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GLOBAL UPDATE



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HIV/AIDS Research Pioneer Doug Shaffer Recounts Success Stories from Africa

Arguably one of the few former U.S. officials with a long-term view of the public health arc of the HIV/AIDS pandemic is Doug Shaffer, M.D., M.H.S., B.S. Pharm. Shaffer recently left the FDA's Office of Global Policy and Strategy (OGPS) and retired after 27 years of federal service in some of the most challenging international locales, including over 20 years in sub-Saharan Africa.



Doug Shaffer, a public health leader whose heart is as big as Africa itself. We in OGPS are honored to have had the opportunity to know him as a colleague.

Shaffer led complex interagency programs at both the Departments of Health and Human Services (HHS) and State, served as a medical officer in the FDA's Center for Drug Evaluation and Research from 2000-2004, and before retiring was the Associate Director in the OGPS Immediate Office, as office lead for interagency initiatives such as the President's Emergency Plan for AIDS Relief (PEPFAR).

Established in 2003 by President George W. Bush, PEPFAR is the largest funding commitment by any nation to address a single disease in the world, credited with not only preventing millions of HIV infections but also helping to change the trajectory of the global HIV epidemic. The U.S. government has invested over \$110 billion in the global HIV/AIDS response through PEPFAR, saving more than 25

million lives and facilitating progress toward control of the global HIV/AIDS pandemic in more than 50 countries.

When asked to describe one highlight of his long and diverse career, Shaffer noted, "I am a clinician — and pharmacist — at heart. PEPFAR is certainly at the top." He witnessed how PEPFAR brought lifesaving treatment to communities and changed the trajectory of HIV in Africa through antiretroviral (ARV) drugs. He divides this time into three buckets: Pre-PEPFAR, PEPFAR, and Post-PEPFAR Global Health Diplomacy.

Pre-PEPFAR, Shaffer taught medicine and helped establish Kenya's second Institutional Review Board/Independent Ethics Committee at Moi Teaching and Referral Hospital, which was registered with the HHS Office for Human Research Protections, allowing the institution to apply for and receive HHS-sponsored research funding. The experience gave him the opportunity to work with a talented team doing

qualitative research that helped develop policies around participating in pre-PEPFAR clinical trials, outlining participant preferences and commitments to post-trial access to ARVs.

When Shaffer initially left the FDA in 2004 it was to join the first U.S. Embassy PEPFAR team in Kenya. "I was in Africa at a time when HIV/AIDS was feared as a death sentence and hospitals were overflowing with illness and sadness," Shaffer said. "Access to ARVs was a game changer and attenuated both disease and stigma."

Living mostly in the tea fields and plantations of rural Kenya, he worked on a program with the primary goal of advancing HIV vaccine candidates through clinical trials. "It was a



The children of Nandi Hills. Image courtesy Doug Shaffer.

remarkable time, from working with the embassy team on rolling out the emergency response with the government of Kenya, to opening up HIV prevention, care, and treatment programs in more rural settings where I lived," he said. "Working hand in hand with health care providers, it was critical to have access to HIV services in rural settings, particularly before starting clinical trials."

Shaffer returned to the State Department to serve as Chief Medical Officer at the U.S. Office of the Global AIDS Coordinator and Health Diplomacy prior to returning to the U.S. Embassy in Kenya as the HHS Health Attaché. This post-PEPFAR period, dominated by COVID-19, meant a transition to more policy-focused work



Little boy discovers the joy of water. Image courtesy Douglas Shaffer.

and global health diplomacy. The shift also gave him a unique opportunity to do interagency work beyond traditional health agencies and collaborate with economic, political, and foreign commercial teams. He served as the U.S. Embassy's initial COVID-19 coordinator, working with the Kenyan Ministry of Health on its response.

Shaffer first came to OGPS in July 2022 while on a detail with HHS and was selected as an Associate Director a year later. In addition to working on PEPFAR, he helped lead the FDA's efforts to help

establish the African Medicines Agency, which is dedicated to improving access to quality, safe, and effective medical products in Africa, as well as improving access to ARV drugs to treat HIV in Africa in collaboration with the World Health Organization.

Shaffer is now back in Kenya, based in Nairobi with the nonprofit International Vaccine Institute, which has selected him as Deputy Director General of Global Affairs and Communications. He remains friends with

health care providers across sub-Saharan Africa who helped turn the tide of the HIV epidemic, considering them — like so many involved in PEPFAR's efforts — "heroes to their patients, communities and villages, and countries."



Flamingos take flight at Lake Nakuru. Image courtesy Doug Shaffer.