FCON COVID-19 Deployment
Oral History Interview
CAPT Postelle Birch-Smith, PharmD
and
LCDR Ashlee Janusziewicz, PharmD

FCON History Committee
FDA History Office
Collaborative Oral History Project
Edited Transcript
Date of Interview: April 29, 2021

Table of Contents

Oral History Abstract

In this interview, CAPT Postelle Birch-Smith and LCDR Ashlee Janusziewicz discuss their deployments as Public Health Service officers who are in the USPHS Commissioned Corps in response to the COVID-19 public health emergency. CAPT Birch-Smith is a pharmacist with the Compliance Compounding Team at FDA. She was deployed to the Secretary's Operations Center (SOC) early in February of 2020. There, I was tracking the COVID-19 cases in the United States and supporting the operations side of the SOC. In April, Birch-Smith served on a split deployment to Washington State and then to Detroit, MI, where she served as the Chief Pharmacist at a COVID hospital set up in the Detroit Convention Center, dealing with patients who had been diagnosed with COVID and elderly patients who were being released back to nursing homes. LCDR Janusziewicz, a Pharmacy Officer at the FDA in the Office of the Commissioner, deployed to San Antonio, Texas in August 2020 to work with the Operation Warp Speed program on the convalescent plasma national stockpile for COVID treatment. She later deployed to the Commissioned Corps Headquarters where she served as the Rostering Team Lead in the logistics division.

Keywords

Commissioned Corps; convalescent plasma; COVID-19; deployment; Detroit, MI; Operation Warp Speed; San Antonio, TX; US Public Health Service; Washington state

Citation Instructions

This interview should be cited as follows:

"CAPT Postelle-Birch Smith and LCDR Ashlee Janusziewicz Oral History Interview", FDA History Office and FCON History Committee, U.S. Food and Drug Administration, Department of Health and Human Services, April 29, 2021.

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

Index

Interview Transcript

VB: This interview is a contribution to the FDA Commissioned Officers Network and the FDA History Office's collaborative oral history project to document the deployment experiences of PHS officers. Today, we are focusing on Therapeutics Logistics in the COVID-19 emergency response, and we are speaking with Captain Postelle Birch-Smith and Lieutenant Commander Ashlee Janusziewicz. I am Vanessa Burrows from the FDA History Office.

JS: This is John Swann from the FDA History Office.

LP: Hi, this is Captain Laura Pincock. I work at FDA within CDER. My role in this particular project is with the PharmPAC History Work Group.

VB: Captain Birch-Smith, would you please introduce yourself?

PBS: This is Captain Postelle Birch-Smith. I am an acting team lead in the Division of Compounding II in CDER.

VB: Thank you very much. Lieutenant Commander Ashlee Janusziewicz, would you please introduce yourself?

AJ: Yes. Hi, good afternoon. This is Lieutenant Commander Ashlee Janusziewicz. I'm a Pharmacy Officer, and I'm currently stationed at the Office of the Commissioner in the Office of

the Chief Scientist. I manage the government employee ethics training for all of the FDA's special government employees associated with advisory committees.

VB: Excellent. Thank you very much. Before we get into any discussion of your deployments, could I ask both of you to tell us a little bit about your professional background: how long you've been at FDA, how long you've been with the PHS, and any other details about your career that you think are relevant to share?

PBS: Yeah, I can go first. This is Captain Postelle Birch-Smith. I have been a United States Public Health Service Officer for 22+ years. I started my career as a psychiatric pharmacist at St. Elizabeth's Hospital in Washington, DC in 1998. From there, in 2003, I moved to the FDA in Silver Spring and worked in the Office of Generic Drugs as a Labeling Reviewer. I've also worked in the Division of Training and Development, which is now the Division of Learning and Organizational Development. From there, I moved to the Office of Compliance Compounding Team in 2012, and I've been there ever since.

JS: Thank you. And Lieutenant Commander Janusziewicz, could you also just share your background?

AJ: Yeah, sure. I became commissioned back in 2010, so we're going on 11 years of being commissioned in the United States Public Health Service. I initially started in 2010 in the FDA's Center for Drug Evaluation and Research in the Division of Training and Development.

I actually worked with Captain Birch-Smith in two of my previous roles in the agency. There, I managed the Continuing Education Program, specifically the Scientific Rounds Program that's held biweekly at the FDA campus. And then, in 2013, I moved within CDER to the Office of Compliance's Office of Unapproved Drugs and Labeling Compliance, where I started out in the same team as Captain Birch-Smith, where we were investigating compounding companies and looking at inspection reports and writing regulatory actions.

Then, I moved over, within the same office, to doing review of adverse events and complaints for compounded products. And I built up an entire branch for that program. Then, most recently, last year, I switched to the Office of the Commissioner, where I now deal with the advisory committee management.

JS: Terrific. Thank you. Thank you both very much. We'd like to begin, and this interview will go into some questions about the details of your deployments and other issues relating to those deployments. I wonder if we could begin with you, Captain Birch-Smith. If you both could tell us the approximate dates, the locations, and, in one or two sentences, what the nature of the deployment was, what your responsibilities were, just a very brief look at that before we get into the detailed questions. So, Captain, can we begin with you?

PBS: Yes, I've been deployed twice, on two separate COVID missions. The first one was at the SOC early in February of 2020. There, I was tracking the COVID-19 cases in the United States and supporting the operations side of the SOC. That deployment lasted two weeks. And during that time, there were very limited COVID-19 cases in the United States, so it was a very

brief deployment. Then, after that, I was deployed in April, most of April and part of May of 2020, initially to Washington state to support with COVID-19 cases.

That mission split, and it was requested that I move to Detroit to serve as the Chief Pharmacist at a COVID center in the Detroit Convention Center. That mission lasted 30 days. We had two weeks of isolation to ensure that we had not developed COVID. At the Detroit Convention Center, we were in-taking patients who were diagnosed with COVID, elderly patients who were going to be discharged to nursing homes in the Detroit area. At that time, the COVID protocol was a lot different; we were actually waiting for them to test negative for COVID. So, it was very interesting.

JS: Just a quick question: a follow up. How much time had you spent in Washington, and was that going to be the same responsibility there as you had in Detroit?

PBS: Yeah, I was going to be the Chief Pharmacist in Washington State and, like I said, the mission changed. I was there about two or three days, and I was sent new orders to move to Detroit and support Detroit in setting up the COVID clinic. It was actually a COVID hospital in the Convention Center in Detroit.

JS: Okay, thank you. Lieutenant Commander Janusziewicz, what about your missions: the locations, approximate dates, and general assignments that you had?

AJ: Sure. So, my first COVID mission began August 24th, and it lasted a month. I was deployed to San Antonio, Texas to work with the Operation Warp Speed program on the convalescent plasma [national] stockpile for COVID treatment.

Most recently, I was deployed to the Commissioned Corps Headquarters from January 31st to March 6th to work in the logistics section [of the command cell], specifically doing rostering. I was the Rostering Team Lead, and I reported up to the Logistics Chief and the other Section Chiefs to give them updates on what the processes and statuses were of the current rosters that were being worked on. And I'm actually getting ready to deploy there again, coming in the next few days.

JS: Okay, thank you. Thank you both very much. Captain Pincock, would you like to take over?

LP: Sure. Thank you. I really enjoy hearing about all the interesting variety of deployments that our PHS officers undergo. On your actual orders to deploy – there's actually two parts to this question for each of you. Do you have any insight into how your assignment was determined? And then, what input, if any, did you have into your specific assignments or duties? So, the first part is: how was your assignment determined? The second part was: what input did you have into that duties or assignment? We can start with Captain Birch-Smith.

PBS: So, the first part of the question was: how was the deployment determined?

LP: Your particular assignment in the deployment.

