FCON COVID-19 Deployment
Oral History Interview
CDR Danielle DiDonna, MS, PAC

FCON History Committee
FDA History Office
Collaborative Oral History Project
Edited Transcript
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Oral History Abstract

The FDA History Office and members of the FCON History Committee interviewed Commander Danielle DiDonna for a collaborative oral history project to document the experiences of Public Health Service officers who are in the USPHS Commissioned Corps during the COVID-19 emergency response. CDR DiDonna discussed deployments to Florida in support of COVID-19 direct patient care and to El Paso, TX for patient screening efforts at the US-Mexico border. She also described a virtual deployment ordering COVID tests for both pre and post inspection employee testing for FDA inspectors to mitigate the spread of COVID. CDR DiDonna served as a medical practitioner prior to her work as a regulatory officer for the FDA.

Keywords

Commissioned Corps; contact tracing; COVID; COVID-19; deployment; emergency response; FDA Commissioned Officers Network (FCON); Florida; hospital; Public Health Service (PHS); testing

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Glossary

510(k)	Section of the Federal Food, Drug, and Cosmetic Act establishing a premarket notification requirement for medical devices that can demonstrate substantial equivalence to approved products
ACA	Affordable Care Act
ACF	Administration for Children and Families
ACS	Alternative Care Site
AEG	Agency Executive Group
AMSUS	Association of Military Surgeons of the United States
ASPR	Assistant Secretary for Preparedness and Response
ASPR TRACIE	Assistant Secretary for Preparedness and Response Technical Resources, Assistance Center, and Information Exchange
BARDA	Biomedical Advanced Research and Development Authority
BOP	Bureau of Prisons
BSL Lab	Biological Safety Levels Laboratory
CAP Team	Capital Area Team, U.S. Public Health Service
CAPT	Captain, U.S. Public Health Service (O-6)
CBER	Center for Biologics Evaluation and Research, FDA
CBP	Customs and Border Protection Agency
CBTS	Community-Based Testing Site
CCHQ	Commissioned Corps Headquarters
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research, FDA
CDR	Commander, U.S. Public Health Service (O-5)
CDRH	Center for Devices and Radiological Health, FDA
CFSAN	Center for Food Safety and Applied Nutrition, FDA
CMO	Chief Medical Officer
CMS	Centers for Medicare and Medicaid Services
CONOPS	Concept of Operations
CPR	Cardiopulmonary Resuscitation
CRAFT	COVID-19 Response Assistance Field Team
CTP	Center for Tobacco Products, FDA
CVM	Center for Veterinary Medicine, FDA
DART	Disaster Assistance Response Team
DHS	Department of Homeland Security
DMAT	Disaster Medical Assistance Team
DOD	Department of Defense
ECMO	Extracorporeal Membrane Oxygenation cardiovascular life support device
EHO	Environmental Health Officer
EMS	Emergency Medical Services
ER	Emergency Room
ESF	Emergency Support Function, FEMA
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency

FMS	Federal Medical Shelter, FEMA
FOIA	Freedom of Information Act
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIS	Indian Health Services Agency
HRSA	Health Resources and Services Administration
HSIN	Homeland Security Information Network
HSO	Health and Safety Officer
HVAC	Heating, Ventilation and Air Conditioning
ICS	Incident Command System
ICU	Intensive Care Unit
IMG	Incident Management Group
IMT	Incident Management Team
JIC	Joint Information Center
LCDR	Lieutenant Commander, U.S. Public Health Service (O-4)
LT	Lieutenant, U.S. Public Health Service (O-3)
MCAS	Marine Corps Air Station
MD	Medical Doctor
MMU	Monrovia Medical Unit (Liberia Ebola Response)
N95	Particulate filtering facepiece respirator, NIOSH rated "not-resistant to oil" filtering 95% of airborne particles
NCTR	National Center for Toxicological Research, FDA
NDMS	National Disaster Management System
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NP	Nurse Practitioner
NPI	National Provider Number
OASH	Office of the Assistant Secretary for Health
OC	Office of the Commissioner, FDA
OFDA	Office of U.S. Foreign Disaster Assistance
OLS	Office of Laboratory Safety, FDA
OMB	Office of Management and Budget
OPDIV	Operating Division
OPM	Office of Personnel Management
ORA	Office of Regulatory Affairs, FDA
OSHA	Occupational Safety and Health Administration
PA	Physician Assistant
PAPR	Powered Air Purifying Respirator
PCR	Polymerase Chain Reaction (test)
PHS	Public Health Service
PPE	Personal Protective Equipment
PTSD	Post-Traumatic Stress Disorder
RDF	Rapid Deployment Force
RedDOG	Readiness and Deployment Operations Group
RIST	Rapid Incident Support Team, U.S. Public Health Service

RN	Registered Nurse
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SAMSHA	Substance Abuse and Mental Health Services Administration
SAT	Service Access Team/s, U.S. Public Health Service
Sitrep	Situation Reports
SME	Subject Matter Expert
SNS	Strategic National Stockpile
SOC	Security Operations Center
SOFR	Safety Officer
SOP	Standard Operating Procedure
TAT	Technical Assistance Team
TDY	Temporary Duty Assignment
TPN	Total Parenteral Nutrition
USACE	Army Corps of Engineers
VA	Veterans Administration

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Interview Transcript

VB: So, this is the first interview being conducted in the FDA Commissioned Officers Network, COVID-19 Deployment Oral History Project, and we are delighted to be speaking with Commander Danielle DiDonna. On the call right now are Vanessa Burrows, historian for the FDA, as well as –

JS: This is John Swann, also an FDA historian speaking from Bethesda, Maryland.

LR: This is Captain Laura Pincock from the FCON History Committee.

OB: Good morning. This is Lieutenant Commander Oumou Barry representing FCON History Committee, as a Chair of the Committee.

DD: And I am Commander Danielle DiDonna, and I'll be interviewing. I'm currently with the FDA and the Division of Imports Compliance Branch Headquarters. And I'll be speaking about my deployment experiences.

VB: And Commander DiDonna, are you currently on the West Coast?

DD: Correct. In Southern California. I'm stationed in Long Beach. That's my duty station with the FDA. It's a remote headquarters position.

VB: Excellent. Thank you. You served a number of deployments in the COVID-19 public health emergency response, and we can go through them sequentially, or you can mention them out of order, whatever you think is natural. But we'll have to be careful about distinguishing which deployment we're speaking about and if you will amend the record to include information about it. So, if you want to say my first deployment and my second deployment, so on and so forth, that's fine. Or if you want to be more specific, that's fine as well.

So, when you were first informed early in the public health emergency that you were going to be deployed, how were you contacted, and how did you receive this information, and where were you deployed to?

DD: For my first experience, I was contacted by RedDOG -- they coordinate deployments for Public Health Service -- and I was contacted by them and basically told that I was being rostered for a deployment and I would be screening at a border site for travelers coming back that had potentially been exposed to COVID-19. So, this was very early on in the stages of COVID. It was a little over a year ago. And there was not a lot of information known at the time. I don't even know how much it was being spoken about in the media. Definitely not to the extent it is now. So, there wasn't a whole lot of information known, and they just asked me to prepare. I didn't have much notice. I want to say maybe five days or so. And, of course, when they contact you originally, there's not a whole lot of detail when they give you the ready notification. I received the details a little bit later.

I did go to the Mexican-US border, a large port of entry. And that was my deployment station. I was told, I think the day before going, that I was going to be the team lead of our small group. I was the only medical provider, and there were a few other nurse providers, with me, so

I think because of how the medical hierarchy is, I was chosen to be the team lead on that mission. We were working collaboratively with Customs and Border of Protection, because as I mentioned, it was a border crossing, the largest border crossing on the southern border. It's huge. At the time, the significance was because COVID had been discovered to have originated in China, the Los Angeles International Airport, which typically has a lot of traffic from China, had closed down flights.

Customs was noticing that individuals were trying to circumvent the closure by flying into Mexico City and driving through the border. So, this was an attempt to screen people. We also worked in conjunction with CDC in the local area because there were complications as far as stopping people from coming in that may have been in the hot bed, so to speak, of COVID in Wuhan. If they had traveled through there or were coming back from there and they were actual citizens, it's hard to really stop people from entering. So, early on, in my mind, I was playing through this and thinking that things would unfold the way that they had, because we were documenting that people were coming from that area, but we had to allow them entrance ultimately. The only ones that were not allowed entrance, and were turned around, were not U.S. citizens, they were just people who were on non-essential travel.

