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DR. PAUL DE LAY

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INTERVIEW

Q: Today is March 11, 2022. We are starting a conversation with Dr. Paul De Lay. I will start the conversation by asking you about your childhood, your background, where you grew up, and some of the influences in your early life.

DE LAY: All right, I'll try to make this as concise as possible.

Q: No need to be concise!

DE LAY: I was born at the Bethesda Naval Hospital, which has now become the Uniformed Services Hospital on the NIH (National Institutes of Health) campus. Back in 1949, my father was in the Navy. He was a lawyer in the Judge Advocate General Office. I'm a Navy "brat." I lived on naval bases all over the world. The family started out in Washington DC, then moved to San Diego, and then to the Great Lakes Naval Base in Illinois. And then San Mateo in California. From there we shipped out to the U.S. Naval Base on Guam, in the Mariana Islands. We then returned to San Diego, and finally my father retired to Monterey, California to practice law.

I think partly because my dad was a lawyer, I felt I needed to go in a different direction. My grandfather was a doctor in the Navy and was the Chief Medical Officer on one of the hospital ships during World War II. Then he later trained to become a psychiatrist and treated cases of PTSD from the war. From early on, I wanted to be a medical doctor. I wasn't quite sure what that entailed other than from the TV shows that were currently on: Dr. Kildare, Ben Casey, etc, which must have influenced me in some way. I received my undergraduate degree at the University of California in Santa Cruz and spent a year abroad in England at the University of Sussex. I had already traveled so much in my childhood that I knew that it was a key part of my life and I felt it always would be.

When I went to medical school at University of California at Davis, infectious diseases was the one specialty that most fascinated me. Infectious Diseases have had a profound impact on the history of humankind. This was in the '70s and I was told by my advisor that Infectious Diseases was a dead-end specialty. At that time, drug development was focusing on second and third generation antibiotics, including new cephalosporins. There was a sense that modern pharmaceuticals could deal with any new infectious agent. I was told that the only time that Infectious Diseases specialists would be called upon would be in very rare and unusual cases of infection, often associated with people who have had organ transplants and were on immunosuppression drugs.

The advisor said that the "hot" specialties were rheumatology and endocrinology. However, I felt that this advice seemed to focus on medical care in high income countries and ignored the problems throughout the rest of the world. It did mean that to get infectious disease and tropical medicine training, I had to go outside the United States. In the 1970's schools of public health with an international focus were rare in the US. I

ultimately went to the London School of Tropical Medicine and Hygiene. I earned a diploma there and also spent a year in Thailand, partly at a leprosarium. There was Tulane University in Louisiana and a couple of others like Johns Hopkins, but you really did have to go overseas for a more comprehensive training. That's changed dramatically over the past several decades. Currently, there are many US universities of public health that have an international scope of work.

Q: To recap some of the background, you were a military brat, but you never considered going into the military yourself? You were also growing up during Vietnam. I'm wondering if that had any influence on your decision making?

DE LAY: Growing up in a military family, quite honestly, I was not able to profess a desire to evade the draft. I clearly remember having this conversation with my father. Seeing as the draft was in place and the war in Vietnam was expanding, would I go if was called? I said, yes, I would. That was a period when there were limited dispensations if you were in college, so I wasn't immediately called up. As the US made the switch to a draft lottery system, I was fortunate enough to always have high lottery numbers, so I was not called up. However, halfway through medical school, I did join the Commissioned Corps of U.S. Public Health Service, partly to pay for medical school tuition and living costs.

I did my clinical training, my internship, and residency at the US Public Health Hospital in San Francisco. This was one of the port city's "quarantine" hospitals that were set up in the 1790s, mainly for diseases that were brought in by passengers and crew on arriving ships. I also spent three years at Keams Canyon, a Hopi and Navajo Reservation, in Arizona. Again, I was focusing on where I could get experience with infectious and tropical diseases. Working on the Native American reservation had many similarities to working in parts of the developing world. There were many persons with tuberculosis, diseases of malnutrition, outbreaks of *Shigella* diarrhea, etc. Those were all important experiences for me as I became a practicing physician.

Q: You've always wanted to work internationally?

DE LAY: Yes. The excitement, the exotic, the exposure to other cultures, and all the other facets that attract many of us, particularly those working in the foreign service, USAID [United States Agency for International Development], to experience life beyond where one grew up. My wife grew up in Michigan. She remembers her kindergarten and first grade classmates, because they all continued together throughout their school attendance. I never was in any school longer than two to three years, so I have no linear history of a neighborhood, a school or a house. I think that experience gets embedded; the idea of constantly moving on. I also remember reading that the CEO [Chief Executive Officer] of IBM [International Business Machines Corporation] said "you should change your job every seven years." Not necessarily change who you're working for, but just change the location, focus or the nature of the job. That advice struck me, and it was partly the reality that travel and international work reinforced each other. Looking back, I found it incredibly rewarding, stimulating and exciting.

Q: I've got a theory that children who are moved around their whole life, they may miss some things, but they develop skills to quickly make new friends or to scope out a new area. Those are skills that are harder to come by if you've stayed in one community all your childhood. So, you certainly had developed some of the skills needed to be able to pick up and move.

DE LAY: It's interesting when I look back. I loved working at USAID. In fact, I worked longer at USAID than any other job. I was there for twelve years and for my other jobs, it was five to ten years. I noticed that a lot of people who work at USAID came from the Midwest, rather than from the coasts. I never quite understood why. Was it a desire to see beyond the experiences they had while growing up? It was an impression I had of the demographics of USAID staff and for Peace Corps as well. I don't know what you think about that.

Q: I think so. Certainly, Peace Corps was a vehicle to expand your horizons. Certainly, in the '60s and early '70s, there was a desire to do that. I think it may have attenuated somewhat in the '80s and '90s, for all sorts of reasons. But I agree with you. I've never seen a study that traces where people grew up and subsequent international careers, but I suspect your impression would be validated by such a study. That's interesting. As part of your medical training, and then subsequently, public health service, you worked on Indian or a Native American reservation?