PBS: The first assignment to HHS headquarters, I had no input. It was actually my roster month and I had absolutely no input. The second deployment, I was rostered again. I did not have input. However, I was briefed on the mission when it was requested that I serve as Chief Pharmacist, and, of course, I said yes. I believe I've answered your question. Is that what you were looking for, Captain?

LP: Yes, thank you.

PBS: Lieutenant, I have one other, as far as the transfer to Detroit, there were two Pharmacy Captains who were going to be the lead. It was me and Captain Smith. Headquarters actually called us both and described the mission to Detroit and asked us, would one of us be willing to move to the new mission? I volunteered to leave Washington State and go to Michigan. So, I did have a choice of whether to stay in Washington or to move to Michigan, and I ended up in Detroit.

LP: Okay. Thank you very much. Lieutenant Commander Ashlee Janusziewicz?

AJ: Sure. For my first deployment, which was the Convalescent Plasma Program, I know prior to getting assigned this deployment, I was contacted multiple times. First, about being deployed to Headquarters. Then, second, about a contact tracing deployment. Then, third, I got this one.

When I first got the call to deploy, I wasn't exactly sure which deployment it was for, but once I got on site and we learned about the different duties, due to my background as a healthcare provider, the rest of the people I was deployed with were all HSO category. So, when we got there, I fit more into the role of fielding calls that were coming into the donation center because of my background. So, I did get to choose a little bit there in terms of what my assignment was.

Then, with my role at Headquarters, which was by recommendation with somebody that I had worked with previously. I did not come in volunteering to be the Rostering Team Lead, but I think due to my experience in the past with supervising, they had recommended me. And so, I just kind of fell into that role.

LP: Thank you very much. So for both of you: when you think back to this time when you were first contacted about deploying, and for Captain Birch-Smith, talking about your first deployment, if you put yourself back in that time period, could you describe to us what your concerns were, or what your knowledge of the public health emergency was at that time, and if you had any particular worries about departing on this mission?

VB: We may need to skip Postelle; she texted us or chatted that she's off to the restroom. Maybe we could go to the Lieutenant Commander first.

PBS: I'm back, but I would need the question repeated. So yes, if Lieutenant Commander Janusziewicz could go first, that would be great.

AJ: Sure. My first deployment was closer to the end of the summer. At that point, I think we had known a lot more about COVID, and they were also getting ready to gear up for the vaccines; they were already in clinical trials. I didn't really have too many concerns with deploying, especially because before I left, we had the rare opportunity to meet with the team we were replacing that had been there for 60 days. So, we had the opportunity, before we left, to have a pre-mobilization call. We got to talk to the people that were on the ground that had been doing it for a while to just get an idea of what we were walking into. I felt a lot more comfortable with that.

I will say, the only nervous thing was, prior to this, with everything being locked down and the kids being kept home from school, I was still leery. This was my first plane ride, other than just being in my own individual vehicle with my own family. That made me a little bit nervous in terms of exposure, but once we got there, we were surrounded by other staff at the facility that were wearing masks. You could go down to the donation center where people were coming in, but most of the people coming in had just recovered from COVID.

They had protocols in place that you had to have so many days since you either recovered or since you got plasma yourself. I felt like the level of risk was pretty low. My only concerns were, this was my very first deployment, boots-on-the-ground. It was just a matter of getting over the hump of leaving my two young children, and having school starting up again, and those kinds of things. But that's it.

VB: Thank you for sharing that. Just to repeat the question for you, Captain Birch-Smith. I was just wondering if you could think back to the period of your first deployment and, when you

were first told that you were going to be deploying, what your impressions of the pandemic were at that point, and what particular concerns you might have had about going on this mission.

PBS: Yes. During the first deployment, we weren't even wearing masks. It was February. If you all remember, the Diamond Princess had the COVID cases, so it was very new. Here in the United States, we had very little evidence of a large quantity of Americans being infected with COVID-19. However, during the second deployment in April, the cases had risen greatly. Detroit was a serious hotspot. At that time, I had learned a family member had recently died from COVID, so my level of anxiety was a bit high, and my family was a bit nervous, as well. However, when I arrived in Washington, as well as Detroit, there were really well-thought-out safety precautions taken to protect the PHS officers that were there.

[00:19:57]

I recall a discussion when we were setting up the pharmacy, because we had to set the pharmacy up from scratch, which was something I had actually done as a psychiatric pharmacist. So that was fun. There was a debate regarding whether the pharmacy would reside in the hotspot. The hotspot was the area, directly, where the patients were being cared for. We went back and forth a lot and until we figured it out, because at that time, there was a problem with getting PPE. PPE was like platinum at that time.

Our argument ended up being: if we go into the hotspot, then we will use more PPE than what's needed, and we actually set up systems to reduce our interaction with the hotspot. We were only going into the hotspot maybe two or three times a week, and only one person would be

designated to go into that area. So, one person would be required to don the PPE that was required for the hotspot. Other than that, everyone else pretty much stayed out of the hotspot. The precautions were there. We were all comfortable.

PHS was in charge of the dining area. We were the lead group, because my mission we did as a collaboration with the Detroit Department of Health, which made the mission pretty unique, because it shifted our standard PHS pecking order. All decisions were made as a collaborative effort with the State, and the State was the lead. It was not PHS. I worked directly with a pharmacist there, one pharmacist from the City of Detroit, so my anxiety level quickly dissipated as the mission moved forward.

VB: Thank you so much. Captain Pincock, did you want to take over from here?

LP: Now, we'd like to talk a little bit about each of your deployments in chronological order, a little bit more about the day-to-day activities. Lieutenant Commander Janusziewicz, please explain your role in Operation Warp Speed working to stockpile the convalescent plasma. If you could, describe your team and network during your deployment. Was the incident command structure impacted with the White House's leadership with this effort?

AJ: Sure. We were replacing a team of four. The previous team was also comprised of four HSOs, and then our team was three HSOs, plus myself, as a pharmacist. When we arrived on site, there was normally a morning huddle. The location that we were at was South Texas Blood and Tissue Donation Center. The morning huddle was attended by various donation center staff, including nurses, the Donation Room Manager, and the Plasma Program Director. The meetings

were led by the Center Director. He would provide us with [corporate based updates (including any recent changes in government regulations) and] the convalescent plasma totals from the day before, just to see where we were tracking in terms of donations.

Then, we would discuss any updates in processes and any challenges. When the team prior to us first started there, the donations were very low. The number of people they had to call for donations was also very low. The team before did a lot of groundbreaking work in terms of building up the call list, but what they were using was literally a spreadsheet. It was called a Smartsheet, but we joked the entire time that it wasn't very smart, because you would make changes in it, and it would never save. It caused a big headache for everybody. But during those meetings, that's where they would give updates on the goal of having either a new system to be used, or changes and how we were supposed to utilize the Smartsheet.

We would also break after that meeting to start working for the day. Three of the officers of our team were assigned in the call center to be calling potential donors, or, for those donors who scheduled a donation, to just call them and remind them about their scheduled donation. Due to my clinical background, I was selected to field calls that were coming in about convalescent plasma donation. So many of the calls that we received resulted in someone wanting to go through the qualification process, so I would work with them to provide the appropriate documentation.

Then, I would go and work with the Center's nursing staff to clear and qualify the donor. I would contact the donor back to talk to them about what their screening resulted in: whether they could donate, whether they couldn't, or if there were additional steps that we needed to take.

In addition, there were some other ad hoc duties that we kind of thought, with our background and our experience, that we would be helpful with. One of the things that I like to

do is, I like to have a lot of organization and consistency in terms of the processes that we were following. Near the end of our deployment, they ended up hiring some temp staff to come in to basically replace us and to work the call center. And we were responsible for training them.

Part of the training is a lot of the staff that came in didn't have any public health background. No healthcare experience. Most of them had either drawn blood, they were phlebotomists, or just had done desk jobs before. They didn't really know any of the technical terms, or how to answer a lot of these questions coming in. So, I created a sheet based on a lot of the common questions we were getting and how to appropriately respond to those.