There were some very interesting things I encountered on that mission. It was great to collaborate with other agencies, to educate them about PHS a little bit more. Fortunately, I have a lot of experience in doing that in Import Operations with FDA in my district for many years. We did many, multiagency operations. So, I think it's always good. It's always good press, if you can represent the Corps well in variety of ways. People ask, "well, you work for FDA every day," yes, but I'm also a physician assistant who still continues to practice, so I can be utilized in

this capacity as a clinician as well. It just makes me a more versatile professional, and asset to the Corps to be able to handle these different assignments.

VB: Absolutely. And just to clarify, this was really early in the pandemic -- before the World Health Organization ever declared it a pandemic. Can you indicate what dates you were on this deployment in San Ysidro?

DD: I don't have the exact date. Let me see. If I can pause for a second, I can look up the email and give you the exact date.

VB: Well, when we, initially contacted you about participating in this project, you indicated it was in February and March. Does that ring true?

DD: Yes. It was about a year ago, maybe a little over a year ago.

VB: So, we were still learning a lot about the public health emergency at that point. What information were you provided in preparing for your deployment or once you arrived?

DD: The basics, because we knew it was a respiratory disease. A lot of deployments, they'll do a respiratory fit test, so that was mentioned ahead of time to prepare for respiratory fit testing. Of course, they asked if I had anything that would prevent me from physically performing that test or from wearing the mask. And that was not an issue for me. So, little things like that. It was very early on, so I remember vividly going back to the office where I worked at FDA at the

time, and they do respiratory fit test us for my main job with FDA, because at times you're in warehouses and you may be exposed to fumes and what not. And I remember getting my respirator. It's the mask that has the two circular filter pieces on the front. So, it's a big mask.

When I got there, we were relieving another team, and I just remember the other team lead and I speaking, and she said, "You know, you probably won't wear that here. You'd probably look silly wearing that." So, it was lucky for us that we were outside a lot of times in open air, because as these cars were coming through and as people were walking across, it was open space. There were only a few times where we actually had to accompany the CBP when they were detaining individuals and going into a closed environment. So, even though we were dealing with people that had been in China days before that, I didn't feel that my risk, personally, was going to be high based upon the fact that we weren't in close quarters with these individuals. We did have masks on. We were outside. So, looking back we didn't get a whole lot of information before arriving on site.

In actuality, the fit testing came towards the end of the deployment. Just logistically it was difficult to pin down who was going to perform that testing for us, because there was a very small number of us PHS, comparative to working in the CBP environment, the Customs and Border Protection Agency. So, that coordination was made through headquarters. At the time, it was just overwhelming. I think around that same time, they had people who were deploying to Japan, people who were helping with individuals that were being housed on the cruise ship that they wanted to quarantine. So, there was a lot going on around this time. So, it's difficult to coordinate all these efforts. What I understand is there's a very small number of people who coordinate the deployments for all officers all over the country. So, there wasn't an abundance of information prior to going.

VB: You mentioned having to go back to your office and also just how your experience working with different agencies and particularly Border Patrol was an asset. Did you at any point in this deployment, have to wear two hats or balance between your routine FDA role and your deployment role? How did the transition between the two work out?

DD: Well, fortunately, I have a very supportive supervisor and she is well aware of my dual roles, that I am a PHS officer and an FDA employee. So, the work that I was doing, I was able to put on hold while on deployment, and then just come back and pick up with my work. Did it cause a little bit of shuffling at the duty station? Yes, definitely, because someone else had to pick up the slack while I was gone. But fortunately, we had enough staff to make that a possibility. In my earlier years with the Commission Corps, I worked for Immigration Health Services, and I almost didn't deploy the entire time I was there, because taking me out of that clinical environment that was chronically understaffed would have really handicapped the facility. I think that might be the beauty of using FDA officer for deployments. Because with a lot of this policy work, or inspections, you can press pause for a minute, and then you can come back to something like that, whereas a detention setting with patient care is a 24/7 responsibility.

And it's difficult. Some of those clinical roles in PHS are difficult to fill. They're a less pleasant environment, so I think it's harder to recruit, harder to maintain staff in those environments typically. This creates more of a burden in other types of agencies I would say outside of FDA, particularly clinical ones. I did take my computer with me, and I did do some work while I was there off shift, because we did shift work, but it wasn't an expectation. It was

more of me wanting to be proactive and not wanting to come back to a huge backlog. I was trying to minimize obstacles in my transition.

So, things that I've learned like that, little tips and tricks, over the 18 years I've been in the Corps have helped me personally with deployments. I don't know that you have to do that, or everybody does that, but it's just something that I've always tried to do. Of course, there are certain deployments where it's not possible, but some of them it is entirely possible to bring your laptop. And a lot of times when you're away from home -- and being completely transparent and honest, when I don't have two kids that are in my hotel asking me a million things and have to feed, and clothe, and take care of children -- it leaves much more free time than I would typically have when my workday is done. So, I just try to use that time wisely, in essence.

VB: Understood. So clearly, the capacity of your office to release you from your role to serve the deployment was one consideration. Do you have any insight into how your assignment was determined, or did you have any input into your specific duties, during any of these deployments?

DD: Not my first as much, but my second, when we went to augment Memorial Health Care in South Florida, in the Miami-Fort Lauderdale area, that was a month long deployment, and it was a larger team comprised of several different categories, and because it was a healthcare system, we were spread out over their network. So, there was a main hospital, which was a level one trauma center, and then there was a smaller satellite local community hospital, but in the same network. So initially when we got boots to the ground, there weren't a whole lot of, options, I'll say, for where you were going to be assigned. They were just plugging people in,

and that was an interesting deployment was well, because the first day we were there, we met with hospital executives all together as a team and learned that they had just heard of our arrival 24 hours prior to us getting there.

So, there wasn't much preparation, and that made it a little difficult when we got there. This was unusual for deployments in that we were not setting up our own tents or reporting to officers within our own ranks.

[00:20:00]

We weren't really working with DMAT in a community setting. This was an actual hospital that we were trying to augment staff and to function as hospital staff. But of course, when you do something like that, you need to have access to your medical record system. You need to have proper credentialing when you're dealing with community patients, and all the legality that goes with that, providing medical treatment., the hospital and their comfortability with our skill level. I said in the first group meeting with our strike team and the hospital executives that I'm familiar with family practice, correctional medicine, women's health and behavioral health as a practitioner. I have very limited experience in level one trauma care. So, I don't run codes. It's been a long time since I've participated in them. And right away it was described to us that they weren't going to put any of us in that type of setting.

And my experience was much less typical than you would require for a level one trauma ER. There were doctors there from FDA that had been in primarily research roles for years and were not clinical at all. That's a definite challenge when you have to go into the field and remain clinical. So, I do my clinical hours, that's one extra duty that I have as an Officer. I practice

twice a month in primary care in the community to maintain those skills, but again, sometimes you need to pre-plan and, and know what the need is, so that you can plug individuals with those skills sets into those areas of need. I'm not sure that PHS adequately preplanned for this deployment. It didn't appear as though they did, but when we go there in keeping with the mantra of PHS, you had to remain flexible.

For the first two weeks of that deployment, I was basically functioning as a screener/triage person to the ER from the emergency transport entrance. So, when emergency crews would bring in individuals, I would have to screen them, in attempts to keep COVID positive patients separate from patients that were not COVID positive or who's COVID status was unknown. At this time, July-August of this 2020 there was more known about COVID and everyone's fear of spreading COVID and contracting COVID was at its height. So, there was a tremendous effort to try to segregate people in the hospital to mitigate spread. So, that was my role initially. And because it was entrance to the ER of people coming in to do shift work, I had to screen the employees to make sure that they weren't febrile or exhibiting any symptoms of COVID themselves before they entered and had their shift. So, it wasn't a whole lot of in-depth clinical practice.

And as time went on it became apparent to hospital leadership that maybe putting people like myself, who could see patients, in their smaller hospital, the satellite hospital, to do what was essentially a wing of the ER that was turned into a walk in clinic for people who, had COVID symptoms, were requiring COVID testing, or who had gone through their infectious period and were trying to get retested to get back to work. Retesting to ensure cure was a whole other issue at the time. Because of what was evolving with COVID and the fear of contracting it,

many employers in South Florida who's employees reported COVID infection, were then faced with difficulties getting back to work without producing a negative test.

We began functioning essentially like a COVID clinic/testing site. We also did some work with the employees, in an occupational health role. They had an employee outbreak at the hospital, so they began testing the hospital employees on a rotational basis every few weeks. So, a group of us were assisting with swabbing, the actual hospital employees, so that they could mitigate, and make sure everyone who was on site and being constantly exposed wasn't contracting COVID. So, towards the middle, when I transitioned to that role, it became more compatible with my skill set than just doing screening and checking temperatures. But again, when there's not that much time to prepare, I think it's just natural for these things to happen. It was a good save, if you will, that we were able to transition midway through the deployment. To do what I feel was more helpful and was a better display of what our skills could offer to the hospital to really help out on a greater level. Does that answer the question?