DE LAY: Yes, in the 1970's It was called the Hopi and Navajo reservations in the north-east part of Arizona.

Q: Indian Health Service too. You were basically dealing with diseases of poverty, I suspect. So, after you were fully commissioned, and before you got to USAID, you were still part of the Public Health Service. I think you stayed part of the Public Health Service, correct?

DE LAY: I did. There's this major discussion going on now, which I'm sure you're aware of, as to why the public health system in the United States seems so ineffectual at this current time and how that's been manifested in problems and challenges that arose during the COVID pandemic response. As I said, I trained at one of the USPHS hospitals, also called "quarantine" hospitals. Those were all closed down by President Reagan in 1981. To some extent, that was the beginning of a diminishment of public health in America and a move toward prioritizing individual clinical medicine.

During the late 1970's, under President Carter, the United States was admitting about 168,000 refugees per year with I-94 immigrant status. Many of them were Hmong, Karen, Lahu, Laotian, Vietnamese, ethnic Chinese, and Cambodians. In the press they were often called "Boat People", though many fled their own countries by land. They were all coming from southeast Asian countries after the fall of Saigon. It turned out that the threatened "domino effect" actually did occur. The clinic, which was established at

the US Public Health Hospital, was moved in 1981 to San Francisco General Hospital (SFGH), which is now called Mark Zuckerberg hospital.

I worked there for eight years. I was the medical director of what was called the SFGH Refugee Clinic. We provided initial screening and follow up care. It was a general medical clinic, but with many tropical disease cases and located in the center of San Francisco. We had translators that covered 18 different languages. For me, it was the best of both worlds. I could see a wide range of “exotic” diseases, such as leprosy, malaria, tuberculosis, intestinal parasites, etc, and then go home to my house in Berkeley. As part of the job, I would also go overseas for short trips to the refugee holding camps that were mainly in Thailand, Malaysia and Singapore, which was where many of the refugees were housed, until they were allowed into the United States or granted asylum in other countries. It was an incredibly exciting and rewarding time for me.

This was in the early 1980’s and the beginning of another global health disaster-the start of the AIDS pandemic (Acquired Immune Deficiency Syndrome). My Refugee clinic was located on the floor below the newly established AIDS clinic that served most of San Francisco and the Bay area. I had already started seeing and caring for AIDS patients when I did attending physician assignments at the specialty clinics located at the University of California at San Francisco. AIDS was taking a devastating toll. Without any available treatments, many persons infected with HIV died within eighteen months of diagnosis. It was a horrendous time and the AIDS pandemic was exploding all over the world, particularly in Africa.

In the practice of infectious disease and tropical medicine, for many doctors, the ultimate goal, the “Mecca,” was to work for the World Health Organization, WHO. So, I decided to contact colleagues who were already working there. In 1988, the WHO Global Program on AIDS was setting up country offices in the hardest hit countries. I was recruited by Dr Jonathan Mann, who was the head of the new Global Programme on AIDS and I was appointed as the Team Leader of the WHO AIDS Office in Malawi, East Africa. East and southern Africa had the highest levels of HIV infections and deaths from AIDS. I spent 3 years in Malawi and worked closely with many international partners, including UNICEF and USAID. That's where I met Carol Peasley and Gary Newton from USAID, who worked literally across the parking lot from my office.

Though WHO plays a critical and admirable role in global health, the organization is not without its own challenges. United Nations organizations tend to be understaffed and very bureaucratic. Also, I was no longer directly diagnosing or treating patients, but focused more on setting up testing facilities and establishing policies and systems for preventing HIV transmission and providing treating persons with AIDS.

While I was in Malawi, I met Dr Jeff Harris, who was recruited from the CDC to head up USAID’s nascent AIDS program in Washington, DC. He offered me a position in 1991 and I was seconded from WHO to the USAID office in DC.

Q: Can I ask you to pause there and reflect? What did we know about HIV [Human Immunodeficiency Virus] and AIDS back then? You alluded to the fact that it was a death sentence in the early days. You did have clinical experience in San Francisco. You probably knew before many people just how lethal and how contagious it was. Can you just characterize how it looked then because clearly, things have changed?

DE LAY: I'm still active in the HIV-AIDS world and I continue to do consulting work with UNAIDS and WHO. After I retired from UNAIDS in 2013 I served on the Board of Directors for FHI [Family Health International] for eight years. Much of their work focuses on HIV and AIDS. There's a lot of discussion, now, in the general press and in the technical literature, about the similarities between the HIV-AIDS epidemic and the SARS COVID-2 epidemic. They're both RNA viruses and many of the drugs that are being used to treat COVID are also drugs that have been used for HIV. What were the strengths and weaknesses of the response to the AIDS epidemic that should be transferred or applied? I think the biggest similarity to me, and the most daunting challenge, was that we didn't know anything about HIV-AIDS at the beginning. It was a novel virus.

It was the same with COVID. The medical community had experience with coronaviruses which acted like other “common cold” viruses. But this new mutation, or “variant,” didn't behave like the other cold viruses. You can pick your cliché: “learning by doing,” “flying the boat while you're sailing the plane.” I think one of the major challenges was understanding how long it takes to respond to a brand new biological threat. With AIDS, it took three years before the causative virus was identified. In the late 1970's we were seeing what we were calling Gay Bowel Syndrome in San Francisco. Young, white, gay men were being diagnosed with amoeba, giardia, and other “exotic” intestinal parasites, when they had never traveled. We were diagnosing eye infections due to Cytomegalovirus, which is a very rare disease in the US. In 1981, the syndrome called AIDS was identified in the medical literature. There was something clearly going on with patients' immune systems. It took three years after it was first recognized as a syndrome, AIDS, to identify the causative virus. It took another three years to develop a simple blood test to diagnose it. Then it took another twenty years to obtain a successful drug regimen for it. We still don't have a vaccine and we still don't have a curative intervention. We can only suppress the HIV virus with our current drug regimens.