Another thing that we were coming across was, there were four of us calling. Whenever I wasn't answering the phones, I would be calling out, as well, to try to get people to come in and donate. We were basically calling through the Smartsheet; we were running out of people to call. So, I was working with the Outreach Coordinator at the Center to start contacting more healthcare facilities in the area to make sure that they're aware of the Convalescent Plasma Program, why we have it, and what it's used for.

We were able to get in contact with five of the local medical centers that were then going to help spread the word. They were going to put it in their newsletter; they were going to put flyers around the hospital and the medical center. It was a teaching hospital. That was basically our day-to-day duties.

LP: And the last part of that question was: was the incident command structure impacted by the White House's leadership of this effort?

AJ: We unfortunately didn't get a lot of that clarity, in terms of how Commissioned Corps Headquarters was working with the White House. It did feel a little bit frustrating at times, because I felt like if Headquarters or the White House really knew what was going on at our level, they might have wanted to intervene at some point. Especially with one of the officers on our team who actually has a lot of lab experience, [who was not being utilized in the lab, where there were issues].

Another one of the big issues that we were finding during our deployment is, a lot of the people coming in to donate needed to get certain blood tests done before they were cleared for plasma donation, so they would come in to get their blood drawn. Then, the laboratory, which was literally at the same facility within walking distance in a separate building [would be responsible for testing the samples]. Their laboratory was so backed up that a lot of the samples that were collected could not be used, because they had expired.

We had to call these people back, to come in to re-give another sample, in order to qualify them to donate. We kept saying to the staff there that, "Hey, we have an officer who is very qualified to work in a lab, who can assist you, whether it's to see if there's any inefficiencies or just to even help with workload." The entire time, they just kept him on calling people on the phone.

I think there was definitely interaction with the White House and it was driving the whole reason why we were there. The team previous to us was there for 60 days, but I'm not sure how much they knew, in terms of what we were seeing versus what the place that we were working for was telling them.

LP: Okay, thank you. Captain Birch-Smith, could you explain logistical concerns that you dealt with in February 2020, that was your logistics deployment, and with whom you worked with to confront these issues?

PBS: Honestly, there were no logistics issues. As I stated previously, COVID was pretty new. We had a set schedule; it was pretty straightforward. We replaced two officers and they had it running like a well-oiled machine at that time. There wasn't a lot going on. Again, I didn't have any logistical issues at all with the first deployment.

LP: Okay, thank you. Now, for the Detroit COVID Center deployment, what was the general situation like in Detroit? Keeping in mind there were larger-community public health concerns, such as with the water quality, et cetera, beforehand, were there any local unique local factors that impacted the response?

PBS: I am unaware of any local factors that – well, let me go back. I stated before that this was a collaborative deployment. So, we were working with the Detroit Department of Health. We also worked with the Army National Guard, and we had USPHS officers together. Establishing the chain of command was a challenge because, as I stated before, United States Public Health Service was not technically the lead. So, our decision-making, and even our requests that were made throughout the mission, they followed a different chain of command than we are used to. And it did offer a little bit of confusion at times, with the officers, because, of course, we're used to being lead and doing things our way. But we adjusted, we adjusted.

LP: Captain, I just have a follow up question, if I may. This kind of goes to where you started out on this deployment and where you ended up. You mentioned that Detroit was a COVID hotspot. Was that the same case with Washington, where you were in in the state of Washington at the time?

PBS: Yes, yes. The initial mission was to support one of the hospitals in Yakima. There, it was definitely a hotspot. However, the mission was not clear, and, actually, those officers who went to Washington, a lot of them did not even get to go to the hospital for those days. So, there was a lot of disconnections. I don't want to say anything wrong, but there was not great communication with the Washington mission. And this is what I learned after I left. So, yes, I'm speaking post-Washington for me, because I remain in close contact with some of the Pharmacy Officers who were in Washington.

JS: I mean, are you referring to in internal communications within the Service, or with state authorities, or…?

PBS: It seemed to be all the way around, but I don't want to speak too much on that, because again, I'm coming from a secondhand perspective.

JS: Okay.

PBS: So, as I stated, I was only in Washington for two days, and one day was just to get boots on the ground. And then the next day, it was requested that I move to Detroit, so I didn't spend a lot of time on that mission, personally.

JS: Okay. Thank you. If I may, just regarding the first deployment, what sort of epidemiological or other things were, and you referred to the SOC, what were you looking at when you were stationed with SOC in that first deployment? You were obviously casting about for what was happening with COVID, but I wondered if you could just give a little bit of a sense of how you were doing that, as part of that deployment.

PBS: So, the deployment was logistical. My job during that time was to keep track of the COVID cases in the United States, as well as the cruise ships that were on the water with Americans on it. It wasn't a lot of epidemiology. However, we met with Centers for Disease Control, National Institutes of Health, different offices in the Secretary's Operations Center. It was every HHS office, Health and Human Services office, including the Surgeon General's Office.

We were all involved in those daily briefings. We would gather information from different sources, whether it be different HHS Super Offices. I was responsible for producing a report twice daily regarding the cases in the United States, where they were, where the Americans would be going next. We were sending them to different military installations across the country. I think at that time, it was California, and it was about four different military installations where we were moving those Americans to for quarantine. So, our mission was to

get them back into the United States safely and offer them a safe place to quarantine once they touched American soil. Does that answer your question?

[00:39:44]

JS: Yes, that does answer it. Thank you. If you don't mind, I just wanted to return briefly to your second deployment, in Detroit. In asking this question, I want to preface it by saying that a lot of the people that will be using these, transcripts and researchers probably don't know a whole lot about the Public Health Service, and certainly not the day-to-day activities of Public Health Service officers on deployments like this. So, it might help, if you don't mind, just saying a bit about what the responsibilities of a Chief Pharmacist in a situation like this would be, particularly at a time like this, and in the nature of what you're dealing with during a pandemic. And, to what extent it was representative of what a Chief Pharmacist would do, in a situation like this? And how did the COVID situation make things different, if you know what I mean?

PBS: So, this was my first opportunity to serve as Chief Pharmacist on a mission and being in the middle of a pandemic made it all the more challenging. The first thing I was introduced to when I arrived in Detroit was, the Assistant Secretary for Preparedness and Response asked for the national stockpile. So, we received medications in the pharmacy which did not exist, to add to that. From the time we received that batch of drugs, I was told that I, along with the other Chief Pharmacist for the State on the City side, we were responsible for that stock problem, but more so me, because I was there as a United States Public Health Service Officer.

Getting familiar with the drugs in the stockpile was interesting. Additionally, when you arrive to these brand-new situations, I would say you should come with an open mind. I named it 'contortionist leadership', meaning you shift shape into whatever's needed. That's the attitude I brought with me. I'm a "yes" to everything, and I will assess and evaluate what I can to make it easier and flow better.

As a Chief Pharmacist, you are the go-to person in the mission. You may or may not have several officers. In my case, I had four PHS Officer Pharmacists, I had one National Guard pharmacist, who arrived later in the mission, and I also had a contractor pharmacist, who showed up later in the mission. The initial duty was to set up the pharmacy. Again, I mentioned before the pharmacy initially being in the hotspot, and then we came to the decision that it would be moved right outside of the hotspot, past the neutral area, so that we wouldn't have to use PPE. You don't always get a clear plan for how things will work. However, what I ended up doing was pretty much interviewing my staff pharmacists. And we worked within our strengths. I had two clinical pharmacists, so they were absolutely dynamic. The rest of us had had clinical pharmacy experience. Of course, mine was years and years ago, but it did come in handy.

What to expect as a Chief Pharmacist, there should also be a willingness to follow. We had a few, I don't want to say disagreements, but there was some uneasiness about PHS being the lead for the mission. We were asked to handle certain operations as if we were the lead, but we really weren't the lead, because the city was the lead. So just getting clarity on that was truly unique in this situation, where we didn't come in as the lead. I think that's all I want to share, but just being super flexible, being open, being willing to do what it takes. I know the pharmacists and I, we set up a 24-hour schedule.