VB: And then some. Thank you so much, Danielle. Can you just maybe briefly touch on your more recent deployment. It's unique in that it's a virtual deployment, isn't it?

DD: Yes, my last two deployments. If you can believe it, I'm currently supporting two deployments, but it is under the same program. So, FDA has an agency-wide effort with the contract tracing program, and there are several pieces to that program. In October of 2020, I was asked as a provider to become 1 of 3 who are ordering COVID tests for both pre- and post-inspection employee testing. We're set up with Lab Corps. I use my NPI, my national provider number, as a clinician to order the test when requested by an FDA employee -- either someone

requires it because the institution they're going to inspect requires them to produce a negative test before they'll allow them in, or the converse, they've gone on an inspection and somewhere along the line, they were exposed to someone who may have been positive for COVID at the facility during their inspection. So, the facility reaches out to them to do their own contact tracing, and then we order a post-inspection test. Before we order the post-inspection test in that scenario, we refer them to the overarching contact tracing program, which does a clinical risk assessment. And those are medical providers, MDs, and mid-levels who perform, a risk assessment and basically try to, stratify if the individual has had a significant enough exposure, which would merit testing for COVID. We use CDC guidelines for that assessment, and then we would reply back to the COVID testing unit, yes, this person needs a test, or no, this person's risk is not such that they would require a test.

So, I've been doing COVID testing on a rotational basis since October 2020. Every third month, I'm the primary. So, that is done collaterally to my regular FDA role. I'm not taken out of my FDA job to do that. I just do it on the side, which is challenging, because it's basically shuffling between two jobs at once. But it's for brief stints, so it's doable. And I perform this role alongside two other FDA physicians. The role that I'm currently in, and I have been for the last three weeks, is the risk assessment officer within the contact tracing program. So, anytime an employee is exposed either at work or in their personal life, they can report -- it's a voluntary report program. The employee would contact their supervisor, who would then direct them to email this contact tracing inbox with a brief description of their scenario and include their phone number. I would monitor this inbox and do phone interviews to assess their risk, and most importantly, assess how that risk effects other FDA employees. In other words, was this potentially exposed employee in an FDA facility or around other FDA employees within 48

hours of their symptoms appearing, so that we can do the best, mitigation for cleaning and other contact tracing interviews of any additional employees that were potentially exposed to that individual.

That program function is all done through email to reach all employees throughout the U.S. There are several patient portals that we use to track those interviews and outcomes. There is leadership in this program within FDA that is monitoring the level of employees that have been affected and how it's impacting the actual workflow at FDA offices. I'm doing that currently, and I'll be in that role until next week on the 16th, and I started it on the 12th or 13th of February. And then, when I get back to my duties at FDA, I have about a week or two break, and then I'm primary again for the COVID testing unit in April, but I'll still be doing my FDA job at the same time.

JS: That's been terrific information, Danielle. Really appreciate it. And it captures really well the variety of deployments you've been involved in beginning in February and with the first one, the work in Florida in July and August of 2020, and then, of course, the virtual exhibit since October of 2020. It's helpful to know what's been going on in each of these. I wonder if -- I don't know if this is possible, to get a sense -- because the people that are going to be learning from this, really don't have any idea of what it's like to be on a deployment, sort of the day-to-day grind. You mentioned it's shift work. Certainly, the first two deployments were shift work, but I wondered if there is such a thing as a typical day? And I'm sure there isn't, but if there were or something close to that, what's it like once you land in a new deployment, you have to orient yourself and it must take a while. I think you don't have the luxury of adaptive time here,

but it must take a while really to get your bearings and jump in and start doing this crucial work. So, I mean, can you capture what that was like and certainly in your first two deployments.

DD: Mm-hmm. So, the first deployment wasn't too bad, I'll say. The worst for me is when you have to change time zones, because you travel usually pretty extensively. Sometimes you have layovers and by the time you get there you're turned around and you don't know what time it is. It might feel like it's 6:00, but it's actually 9:00 and you've got to hurry up and go to bed, get packed in, so to speak, to your hotel. Maybe grab something to eat really quickly and hurry up and get to bed, because you're going to be expecting to get up really early in the morning and those are always the toughest for me because when you wake up at 7, it's really 4. If you've got to be ready in the lobby at 7 to go and start your day, it really doesn't feel like 7:00 to you. You're not in that time zone, so that's the tough part. And then, for me I always joke around and say just as I'm getting used to being in that time zone, I have to switch back to my other time zone, so, that's difficult.

But there is, as you mentioned, no real "typical day." It really depends on the deployment itself and what the roles are. So, for the first deployment at the border, we did shifts. We were covering almost a 24-hour period, and myself and my one partner were on from 7 'til 5:30-6. And then, we would have the second shift come in at about 4:30 or 5, so we would overlap, brief each other, discuss any cases that we needed to discuss or work that needed to be done on the next shift, anything new that came up. And then we would switch off that way. And for that particular deployment, there were no days off. So, that was a continuous rotation from day one until the last day, which was like a handover. So, that was a little bit shorter of a time, and in this scenario, it's all different, but because there wasn't a whole lot to explain, it didn't

take a whole shift to explain that. So, we finally got a break on the last day enough time to pack up and get ready to go home. So that's how that initial deployment went at the border.

While we were at the hospital, that was also shift work, and the team was spread out amongst several different locations as I mentioned. So, I can speak to my personal experience, and that was we worked 10-hour shifts, four days in a row, and then they would give us a rest day, and then we would continue. So, it did work out. It sounds like it's pretty good, but if you're looking at a weeklong period, it's a lot of hours to be in the hospital, with a day off. So, it is longer hours for sure on most deployments, and you just use your one rest day to wash clothes and catch up on sleep. There wasn't a whole lot to do outside of the hospital, and especially considering the time with COVID rates rising. We were asked to not really do much in the community, because we didn't want to expose ourselves. So, really the day off was like a rest day/wash day. I did bring my computer and go through emails and things of that nature, just to not get completely overburdened when I returned. But those were the typical shifts. And then most of the people were on either a day or a mid-shift. I don't believe in the hospital that anyone on my team worked overnight. It was basically like a 10-hour shift rotation.

JS: So, you had mentioned earlier that in your clinical work you were involved in before this happened, were you -- I don't know if you can compare any previous deployments prior to these COVID employments that you were involved in, -- how they would compare. Any deployment must be incredibly stressful, so were there earlier employments you had or anything you could draw from those that could help you as you moved into these new types of arrangements during the pandemic?

DD: Well, definitely my deployments to the border. I went twice. One with unaccompanied minors and then there was an influx of families together at the border, so both of those deployments, if I had to qualify them, what I would say there was a higher level of clinical skill needed and met more with what I do clinically.

[00:40:00]

A lot of primary care, a lot of people coming in with chronic medications because they're trying to come to the states. A lot of infectious disease, because people are traveling in groups, and then when they're housed, a lot of times they weren't ready for the numbers of people because these immigration facilities or customs and border stations are meant to hold 40-50 people at a time. They're not meant to hold hundreds of people at a time. So, just the sheer numbers of people living in such close quarters is just a perfect environment for anything infectious spreading. So, we had chicken pox outbreaks. We had scabies outbreaks. We had conjunctivitis. So, we just tried to use whatever we could and make recommendations to CBP about how they could try to minimize some of the spread of some of these things. We came up with ideas to house people known to have the same infection together.

So, little things like that, might have been precursors or trainings for dealing with something like COVID. But in those scenarios, we were doing more of the medical treatment. And I think it was because the environment was different when you're in a government setting and with your own, so to speak. You can have a lot more of autonomy and do more clinically. The experience I had with Strike Team 13 in Florida was different, because we were working

with civilians, and we were far outnumbered by civilians and using us to our real clinical capacity was challenging with something like that.

JS: Well, in this pandemic, there must have been concerns. I mean, as you jumped into all of your deployments, did you have any particular concerns about your own safety in the midst of this pandemic on your deployments?

DD: Yeah. I was a little concerned, and my family, of course, was concerned when I went to Florida. It is tough logistically with my family arrangement. Typically, I'll have my parents come, who live out of state, to help support my husband who is also in law enforcement and has a very difficult and fluid schedule as far as timing and things like that. It doesn't really lend well with having two young children, so usually someone has to come and stay with my family while I'm gone. So, for my situation the whole preplanning piece was difficult, because I didn't want my elderly parents exposing themselves to come over to help me but then get sick themselves. So, finding childcare for me to go was the first concern and issue to deal with.