When you look at COVID, all those developments were condensed into one year, which is amazing. Within 12 months from the first known infection, we knew exactly what the infectious agent was. We had a laboratory test almost immediately, but because of existing CDC protocols there were problems getting the testing kits to the State laboratories and to the hospitals. We had an effective vaccine within a year. One of the reasons for the rapid progress with COVID was that we had new technologies that had been developed over the past 30 years and we had learned a lot about how RNA viruses infect and multiply and can be stopped. So, we were able to build on that. And in reverse, some of the new research on COVID is being used to benefit the response to AIDS. Research scientists are now trying to use the “mRNA” technologies to develop AIDS vaccines, but I'm not really convinced that this concept will be transferable. HIV attacks

the T-cells which are a basic part of our immune systems. COVID attacks respiratory cells, primarily the bronchial cells. So, it is indeed a different type of virus.

In the early years of the AIDS response, we had a very limited toolbox. In Malawi, the first thing we did was to set up a surveillance system to determine how many people were infected and to protect the blood supply, so that HIV would not be transmitted by blood transfusions. This took considerable time, because we had to bring in diagnostic machines and reagents and train the laboratory technicians. We also developed communication programs to warn people about HIV and AIDS and how one could protect themselves. Because this was a new virus, we went down some blind alleys. For example, when I first was hired by Jeff Harris at USAID, I was assigned to find methods to diagnose and treat other sexually transmitted infections in low resource settings. Preliminary data had shown that a person who had Gonorrhea or Syphilis, for example, was more likely to transmit and acquire HIV/AIDS. In retrospect, this was a misdirection. Treating background sexually transmitted diseases really didn't have much impact on overall HIV transmission.

We are seeing this same sort of course changing and misdirection, with the COVID epidemic. Now there are many who mistrust the scientists – “they don't know what they're doing, because they keep changing what they are telling the public”—but, the knowledge base just keeps expanding. I think seeing this same dynamic in the COVID response compared to the AIDS response has been instructive. It is an ongoing battle, a quest to understand what the enemy really was and what were the weaknesses that could be capitalized on. I don't think there's any question that will confront other novel viruses, mutating from Marburg virus or Dengue or some other pathogen. New infectious diseases will keep coming at us and with each new pandemic, we often have to relearn everything.

Q: Early on technology wasn't as good as it is today. But do you think some of the slowness in the battle with AIDS was because it was related to sexual behavior and our puritanical reaction to anything icky?

DE LAY: Yes, definitely. But I think the biggest struggle with HIV, like COVID, is we had a lot to learn, and we had to keep learning. Then we had to keep adapting and changing course. Currently, there are challenges with some of the PEPFAR [President's Emergency Plan for AIDS Relief] strategies, where there is much more of a focus on treatment than on prevention. The treatment has not really had the impact on incident infections that we had hoped it would and there's a lot of reasons for that. So, we keep learning and learning.

Q: It was a political football too.

DE LAY: The other challenge, you're right, with AIDS is it's all about “sex, drugs, and rock and roll.” The pandemic involves gay people, prostitution drug use. It did not fit at all with what were considered global health priorities at that time. AIDS was not a disease that many international development agencies wanted to or were prepared to confront.

I give a lecture every year at the London School of Tropical Medicine about how global health priorities have changed over the past several decades and how global health programs have changed. Some of it relates to changes in economic development policies. Back in the 1960's, international development focused on helping countries achieve economic prosperity. Then there was a shift to focusing on the poorest of the poor, which occurred in the late '70s and '80s after the Declaration of Alma Ata. Then the focus shifted to this very narrow set of interventions: bed nets to prevent malaria, childhood immunizations, family planning, oral rehydration for childhood diarrhea, prenatal care, and exclusive breastfeeding. This was counter to the "health for all" goals that were the core of the Alma Ata Declaration of 1978, because the Declaration was seen by many international development experts as too ambitious, unrealistic, "a pie in the sky" goal and, admittedly, the Declaration was seriously lacking in detail as to how these lofty goals could be achieved and how this entire endeavor would be funded.

So, there was this counter reaction in 1978, and to some extent, our health programs became much more narrow in scope. I think there are a lot of reasons for that. Rockefeller Foundation, UNICEF [United Nations International Children's Emergency Fund], and World Bank were all heavily involved in reconfiguring international development. Essentially, the focus would be on a specific set of interventions that had proven to be extremely effective and would dramatically increase child survival. When HIV/AIDS came along, this was a disease of twenty to forty-year-olds. Sex, drugs, homosexuality, and prostitution didn't fit at all with our health policy paradigm.

During the 1990's, while I worked at USAID, I was very aware of the tensions, resentment and competition between the different international development programs. I think it was inevitable, particularly because of the perception of overall limits on available resources. It was one of the things that depressed me about the global health world, which advocated for a total community response, but then realizing that there is fierce competition for resources within that community. There was a sense of "my priority is more important than your priority."

I think the annual budget for HIV/AIDS, when it began at USAID in 1987, was only six million dollars. Most of that money was then given to WHO to set up their Global Programme on AIDS and a small amount was used to develop two USAID programs-AIDSTech and AIDSCap. The first three Chiefs for the USAID program were brought in from the CDC--Jeff Harris, Helene Gayle and then Jacob Gayle. In discussions with Duff Gillespie, who was the overall Director of Health and Family Planning, I sensed that the AIDS program at USAID would either remain limited in size and scope or eventually disappear.

Q: Right. Not just Duff though. I think a lot of people really wondered how serious this truly was or was WHO just hyping the issue. I think that your tenure is when we really came to grips with just what a challenge this was for development. There was rivalry. You cited several things. The fact that the whole health program was focused on a very different demographic, the competition for resources within health, and within the

broader health community. The regional bureaus weren't always your friend either. You had to deal with the bureaucrats, in addition to the technical issues.