Oh, the other thing, we did not have computer systems, which made it very challenging to complete pharmacy work. We were doing old school, lick-and-stick prescriptions in bags that were handwritten. We used computers as typewriters. We had manual bookkeeping. Everything was manual there; there was little to no technology to support us, besides a bar coding machine, which we received to identify each patient. Just getting used to not having technology was a challenge. With a pharmacy computer system, we could have done a prescription in a minute. It may have taken 10 to 15 minutes to get everything in, and it was pretty challenging.

One thing I found beneficial during this time, was we started having meetings with all of the – it was two other chief pharmacists at different locations. One in particular was at the New York Center. They had a huge hurdle to overcome, because they became pretty much an ICU. We didn't have that issue. However, we were set up as if we could care for critical patients. Again, the patients were elderly and moving to nursing homes, so the convention center was definitely equipped to handle critical patients, as well. Having the meetings with other Chief Pharmacists was very beneficial, because we could share how we were handling certain situations.

We had the unique experience of ordering from the Detroit hospitals, versus ordering through the HHS system. I received training on the system to order mass, but, again, the city was the lead, so we had a different ordering system than the other locations for deployment. Again, contortionist leadership is the goal. It should be the goal, open mind, don't get stuck on one way of doing anything, just be open, and willing to support and utilize your people where they have strengths.

JS: That's very helpful, and clearly, it's a situation where you have to think pretty quickly on your feet, in a situation like this. You distinguished the business of ordering directly from the HHS hospital versus hospitals in Detroit. Was there one source that was little bit easier to work with, or what were the practical differences between those choices, there wasn't a choice, but between those options.

PBS: The way we were doing it, ordering from local Detroit hospital was very efficient and effective, because we had a runner who would pick up the drugs we needed and bring them to us within a day, versus ordering the other way, it may have taken several days to get a specific drug. So we had the, I can't remember the hospital we were working with, but we had full access to their formulary, which was a lot more robust than the HHS formulary.

JS: Well, on the subject of formularies, one wonders that, at this point in time in the spring of 2020, what drugs really were available? What was the therapeutic armamentarium for a COVID patient that you were dispensing to in April and May of 2020?

PBS: We were using a lot of supportive drugs. If anyone, Laura or Ashlee? I can't remember the name of the drug.

AJ: Are you talking about Remdesivir? Because they were using steroids, too.

PBS: It was a drug that President Trump, at the time, said that the drug worked, and then later, we found out that it wasn't effective in COVID patients.

JS: Are you thinking of hydroxychloroquine?

PBS: Yes. We did have that drug, and we were dispensing it at the time. The other drugs were supportive, like albuterol, and a lot of drugs that are typically used for asthma. We also provided patients with drugs for other disease states, like, diabetes, hypertension, hypercholesterolemia. Of course, patients have comorbidities, so we were also dispensing those drugs. But as far as the COVID-specific drugs, again, it looked like "you're an asthma patient", minus the chloroquine.

JS: Did you ever encounter or hear of an encounter where patients or patients' families were asking for particular treatments, or was that pretty much unheard of?

PBS: No, we didn't have that situation. No.

JS: Okay, thank you. And to Commander Janusziewicz: I wondered if we could just return very briefly to your work with the Operation Warp Speed stockpiling of convalescent plasma. It sounds like outreach was a really important part of this effort, obviously, to recruit patients or recovered patients. And you mentioned that there was there was outreach to the local medical centers there in the San Antonio area. There was an Outreach Coordinator, is that right? How did you interact with that person? Where was that person from? Was that a Public Health Service Officer? It must have been somebody who knew the clinical centers in the area pretty well. Is that fair to say?

AJ: Yeah. This was somebody who was recently hired by South Texas Blood and Tissue Center. They had been doing this work a little bit, but with COVID, South Texas actually lost a lot of their normal clients. They normally serviced a lot of local hospitals with blood for elective surgeries, and since all of that kind of went out the window, they ended up having to let go of half of their staff. So, she was just recently re-hired about a month before we had arrived. And I believe in her previous role, she had already had a lot of contacts locally. But she was a one person show. She could only do so much, and she was also going out in person. They were having a lot of events.

The thing within Texas is, there is a lot of poverty in the area. They were trying to go out to more of the rural areas, where the people there didn't have vehicles. They depended upon buses and things like that, so the donation centers hours and the distance and the need for travel impeded their ability to donate, even though they were a hotspot for a lot of COVID-positive cases. So, they were starting to go out into the communities to ramp up efforts for mobile convalescent plasma donations. And then, in addition, just trying to spread the word to a lot of the local larger hospital systems in the area.

JS: I know you weren't in involved in it in this level of detail, but I wonder, to the extent you're aware of it, how did this work? If a COVID patient wanted to donate convalescent plasma, they first find out if they have the level of antibodies that would be necessary, and then they'd go to a clinical center and donate the blood, and then that would be processed. Can you give a sense of how that happened?

AJ: Sure. There were a couple of different ways. One way is: some patients who weren't sure whether or not they had ever had COVID could come in and did give a normal blood donation. At the time that we were there, the donation center was testing all blood donations for any of the COVID antibodies. If we found somebody came back positive, we would then call them and say, "Hey, by the way, your COVID antibodies did come up positive. We were wondering if you were interested in donation," and we'd go through the process with them.

Then, the other way is: whether they were COVID positive or they had heard through word of mouth about the plasma donation, they would call us, and they either had to submit a positive test result that they had. Or, they had to come in to do a blood donation, just so that we could test for antibodies.

[Although there were] a lot of patients in the hospitals that were testing positive for COVID, fighting the infection, [obtaining their information for contacting proved difficult]. Unfortunately, HIPAA became an issue, because we thought that would just be a direct way to find potential donors for the future, once they did recover. Unfortunately, nobody could ever provide those names to us. We just had to wait for them to be educated and for them to contact us directly.

I actually had, right before I left, one of the very first patients in San Antonio to receive convalescent plasma, come back to donate to help others. I think it was a three-month waiting period from the date that you received the last dose of plasma to when you can then donate yourself. But he came back and talked about his experience with the coronavirus; and then his wife, the entire time, was coming in and donating her plasma while her husband was recuperating.

JS: Wow. That's remarkable. Thanks for sharing that. Obviously, you had mentioned that things ramped up, but starting with the team that preceded you in terms of getting volunteers, to what extent would you say, 25% more? Or noticeably more, I take it?

AJ: Yeah. Between when we came in and when we left, which was about 30 days, we saw an average increase of about 27% of people coming in on a daily basis to donate. So, we did see a good increase from when the first team left until we left. We did reach an average of 50+ donors per day, per week, for seven days. That was one of the goals; they wanted to see at least 50 donors or more every day. The reason why that was a goal is because a lot of people would either schedule, and then they would forget, or something would come up, or they would come in, and they'd want to give, but [pre-donation screening would identify an issue and prevent them from being able to donate]. Their pulse might be too high, or they do a quick blood prick, and they find something in their blood results that [prevents them from being able to] donate then. Even though they might have had 75 people scheduled for a day, only 40 might have been able to give between all those other factors.

[00:59:48]

Then, in terms of the stockpile, when we came in, a lot of what was being donated was going right back out the door, so they weren't able to retain a lot. And they had a six-week goal of so many units of convalescent plasma. Before we left, they were actually able to meet their six-week inventory goal a lot sooner than expected. I think of the reason why, the public health service was called in is they wanted to start to create a national stockpile. When we left, there

ended up being 300 units of the convalescent plasma that was then put into the Biomedical Advanced Research and Development Authority stockpile that could then go nationally. Everything else that was being collected and donated was being sent out locally, but then the 300 units was being stored up for national use.

