

Global Monthly Update

April 2020

OGPS Launches Ambitious Five-Year Strategic Plan

The Office of Global Policy and Strategy (OGPS) entered its second year last month with the release of an ambitious five-year strategic plan, unveiled during an All-Hands teleconference with staff on April 7.

The OGPS Strategic Plan for Fiscal Years (FY) 2020-2024 "outlines our priorities and goals as we continue to leverage our resources and strengthen our programs to achieve our mission," Associate Commissioner for Global Policy and Strategy Mark Abdoo said. The plan identifies four complementary and connected strategic priority areas for our office: Organizational Excellence, Policy Coherence, Global Partnerships, and Information Collection and Dissemination. "These four areas will guide our work and direct how we put our mission into practice," said Abdoo.

Our Planning and Evaluation Team led the effort, with the help of the consulting firm Booz Allen Hamilton and an internal Strategic Planning Workgroup composed of representatives from each of our OGPS sub-offices.



Work on this plan provided the opportunity to look back over past actions, determining what worked and what did not. Booz conducted a comprehensive assessment that included a SWOT analysis, a gap analysis, the review of archival documents and interviews with leadership. All told, Booz examined 71 internal OGPS documents, including EVS analyses and operational plans; 20 external documents, including legislation, U.S. Government Accountability Office reports, OGPS "From a Global Perspective" blog posts, speeches and remarks by leadership; and additional relevant materials. They also conducted 11 interviews with OGPS leadership and management and obtained feedback from 11 OGPS employees.

The strategic report is a living document. Requests for input will continue throughout the five-year cycle and will be captured in the document on a yearly basis. In the long-term, there is a plan to align the strategic plan with our operational plans. We intend to make the plan available to the public.

Nicki Conklin Featured in ORA Campaign

EDITOR'S NOTE: To build staff morale, ORA has been posting employee profiles – in their own words - on both its internal website and FDA's external website. Recently, Nicki Conklin from our Latin America Office was featured in of one of these profiles. We think her story eloquently illustrates why our foreign posts are so important. We've reproduced the article in its entirety since the article was posted on ORA's internal website, which is not available to most of the staff in OGPS.



Since childhood I have been interested in the Spanish language and in Latin America. I took Spanish throughout school and early in college, studied abroad in Mexico City for a semester, and enjoyed the cultures of the Latin American region through travel and friendships with people I had met over time.

I discovered the Office of International Program's Latin America Office (LAO) in 2010 while I was working as a nurse for Indian Health Services (IHS). I wanted to live abroad, and I hoped for my kids to grow up with international experience, so I figured a position in LAO would be a terrific way to accomplish these goals.

A few years afterwards I transferred from IHS to FDA to work as an investigator for ORA. Due to my nursing background, I was initially placed on the biologics track, but soon afterwards moved to foods – partly because I wanted to gain experience with the dominant commodity exported from Latin America to the United States.

In 2015, I applied for a 30-day detail with LAO to conduct inspections in Costa Rica. During the detail, the LAO director assigned me a small policy project and, although I had not previously worked in policy, I found the work to be challenging and interesting. At the time an international relations specialist position in San José, Costa Rica, was open and I was encouraged to apply for it. After thoughtful consideration, my husband and I determined it was the right time for our family to make the move.

In policy, as in diplomacy, most efforts require years of investment to see tangible results. In my case, I've been privileged to lead projects that already have measurable outcomes. Results do not come easy. Working in this office requires an exceptional level of flexibility, tenacity, and diplomacy. However, success in this job means that I have contributed to public health advances on an international level. The work satisfaction I have experienced when considering these results, and the interpersonal and intrapersonal leadership skills I have developed in the process of achieving them, have been exceptional.



Nicki Conklin served four days with the U.S. Public Health Service officers and other uniformed personnel of the Army and Navy when the U.S.N.S. Comfort visited Puntarenas, Costa Rica, July 2019.