DE LAY: The same thing happened at WHO. When Jonathan Mann set up the Global Programme on AIDS, everyone else at WHO was concerned and jealous. The Director General of WHO ultimately fired Jonathan, primarily because he was trying to go around the bureaucratic morass that WHO had become. The WHO regional offices were weak, and the methods for selecting and providing oversight to country level WHO representatives was inefficient and often corrupt. So, it wasn't unique to USAID. These same tensions were occurring in other international development agencies like Swedish SIDA [Swedish International Development Cooperation Agency], DfID, GTZ, etc. I think it's an important lesson, that as new problems in international development arise, how can we be more open to them and be more collaborative. As for over-estimating the size of the AIDS epidemic, I'll say quite honestly that there were experts in the AIDS world who were way off track in assessing how bad the pandemic was going to get.

Q: Or how quickly a vaccine would be produced.

DE LAY: In the late 1980's in the US, many experts thought that HIV was going to leap from the gay community to the general heterosexual population and be just as severe as was being seen in Africa. Well, that didn't happen. Jonathan Mann, after he was dismissed from WHO, went to Harvard University. He published two books that predicted 120 HIV million infections by the year 2000. That didn't happen. It wasn't unique to AIDS; the direst predictions often occur when there is a new disease or new threat. Paul Erlich's book, "The Population Bomb" predicted global catastrophe unless birth rates could be decreased. Often at the beginning of a new challenge, we don't have enough knowledge, and we're doing the best we can. But, then we must be willing and able to reassess as we get more information. That's the lesson of AIDS and of COVID.

Q: There are some other lessons too. Outside of USAID the NGO [Non-Governmental Organization] community was getting very active. I don't know whether it affected you at USAID, whether you were getting pummeled with requests to do more from the HIV-AIDS focused NGOs or the reverse. The child survival NGOs were saying wait a second, to you as well. Can you talk a little bit about that broader environment? Then I am going to ask you about Jesse Helms.

DE LAY: The NGO community has been one of the major strengths of the AIDS response. In the US, you had affluent, well educated, gay men in New York, Boston, New Orleans, and San Francisco who were able to take on established institutions and radically alter the way that they operated. They essentially, in their battles with NIH [National Institute of Health] changed the way we deal with all new diseases. They pushed for the creation of a rapid assessment process for promising drugs and technologies that dramatically accelerated access for all who needed them. That was a huge change within the United States. It was the NGOs that put AIDS on the map as far as the resources needed to respond. In the early years, the U.S. NGOs were not as focused

on the international response. They felt we've got to fix it here in the US first. It's devastating our domestic communities; so we can't afford to go off around the world. They really weren't in opposition to the international efforts, but they weren't that supportive until the highly effective antiretroviral therapies (HAART) were discovered in the late '90s. As HAART became more generally available, the U.S. NGOs expanded their focus to international efforts. They became a powerful voice for the creation of the Global Fund for AIDS, TB, and Malaria. They supported the UN Declaration of Commitment in 2000, which was a massive global effort to accelerate the response and created the first global targets to measure achievements.

The NGOs in other affected countries include many faith-based organizations (FBOs). When I was in Malawi, the strongest were the Christian based hospitals-the Catholic, Adventist and Salvation Army hospitals, and they were the most progressive as far as treating persons with AIDS. In the early years, it was pretty much limited to palliative care. The faith based community was generally very positive and effective, but there were some exceptions. In Uganda, some of the FBOs strongly opposed distribution of condoms to prevent HIV transmission and advocated for "abstinence-only" programs.

The NGO community has consistently played an important role in increasing access and acceptability of development programs. I would have discussions with Duff, Scott Radloff, Margaret Neuse, and Liz McGuire, about how the family planning community, international public health and the Planned Parenthood Foundation used local women's groups for defining acceptability issues, increasing user friendliness, and improving how family planning programs were rolled out using community organizations. In the AIDS response, we had tried to duplicate that, but there wasn't as much exchange of ideas as there should have been.

I remember when Family Health International (FHI) convened a major learning conference, as they closed the large AIDSCAP program in 1996, in preparation for the next wave of programs. There were attendees from the family planning community who asked if the AIDS community was aware of numerous family planning studies on how to use community groups to roll out certain types of services, how to increase user friendliness, and how to reduce stigma. The program staff stated that they were not aware of such research, instead they performed the same types of research all over again. There clearly wasn't effective sharing and cross fertilization of studies on how best to deliver community services, as a generic issue. It was a sobering reminder how insulated and "siloed" the international development community was.

*Q: I certainly understand what you're saying. The number of times we've had to rediscover the importance of girls' education, I just want to scream as we keep rediscovering it! As you think about that period, could anything have made a difference? Or does it come down to some special leadership that says we **will** try to look at examples from other sectors?*

DE LAY: I think there must be an active effort that's planned, driven by resources, managed, and monitored. I don't think it happens naturally. We are accustomed to

working in silos. I like the recent rethinking of how USAID would grant new projects. It's already incredibly resource intensive, but there needs to be more effort to make the design and implementation of projects be more cooperative and willing to embrace new approaches. There is a critical need to look at cross sector experiences and where can we pull lessons that could benefit the broader development response.

In the mid 1990's, I was a member of a large USAID program design team which were planning new health and family planning programs for Kenya. This trip was labeled a "joint program design" and I had thought that there would be a defined process in which the HIV/AIDS team members would regularly meet with the child health and the family planning staff and explore how we could work together to integrate and share training activities, clinics and resources and ways to utilize the same monitoring and evaluation system. However, I was a bit too optimistic. Ultimately, the only sharing was that we stayed in the same hotel and flew on the same plane. We were still working in silos because of the way earmarked funding and reporting requirements were set up. I understood the challenges with how funding flows, but it was still disappointing. Clearly, there needed to be a different "mind set" to change this and it needed to come from the top down.

Q: Right. To what extent did the earmarking get in the way of collaboration, as opposed to facilitating it?