JS: So, some was used locally. Others were transported to a centralized site of some kind. Is that right?

AJ: Right.

JS: So how many centers were operating besides yours in San Antonio?

AJ: Well, that I'm not sure of. I know one of the things that came up is, there's a lot of plasma centers all over. Every city you go to, there's plasma donation centers. But there was one caveat that we learned when we were there, is a lot of those are then used for pharmaceutical-based things; they aren't used for the convalescent plasma treatment for COVID. We were having a lot of difficultly in getting people to come into do any [donations] with us, because, obviously, we couldn't pay them for that, but these other plasma donation centers were paying because then they were getting their costs covered by the biomedical research and pharmaceutical companies.

So, we did have a lot of that competition where they're like, “Oh this place is giving me so much money.” But it was just the way that the operations were set up. In terms of the actual

convalescent plasma treatment, I'm not sure how many centers there were doing that, but I just know there were a lot of other centers collecting plasma, but not for the same purpose.

JS: Thank you for that. I appreciate it. I want to move on to ask both of you, and this goes to both any prior deployments, as well as your experience in FDA. In the deployments you've narrated here, were you able to draw on experiences gleaned, either in prior deployments or in your day-to-day work at the agency? Captain, can we start with you please?

PBS: You want the short answer? No. I did not pull from any of my previous deployments. They've all been unique. Like I said, you just come in with an open mind and pull from your experience as needed, so I was pulling from my experience as a hospital pharmacist. As far as previous deployments, even this go-around, the way we reported up was different, as I mentioned previously, because we were not the lead. Each of the deployments was very unique. I had never served in the logistics capacity that I served in during this deployment, because my last deployment at the Secretary's Operations Center was at the travel desk. All of that to say, no, not really.

JS: And Lieutenant Commander Janusziewicz, how about you?

AJ: I think flexibility is the key. I don't think anything can ever prepare you for the unique aspects of each deployment. I had never dealt with anything related to blood, plasma, or anything like that, but I was able to utilize my clinical and healthcare background to quickly come up to speed. It helped that I was familiar with a lot of the terms, and I had learned a lot of

this back in school. But it's just a matter of being willing to do anything, having a strong work ethic, and teamwork to meet the mission that was at hand.

JS: Yeah. Great. Thank you.

VB: Lieutenant Commander Janusziewicz, I wanted to ask, and I'm sorry if you did explain this and I missed it, but just as a point of clarification: the population that was donating in south Texas, was that CP supply only being used in the same area? Or was it put into the national stockpile and then distributed around the country?

AJ: So, my understanding is that, for the most part, all of the plasma that was being collected and donated was being used locally. How far within Texas it went, I don't know. But near the end is when they were finally reached their six-week inventory goal for this specific center, then they were willing to start to contribute to the national stockpile. So that's why, I think on September 9th, which was a couple of weeks before our last day, that's when they started to contribute. And then when we left, they had 300 plasma units in the national stockpile.

VB: That's remarkable. Did you have any visibility, or, I don't mean to ask for hearsay, but any insight at all into how the plasma was distributed, like the process for requesting plasma to treat patients, or anything at all about how it got from the donation site to a treatment facility?

AJ: Sure. On our very first day, when we arrived, we were able to get a tour of all the FAC facilities, including the BARDA, the laboratories where they were processing and testing

everything, both blood samples and actual donations themselves. We did get to go into the area where they house the donations for fulfilling orders that they're getting. Basically, they would just get a call from a local hospital, and they would put in an order. I think for a while there, they were having limitations on how much you can order, just because they wanted to be able to service as many people as possible. I think near the end, once they had a larger inventory, they were able to just give it out to whoever called in.

I know that some of the people that were calling in to donate, they said, "I'll donate, but I just want it to go to my family member." Unfortunately, at the time, we were told to respond that, "Listen, there's no inventory issue. The donations, if a hospital needs it, or the physician treating your family member wants them to go on plasma as a treatment option, all they have to do is call us and it will be sent there." That seemed to be the process. It seemed to be pretty simple.

VB: That's really interesting and thank you for explaining. It occurs to me that you were deployed in September in Texas, so you're pretty close to the Gulf of Mexico, and it's hurricane season. Were there concerns about tropical storms or hurricanes potentially really jeopardizing the collection of plasma and other aspects of the COVID-19 response?

AJ: In terms of the plasma, no. I do know we were at a local hotel in the San Antonio area, and we were already in the same hotel as other traveling nurses. There were nurses coming in and out who would stay there for so long and work at the local hospitals, and then go back home wherever they lived in the country. But then, there was a tropical storm coming, and so a lot of the people from on the coastline – I guess the Public Health Department provided vouchers to

people so that they would evacuate and wouldn't stay, and where they mostly evacuated to was San Antonio. That area got really overcrowded for a weekend. It was a little bit concerning, in terms of just COVID exposure, that now, San Antonio was just a hotspot in terms of number of people, and everybody was coming in. But other than that, it didn't affect our work or any of the donations, and the actual tropical storm didn't end up causing too much damage. So, everybody was able to come home after a few days.

VB: That's a blessing, certainly, an unwelcome snafu in the midst of a national crisis. Did you know of any other officers that were deployed to the area to respond to the storm, or maybe that wasn't even necessary?

AJ: I don't know if they ever ended up bringing anybody ahead of time, but we were never made aware of anybody.

VB: Understood. Captain Birch-Smith, I wanted to briefly return to your discussion about dispensing therapeutics in Detroit, and just ask if you're willing to share a little more detail about the process for requesting specific therapeutics, and whether or not there were test cases or specific protocols for not dispensing certain medications in conjunction with each other, or any therapeutic guidelines that were specifically spelled out when you dispensed various therapeutics, either for COVID or for comorbidities?

PBS: When the patients arrived, the patients were being discharged from local hospitals to the Convention Center. The protocol for medication is that they were given a three-day supply upon

discharge from the hospital and into our facility. We did not have any real restrictions regarding medications. Any medication that came in that was not on the formulary, we would order it, and usually by the third day we would have it. We did not run into any issues where we could not get a specific drug. I think maybe one or two patients had some unique drugs. I can't remember the name of the drugs, but there weren't a bunch of incidents of drugs that weren't available on the formulary. Did you ask about the way drugs were ordered?

VB: Yeah, it would be interesting to learn what the procedure was for putting in a request and having them supplied. Alongside that, I realize this was April of last year, so it was before there were any very significant disruptions in the supply chain, but were you participating in monitoring any potential shortages? I know in FDA, there was an awful lot of work in our portion of the response to try and monitor supply chain glitches. Did you interact with anyone at FDA about it, or was it strictly through the Corps and through ASPR to learn about supply chain issues?

PBS: No, we didn't run into any supply chain issues at all, not that I can recall. But the process for ordering, again, as I mentioned before, was pretty basic. We used paper to order the drugs. The staff pharmacists would evaluate the medication for any interactions. We were using apps on our phones to evaluate medications. We had a few contraindication and potential drug interactions that our pharmacists caught; they were resolved pretty quickly.

But that's basically how we got it done. Physicians would order, and the nurses would pick up the drugs in a neutral area outside of the pharmacy. Between the hot zone and the

pharmacy was a pressure system where we would drop off drugs to ensure there was a clean transfer of medication into the patient care area.

VB: Thank you. Clarifying that, I wanted to ask both of you a little bit about the team, or the network that you interacted with, who were your most frequent points of contact during your deployments. Who was crucial to you getting your work done, and what was the nature of your communication with these people? I know you both had contact with a number of people, both PHS officers, and Captain Birch-Smith, you've mentioned National Guard, and the Detroit Department of Health, and so on and so forth. If you could give us a glimpse into the sort of ecosystem of each of your deployments, it would be really useful to learn about.