Beyond the demands of our individual projects, we serve as liaisons between FDA and the 44 countries and territories of the Latin American region. Each country has its own system of government and cultural norms. Furthermore, not only do we report to FDA headquarters, but we are also responsible to the embassy community and the State Department's country strategies in Costa Rica, Mexico, and Chile, where the LAO posts are located. This involves keeping the ambassadors up to date on our current activities, supporting the local foreign service officers as they write reports and make analyses, and attending embassy-related meetings, receptions, and ceremonies.

I was asked what I miss the most about the United States. My response surprises me because I had always wanted to live abroad so that my family and I could experience other perspectives of the world and other ways of living life. I wanted to my kids to know that different is not bad, it is just different. Two and a half years into this adventure, I will tell you I have experienced a lot of difference – so much difference that I find myself missing the familiar. Sometimes it does not make sense, other times it is annoying, but, in the end, it has proven itself to not be bad, just different. Consistent exposure to 'different' has required me to open my mind and heart so much further than I had expected to, not to just live while I'm here in this experience, but rather to thrive.



Nicki Conklin and her LAO colleague, Allan Gonzalez, participating in the U.S. Embassy celebration of Costa Rican culture and independence at the Turno event, September 2017.

Beyond work, and experiencing all the differences, my family and I have enjoyed our time in Costa Rica. Family time and children are highly valued in Costa Rican culture, and we find ourselves spending a lot of time together whether at home, out on a hike, or at the beach surfing and boogie boarding.

Although it can be complicated raising kids abroad, our whole family has grown through the experience. One of the benefits is related to the fact that the kids go to an international school with children from over 30 other countries. When they speak of a new friend I am always interested to know where the child is from, how many countries the child lived in before moving to Costa Rica, and how many languages they speak. Many of these children are aware of political strife and situations occurring across the globe that mainstream U.S. news does not tend to cover in much depth. Not only do we talk about these situations at home, but we also benefit from the sharing of cultures, foods, holidays, and celebrations.



Bins of recently harvested apples observed by participants of a LAO/CFSAN designed produce safety initiative in Chile, March 2019. The event helped the participants convert theoretical knowledge taught during the Produce Safety Alliance Growers' Training into practical, applicable understanding. This event accomplished its objectives with such success, the government of Chile asked LAO to host a training on the initiative in Chile so that food safety technicians there could conduct similar inquiries on Chilean farms.

My experience with the Latin America Office and living in Costa Rica has been profoundly formative. I have faced unique and unprecedented challenges providing me an incredible opportunity for career development and personal growth. This position may not be for everyone, however, if you like adventure and challenge, and you want to grow in your professional capabilities, the Latin America Office is the place to be.

Transitions



Vanessa Shaw-Dore is the new director of the OGPS China Office (CNO). Vanessa was previously the CDC Division of Global Health Protection (DGHP) deputy program director overseeing Global Health Security Agenda (GHSA) work in Vietnam. Prior to her time in Vietnam, she served as the CDC DGHP GHSA deputy program director in the Democratic Republic of the Congo. Before CDC, Vanessa served as a branch chief in the Health Resources and Services Administration HIV/AIDS Bureau, Division of State HIV/AIDS programs. She has an MPH in Community Health Sciences and a BS in Biology, with a concentration in Molecular Biology. Vanessa will be assigned to White Oak after we return to normal operations until she is cleared to relocate to Beijing.



Latasha Robinson was promoted to Deputy Director, China Office, effective March 30. She was previously an international relations specialist for the CNO. Prior to serving in OGPS, Latasha was the branch chief in the Labeling and Dietary Supplement Compliance Branch at the FDA Center for Food Safety and Applied Nutrition (CFSAN) and earlier she served in numerous CFSAN positions, including as acting director of the Division of Enforcement.

Latasha is a Navy veteran and holds an MS in Regulatory Science with an emphasis on Drugs and Biologics and a BS in Biology with a Minor in Chemistry.