DE LAY: When your program receives earmarked funding, you're certainly happy to have these dedicated resources. But it creates an environment where you think "now I must set up a new, separate system that's only going to be for specific friendly members of Congress (Jesse Helms, Patrick Leahy, etc) We all say we hate earmarks, but we also all love them and use them. I think it would be a tremendous challenge to change that.

I recently read John Norris' book, "The Enduring Struggle-The history of USAID and America's uneasy transformation of the world." The book was launched at a recent USAID Alumni Association meeting. The book details the evolving thinking about development and what works and doesn't work. I asked John if anybody has ever done a comparison across development agencies? For example, what are the differences between Swedish SIDA and Canadian CIDA? Look at what is happening at the United Kingdom's DFID [Department for International Development], which has now become more like an investment bank rather than providing development grant funding. It's even changed its name to the Foreign and Commonwealth Development Office [FCDO]. The US has created something similar-the International Development and Financing Corporation which operates in parallel to USAID but focuses on investing in local private sector enterprises. When asked this question, John said that when writing the history of USAID there wasn't enough time to try to do a comparison of development agencies.

I don't want to be a Pollyanna, thinking that everyone can work together in one big happy family and that family planning clinics can serve sex workers and drug users' needs for limiting sexually transmitted infections. There must be some realism, but I do think we are missing a wide range of opportunities. Earmarking is part of that problem.

Q: Right. You must have gotten involved in donor meetings when you were at USAID, but did you see the same kind of rivalry and one-ups-manship? Did international donor meetings make it easier to do programs collaboratively?

DE LAY: There were meetings with other development agencies. We would have staff come in from DIFD, Canadian CIDA, and Swedish SIDA. There were attempts at collaboration and it depended on the Directors. It really had to be a fiat coming down from above. We did spend a lot of time working with the European Union, which had been examining how to make programs sustainable in the long term. All European Union HIV/AIDS grants had a four-year “phase out” written into the agreement. Each year of the grant, the local government had to cover an increasing twenty-five percent of the cost of the program. So, at the end of the four-years, it was completely sustainable and being funded by the host government.

In USAID, in the HIV/AIDS world, we never seriously considered that. There are multiple reasons for that. We all know that there was a genuine attempt by USAID to phase out of paying for childhood immunization programs—particularly as countries moved from low income to middle income status. But that concept fell apart in many countries and immunization coverage plummeted. The newly formed Global Vaccine Alliance (GAVI) in 2000 was designed to promote newly available vaccines, but ultimately they had to backtrack and help countries with the existing, routine vaccines like DPT [Diphtheria, Tetanus, Pertussis] shots.

In the past several years of my retirement, I have given a lecture to the students at the London School of Tropical Medicine and Hygiene about who are the global actors in the development world. For example, if you're in global health, who are the various critical partners and what are their comparative advantages? Who and what is a multilateral organization? What is a bilateral? What is an NGO? The U.S. Finance Development Corporation, what is that? Is it competing with USAID? Why do they exist? How is it different in the family planning world versus the tuberculosis world, versus the AIDS world? Each of these actors ascend and descend depending on what governments are interested in funding at the moment. So, you're constantly learning a new family of organizations.

Q: You have an ecosystem that you have to work within.

DE LAY: Yes. Again, when you work in one specific area of development you can easily get trapped in your own silo, and then your concept of what works, and what doesn't work, becomes limited.

Q: Right. You mentioned AIDSCAP [AIDS Control and Prevention Project]. I think there was an AIDSCOM and an AIDSTECH. They were modeled on these major contracts that had been developed for child survival, I believe. Did you find that those were effective in getting programs going in field missions, or were they not a good fit with what you were trying to accomplish?

DE LAY: When I was in Malawi from 1988 to 1991, I was there as the WHO Team Leader of the HIV/AIDS office, that was based in the Ministry of Health, working directly with the Malawian AIDS department. Undoubtedly, the best resource and partner that we had was USAID. Carol Peasley was Mission Director and Gary Newton was the Health Officer. AIDSTECH helped set up our HIV blood testing, screening and surveillance systems all over the country. I had funding from WHO, a three-to-four-million-dollar budget each year. We could do anonymous HIV testing; we could determine which districts were hardest hit by the virus and provide clinical testing support for the District Hospitals and Clinics. We also supported the private hospitals, many of which were administered by religious groups. That was AIDSTECH.

AIDSCOM was the education project-focusing on informing people about the risks of HIV and how one could protect themselves. This included using general communication channels like radio broadcasts, theater groups, newspaper stories, posters, etc. Both USAID and WHO supported the procurement and distribution of condoms. In addition, there was a major effort to develop school curricula targeted to different age groups. What do children and teenagers need to learn at each age about transmission of HIV? As would be expected there were major challenges to ensure that the curriculum was culturally sensitive and acceptable. Developing the curriculum was a two-year process. Ultimately, the Department of Education never used the materials, because of the traditional sensitivities about sex and sexual behavior. But they were ultimately used by Zambia and a number of other countries.

These two projects covered the essential core of interventions that we had available at that time in the late 1980's: public education and awareness programs, school education, HIV testing and screening, distribution of condoms, and palliative care when AIDS patients were dying.

USAID was an invaluable resource. There was mutual respect and a wonderful collaborative relationship. So, when Jeff Harris asked me to come to Washington and join USAID, it just clicked. Several years later, AIDSCAP became the major USAID project and then PEPFAR was created in 2003. I have great respect for USAID and the time I spent in Malawi was probably the most rewarding, challenging, enriching period of my life--and never boring.

Q: This will be a rough segue, but the Hill was also very important, both because of the earmarking and because of the resistance that you got. I know there are stories of how Jesse Helms came around to support USAID's HIV/AIDS programming. I'm just wondering if you could reflect a little bit on the support you had, what role you played in that, and then the resistance and how you overcame it?