PBS: For the first deployment, my contacts were pretty much the entire Secretary's Operations Center. Everyone in the SOC. We worked in the same space. I can't tell you what the different jobs were in the SOC, but we worked collaboratively to produce reports on a daily basis. As far as the Detroit mission, I was in frequent contact with the Medical Director, who was the top member of the Detroit Department of Health Physicians. So, we all had frequent meetings. Additionally, we worked very closely with the Chief Nurse, the Chief Social Worker, and the Chief Physician, who were all PHS Officers. We met on a daily basis. Additionally, we met with PHS Command on a daily basis. We submitted reports to PHS Command to describe any logistical issues; anything that needed to be ordered.

One particular difficult situation was when we were in Detroit. Although it was April, it was freezing. We had to protect the drugs as well as protect the staff that were in the pharmacy, because it got really cold. Even ordering heaters for the pharmacy, because, if you can imagine,

we were in a huge open space with super tall ceilings. Regulating the temperature within the building was not an easy feat. Because it was April, I believe that they had stopped turning on the heat in the center, so it created a lot of challenges. We were wearing long johns and gloves, and it was very difficult. But, of course, the primary goal was to ensure that the drugs were in a controlled-temperature environment. That was a lot of back-and-forth, because ordering equipment was not as seamless as ordering the drugs. We had to go through several different layers of approval in order to acquire things like heaters and additional laptops. So, equipment was definitely a challenge.

[01:19:48]

Additionally, I frequently spoke with the Chief Pharmacist at PHS headquarters. We spoke, I believe it was weekly, and there may have been some email exchanges throughout the week if there was a particular issue. I know we went back and forth on the heaters many times. But that was a part of the duty as a Chief Pharmacist, to ensure that Headquarters was aware of the needs and the most current state of pharmacy operations at the deployment site.

VB: That sounds like a very complex and unwelcome impediment to fulfilling your mission: not even being able to get heaters in a timely manner. Thank you for sharing a little about your larger network with us. Lieutenant Commander Janusziewicz, would you tell us a little bit about your team and your point of contact, who you relied on most in your mission?

AJ: Sure. We worked pretty independent as a team. Like I said, we were fortunate enough to be reloading another team, so we had about, I'd say, four to five days of overlap with the other team, who was able to train us up and give us the lay of the land. Once they had gotten tested and left and went back home, we just continued to work with the staff at the center.

We had one main person, who had been working at the center for a long time, who knew the ins and outs of every aspect of not only the plasma program, but also the other programs that were intertwined into it. If somebody had a question about blood donation or other things, she was our go-to person, as well as the nurses that were on staff. They fielded a lot of the clinical questions related to whether or not somebody could be cleared based on a result that came up on their blood test.

Our Officer in charge on our team, he was the one that was really in contact with Commissioned Corps Headquarters with any issues that we had, and any reporting requirements we had to do. He was like the funnel for everything coming down from Headquarters, as well as any concerns that we had that went up, that he raised.

Then, for my second deployment with Commissioned Corps Headquarters, when you deploy to the Command Cell, most of the jobs are intertwined. You have to work with a lot of the other sections in order to make sure that the missions that are going out, or that are infield, are operating successfully. Like Captain Birch-Smith said, making sure that they're aware of issues and taking care of them. It's a group effort when you're in the Command Cell, making sure that, even if you're not the right person to answer it, that it goes to the correct person, so that the issues can get taken care of.

VB: Thank you very much. I ask, in part, because it's just really illuminating to learn about how decisions get made, and how work gets done, and how the different team members that need to work together to accomplish the mission. But I also ask because I realize that having a strong team that you feel supported by is really crucial when you're in a high stress environment. Certainly, the last year of the pandemic has redefined what a high stress environment means. I wanted to ask both of you about how you dealt with the emotional toll that the pandemic experience, and specifically your deployment experiences, had on you. What sort of stress releases were available to you during your deployment? Did you have opportunities to commiserate with your team members, or even just a quiet space to relax. How did you manage your stress during this really difficult time?

PBS: I can go first. One thing we could not do in the hotel was exercise. During that time, everything was closed, so we had to find other outlets to exercise in. Not to mention, the schedules were pretty brutal, working sometimes 12-hour shifts. So, it was hard to find time. It was basically, go back to the hotel, get something to eat, and get up to do it all over again. It was a pretty much a Groundhog Day, initially. But there were times when we were able to schedule days off. Detroit had a very nice waterfront where I would walk.

Additionally, the team members, the pharmacy staff, we really became like a family during that time. We actually still communicate with one another. We would get together and sometimes eat dinner together. If we were on the same shifts, we would sit down and eat lunch together. We communicated constantly. We definitely built a very nice pharmacy community, and we were pretty popular on the deployment. People would always come and sit and talk to the pharmacy team a lot.

Those were definitely stress relievers; being able to have a group that was very cohesive, very flexible, and they did whatever it took. If I said, "I'm staying late," they would say, "We're staying late with you." When we had the problems with the heaters, I went out and got everyone long johns, because I felt so terrible that it was so cold in there, and they had to be in that environment. We just worked very well together. I didn't mention, I also managed pharmacy technicians.

Between the pharmacists and the pharmacy technicians, everyone really worked together to make the environment as comfortable as possible. One of our pharmacy technicians had recently lost her father to COVID-19. We rallied around her; made sure we checked in with her. Again, we all communicate in some sort of way, whether it be by email, or a group chat. We're Facebook friends. So, the team was a source of respite for everyone.

VB: That is so good to hear. And I'm so glad that you guys had each other there for support and that you still have each other. Lieutenant Commander Janusziewicz, would you like to tell us a little bit about how you and your team members managed stress during your deployments?

AJ: For me personally, I just tried to cling to my faith and focus on gratitude. The last year, with everything, with COVID, and death, and all other things going on in the country, it rubbed me really raw emotionally. I was in a place where I was humbled and just trying to focus on everything that I was blessed with. We were fortunate enough that our [hotel had a] gym that was open, and so a lot of our team would see each other early in the morning before we were going to leave to go on site. We were just trying to keep up with working out and keeping ourselves physically fit.

I know there was three of us that had kids. One of the officers actually was local to the area. His family only lived two hours away, but, for the other two of us, we all are from the East Coast. We tried to keep things as semi-normal as possible with our schedule. Before I deployed, I brought a book that I had been reading to my kids with me. Even though it wasn't the right timing, whenever I would get back for the day, I would ensure that I called them to read them a book before they went to sleep, just to try to keep things a little bit connected back to home.

And the other families, actually, all of the team except for myself, had some sort of ties to the area. One person grew up there, and his mom lived there still. The other person had family in the area, too, but then he experienced his grandmother passing away while he was there. It was a matter of covering for him so that he could attend the funeral and process things emotionally. So, we were really there for each other, and we all had different ways of dealing with things, but we try to keep everything light. One thing that I did like: I tend to be an introvert, but they made it a point to go out to lunch every day, just because there wasn't really any option there, and we were living out of a normal hotel room. We made it a point to bond every day, and every opportunity that we had to eat together, and make sure that we're checking with each other, since we were we're away from our family.

VB: Thank you for sharing that. It's meaningful to hear about your personal dealing with how you stayed in touch with your kids, in such a difficult situation, too. I wanted to shift a little bit and ask a larger picture question about the trajectory of the pandemic and the response. Since you both served multiple deployments in different areas of the country, you have this unique perspective that not many Americans have, you are able to have some geographic comparison for how people in different areas of the country experience the pandemic. I was wondering if you

could tell us a little bit about what you observed in San Antonio and in Detroit, compared to in the DC area. How were did different areas of the country impacted? How did the local population seem to be experiencing the pandemic? I realize you served deployments at different phases of the pandemic, so if you have some insight into how the progress or evolution of the pandemic impacted different areas, that would be really interesting to learn about too.