And then, of course the whole fear that I would get sick there and be away from my family and/or get sick and potentially bring something home to my family was definitely a concern. But my concerns were addressed, and many other officers had that same concern. When we met with hospital staff they made it very clear that they would make any personal protective equipment readily available for us, and I felt that it was. I felt that that was something that they held to, and it made me a lot more comfortable being in that environment. I can't say that I wasn't nervous. They tested us before we went home, since you never know if you're going to be one of those asymptomatic carriers. And when I was in triage in the ER I had several

patients that came in in acute respiratory distress, using accessory muscles to breathe, literally within minutes of my taking their vital signs, coding in the ER. So, I did get a little anxious about getting that last test, because I knew I was in very close proximity to people who were very sick with COVID during the deployment.

JS: And how often were you tested?

DD: We were tested twice during that deployment. Once because there was a hospital outbreak, and so we were tested along with all the other employees. And then, again, they tested the entire team before they allowed us to travel home. You had to have a negative test in order to get on your plane. And everyone did, thankfully, from my team. We all had negative tests, so, we were all allowed to go home.

JS: I'm sure reassurance there. Thank you.

VB: Danielle, can you describe a little bit what it was like arriving in Florida and how you and the rest of Strike Team 13 assimilated into the Hollywood Memorial Healthcare Hospital staff ecosystem. How did you come to work with the other staff and was there a hierarchy established or what were those interactions like between PHS officers and the hospital staff?

DD: Like I mentioned before, the first the whole entire team met and had a few hours with executives of the hospital touring the hospital because it was a huge hospital and you have to get your bearings on where you're going, and they showed us some of the different areas that they

needed people. They didn't know that we were coming much before we arrived. So, they wanted to get a sense of what our skill sets were, who was a nurse, who was a midlevel provider, who was a doctor. I believe even there were two doctors who were not practicing clinically, but they had them doing some type of teaching, where they were putting together presentations about COVID, and so they found a way to use all of us. They even had some social workers there. And I believe they set up an iPad program, so that patients who are unable to have visitors due to COVID hospital restrictions, were able to communicate with their family members and see them to have some semblance of normalcy or sense of connection to their family during the time when they were ill.

That was a big, big part of the mission, and then of course the clinical piece, and there was a hierarchy. I'll say, when I was in the main hospital, it was definitely a different air than when I got to the satellite hospital. The main hospital was very fast paced. It almost seemed, in some ways, that we were in their way more than we were helping. Of course, hospital staff talk, and once they found out who we were because we were obviously new people – and for this deployment, which was also something totally different, we did not wear uniforms. Because we were working in the hospital, we would come to the hospital and change into scrubs. They had everybody change into scrubs, and then change out of scrubs daily again as an infection precaution. But also, so that we would look like hospital staff. So, once people got the skinny on who we were and what our specific roles were, there was debate on where employees felt we should be placed. During one incident an employee from the ER fast track actually got into a shouting match with the charge nurse over me being a physician assistant only screening and checking temperatures. She was just shouting at him, saying, "Why is she here checking temperatures? We need her help back there, referring to patient care I assume."

There's a lot of talk now about COVID fatigue and COVID burnout, but I think that's something that's been going on for some time. We're talking about late July/August, having dealt with this already for several months. I'm sure people were already feeling burnt out at that time and very stressed. And then, we got to know that there were others – such as traveling nurses -- and I don't know that people that worked there clearly understood that we weren't paid help. Some traveling nurses that I met during the rotation were like, "oh, my God, I'm going to make like $10,000 this month" or something ridiculous that you would never expect, but because of the risk, because of the need, people were coming in as contractors and making a lot of money, and I think that initially there may have been some confusion about how we fit into that picture. As an officer, I have to do whatever job I'm given, and I realized the comment wasn't really directed at me. It was more directed at the system, and employees' frustration surfacing. So, I didn't really take it personally, but it does make you feel awkward when you're in that situation. All I said was I would love to help. You know, I'm here to help in any way that I can, but if legally I'm not allowed, or if I don't have access to your medical record, it doesn't make sense for someone to have to come behind me and redo everything I've done, because I'm not credentialed here, and because I can't document what I do in your medical record. So, little things like that did present a problem, and you could definitely see there was a hierarchy.

Now, when I transitioned midway to the smaller hospital, there was more of an acceptance and a sense of gratitude for us being there, because we were actually able to see patients. Someone did have to sign off on all our charts. So, again, it still posed a problem that we didn't have a credentials and access to their medical record to do the patient care exclusively to free up someone to do other tasks, or see other patients, or just have a break. They described it as still being a significant help because there were periods where they would see 80 to 100

patients in a day, and it was just overwhelming. Now having us to see the patient, give a quick presentation of the case be able to tell them in three minutes and then just click through some templates that they had prepared to move the process along proved helpful.

And then, of course, people augmenting the hospital's occupational health and being able to have three people testing as opposed to one person testing for everyone in the hospital. It definitely help bolster the system and increase their numbers and capacity to effectively get to all the employees. So, yes, even though, typically, I'm a practitioner; I can do things independently, we were in a more supportive role. We were not like we have been in other deployments doing things completely independently and within our own hierarchy of PHS officers devising a system of how we were going to approach the deployment. We were basically taking orders from other people in the hospital and just there to support and help in whatever way we could.

VB: Can you contrast the experience in Florida and the decision-making power of the hospital administration, with your first deployment and your daily interactions or the way you interfaced with people from other agencies in the San Ysidro situation?

DD: I think that when you're within the government system, there's much more autonomy that you can have. Even though we weren't in, necessarily, a CBP medical record, or their EMR, we were still able to assess the patients or the travelers, when they were coming across, and decide how to process them. We communicated what our impressions were to CDC officials. During that deployment there was one incident where we found several Chinese men who had been in Wuhan a few days prior, had flew into Mexico City and were trying to be smuggled across the border. CBP found them in the trunk. And CBP are clearly not medical people, and there was a

huge, commotion and cause for concern because now that these people were not citizens, were not going to be allowed to enter clearly, but had been in the "hotbed", they didn't know how they were going to house these people or what they were going to do. There were no negative pressure rooms at the station. Bringing them into a cell would mean that whatever they were breathing would potentially be dispersed through the ventilation system all throughout the facility. So, in this instance, they looked to us, PHS, and our CDC counterparts, to make recommendations, on what they should do for these people and how they should handle this type of scenario and mixing them.

A lot of times, you have people sit in a main holding area until they get them into a specific cell, and taking from my experiences of my border deployments and how we try to manage infectious disease in a place that's not ideally set up to manage infectious disease, I was able to give some guidance. Obviously, not the best-case scenario, but a plan B so to speak of what you could do to try to mitigate any spread of infection, and ease the concerns of CBP staff working in the building. I joked around that night with my partner and said, "We're probably going to die of cancer, because I think we just inhaled about 20 cans of Lysol spray." You know, when we brought these Chinese nationals into the holding area, every CBP officer had a can of Lysol spray out. They were frantically spraying Lysol in the air and spraying down all the surfaces. The fear of the unknown was definitely apparent, and I think that our medical expertise, bringing it into that environment helped maybe calm some of those fears and let people know that just because you came in contact with this person for two seconds we don't even know if they're positive. They're not symptomatic. They don't have a fever. I can say that it was a little concerning, that we weren't able to test them. But at this time, it was the early phases of the pandemic, so getting tests for people in the community was difficult, much less

getting tests to government agencies that may or may not run into a need like this. So, that part was challenging, but overall, I definitely feel like when our missions are internal with other government agencies, you have a much greater purpose clinically that you're able to execute and much more autonomy to make decisions, regarding what you're going to do. I will say that the Strike Team 13 experience in Florida was like no other experience I've ever had as a PHS officer deploying. You know, while I thought it was helpful, it was also very limiting at the same time.

[00:59:58]

OB: Commander, this is Lieutenant Commander Barry. Thank you for all you have done to help fight this virus. I just wanted to clarify, for all of your deployments, did you get a chance to deploy as a team? Meaning, did you have other officers, Public Health Service officers, assigned to the same deployment at the same site?

