INTERVIEW WITH

Dr. CRAIG VANDERWAGEN

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Craig Vanderwagen
Interviewed at National Library of Medicine
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Dr. Craig Vanderwagen: CV
Sheena Morrison: SM

Sheena Morrison: The following interview was conducted with Dr Craig Vanderwagen. It was conducted on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on April 8th, 2010, at the National Library of Medicine in Bethesda, Maryland, and the interviewer is Sheena Morrison.

Dr Vanderwagen, may I call you Craig?

You were the first Department of Health and Human Services Assistant Secretary for Preparedness and Response, right?

Craig Vanderwagen: That's correct.

SM: Can you tell me something about the circumstances under which this position was created?

CV: Yeah. After the events of 9/11, and then the following month the anthrax attacks at the senate and down in Florida, then Secretary Thompson decided that he needed to have a more coherent understanding of how HHS would operate and manage in environments where you had disasters or man-made events that challenged our ability to respond to the nation's health needs.

Recognizing that the operating divisions have activities--CDC for instance has wide responsibilities for public health and engagement with state and local public health departments, et cetera; FDA has its regulatory role; NIH its role in basic science, et cetera--he felt that there was a need to coordinate and provide a focus for the department's ability to respond and understand how these events developing, unfolding, and what could be done in response to them.

And oh yeah, by the way, are there ways for us to prepare for these events so that we aren't operating simply in a reactive mode, but in fact have thought through some of the scenarios, and so on. So he established what was called, and this is by executive direction not by an act of

Congress, the Assistant Secretary for Public Health Emergency Preparedness, and he brought in some very renowned individuals to work in that operation.

He brought in the man who had conquered smallpox in the '70s. He brought in other individuals from CDC and elsewhere in the department and established a staff operation of 25-30 people. Shortly thereafter, Congress passed legislation and funding appropriations to provide grants to the states, both for hospital preparedness and for public health preparedness. And the public health component was to be administered and executed by CDC; the hospital preparedness piece to be executed by HRSA. However, this new office that he formulated would provide guidance, direction, and policy consistency to that process.

SM: And that's the public health preparedness.

CV: Right. So, you had this Office of Public Health Emergency Preparedness, and an OS, Office of the Secretary designated individual leading that that was titled the Assistant Secretary. But this was not any legislative act;

it was more an administrative act on the part of the Secretary with support from the White House.

So, this was in 2002, and that operation continued with a relatively small staff. They did establish an Operations Center in what used to be a large conference room on the 6th floor right next to the secretary's suite that was manned 24hrs a day, 7 days a week to monitor events, had situational awareness, and provided the Secretary with a locus for department wide coordination of activities and response, as well as preparedness. So you had this small nucleus operating in the department.

Concomitantly, Congress passed legislation, as they said, for grants to the states. They also passed Project Bioshield in 2004. They established a fund to underwrite research and advanced development of medical countermeasures, particularly focusing on biological events. And in that event, Dr. Fauci and the folks at NIAID had a significant influence in convincing Congress of the utility of this. And the significant amount of that funding was directed at NIAID for discovery research--less for advanced development--but primarily for continued discovery research for new vaccines, broad spectrum antibiotics, and

other tools: medical countermeasures that could be used in a biological event.

Well, then in 2005 you had Katrina, and while you could argue that the president's major failing on an international basis was the decision to go to war with Iraq, certainly the domestic challenge that got the most attention and challenged the credibility of the federal government to be prepared and responsive to events was Katrina. And without getting into an analysis of that particular event, it was a failure; a government failure. I spent three months on the ground shortly after they sent me down three days after the flood. I spent three months on the ground in Louisiana, and my sense is that it was a state, local, and federal failure. But clearly, the feds provided little leadership, coordination, or direction.

Subsequent to that, then there was a great deal of congressional interest in how do we strengthen and reinforce our ability to prepare and respond to events? That happened to be a natural disaster. Katrina was followed two weeks later by Rita, which took out the south west corner of Louisiana. And so there was a great deal of interest in how do we strengthen the ability of the nation

at the federal level, as well as at state and local level, to respond to these events. This led to a strengthening by executive action on the part of then Secretary Levitt to try and strengthen up the capability of the department and to strengthen this Office of Public Health Emergency Preparedness.

So, throughout the fall and winter of 2005 into 2006, there was intensive effort put in analyzing what the failures were, what needed to be done, and how to strengthen the department's capabilities. I'll talk some about the dynamics of that in a moment. Then in 2006, Congress decided to take action, and they passed the Pandemic and all Hazards Preparedness Act that was signed by Bush in December, established the Assistant Secretary of Preparedness and Response in the Department of Health and Human Services with two large areas of responsibility: One, to coordinate all federal public health and medical response to events and preparedness for same. And secondly, to take advanced development of the discovery science being generated at NIH and its supported institutions to actual products that could be used in events. And that really then established the Assistant Secretary for Preparedness and

Response with a set of authorities and expectations and funding.