PBS: I do have friends in Detroit who I spoke with while I was there. During the time of my deployment, there was a sense of disappointment with how the pandemic was being handled by the city. And let me say this, based on my conversations with friends who live there, they were disappointed, and there are news articles to support what I'm saying.

There was a hospital in a poorer area of the city where, in the newspaper paper articles, they describe so many deaths in the hospital that they were stacking the dead bodies up in rooms. Unfortunately, our mission did not support relieving that hospital of its numerous cases of COVID. They were beyond capacity. However, there were other hospitals in more affluent areas of the city that actually had beds. And it was really a source of sadness for me to know that this particular hospital that I'm referring to, I can't remember the name, that we weren't able to support, because, as PHS officers, we go where we're requested. I'm not sure what the City's ask was at that time, but clearly, based on what was being shown on the news, as well as being written in newspaper articles, there was a huge need that wasn't being met. I did have a sense of sadness that we weren't able to support that particular area of Detroit with our unique set of services.

VB: That's very upsetting to hear. I can only imagine with everything that you were doing to try and help people in Detroit that it would be extremely saddening and frustrating to not be able to go where it seemed like the need was most. Lieutenant Commander Janusziewicz, would you like to share a little bit of your perspective having been in San Antonio last September?

AJ: When I was there, the cases were still going up. But, in terms of major surges and capacity, that wasn't really an issue. But as we were contacting potential donors and speaking to people, I did have multiple calls where they told me about their experience with the coronavirus. One call in particular, I was on the phone with this woman for probably an hour or more. She was just telling me all the stories about her ex-husband and his wife, and how they'd call because they couldn't breathe, and they'd get an ambulance, and the ambulance would just keep driving around, because there was really nowhere to accept them. And how she was thankful she ended up getting plasma herself. But the other two family members that she was speaking of, they ended up passing away. That was the gut-wrenching thing. I myself have been blessed enough to not know anybody that has gotten the virus. I'm thankful for that, but to get the firsthand experience from all of these people local to the San Antonio area, and to hear what they went through, and how they experienced it, definitely was eye-opening. I was thankful for their firsthand accounts for that.

VB: That is so sad to hear, but I'm glad that your mission was able to at least help that woman get the therapy she needed. It occurs to me that, after an experience like this, it might be quite difficult to transition back into your normal tour of duty at FDA. I was just wondering what that process was like for both of you; particularly from your deployments out of state, but really

anything you care to share about serving in this response and then coming back to your normal role, if you took a little time for yourself, if you quarantined, if you had received a COVID test, and just how you managed shifting roles back to your FDA lives?

[01:39:22]

PBS: For me, I took the 14-day quarantine. We were given the option to return home or to quarantine in a hotel in this area. At that time, they were bringing officers back to the DMV to quarantine for 14 days, and I took that time to quarantine in the hotel, which was very good, I think most all of us, except one of the pharmacists, decided to quarantine in the hotel. That was because she had small children that she wanted to get back to.

But that time was needed. We got a chance to decompress, and that was a time we bonded, we walked together, we exercised together, we played cards. We just disconnected from the deployment experience. It was very helpful, even though some of us—I think I may have picked up my work computer a couple of times during that time, even though it was requested that we don't do any work.

Coming back into the office, things had changed a lot, because my workflow was not nearly the same as it was before the pandemic. There was a lot of shifting of our focus to providing compounded drugs to meet drug shortages. Or, for instance, the hand sanitizers, we all know everyone bought every hand sanitizer off the shelf, so the compounding pharmacies began compounding hand sanitizers. There was this big hand sanitizer initiative.

Also, some of the facilities, the outsourcing facility, and the facilities, and the compounding pharmacies turned to compounding drugs that were in shortage. The work shifted

a lot for me as far as my particular division, because the workload has shifted. And when I say shifted, it's shifted to less, because our work is based on our ORA counterparts going out in the field and conducting inspections. And because the COVID was really hot during that time, there were no inspections being conducted. So, my division was able to refocus and start working on some of our infrastructure issues. A lot of work groups came out of the pandemic. Everyone is on a work group, and we've been drafting policy, updating policies, updating processes, updating documents, templates… It became a time to complete tasks that we weren't able to complete when we were in pandemic. We are building up our infrastructure within division, which is a good thing.

The other thing that has come up is the number of deployments. Our work is ramping back up now, however, with the increased deployment activity, we are put in a position where we have to cover deployed officers. We have quite a large number of officers in my division. Work has been on a slow uptick, but right now, we're starting investigation inspections again, the workload is a bit heavier now. I know I went a little too far beyond my deployment, but I just wanted to mention the long-term effects of this entire pandemic.

VB: Thank you for going into that. It is really useful, and just educational, to learn about the long-term impact on FDA field operations in general. I'd like to return to that in a second, but first I'd like to hear from Lieutenant Commander Janusziewicz about how you transitioned back into your role at FDA, and if you took some time before returning home.

AJ: Sure. Right before I deployed, I had about maybe 24 to 48 hours' notice, so I worked with my supervisor just to ensure when I was leaving, so he could be prepared. I am the only

officer in my office, and I'm the only one [trained and] that does the job [I'm assigned] to do. Our office is very small, and so each person has their own unique role. While I was gone, I was able to maintain a lot of my normal duties. I would just do it late at night. But probably halfway through my deployment, the work started to ramp up. Many people watched the Advisory Committee meetings for the vaccine [reviews and emergency use authorizations]. There's a lot of legwork and behind-the-scenes work that happens before that kind of meeting can even happen.

That's where I came in. I'm on the initial steps of preparing for that meeting. When I was gone, I was getting a lot of increased requests for ensuring that these special government employees, the ones that are providing their unbiased opinions during the meetings, were ready and were meeting the ethics regulations. I was processing a lot of those people that were participating in those meetings while I was on deployment.

When I did come back, my boss tried to tell me to take leave, but I just wanted to get a few things processed. I did end up taking, I think, one or two days post-deployment. But after that, the end of the fiscal year and calendar year is when a lot of our busy work is done: a lot of the reporting that goes up higher, as well as our annual ethics training for all of the Advisory Committee members. Right when I came back is when we were hitting the very initial stages of a lot of that work, so I never took any long vacation. Since our deployment was considered low risk, we just had to do a COVID test, and as soon as we tested negative, we were then able to come back home. So, I didn't do any quarantining or anything like that, but I came home and surprised my family. They didn't know I was coming. And that was that.

VB: I'm glad you got to be with your family sooner but sorry you didn't get any time in between. VRBPAC meeting was less than a month after you returned, if I recall correctly. And the end of the fiscal year was the week you returned, so you must have been just extremely busy immediately after returning.

AJ: Yes.

VB: I wanted to ask you both in a question of reflection about this response experience as a whole for the Corps. There have been so many officers that have been deployed and served multiple deployments. It seems pretty clear that this is one of those responses that's going to have a significant impact on the Corps as a whole. I was wondering if either of you have any insights into lessons that we can take from the COVID-19 response in helping to improve future emergency responses, or tips for officers that will be deploying in the future — anything along those lines that lessons we can take from this experience.

PBS: One thing I can say about this pandemic experience is: this, to me, defines us as Officers. We are coming out of a culture where we were used to two-week deployments. We all know coming into the Corps that we have a dual position, meaning we work in our respective offices and jobs, and we have this additional responsibility to be prepared to respond to public health emergencies as needed. This one really changed things. I've been in the Corps for 22 years, almost 23 years, and I never would've imagined being out on a deployment for 45 days.

However, I think officers should keep this experience to the forefront of their minds, as officers. This is why we are here. We are not just federal employees. We are federal employees

who have the added tasks, or charge, to respond to national events. I've heard a lot of complaining. I complained initially; I said, “45 days? What?” I had never done a 45-day deployment. However, it was the most rewarding experience ever.