DD: Yes, for the CBP mission, it was a small team. There were four of us at a time, so two officers per each shift. And then for the Strike Team 13, there was a rather large group -- I want to say somewhere in the neighborhood of 40, maybe 45 people total. All working together. When I say together, sometimes we weren't at the same post. I was stationed at my own post at the ER, for those first two weeks. So, I was alone working for most of my shift with other civilian hospital employees and paramedics that were coming in while my officer counterparts that were with me on that shift were at different triage points in the ER. So, we had one midlevel, who was a rover, going around and helping bring supplies to people. And then, we had another PHS midlevel that was in the walk-in side of the ER. So, people who were healthy

enough to drive themselves to the ER or get there by means other than emergency medical services, this other officer was stationed at that triage point. So, when you say working together, yes, we were all sent there together, but a lot of the times, in that deployment, we were separated, during the day and spread out, just because it was such a large hospital system. And then, even though this deployment is virtual, I am working with other PHS officer on the Risk Assessment Team as well as the COVID testing unit. There are two other physicians on the COVID testing unit and myself for all of FDA, and then right now, on the contact tracing/Risk Assessment Team, I am the PM shift, so I start at 12 noon, and then I work until 8 or 8:30 in the evening, which is why I'm able to do this interview right now. This is my off time. So, there's another PHS officer that is on shift right now for the risk assessment.

OB: Okay. Thank you for that. So, for the deployment where you and the officers were at the same side, did you all get a chance to work together after the assignment, meaning did you have some not during duty time to follow up on some stuff at the deployment site, like on weekends? Were you able to get together after the deployment work to follow up on things that were not completed at the deployment assignment at the other office? Like, were you able to do stuff beyond the assignment, to follow up on things that were not completed at the deployment site?

DD: Like from the team that we were relieving, you mean, or are you talking about my job at FDA, was I able to have time to do work that was left at my regular job site?

OB: No, at the deployment site, did you have an assignment that you were not able to complete during your deployment hours and you still had to get together with the other officers

after the deployment of duty to follow up on the things you were not able to complete at the site? For example, if you were scheduled to work from 8 to 4:30 or something and then, you have stuff to follow up with, did you meet with the officers during off hours on or on the weekend to make sure those assignments were completed?

DD: Not assignments per say, because like I mentioned, when we were in the hospital, we didn't really have any responsibilities that were solely ours. We were just there supporting, but we did have regular briefings, yes, outside of clinic hours. How it was set up on that deployment was that the doctors all met to discuss issues and share experiences. The mid-levels had a lead mid-level -- and so this was this how our transition came about. In these meetings that we would have discussing our different experiences and what was going on, it was determined that they would take the three of us that were in the main hospital and put us into the smaller hospital or a more useful capacity than how we were being used there. So, it was more of a debriefing session than really finishing work. There wasn't work that really needed to be finished. All the work that was conducted was done on shift, and you didn't leave until the work was completed. Like for my particular post, I wouldn't go to lunch. I wouldn't go to the bathroom if there wasn't someone there, you know to relieve me. So, that was the type of work that we were doing there. In this deployment that I'm on now is similar. But there is some stuff that overlaps.

So, if we're not able to get in touch with a particular employee that we need to interview for risk assessment that needs to get passed onto the next shift. So, it's more of a shift change that we have amongst the PHS officers. We've initiated our own communication where we'll do a shift change email. And then, we also have daily a huddle with PHS, with leadership, and with the, occupational health civil service counterparts that are also working this program of contact

tracing and FDA, because it's an extension of the occupational, health department. So, we have what's called a daily huddle and that takes place at 12:00 every day. So, that is where the pass goes on. If there's something that the dayshift is working and they have not completed, then it gets passed on to me for the evening and communicated to me at the daily huddle.

JS: Forgive me for jumping in, Oumou. I just wanted to follow up that with just one question if you don't mind. So, Danielle the example you gave in Florida is a good one, but I image it could be very stressful deployment. And I'm wondering if there an opportunity to after hours, after the shift, to unload or just have an opportunity to share experiences and get some relief from those kinds of conversations. Did that ever happen?

DD: Oh, yeah, that happens, and I mean, for me and my experience, and I think just my personality, lends to that, because I'm more of a talker clearly. So, I've made work buddies with my counterpart, Dr. Reyes, who is also a PHS officer. And after we have huddle meeting and her shift is over and mine is beginning, very commonly, we'll text and/or if something major comes up or there's a big discussion about how we classified someone, or how we're documenting something we'll go and have our sidebar conversations. I'm a pretty easygoing person. To me, stress is relative. Yes, it's stressful, to have differences of opinion and when you're working with difference people -- like we've talked about, there's a hierarchy of PHS in rank. There's a hierarchy of medicine in your status or degree. So, navigating that at some times is difficult, and I think over the 18 years, I've just learned to be a much more flexible and let things roll. And I think if you're going to give assistance to others or try to give tips on how you can navigate these situations and these deployments successfully, I mean, that's one of the things

that's very high on the list that you must be flexible and try. You know, it's a lot of times easier said than done, but I try not to take things personally.

That's one way I could describe how I process the difficult parts. And if you get a deployment buddy, which is another thing PHS suggests, a buddy system. At times, you can have mental health briefs and vents sessions with your deployment buddy and it helps you get things off your chest and back to neutral. We all get stressed out, even in this current deployment, it's tough. I'm married to my computer. I mean, my computer is on 24/7. Mentally it's challenging. People say, "oh, that's great, you're working from home." But a lot of times, that's even more stressful than when you're deployed somewhere on site. Yes, I have the conveniences that I can still care for my children and I'm grateful for that. But I am married to this computer six days a week all day, and that's a lot. That's a lot to take on for some and it can impact mental health.

And when you're on these huddle meetings and people come from various backgrounds -- I come from a background in correctional medicine, where I'm taught to document everything and to cover myself and to make sure I show in my notes and in my documentations my thought process, so that if anything should ever happen, it's very easy to understand why I acted the way I did and what my intent was. So, interagency and within FDA, I feel like we might be working with more of the scientific practitioner than the actual practitioner. So, it is frustrating sometimes to not have people realize that or to say "well, it's documented, we emailed this individual, and we couldn't get in touch with them." And even though their supervisor reported it as hearsay and there are certain scenarios like that where I might disagree, with the approach, but I just have to take a step back and realize everybody comes to the table with their education and that's impacted by their personal and professional experience. And maybe they don't have

the same experiences that I have, and so that's where they're coming from, not to be difficult or not to just disagree. It's just they don't have that type of background. We're just different. So, I think that if you're able to step back and realize that rather than taking offense to someone disagreeing with your thought process, it makes the experience easier and flow much more smoothly.

JS: Thank you for sharing that.

OB: Thank you for sharing that, Commander. I completely agree with you. Virtual deployment can be challenging, because of the fact we don't have a limit. Sometimes, you feel like you can just take your laptop and return to something quick, and you end up spending hours on the computer. So, I believe you had mentioned for the Florida deployment, you interfaced with other health professionals. I wanted to also find out for that particular deployment, did you interface with other government entities or uniform service officers, like officers from different services, like Army or Air Force?

DD: No, I can't say the border deployment's that I've done outside of COVID, we had some Coast Guard, deployed with us, and DMAT deployed with us, but I've never had a deployment yet where I've had to interface with Air Force or Army specifically. I know that they're mentioning now that we may start doing that because there's going to be a larger effort for this vaccination, all hands on deck and I've just heard through the grapevine and even on TV and the media that they're deploying the military to help with this effort. But thus far in my experience,

no. My experience has included only other government agencies, CBP, CDC, immigration enforcement, and Coast Guard, and DMAT.

OB: Okay, thank you. And also, you mentioned that you felt like you had enough personal protective equipment for your deployment. I wanted to clarify, did you feel like your team had the same feeling? Did you have enough resources to support you to do your deployment? Did you and your team have enough resources to support you with your deployment?

DD: I felt it was sufficient. But again, this is my personal opinion. And I will qualify it by saying that I feel like there's a scale of fear for this. I'll say that there were officers that I worked with, even in the small hospital where it was like an outpatient clinic. So, we didn't see the sickest of the sick in this particular location. There were COVID positive individuals, no doubt but more the ambulatory, not like severely ill COVID. Still, you had officers that would change their shoes. They would change everything -- they seemed to me, in my opinion, very skittish about COVID. For me, I felt like if I was given a gown, I was given gloves, they gave me scrubs that I changed into. They were clean. I came into the facility. I changed into clean scrubs. I changed out of them. I didn't really feel the need to bring a different pair of shoes. Typically, I don't sit on the floor in the hotel room, and I wash my hands, so I didn't feel like I was going to catch anything from my shoes.

But we were at one point asked to recycle masks. At the main hospital, it seemed like they had an overabundance of PPE. I could get a different mask from the morning to if I went to lunch and took my mask off in the cafeteria, when I came back, they would give me a brand-new mask. No questions asked. But in the smaller hospital, was available, but they were more

conservative with use of the PPE. They had a cleaning service, where we had a bag system where we would write our name, put our mask in the bag, and they would rotate cleaning the mask and send it back to you. So, in the last two weeks, I probably used the same three masks over and over again. I know that they were cleaned for me on a rotational basis. But, nonetheless, I still had an N-95 mask to use.