DE LAY: When I moved to USAID in Washington DC, the Agency staff were doing regular visits to the Hill. We would often do lunch presentations, and I did many of them. There was a great deal of information provided to the Congressional staff on the Hill focusing on what we knew about HIV, what we were learning, and what were the

successes. Senator Patrick Leahy and Senator Ted Kennedy were major supporters of our efforts. Under President Clinton, the Office of National AIDS Policy (ONAP), was created, and the director of that office was Sandy Thurman. She was the primary force who decided to lead a direct appeal to Senator Jesse Helms, who was a senior leader in the Senate Foreign Operations Office and very much opposed to foreign aid, particularly for AIDS. Sandy made a major effort to engage Senator Leahy's staff and Mary Lynn Qurnell became the point person on his staff who was responsible for HIV/AIDS issues.

Working with Sandy, we organized a Congressional Delegation (CODEL) in 1999. Mary Lynn accompanied us. Other group members included Rory Kennedy (the daughter of Robert Kennedy), Senator Ted Kennedy's staff person, Michael Iskowitz, and two members of the Congressional Black Caucus: Congresswomen Barbara Lee and Sheila Jackson Lee. The CODEL visited Zambia, Uganda, and South Africa. We met with many of the shining lights and the inspirational people who were involved in the AIDS response, including Desmond Tutu in South Africa. The group visited "The Memory Book" project in Uganda. In those days, mothers infected with HIV confronted imminent death and realized that up to 30% of their babies would also die from AIDS. There were no effective treatments at that time. The mothers would assemble these "memory" books, so that the child, the orphan, would have a record to look back on after their mother had died. These visits were inevitably very emotional, and many tears were shed. The memory books themselves were heartbreaking. These visits clearly had an impact on Mary Lynn and she became one of the strongest allies we had on the Hill.

Upon returning to the States, she continued to advocate for more US involvement in the AIDS pandemic, particularly in Africa. She had a profound impact on Senator Helms. He was very uncomfortable with the drug use issues that we were dealing with in Asia and in Eastern Europe, and homosexuality. However, when the issue was orphans left behind by AIDS, his response changed. How were we going to stop the steady increase of orphans? How are we going to support them? Subsequently, increased resources were allocated to orphanages.

Looking back, it was apparent that having Sandy Thurman as a resource in the White House, and Mary Lynn working as a staffer for Helms made a huge impact. Pushing the AIDS response agenda was still an ongoing challenge-within USAID and with Congress, but there was a sea change in 2000. Other advocates joined over time, including Senator Frist and others from the Republican side, and Senator Leahy from the Democrats continued to be a powerful champion.

Q: So, you mentioned the sea change that happened when the antivirals and antiretrovirals became more available and the possibility of, at least, remission, or slowing down the epidemic. Can you talk a little bit about that? I'm a little fuzzy here, whether USAID was funding some of the anti-retroviral work or whether that was done elsewhere?

DE LAY: Yes, we did. Introducing effective treatment as a part of the US AIDS response became a major issue in the early 2000's. Highly Active Antiretroviral Treatment

(HAART) became a reality in the late 1990's in the US and other high-income countries. Because of the cost of the drugs and the perceived complexity for delivering treatment in low resource settings, there was very strong pushback from multiple sources that treatment could not be introduced into our USAID programs.

Family Health International (FHI) was one of the major international NGOs that USAID funded for implementing HIV/AIDS programs around the world. There are regulations that prevent such organizations from directly lobbying Congress to advocate for new or expanding projects. However, FHI became part of a "Proof of Concept" research study, using their own Foundation Funds rather than USAID funding. The purpose was to show that these drugs could be delivered to people in Africa safely and at low cost. And that these treatments would stop the progression of disease and give HIV infected people a normal lifespan. Proof of concept studies have been used in other health and social service programs, including in family planning and child survival. There were four major studies performed and they were extremely successful. In fact, treatment compliance worked better than it did in the United States, partly because the drug therapy was started earlier, before a person became severely ill.

Also, there were two major studies that came out in 1999 that showed you could prevent mother-to-child transmission of HIV using a simple, short course of antiretroviral therapy. These two new sets of interventions had a huge impact on HIV/AIDS programs around the world and dramatically expanded the scope of these programs.

It was during this time of changes in the AIDS response that PEPFAR was born. When President Bush took office and was told about the severity of the pandemic and the recent discovery of effective drug regimens, he said "let's do this." There was already support coming from the Republican side of Congress. USAID was asked to select the priority countries for a roll out of programs. We picked twenty countries with severe epidemics. where we would initially start programs to prevent mother-to-child transmission. However, within a couple of months the White House decided to go much further and add full treatment for all infected persons. It was a revolutionary change.

Q: Revolutionary?

DE LAY: Yes, revolutionary, for a number of reasons. The effective drug combinations here in the US were costing about \$30,000 dollars per patient per year. Eventually, through use of generic rather than branded drugs and because of rigorous price negotiations the cost for one year of treatment in low-income drugs became about \$300! Never before in the international development world, was there a decision to provide life-long chronic therapy for a massive population of patients.

Q: Right.

DE LAY: In 2003 PEPFAR became the U.S. treatment program. The first Global AIDS Coordinator, Randall Tobias, created the initial mechanisms, including country operating plans and country operating reports. for the priority countries. About the same time, the

Global Fund for AIDS, TB, and Malaria was created through a United Nations mandate, which was initially set up primarily as a drug procurement system but eventually also funded comprehensive treatment programs.

In these early years of mass treatment programs for AIDS, there was some tension and confusion between the programs. About the same time, WHO introduced its “Three by Five” program which set a global goal of three million people on treatment by the year 2005. WHO originally planned to set up its own WHO treatment clinics in countries, but eventually took on a more technical and policy support role. It took several more years for all the UN and bilateral organization programs to begin to work together in a more cooperative and non-competitive way.

One major problem with the introduction of mass treatment did arise. Some early studies appeared to show that if you treated a large proportion of the HIV infected population, you could theoretically decrease transmission of new infections. Thus, there was less need for complementary full scale prevention efforts. This led to a decrease in funding for primary prevention.