Additionally, I believe that Offices should also prepare for these potential events. We've come to the point where it is no longer an ask. It is, you must deploy. We don't get to say, “Oh, we can't go because of this.” A lot of officers have not even been deployed in the past, because we got a choice; some people were given a choice. If there was something going on, they would just go to the next officer and deploy them. So, it is a definite culture shift to the officer and to the agencies we are employed at. I think that this should really encourage different Offices to create some type of contingency plan.

I think my particular Office has responded well to the pandemic and the multiple deployments. Officers should also continue to plan, as well. When we are aware of particular events such as this, or it could be a hurricane, or an earthquake, or, now, we have the unaccompanied minor deployments happening right now.

We really should stay on top of what's happening in the United States, and even abroad, and make sure that our OPDIVs are going to be put in the best position possible. Meaning, if you can do some pre-work before you're deployed, do it. If you can make sure whoever's going to be covering you, make sure you have people in place to cover whatever your work is, and offer whatever support you can prior to your deployment. So, the goal should be to have your Office and the Agency continue with the mission of the Office, the mission of the OPDIV. Yes, I think this has really been a huge culture shift for us all.

VB: That's really great to hear. Thank you for that explanation. It certainly sounds like advice that would be well heeded in future preparations. Lieutenant Commander Janusziewicz, do you have any insights into lessons we can learn from this pandemic that you'd like to mention?

AJ: Yes. I think one thing, and I know there's a lot of talk amongst Commissioned Corps Officers about this, but we're the biggest secret, and now we're starting to see a little bit more coming out in news articles about our work and things that we're doing. But I wish there was more transparency. Even within the Corps, there's all these missions going on, and most of the Corps has no idea where officers are being sent, why they're being sent, or what work they're doing. We see totals of numbers of officers being deployed during a lot of the all-hands calls, but we have no idea what they've done.

I think in the very beginning stages of this, when we had one of the first all-hands since COVID happened, we learned about the cruise ship and those officers that went out on that, and then the officers that were stationed at the different military treatment facilities that were accepting these patients off of these cruise ships. But there's been hundreds more of these missions going on, and it would be just so nice to see, and obviously this project in itself is something that is in line with retaining that information and learning from it. But to see it on a bigger picture level for all of the Corps to know what's been going on, besides just saying, "Oh, you found out your friend got deployed" We're told it's supposed to be hush-hush. You can't talk about details; you can't tell anybody where you're going. It makes it hard to know, as a total, what the Corps is doing, and to be valued.

When I deployed [to the command cell] at Headquarters, as Captain Birch-Smith had spoken to, it definitely is a culture shift. I had been in the Corps for 10 years, and I deployed voluntarily to different missions that were local to the area. But for 10 years, I'd never been deployed. Before I had kids, I wanted to be deployed, send me somewhere, and I never got deployed anywhere. I tried to get on a deployment team, and they were very competitive to get into. Now, they're sending everybody everywhere right now, just because of the high tempo and the need for missions.

When I was at Headquarters, it was really eye-opening to find you could call a hundred officers, and you might get one who can deploy. And it was like, "What? What do you mean you can't deploy?" It is our job, and we were called to active duty, and we get a lot of the benefits, so now it's our turn to show up and show off. I think it's just a matter of, when you get deployed, obviously, there's a lot of emotional aspects to it, both the fear with the status of the pandemic and things happening around the country, in addition to your ties to home and worrying about things back home, but I think once you get boots on the ground, is to focus on your team, your new family, and doing the best that you can while you're there.

VB: Thank you both. Thank you both, really, for sharing these insights, and for sharing all of the memories that you've spoken about this afternoon, and for giving your time to participate in this project. And most of all, thank you for your service for the American people. I wanted to give both John and Laura an opportunity to raise any questions they may still have before we conclude the interview.

JS: I'll just say, I don't have any more questions, but I do have thanks. Thanks to both of you for participating in this. I would say, particularly to Lieutenant Commander Janusziewicz, with your comments: I think it's important for the Corps to know about this, but I think it's more important about the public to know about this, so they have a better idea. So that when ideas come up that would affect the Corps, and maybe in a not-so-great way, that they realize things like this happen and the Corps' importance. Thank you both for sharing your experiences. I'll turn it over to Laura for any comments she might have.

LP: Thank you so much for sharing your stories. This is really important, I think, to helping our service become better and do better things. We're doing amazing work out there, but we need to learn from things that happened in the past and hopefully make them better in the future, both for the Corps and for the people that we serve. So, I just wanted to say thank you for your time today and contributing to this project. And that's it. Thank you.

PBS: Thank you. Thank you for the opportunity. This was really good. Thank you.

LP: Yes; I think the work that you guys are doing is very important, and I'm just humbled and honored to be able to be a part.

VB: Well, we're all honored to be able to be part of recording these stories and just really grateful for your participation today. I'm going to go ahead and close the recording now.

[END OF INTERVIEW]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Library of Medicine
Bethesda, Maryland 20894

Deed of Gift

Agreement Pertaining to the Oral History Interview of

_____

As a conditional gift under Section 231 of the Public Health Service Act, as amended (42 U.S.C. 238), and subject to the terms, conditions and restrictions hereinafter set forth, I, CAPT Postelle Birch-Smith, hereby give, donate, and convey to the National Library of Medicine ("NLM"), acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at 1200 to 1500 on April 29, 2021 and prepared for deposit with the NLM in the form of recording tapes and transcripts. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

Title to the tapes and transcripts shall pass to the NLM upon their delivery and the acceptance of this deed by the Director, NLM. The Director, NLM, shall accept by signing below.

I place no restrictions upon the use of these tapes and transcripts by the NLM.

The NLM may, subject only to restrictions placed on it by law or regulation, provide for the preservation, arrangement, repair and rehabilitation, duplication, reproduction, publication, distribution, exhibition, display, and servicing of the tapes and transcripts as may be needful and appropriate.

Copies of the tapes and transcripts may be deposited in or loaned to institutions other than the NLM, including the U.S. Food and Drug Administration. Use of these copies shall be subject to the same terms, conditions, and restrictions set forth in this agreement.

The NLM may dispose of the tapes and transcripts any time after title passes to the Library.

Date: April 29, 2021 Signed:_____

Last position held: Acting Team Leader, OCQC DCII

Date:_____ Interviewer:_____

I accept this gift on behalf of the United States of America, subject to the terms, conditions, and restrictions set forth above.

Date:_____ Signed:_____
Director, National Library of Medicine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Library of Medicine
Bethesda, Maryland 20894

Deed of Gift

Agreement Pertaining to the Oral History Interview of

_____

As a conditional gift under Section 231 of the Public Health Service Act, as amended (42 U.S.C. 238), and subject to the terms, conditions and restrictions hereinafter set forth, I, Ashlee Janusziewicz, hereby give, donate, and convey to the National Library of Medicine ("NLM"), acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at FDA (virtually) on April 23, 2021 and prepared for deposit with the NLM in the form of recording tapes and transcripts. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

Title to the tapes and transcripts shall pass to the NLM upon their delivery and the acceptance of this deed by the Director, NLM. The Director, NLM, shall accept by signing below.

I place no restrictions upon the use of these tapes and transcripts by the NLM.

The NLM may, subject only to restrictions placed on it by law or regulation, provide for the preservation, arrangement, repair and rehabilitation, duplication, reproduction, publication, distribution, exhibition, display, and servicing of the tapes and transcripts as may be needful and appropriate.

Copies of the tapes and transcripts may be deposited in or loaned to institutions other than the NLM, including the U.S. Food and Drug Administration. Use of these copies shall be subject to the same terms, conditions, and restrictions set forth in this agreement.

The NLM may dispose of the tapes and transcripts any time after title passes to the Library.

Date:4/6/2021 Signed: A Shlee Janusziewicz

Last position held: Health Science Administrator

Date:_____ Interviewer:_____

I accept this gift on behalf of the United States of America, subject to the terms, conditions, and restrictions set forth above.

Date:_____ Signed:_____

Director, National Library of Medicine