There was, and overabundance of gloves, goggles that I had. Plenty of sanitary wipes to wipe down my workstation where I was at. So, I felt that was adequate. But again, I'm not overly skittish about COVID. I feel like taking basic precautions is good. Maybe I have more of a sense because I'm healthy overall if I got COVID, I feel I would be able to successfully fight it off, and it wouldn't be a major health risk for me. Others may have felt opposite than I I have felt, if they're more on the anxious side and overly cautious about mitigation for infection. They might have felt like cleaning of the mask was not appropriate or that masks weren't readily available for us.

[01:20:05]

We had to ask to get the mask. That was a different experience maybe that some people felt should have been more -- I know from speaking to officers that were on other deployments, and this is hearsay based on their report, that they did feel that the PPE was not what their expectation was. They did not have it readily available. I know one officer in particular who, because the size of her face is such that she fails all her respiratory fit tests. She has a very petite frame. And so, she's worked in the hospital before. Being a PHS officer, they would always give her special equipment PAPR (ph), and she had an experience where she was deployed and

actually had to wind up staying in the hotel and wasn't actually allowed to go on site to execute the duties of the deployment, because she didn't have the proper protective equipment with this PAPR. She was not able to have proper protection with the N-95 mask that they had available. So, I know that was very frustrating for her as a friend of mine and a fellow officer, but that was not my personal experience.

JS: Well, I wanted to go onto the question about comparing what your responsibilities are at FDA and the Import Operations Compliance Branch. With the deployments you've been on, to what did the FDA somewhat inform what was involved in your deployments? And also there was much that was so different too, I'm sure.

DD: Yeah, I would say, the job that I do with FDA typically does not overlap anywhere with what I do on deployment. It's completely different. At FDA I'm dealing with, compliance of imported products, so foods, drugs, and medical devices, dietary supplements that are imported from other countries, and how they meet safety and efficacy standards measured against FDA law. So, when I deploy, it's typically to do patient care, so completely different. The only time I feel like it's overlapped is because I have background knowledge working at FDA regarding emergency use authorizations.

So, a lot of times now when I'm answering questions from employees, even though we're not really, they want us as occupational health to become people's medical provider. That's not really the mission of the risk assessment and contact tracing. Our role is really for mitigation and to prevent the spread and give basic resources to employees, of course, that have medical information about COVID, but I don't give them recommendations as though I was their

community provider. But I've been asked -- you're interviewing someone on the phone for 30-40 minutes, and of course, they're going to start asking you, "well, what do you think about the vaccine and I've had the vaccine, but is there still a possibility that I could get COVID, and what about the new strains of COVID, you know?"

So, I've been asked these questions, several times, and this has been, for me, an area of contention personally and professionally while on this deployment because my interpretation is many of the occupational health hierarchy that the physicians seem to take everything CDC is putting out as very black and white. And CDC says you've been infected with COVID, you have immunity for three months, CDC says you've had a COVID infection but once you're out of isolation, you're able to get a COVID vaccine. There is no time interval per say that you must wait for that. I tend to be more cautious.

And again, I think it's partly because of my background in correctional medicine where I started as a medical provider, and I'm very hesitant to say anything with certainty. And I know that CDC is, a sister agency and we have officers that work there, and I definitely respect their work, obviously, but for me, as a clinician, I feel that there's not enough known about COVID, and we haven't studied it long enough. And there are new things coming out and different strains and I just don't feel 100% confident giving a blanket statement and saying this is what CDC says, so this is how it is. Because I feel like that could change, and it has changed, as this pandemic has gone on over the past year. There have been times where critical diagnostic or medical information or advice has changed.

So, in my experience, coming from corrections, I don't say anything to a patient unless I'm pretty much 100% certain, so I've been telling a lot of these people that I interact with, the employees that I'm doing the risk assessments for, when they ask me these questions and I'm

confronted with them, I've been putting a lot on their primary care provider. I've been giving the CDC website as a resource very frequently but tempering that with saying that this is the information that we have now.

And as a medical provider, I'm going to keep watching, because as this evolves, I feel like we're going to learn more and get a better understanding. I'm not convinced where we stand now when we say an emergency use authorization that has not gone through full clinical trials -- different steps have been taken to push the vaccine out and we'll hope for the best, but for me it's not a guarantee. And even if you're looking at what the companies are saying you're not 100% covered. They're not guaranteeing you're 100% covered with two vaccinations. So, you'll still have some level of risk. And then my personal feeling if we started developing these vaccines when this first came to light and they were modeling it after the initial strain of COVID 19, now that we have all these other strains, medically from your professional perspective, I don't know that it's, great to assume that this vaccine that was developed months ago will now be effective against these other strain types. How will you know that and how will you prove that? So, like I said, I've taken that piece of FDA, that piece of knowing what emergency use authorization means from the policy perspective, and that influences, partially, how I advise in a clinical perspective. That's been the first time that they've overlapped.

JS: Right. And actually, your earlier clinical experience, though, has informed and helped in many ways your deployments, I gather. And you mentioned when you were narrating the deployment in, Florida, how you encountered some medical officers or others that had been more involved in policy work or scientific work and maybe didn't have that clinical experience that would have been so helpful. And I guess what I'm getting at is I'm wondering if you have a

sense of when deployment decisions are made. To what extent, in your sense, these decisions made in putting officers in deployment positions are concerned with what it is they do at FDA?

DD: Are you saying -- I'm sorry, I'm missing –

JS: Yeah, sorry, I didn't articulate that very well. So, I'm trying to get a sense -- this would be your opinion or what your awareness of this is -- But, when decisions are made to deploy commissioned Corps officers, where they're going, what they're going to be doing, to what extent are those decisions are made based on what the officer present responsibilities are at the agency as opposed to what their professional category might be?

DD: This is strictly my opinion. I don't know, honestly, what goes on behind the scenes, but what I've seen over the years is that it looks like when you get an available officer it doesn't really matter where they're stationed or what their daily duties are. For example, are they FDA? Are they CDC? Are they NIH? I feel like if you need a medical provider, if you get a doc, or an NP, or a PA that you can put into this peg, that's what they do, and there's really not a whole lot scrutiny over what does their resume look like or what are their actual experiences. And, like I said, some of it was eye opening when we were meeting with these hospital officials, and they're having us go around the room and say what our experiences are. I made sure that I qualified, "Yes, I work at the FDA, but I also practice in the community two to three days a month to maintain my clinical skills, in addition to my former role with PHS that was 100% clinical." So, I wanted to make it known that I'm continuing with this clinical piece, and I think that's very important.

I think that now that, PHS is mandating and getting more serious about following up on that, your qualifying degree is something that you still keep current in order to be basic ready and in order to make promotion. I think it's important because I'm a big reader of body language and facial expressions and I've got to tell you that when we were in the room with those executives, we were getting like some really strange looks when you had people say, "oh, I've been a doctor for 10 years and I work in a lab." Now you're in a hospital, what are you going to do? We need clinicians that can do patient care. So, I made quite certain that when it came my turn, that I qualified that I still get my hands dirty, so to speak. Even though, I do this policy thing, I also keep up. So, I think that's important that they look at that and, that they continue to go in the path that it seems like they're going towards now that in order to be basic ready to deploy, you need to have clinical hours actually documented. I think that's a good thing.

JS: Right, no, that's helpful to know. I want to turn to your current virtual deployments, and ask if you might elaborate just a little bit about how this is carried out, how this work is done with the FDA's important, responsibilities for inspections, for going out and doing inspections, be they foreign or domestic inspections. So, logistically, how has this worked in terms of your involvement in FDA's role as going out and doing establishment inspections and making sure that everything is as safe as possible?

DD: I'm so sorry, can you repeat the beginning of that question? Are you asking if I'm going out personally and doing inspections?

JS: I realize you're not going out and doing inspections, but you are, carrying out COVID tests or involved in COVID testing or arranging for COVID testing of FDA inspectors. Is that correct?

DD: Yes, that's correct. That's, the COVID testing unit of the contact tracing program.

JS: Right. And so, you've been involved in this since October 2020. I assume this has been going on before then. But, can you give us a sense of how this is carried out? What your role is, and if there might be any, complements to what's going on in other deployments, or does this involve primarily just making inspectors ready for that part of that FDA's role?

