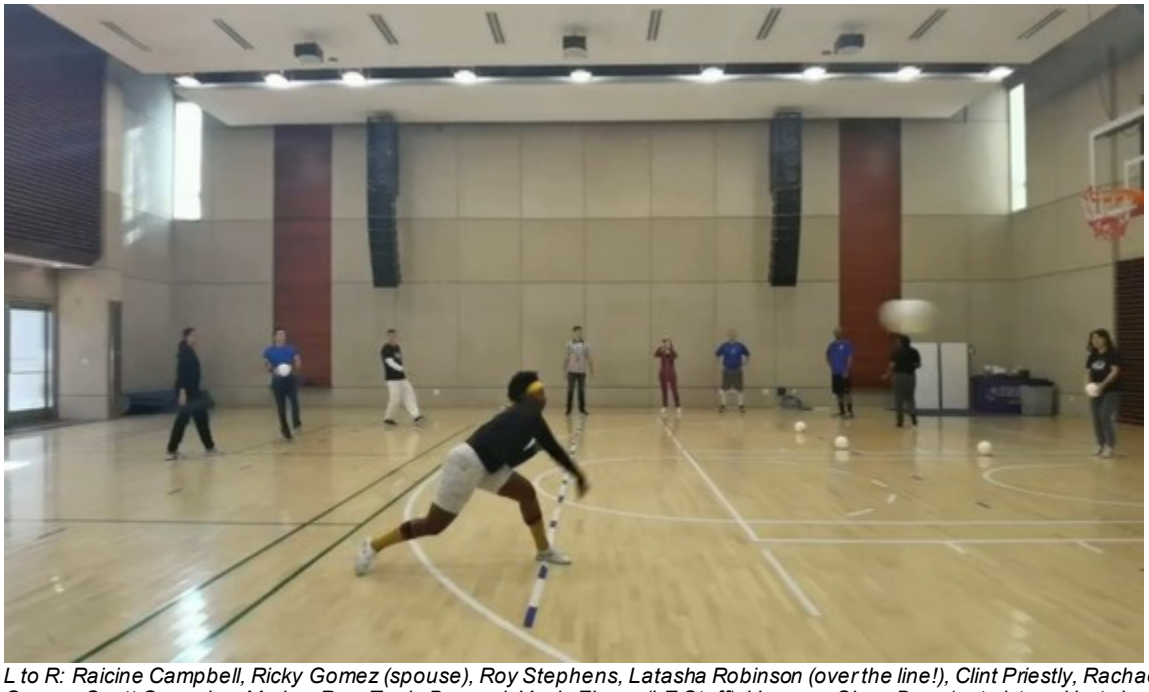


The embassy community is diverse: 12 teams representing Embassy Management, Regional Security Office, Marine Detachment, Language Training Center, IT Support, Consular, family members in high school, the FDA, and others duked it out on a Saturday morning by pummeling each other on the court.

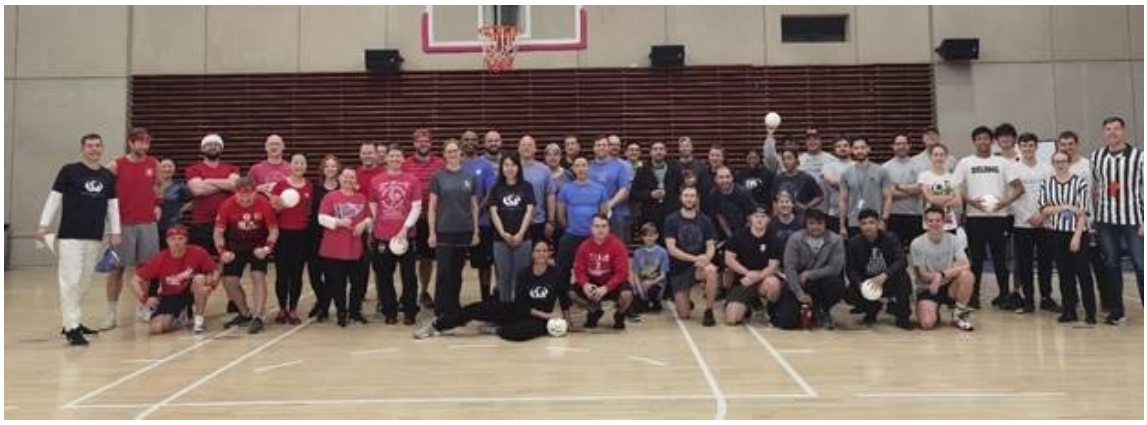
Spoiler alert: The Marines dominated, taking home the first-place trophy—a souvenir dodgeball, and our hearts.

Other winners of the day included the CNO, whose efforts organizing the tournament were greatly appreciated within the embassy. The Marines sold grilled hot dog lunches, and everyone burned calories for three hours running around, throwing balls, and taunting each other.

Some FDA staff were unable to play but still contributed, with Clint Priestly (Foods IRS) and Kristen Gonzalez (spouse) as referees; and CAPT Juliette Taylor (Drugs IRS, TDY) as the scorekeeper and bracket manager. The two FDA teams, Dood and Frug, even faced off (pictured below), with Latasha Robinson's Frug handily defeating Vanessa Shaw-Dore's Dood.



L to R: Raicine Campbell, Ricky Gomez (spouse), Roy Stephens, Latasha Robinson (over the line!), Clint Priestly, Rachael Gomez, Scott Gonzalez, Markus Ray, Tonia Bernard, Yuxin Zhang (LE Staff), Vanessa Shaw-Dore (not pictured but about to be drilled by her own Deputy Country Director)



CNO-led interagency social engagements like this provide vital advertising and networking opportunities for the FDA China Office, which spur working relationships in support of the OGPS strategic priority of engaging USG agencies to advance public health priorities and policy coherence. Following this successful model, plans of inviting fellow embassies for "Diplomatic Dodgeball" are being discussed!