Q: Did we know that? Or did we just assume that? I mean, had there been tests on transmission?

DE LAY: There were excellent studies that showed that when a person consistently took their treatment drugs, HIV was undetectable in the blood and other body fluids. However, if you stopped treatment, the virus would return. HAART is not a curative intervention. It just suppresses the virus and prevents damage to the body. The assumption was, that if it's undetectable, it can't be transmittable. To some extent, that's true. The problem is, not everybody stays undetectable through the multiple years of taking drugs. This can occur for various reasons, for example the immune system can be affected by other diseases. Also, as new groups of young adults begin sexual activity, they can contract an infection and then very rapidly spread it to their own network of contacts. You're not going to be able to identify new infections, using current HIV screening and testing protocols because most at risk persons only get tested every couple of years.

Historically, we've never had an infectious disease where we have been able to treat our way out of an epidemic. Instead, you must find a way to switch off transmission. We can control and limit diseases through treatment, but we can never eradicate them. With our latest research, it appears that if you fully treat everyone that you can find with our current methods of testing, we can only decrease incidence of new infections by about thirty percent. Treatment does have a huge impact on mortality. The newly appointed Global AIDS Coordinator, Dr. John Nkengasong, knows these statistics better than anyone, since he has been head of the African CDC for the past several years. Even with the availability of treatment, we have to continue our primary prevention programs that include reducing sexual and needle exposures, use of condoms, and in some cases taking Pre-exposure prophylaxis drugs.

Q: Right, it's necessary. You mentioned in passing, and I won't make you drag it out, that one of the early concerns with this approach was that the early HAART regimens were very complicated and involved taking different drugs 4 to 5 times per day. There were concerns that people would have difficulty storing drugs and taking them according to complex schedules. We can and did dismiss those arguments. But were there people asking, how does this end? How long would this program need to be supported?

DE LAY: Yes, indeed. I was in San Francisco in the mid 1980's during the early research on effective treatment for AIDS. treatment studies. Zidovudine (AZT) was the first antiviral drug that came out in '87, and it basically only extended life for several months. Patients who were taking it were miserable. It wasn't until the mid-1990's that HAART was ultimately developed, which was a combination of at least three highly active antiretroviral drugs. It's a lesson learned from tuberculosis. Using a single drug, monotherapy, doesn't work for tuberculosis. The same is true for leprosy. But, if you give patients three drugs that act on different mechanisms of reproduction, you can reach a tipping point that can shut down the virus. Initially, the combination drug regimen was very complicated, and adherence was challenging. A patient often had to take drugs six times a day. Some with food, some only on an empty stomach. Storing the pills could be challenging.

There were legitimate questions about how realistic this approach was. The initial costs for these drugs were indeed exorbitant. The USAID Administrator, Andrew Natsios, testified before Congress about some of these challenges. He made an unfortunate remark about patients not having access to watches, so that the medications may not be taken at the correct time. This comment wasn't actually in his prepared speech and he appropriately retracted the comment. He was reflecting on his time as Ambassador to Tanzania, and he was stating that taking these regimens would entail multiple challenges, including the need for reliable supply chains, quality storage of medications, increased and more complicated laboratory testing of persons on treatment to test for viral load and drug resistance, etc. But the "proof of concept" studies did clearly show that these treatments could indeed be successfully delivered in low resource settings.

However, the biggest objections continued to be that chronic HIV treatment did not coincide with the international development community's interpretation of selective primary care. If we started treating HIV patients, why don't we start treating diabetes patients with insulin? Why don't we set up renal dialysis clinics for those with renal failure? There were multiple loud voices in the development community saying that this runs counter to everything we believe in.

Q: Right. Where was that voice coming from?

DE LAY: Certainly, internally, at USAID, but also at most of the other bilateral development agencies, and even in the UN community. One of the strongest voices against the support of chronic treatment came from the World Bank. In 1999, "**Confronting AIDS: Public Priorities in a Global Epidemic**," by Mead Over and Martha Ainsworth was published. While strongly supporting ongoing prevention

programs, the authors noted that it would be a tragedy to introduce chronic treatment. Historically, there were few global health issues that incorporated chronic treatment. There were treatment programs for leprosy which tended to be small and often funded through church-based charities. Tuberculosis treatment is not lifelong because TB can be cured. The introduction of HAART clearly established a new paradigm for the international health community, and I don't think there is any way that we will ever return to a purely selective primary care approach.

Q: Right. So, that voice was always there. Are people still concerned? I know this takes you beyond USAID.

DE LAY: I left USAID in 2003, after 12 years, and then moved to UNAIDS in Geneva. I worked there for 10 more years before retiring in 2013. By then, I think I better appreciated which of our health initiatives were truly succeeding and what were the comparative advantages across the various players in the development community. It was also striking to me that in 1978, WHO initiated "health for all by the year 2000" which was ultimately rejected and scaled down to selective primary health care. But now we have the Sustainable Development Goals (SDG's) of Universal Health Coverage by the year 2030.

Q: So, we've come full circle?

DE LAY: Yes! Forty years later, we have concluded that health cannot be limited to just a small set of interventions, focusing on selected at-risk groups. Still, if you go into WHO and you walk down the hall and you ask for a definition of universal health care, you'll probably get a very different answer at every door. It has come full circle but with these lofty goals, we seem to still have the same challenges. Achievement of universal health care and all of the other health indicators that are part of the SDG's has never really been fully costed, nor have we identified where the necessary resources will come from.

What are the biggest causes of death in Africa? Well, among them are automobile accidents, but no donor is discussing putting in better traffic controls, safer roads, and building shock trauma units for the injured. There is also the realization that bilateral donors can only be part of the solution. Then there is the issue of how to support middle-income countries as compared to low-income countries.