DD: So, in October 2020, it was new. It was not going on before then. It's been myself and two other MDs the entirety of that portion of the program. What we did do is, once some of the restrictions were lifted and it was determined that a very small number of investigators were going to volunteer to continue basic FDA work of inspections, it was determined that certain facilities, because they're their own entities outside of the government have their own policies, and their policies were such that they wanted to protect their own employees by ensuring that our inspectors were negative for COVID. So, they required us to have our inspectors show a negative COVID test within three days of being on the facility for the inspection. So, that's how the program started.

And as it evolved, we started seeing the back end, where inspectors were being notified that they were exposed potentially, that the facility had a worker or someone that was accompanying them on their inspection found out they were COVID positive, and they had been

around them and had been around the same areas during their inspection that this particular individual may have been. And so, they were reaching out to notify them. So, then we started ordering tests, retrospectively for those employees, to ensure that they were safe and of course to ensure that if they were exposed and positive that they refrain from going into any FDA buildings to further spread to other employees.

I think that this effort is paramount to keep up whatever level of FDA activity we can. I don't think it's anywhere near what it's been in quote unquote normal times, but we still have to do high priority inspections, and investigations to ensure food and drug safety. That's still an important priority even despite everything with COVID. So, I think the COVID testing unit and the contact tracing program has definitely been instrumental to keeping that mission critical work going.

What they're also going to do as we're expanding, and more areas are opening up and getting to tiers where things are not completely closed down is to test any FDA employee that is working on site as screening precaution. There's talk of a return to facilities, testing program, which will be born out of the COVID testing unit where employees who are on the return to facilities approved list will have the ability to randomly test for COVID every two weeks. Again, in hopes to ensure as minimal spread as possible and then also giving these employees reassurance that when they go home to their families, they're not bringing COVID there. So, it's helping at FDA, as well as the communities that FDA serves.

[01:39:45]

So, that is my description of that program, and the risk assessment is the backend also for mitigation purposes when you have an FDA employee who is living their life and goes to a small family gathering and finds out that their brother or their sister, who was at the gathering, is positive for COVID and they spent the day with them or spent several hours with them and now they're doing FDA work, they have to come back into the office and do their work. Well, the contact tracing unit is set up such that we can try to stratify this person's risk. We don't force people to get tested in this capacity. The program itself is voluntary, but the intentions there are to minimize the spread of COVID amongst FDA employees, you know?

JS: That's very helpful. A couple of things I wondered about. Does this involve both foreign and domestic inspections, and how have the numbers changed since this started with as you said the small group of volunteers in October, and have the numbers grown noticeably?

DD: My impression is that, yes, it has grown. The inspections are foreign and domestic. It's essentially anything that the firm would require. So, if a foreign firm -- I know in my last role as primary, I had two investigators who were traveling to Japan and I had to fill out, some Japanese customs clearance forms in conjunction with the Lab Corps test report. You know, we ordered them the tests, they were negative, but then I also had to sign a form that we had cleared them. And, of course, this went through leadership of the COVID testing unit and contact tracing program, but for them to come back into the country because there's all sorts of travel advisories. I believe there is a travel coordination group who typically organizes travel for these foreign inspections and what not, and coordinates things that the employee might need to do in order to travel to and from the country where they are going on inspection.

So, the travel advisory requesting that they tested in Japan was orchestrated through an entity outside of the contact tracing unit program. We just gave them the clearance, the pre-inspection clearance, and then a different entity. I wouldn't know where to tell them to get tested in Japan or how they would supply me this information, because there's a lot of concern and caution around the whole protection of privacy with respect to these tests as well. There's like a coding method that we use. We don't usually refrain from emailing any type of personal information whatsoever. We don't email test results. We don't share any personal information via email, to protect the employee's privacy. So, for those reasons travel organization or travel department of FDA would help them with the travel advisories for reentering the country after their inspection.

JS: Right. One of the things we're hoping to try to capture through the eyes of the officers like yourself who have been deployed is to get a better appreciation of the patient experience during this, because clearly, you've seen that up close and in person. So, I wondered if you could say a bit about -- of course, we've not looking to get any privacy or personal information of those that you've been in contact with -- but we are curious about the patients and their families that you've been involved with. You know, what sorts of concerns did they express, to you either, literally or figuratively, I suppose? And if you have any stories to tell of encounters that you had on your deployments that might help us capture that, that would be terrific as well.

DD: Well, definitely the main concern with the COVID deployments was the separation piece. And there's a lot of mental health areas that get exposed when you have these individuals who are really sick. Usually, when you think of yourself being very ill, you think of family rushing to your support and being at your bedside. But of course, COVID has changed all that. I have in

the deployment specifically with Strike Team 13 in the hospital in Florida, I've even had people coming to the emergency department and the wife is pregnant, she might not necessarily have COVID, but she's experiencing some pregnancy complications, some bleeding, and she comes with her partner, significant other, husband, or what have you. And, of course, he's also equally concerned because this is their child and is concerned for his partner. But you have to do your best to calm the person down and apologize that it's such a difficult time right now that they can't be together and just reassure that you're going to follow up. And as soon as information is available, you'll be able to share that, make sure that your wife or significant other has their cellphone. She'll be able to call you. She can facetime you, but unfortunately, you just cannot be physically with her right now. You have to wait outside the hospital.

So, that's tough. It definitely puts you in a tough position and emotions are high with stuff like that, and the same when you have elderly people, and their children want to be with them. And even in my experience in primary care, I've had patients pass out that are COVID positive, that I know are COVID positive, they're elderly, and we had to send them to the hospital and emergency vehicle -- call EMS, because they were passed out. And it's very, very high emotion when you have a child there, even if it's an older child. When I say child, this child was in their 40s. So, it's still very hard, and people's ability to handle stress is different. I think you have to recognize that, and my experience in Corrections helped me with so much of the patient care experience because you learn how to read people, body language eyes, tone and definitely have a lot of exposure to people who are suffering with mental illness and extreme stress. So, it makes it easier to spot those things, and the de-escalation techniques that you learn and adapt into your clinical practice, I think are very useful in these types of situations and these deployments.

Another very, very clear example that I can give was my deployment in El Paso when I was at the border, and there were so many younger women in their early 20s. Some with several young children under 5, which is not the best of circumstances. As a mother, I don't even know how I would deal with that. Let alone not having a home, not knowing where your basic necessities, food, shelter, are coming from, not having much money, not speaking the language, being in a detention essentially jail looking like environment. It's extremely stressful. And then adding illness on top of that. When you have a child who is very sick and they're constantly crying and you can't do the things that a mother would typically do. You can't give them a warm bath. You can't give them clean clothes. You can't give them their favorite bottle or their favorite food. You can't even really give them a dark room to take a nap when you're in a room with 50 other people. You know it's the most stress anyone could probably endure, as a mother in that moment.

So, for me, bringing them to the clinic, giving them a little bit of reprieve out of a room full of so many people, overcrowded, high stress and tension, making sure I reassure them that their child is going to be okay. Giving the child a little bit of maybe extra juice or a sweet cracker or a cookie, something just to be human to that person. You know, part of our job is to be clinical and make assessments. Does this person need hospitalization? Is this something that can be managed outpatient? Is there going to be a bad outcome from this? That's part of the job. For me, the other part of the job is doing what I wanted to do since before I went to school to become a PA, and that's help people. So, I think if that comes across in how you are and even if it's just a small token like that, that is nothing for me, to give. And it made this mother cry and say "thank you for being nice with me. Thank you for treating me like a human." That's extremely rewarding. That was probably one of the most rewarding deployments of my career in

PHS. So, when people are that desperate, primarily you're there to give them medical care, but part of that is doing what you took the oath to do, and that's to help people.

JS: Thank you.

VB: Danielle, it's completely heart wrenching listening to you describe that, and it makes me feel grateful that you were there to help that family out. And I just can't help but think back to last February and how little we knew about COVID then and how difficult it was to even anticipate what was coming down the line. And I wonder if in your interactions with patients, if you had difficulty conveying to them the severity of the situations or, if there are any particular obstacles in terms of health literacy, but just confusion about what the stakes were in this new pandemic when there was just so much uncertainty?

DD: I think that's anybody, not just on deployment. But I think that's anybody in medicine right now. Like I said, even in my clinical practice outside of PHS you have the gamut. You have people who are scared to death to go outside, that won't come in my clinic. I have to walk outside and do their visit in their car, because they're deathly afraid of going anywhere where COVID might be. And then, you have the opposite, that they believe that this is a "plan-demic," this is not real, the numbers are overinflated, they're labeling people dying and actually they're dying of other things. They're just having a positive COVID test, so they're blaming it on that, and I just try to do my best by my patients and say, look when you have a difficult person like that you need to approach it the right way. I feel like this is where people skills come in.