TRANSITIONS

Christopher Middendorf has departed the India Office where he was an international relations specialist for pharmaceuticals. He came to OGPS on a detail in April 2020 from our China Office where he was a drug specialist.

Middendorf joined the FDA in 2000 through the Presidential Management Intern program as a program analyst in the Office of the Commissioner. After four years, he transitioned to the Center for Biologics Research and Evaluation as a consumer safety officer, where he was promoted to branch chief in CBER's Office of Consumer Affairs. In 2008, he became a public affairs specialist at the Center for Devices and Radiological Health before accepting a position with the CNO as a consumer safety officer.

He has a Master of Science degree in animal science from Auburn University and a bachelor's degree in biology from the University of Cincinnati. Middendorf is now the director of regulatory affairs for Pharma and Biotech at a global law firm.

Vanessa Noelte has accepted a position in Mexico as an international relations specialist with the Latin America Office. She previously worked on the Regulatory Cooperation and Partnerships Team of the International Affairs Staff (IAS) within the Center for Food Safety and Applied Nutrition (CFSAN), where she functioned as the international produce safety strategic coordinator and international expert.

Prior to her time with the IAS, Vanessa worked with CFSAN's Office of Nutrition and Food Labeling where she gained experience working across infant formula and medical foods, nutrition labeling and health/nutrient claims, as well as standards of identity.

Noelte was the project manager for the Food Safety Partnership Steering Committee and Executive Committee. She also led an interagency collaborative forum with

international produce safety collaborators, including the U.S. Department of Agriculture and relevant academics.

She has an M.P.H. in health policy from the Yale School of Public Health, with a focus in food policy and nutrition. She also holds an undergraduate degree in the history of public health from Yale University, with a focus on Spanish and premed.

Christopher Priddy has departed the India Office, where he was an international relations specialist, collaborating with India and U.S. Government counterparts, industry representatives, multilateral organizations, academia, and other stakeholders on legal and policy issues concerning food, medical devices, and cosmetics.

He previously served as regulatory counsel at the FDA's Center for Tobacco Products. There, he advised on legal and economic issues concerning new FDA tobacco regulations.

He also represented the FDA on World Trade Organization Technical Barriers to Trade Committee issues and advised on international issues concerning products under FDA's jurisdiction.

Priddy has a bachelor's degree in politics and international studies from Wake Forest University. He also studied law at Temple University in Tokyo, Japan, then earned a Juris Doctor degree from the University of North Carolina School of Law.

He has started a new position in Tokyo with the Department of Commerce as a U.S. Foreign Service Commercial Officer.

BRIEFS

INO Hosts Fourth Annual Regulatory Forum with CDSCO

The India Office (INO) virtually hosted the Fourth Annual Regulatory Forum with the Central Drugs Standard Control Organization (CDSCO) on November 30 and December 1, 2021.

The CDSCO (under the Ministry of Health and Family Welfare) and the regulatory agencies of India's individual states, are collectively responsible for regulation of drugs, vaccines, cosmetics, and medical devices. Among other regulatory responsibilities, the CDSCO issues product licenses to both domestic producers and importers of regulated products. As part of their oversight activities, state regulatory authorities issue manufacturing licenses to domestic firms, while the CDSCO issues manufacturing licenses to importing firms. The CDSCO also establishes standards and regulates clinical trials of medical products in India.

INO Director Sarah McMullen, Ph.D., and CDSCO Drugs Controller General of India V.G. Somani, Ph.D., presented opening and closing remarks at the Forum. FDA and CDSCO subject matter experts presented updates on:

- COVID-19 medical products.
- Regulatory oversight of pharmaceutical supply chains.
- Medical product supply chain integrity.
- Regulatory testing of pharmaceutical products and medical devices.
- Remote regulatory reviews.
- Regulatory oversight of medical devices.
- Medical device inspections.

Over 200 attendees, including staff from CDSCO, the India state regulatory authorities and the FDA, participated in the two-day forum. This was the first time that the FDA-CDSCO Regulatory Forum included topics on supply chain integrity and medical devices. High levels of engagement were seen from participants and the panel Q&A sessions saw many interactions on relevant topics.

INO Staffer Honored for Contract Tracing Efforts

Pankaja Panda, Ph.D., received a U.S. Embassy New Delhi Mission Honor Award for her contributions to the embassy contact tracing efforts during the COVID-19 pandemic. She was able to use her fluency in both English and Hindi to assist the Centers for Disease Control and Prevention in contact tracing throughout the Mission.

Panda, a product safety coordinator for foods, works as a locally employed staff member of the India Office (INO).

"[Panda] is so deserving, and the work she did was so important at a critical time," said INO Supervisory Consumer Safety Officer Natalie Mickelsen, D.V.M.

Dear International Colleague

Following are the most recent Dear International Colleague Letters:

FDA Issues FSMA Laboratory Accreditation for Analyses of Foods Final Rule

FDA Proposes Changes to Food Safety Modernization Act Rule to Enhance Safety of Agricultural Water Used on Produce

FDA Releases Annual Summary Report on Antimicrobials Sold or Distributed in 2020 for Use in Food-Producing Animals

FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

FDA Authorizes First Oral Antiviral for Treatment of COVID-19

Coronavirus (COVID-19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults

FDA Takes Multiple Actions to Expand Use of Pfizer-BioNTech COVID-19 Vaccine

UPCOMING EVENTS

February 4 World Cancer Day
February 14 Proposed Changes to PSR Agricultural Water Requirements
February 25 Proposed Changes to PSR Agricultural Water Requirements

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