Chris Middendorf is serving a detail with INO as an international relations specialist for pharmaceuticals. Prior to joining INO, he was a drug specialist in FDA's China Office. Chris joined FDA in 2000 through the Presidential Management Intern program (PMI now PMF) 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, Chris became a public affairs specialist at the Center for Drugs and Radiological Health before accepting a position with the CNO as a consumer safety officer. Chris has an MS in Animal Science from Auburn University and a BS in Biology from the University of Cincinnati.

Overlooked Last Month

New MOA Promotes Global, Strategic Partnership

India is the largest provider of generic medicines (by export volume) in the world, supplying <u>over 20% of generic medicines globally</u>. The <u>U.S. is the top export destination</u> and accounts for 30% of India pharma exports. Since February 2014, FDA has been cooperating with the Ministry of Health and Family Welfare under a 5-year Statement of Intent to strengthen bilateral cooperation in the areas of regulatory systems for medical products to promote and protect public health.



INO staff and family during President Trump's visit to the U.S. Embassy, New Delhi.

This February, during the inaugural visit of President Trump to India, a new Memorandum of Understanding (MOU) was signed that provides the U.S. and India with an opportunity to continue strengthening their current relationship and common interest in promoting and protecting public health. The MOU highlights the importance of dynamic and effective collaboration to ensure safe and effective medical products and seeks to promote access to high quality, safe, effective, and affordable medications for U.S. and Indian consumers. The MOU was adopted into the Joint Statement: Vision and Principles for the United States-India Comprehensive Global Strategic Partnership by President Trump and Prime Minister Modi.

INO's own Dr. Natalie Mickelsen, supports U.S. Secret Service dogs



During the presidential visit to New Delhi, Dr. Natalie Mickelsen, a senior consumer safety officer in the India Office, had the honor of being the 24-hour on-call veterinarian for the U.S. Secret Service (USSS) dogs and Military Working Dogs (MWD). She provided a veterinary medical clinic and 24-hour pharmacy recommendations and logistics, coordinated canine access to the embassy pharmacy, and conducted phone consultations with the MWD veterinarian in the U.S. when a dog was ill. Fun fact: Dr. Mickelsen was surprised to learn that MWDs are always one rank higher than their handlers.

Dr. Mickelsen is pictured with Cchango (yes, that's his name), a USSS dog, who remained healthy throughout the visit.

Parliament Agrees to Delay

FDA's Europe Office staff has been actively monitoring developments related to the implementation of the EU Medical Devices Regulation (MDR), including the recent release of the European Commission's implementation/preparedness plan and guidance for the MDR. The

MDR helps ensure high standards of quality and safety for medical devices being produced in or supplied into Europe.



The postponement will give device companies more time to align their practices to the new rules. "Given the current pressure on national health authorities and manufacturers of medical devices, there is a fear that there could be shortages or delays in getting the medical devices needed to fight COVID-19, were they to follow the new rules of the Medical Devices Regulation from May this year," the Parliament said.

FDA's Feed Your Mind Initiative Presentation

At the meeting of the European Food Safety Authority (EFSA)-led International Risk Communication Liaison Group (IRCLG) on Apr. 3, FDA presented its recently launched <u>Feed Your Mind</u> educational campaign.



This initiative is part of an FDA-led interagency effort intended to help consumers better understand genetically-engineered foods and to provide them with science-based educational information.

The IRCLG brings together food safety and risk assessment authorities in Europe and around the world with the objective of sharing experience, expertise and best practices in risk communications.

Upcoming Activities

5/8 <u>United We Walk, United We Run, United We Stand Against COVID-19 14th</u>
Annual FDA Classic

This year's annual FDA Classic will be virtual. Employees from all over the country and our foreign posts are invited to participate in a virtual activity from 11 a.m. to 2 p.m. (ET). Pull out your past FDA Classic t-shirts, lace up those shoes, and do the 5K run or 2.5 mile walk in your neighborhood or community. Pending your supervisor's approval, you may be excused to participate in this officially-sponsored FDA event. Remember to practice safe distancing.



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