What I believe is what this person believes. I have to meet them where they are. As their medical provider, if I'm going to have any level of success with them and positive outcome and

just try to temper it with what we do know or what's current. Always give resources. I think when you affirm what someone believes and say "I understand what you're saying and how you feel, but maybe think of this perspective or let me share this experience with you that I've seen so that I can help you and help you maybe avoid, some heartache for you or a member of your family. Because you might not be seeing this as serious as it can be. And yes, there are many people who will get this, and it will be a cold. But the scary thing is, is you really can't tell who those people are."

You know, very early on, they said, "oh it's going to be elderly people that have poor outcomes, clearly, because they have all these other comorbidities, and their immune system is weakened with age, and all those things that we know from our medical education." But then slowly, stories started coming out where you would see 30 year-old mother of three, previously healthy, not on any medications now hospitalized with COVID. To be a firefighter, most people know you have to be in good health. You've got to be fit. You must be able to endure physically, so you have to be in great health.

So, seeing this disease take a strapping, healthy middle aged man down to being on a ventilator and fighting for life, it makes you wonder. And I always try to describe that level of uncertainty to my patients because I think that's where we are. In my opinion, we still don't know enough to give certainty about much of this. And I just say for right now, you have to practice all precautions because you just don't know. It might affect you like a cold, but it might not. And if I'm giving you the best advice, that is to protect yourself as best you can, so you can avoid that whole scenario and not have to find out eventually.

It just involves a lot of discussion. This is what I feel separates good medical providers from mediocre medical providers. It never ceases to amaze me that, -- you know we work for

FDA…with a lot of highly scientific people. But they don't know how to relate. And I mean, you could be such a smart person and you could memorize everything on that CDC website, but you're not able to relate to people and you're not able to get your patient to trust you, then a lot of that information is lost, in my opinion. And I feel like that's maybe where I've been able to shine a little bit, because I do still have that clinical piece and I didn't start out in policy. I didn't start out as a policy pusher or a policy maker. I started out as a clinician, and that's what's in my heart, and I still try to keep that.

VB: You know, it occurs to me that as someone who was deployed so early in this crisis and has been in deployments several places across the country throughout, you've got the unique ability to compare both across time and across regions, experiences of the pandemic. And I wonder if you have any insight into what the experience or the public perception of the pandemic is like in Florida versus Texas versus California, or from February to now?

DD: That's a loaded question. So, I definitely think that there is so many factors that impact people's perception of COVID, and this is not popular, but I definitely think that politics play into it, and that stereotypical persona of certain political parties definitely plays into your perception of COVID and how serious it is. And again, I've had patients from both sides, so you try to have to meet them where they are and then try to find a middle ground to what is the best current knowledge medically that we have. I think in the beginning, people were very scared because of what they saw on TV. And then, I feel like there might have been like a little bit of a lull.

[02:00:00]

And then, once numbers started to increase here, within a few months, I think the panic and the level of fear rose again, and then people started to be like "what is this? What's going on?" Everybody was scared to go places, to be around family, to even go into the grocery store it seemed like it was a major undertaking in the beginning of this pandemic.

So, I definitely think it's evolved over time, and I think it's dependent on the person. And definitely, what I'm seeing from this COVID testing is that we've got FDA offices all over the United States and it comes to my knowledge that there is a gap with your resources that being from California, I don't really ever feel that or realize because I could drive down the street and get a COVID test. And apparently, there are people that are in Arkansas that they might have driven an hour just to get a COVID test, so they're trying to tough it out at home. So, different things like this I feel like have an impact.

I don't feel like it's necessarily the same all over the region. I definitely think that the bigger cities and states like New York, and California, and Florida that have larger population numbers, obviously they're larger hit, but they also have greater resources. So, the people who are in the smaller towns, just because of how we travel it's made its way there, but it might be more difficult for them, because they don't necessarily have all the testing resources and just resources that we take for granted living in big, densely populated cities, that we have all these things at our disposal readily, but not everyone has that experience.

VB: It's almost hard to remember at this point, but I remember over the summer and going into the fall, FDA was very active and the White House Coronavirus Taskforce and so on and so

forth were very active in trying got encourage different regions to adopt what they called common sense public health measures, washing your hands, and social distancing and stuff. And I think we've come a long way with that. And I'm just curious, like did you have to convince any patients along the way of the prudence of common-sense public health measures?

DD: I don't think so. Not in the sense of my deployments, no. Maybe, if anything, on my first deployment I tried the opposite. Like I would try reassuring some of these CBP officers you don't have to get a case of Lysol and spray down everything. You're going to make yourself sick with the Lysol, you know? Just keep your mask on change your gloves, wash your hands, and don't get too close to people, you know? Don't use a whole can of Lysol on every single one that comes in the room, you know? But in the hospital, of course, and at the height of the virus and the infection, the pandemic, in July and August, I don't think you needed to convince anyone in that particular environment that this was a serious thing. Most people were there because they were pretty seriously affected in one way or another.

VB: So, a while back, you mentioned this current deployment is going to end shortly and you're back in your normal tour of duty, and then you'll be deployed again. How are you preparing for the transition and what do you need to put in place once you're in your normal tour of duty and are you going to be handing off your current deployment duties to anyone in particular or have you not been notified yet?

DD: I don't know who the person will be specifically, but the way they have the contact tracing program because you really have to use all of the different portals, and there's a specific

way you have to document in order to preserve privacy. I did a day training that went through a classroom type setting with PowerPoint lecture and then I spent two days with the outgoing clinician to go through real life examples and see how it would actually flow. So, we'll have that same turnover. I just don't know who the person is yet that will overlap. So, the last two days, Monday, and Tuesday, I will be essentially training my relief, my transition. So, I'll be sharing things that I've learned and different scenarios just like was shared with me before I started.

And then as far as the transition, it's been a little difficult this time, because I just started my job with headquarters a month ago. In January, I started, and I wasn't even there for four weeks before I was pulled to this deployment. So, I'm still learning the ropes, so to speak, at my new job and my new role. So, that's been tough. And how I'm going to deal with it is I'm just going to have to push on. When I get back, I'm going to have to probably ask questions and relearn some things. This deployment didn't come at an ideal time for sure, but I was thankful that new supervisor was supportive, and she understands.

And the few times where I have had a little bit of downtime, I actually try to keep my head in the game and continue moving forward with some of the projects I was working on before I left, but I'll just have to make up for lost time and pick back up, and it will be a little bit of an extra challenge, because I'll have to start the COVID testing unit primary again in less than two weeks, on April 1st, I'll be starting that primary role. And that'll be done in conjunction with my main job. So, it's a lot. It's a lot of responsibility and then, of course, like I mentioned, I still do clinical twice a month. So, often times, I feel like I'm being pulled in a lot of different directions, but I've just become accustomed to multitasking as an officer, and I'm used to it at this point.

VB: In your new position, are you I imagine still under a program office in the field? I don't know if you still report to a district officer under the current circumstances. But is there somebody in the matrix that is taking on some of your own duties or keeping some of your projects moving forward that you're in contact with or that will pass those duties back to you? Like, do you have a relay, so to speak or do you just have to dive back in on your own when you return?

DD: The nature of my work now, is done independently, so I'll just have to dive back in. And I don't know how much you guys know about import operations, but basically, I'm in the import alert effectives program. I'm one of a small team of three that are revising these policies that the field using. So, I mean, it's important, but it's not urgent like it needs to be done tomorrow. It's an ongoing thing. And when you start it, the duty is such that it's likely you have to finish it. No one could really jump back in and do mine.

I don't know how to describe it, but when you're working on writing a policy, it's like if you're not in my thought process, you're going to have to do all the work over again a thing. So, this type of work does lend itself in certain ways to being able to deploy, because you can press pause on something like this and just pick back up. It's important, but it's not urgent. It's not 100% time sensitive. I mean, there's a time period where they would like for it to be done. It's not like this must be done next week or someone else is dependent on my result from this in order to be able to do their job tomorrow. They can continue to do their job. What I do is just going to enhance their ability to do it. So, if it takes a little longer for us to get there, that's okay for the time being.

VB: Got it. Well, I feel like we're drawing to a close of our conversation, and I just wanted to give everyone else an opportunity to raise any questions that we may not have brought up yet. If anybody else has anything they want to ask? Or Danielle, if you have any other issues that you think we should raise at this point?

JS: I do want to thank you immensely, Danielle, for participating in this. You've really shared, I think, experiences that those want to know what FDA did and what the people of FDA did in response. There's a lot they're going to learn from this, so I really appreciate that.

DD: That's good to know.

VB: As do I. I'm going to end the recording now.

[END OF INTERVIEW]

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