Donor monies for health will always be limited. Is PEPFAR sustainable for the next 20 years? The cost is \$4 billion per year. If a curative intervention or an effective preventive vaccine became available in the future, is that where the resources should go instead?

Q: Are people starting to say, how do we extract ourselves?

DE LAY: No. I've not seen that yet. I am sure that there are still some people in the development world who do think it was a mistake. However, in the popular press, every article you read says that PEPFAR is one of the major global health success stories of the past 50 years, along with the eradication of smallpox.

Q: Right. Well, this oral history will start to correct that, I hope.

DE LAY: When I give my lectures to international health students, I talk about the ups and downs in development. Primary education used to be one of the biggest areas of focus. Currently, it receives very little funding. Improving agricultural productivity was also a priority. Also now receiving little funding. Many of the students that I speak to don't realize how new development organizations are. Most of these organizations were created in the 1960s and were a product of the original Marshall Plan for the reconstruction of Europe after World War 2. The Organization for Economic Cooperation and Development [OECD] was formed in 1961. Prior to that international development assistance primarily took place under the rubrics of colonialism and missionary work.

Q: The transition from Chief of USAID's AIDS division to UNAIDS, how did that happen for you?

DE LAY: I had been at USAID for twelve years. I had never stayed that long in any job before and I felt it was time to do something different. UNAIDS was created in 1995, while I was working at USAID. USAID played a major role in establishing UNAIDS. There were two reasons why it was set up. WHO had led the UN response to the AIDS pandemic since 1986. However, as the pandemic became more severe and was spreading around the globe, it was decided to evaluate the strengths and weaknesses of the WHO response. One major problem that was identified during the evaluation was the lack of coordination of the AIDS response at country and global levels. WHO was never given the resources nor the mandate to coordinate the other UN organizations. There continued to be competition at country level and infighting over resources. Traditionally, UNDP leads and coordinates country level UN activities. The second major problem with the WHO Global Program on AIDS was that it focused too much on the medical aspects of the pandemic. The transmission of HIV is affected by lack of knowledge and inequalities of access among different vulnerable groups. These vulnerabilities stem from societal issues that diminish the rights of women and girls and exclude many marginalized groups, like men who have sex with men, sex workers, and drug users. So UNAIDS was established to better deal with these issues of social justice and move beyond just the clinical medicine issues.

There are similarities to the creation of PEPFAR in 2003. As the pandemic became more severe and public awareness grew, there was more interest from the highest levels of government and increasing levels of resources became available. USAID had tried to work with and coordinate with the US CDC and other relevant US Government organizations, like the NIH and HHS. However, this never worked very well. There was constant competition and no agency had a clear mandate to lead. PEPFAR, which was to be based in the State Department, had the mandate and ability to control all the federal organizations that were responsible for surveillance, prevention programs, research, clinical medicine, the pharmaceutical industry, etc.

I was recruited by Dr. Peter Piot, the Executive Director of UNAIDS in 2002 and then joined the organization in early 2003. PEPFAR was just being developed in 2002.

Q: Right. So, you knew it was being developed?

DE LAY: Yes, we were providing much of the supporting information on the AIDS pandemic and response, including the surveillance data, the existing prevention and treatment activities, the AIDS orphan situation, the human rights issues, and what was working and what wasn't. I was ready to move on and there was this exciting opportunity to go to Geneva and take on new responsibilities. The Global Fund for AIDS, TB, and Malaria was just being created and UNAIDS was providing all the technical assistance. When I started at USAID in 1991, we had just six staff in the AIDS Division. By the time I left, I think we had nearly thirty staff and our budget grew from eight million to four-hundred million dollars in 2002. The initial PEPFAR budget then jumped to nearly two billion dollars. My job at USAID was becoming more and more focused on managing budgets and hiring new personnel to keep up with the demands. I felt I was moving further and further away from my technical and medical background. It was that classic dilemma of moving away from one's technical expertise to spending more and more time on administrative and management issues.

Q: Increasingly, you were becoming a manager

DE LAY: Yes. About 60% of the newly increased PEPFAR funds would now go to USAID. We needed to immediately hire another 30 staff and to establish a broader set of . So, I went to UNAIDS. I was able to go back to my technical roots and my first job was setting 60 country monitoring systems, so we would have a standardized way of tracking progress. That was another exciting time. I ultimately became the Deputy Executive Director of UNAIDS under Michel Sidibe. About 6 weeks before I was due to retire at the age of 64 in 2012, I had a mild stroke. I wound up missing most of my retirement parties!! My wife and I came back to the States in early 2013.

Q: You did? I didn't realize.

DE LAY: Fortunately, I completely recovered, and we moved back to our home in Alexandria. I have been doing part-time work since then, including serving on the Board of Directors of FHI-360 and continuing to do consultancy work with UNAIDS and WHO. I did a one-year project with USAID to analyze the quality of project evaluations. I'm still teaching at the London School Tropical Medicine and Hygiene and giving presentations at the global AIDS conferences. I feel incredibly fortunate to now be able to pick and choose the work that I do.

Q: Right. My last gig was teaching at Georgetown and setting up a new master's in global development. I was dealing with students, many of them coming in after Peace Corps and wanting to work in development. None of them expected to stay at any organization, be it AID or Gates Foundation, forever. They just didn't expect to stay very long in any one place.

DE LAY: Yes, I understand. In my experience, you can't really learn a job and get enough credibility to advance in an organization unless you work there for at least two to three years.

Q: I'd say I agree with you. I think it's important to get that perspective on the record, because it is a very different work environment, and you do wonder whether AID today could launch and manage anything as massive as what you were involved in. I don't think USAID played much of a role on COVID. It's a very different time.

DE LAY: I did clinical work for 12 years and then worked at WHO, USAID, and at UNAIDS. At this age, there is a bit of a morbid sensibility as one gets closer to the end of life than the beginning. You want to be able to look back and think, "that was time well spent." Thank you for this opportunity to reflect.

Q: You made a difference. Thank you.

End of interview