Now, what did that really mean? Well, the preparedness and response piece of that meant that the grant programs to the states for hospital preparedness got transferred to the direction of the Assistant Secretary from HRSA. It also brought NDMS, the National Disaster Medical System back from FEMA. They had been transferred to FEMA in 2002 in the flurry of "let's put everything in DHS that got pulled from HHS put over at FEMA." But it didn't work effectively, and so Congress in its wisdom moved it back over to HHS under the direction of the ASPR.

It also meant that additional funding for advanced development, and new authorities to facilitate advanced development products, was transferred and granted to the Assistant Secretary for Preparedness and Response.

Let me step back a minute. With Project Bioshield, it became clear that that funding was being used for discovery science, which was fine. We need more discovery science. However, because these products for medical countermeasures for events like this have limited market, there's really no

interest on the part of the pharmaceutical industry to do what it usually does, which is take that discovery science, do the advanced development research, develop the manufacturing capability and quality standards for manufacturing, get it through the FDA licensure process, and then market it.

So, part of the reason that the authority for this advanced development and funding was provided to ASPR was to fill that gap. That is, there was recognition that if the public sector did not take responsibility for the development of some of these products, they would not be developed, and we would not have them when we need them. So, this was a change in the way government viewed its role vis-á-vis this process of advanced development taking discovery science, good ideas from science, and converting them into real products that people could use.

And that's troublesome to some people because, again, it's not a public sector government role that people have viewed as being critical, or important, in the past but I think have come to understand it won't get done any other way.

So that put the ASPR in the position of being essentially a venture capitalist: looking at various discovery science insights that had promise; companies that had some interest in doing it, if they could get some financial support to conduct the advanced development process, and investing in those companies to bring those products to a licensable safe and effective product.

You can imagine the policy issues that are at play there. Vis-á-vis, regulatory responsibility for product safety resides in HHS, and yet at the same time here, the department is funding the development of products. Is that a conflict of interest? It can be, or you can have firewalls that separate the two functions. But that is a policy set of issues that still play today because we don't have a lot of experience with this, as well as the fact that regulatory science needs further development as well.

How do you for instance demonstrate the safety and efficacy of a product in humans where you cannot challenge them with the risk that product is designed to counteract? So for instance, for nuclear exposures and acute radiation sickness, clearly we need to have products that will protect the hemapoietic system, protect the GI system where

people are gonna be exposed to potentially lethal doses of radiation. But we can't do that in a testing phase to demonstrate safety and efficacy. So, what is a rational scientific process for that demonstration of safety and efficacy that we can rationally undertake that meets ethical standards, and yet at the same time, gives us some assurity that the product that we actually are gonna put in people's arms or in their mouths is safe and effective?

So you had a sequence of events: 2002, there was an administrative stand up in the department, the Office of Public Health Emergency Preparedness; 2004, Congress established Project Bioshield that funded more discovery research to develop products to counteract these threats; 2005 we had Katrina where it was clear that the feds and other elements of the public sector were inadequate for response. That led to the Pandemic and All Hazards Preparedness Act which established ASPR, gave certain authorities and tried to rectify gaps that we saw from the Bioshield Act in 2004.

My personal history with this; I'm a family doc by trade. I was born on a res in New Mexico, grew up in New Mexico and California. Went to medical school, trained as a family doc

and went back out to Zuni where I was born and raised, and practiced out there in Indian Health Service and then came here to Rockville and ended as the Chief Medical Officer for the Indian Health Service. Along the way, developed a lot of understanding and insight into quality assurance models, the design of clinical programs, living with an expectation that we could improve the health of Indian people with a budget that was half per capita on an annual basis compared to what everybody else spends in this country. And so we ended up having to work smarter and work harder in order to achieve those objectives, and in fact, we have increased the lifespan of Indian people. In fact, many Indian communities have a better infant mortality, a better mortality rate, et cetera, than the general U.S. population because we developed a solid electronic health record. We developed the use of best practices and evidence based practice. We partnered with the Institute for Health Care Improvement, Dr. Don Burwicks' organization--and you may know he's currently up, nominated as the Director for CMS.

So, that experience was an extraordinarily good experience for a public health primary care provider, serving an underserved population with less money than what was

needed. That creates a whole lot of insight into how to get at things, how to think about what is a strategic goal, what are the tactical tools that we have to work with, and how do we operationally bring those tactical tools together in an effective way to achieve those strategic goals. So that was my sort of primary experience.

I became "Doctor Disaster" [laugh] because as time goes along, Indian communities have lived with 9/11 for 300 years. And so, the idea of disasters is something you live with every day. How do you create resilience? And how do you learn from Indian communities who've demonstrated great resilience in surviving genocide, conscious or unconscious? Surviving an overwhelming oppression teaches you a great deal of resiliency. You learn a lot of lessons about what does it take to bring this community forward. In general, it means the needs of the tribe and the community outweighs the needs of an individual, de facto, because it's the survival of the culture, the language, the people that is the goal here.

So, those kinds of lessons, as part of the day to day experience in Indian country, prepared me to deal with a variety of other challenges. I got real involved with PAHO,

Pan American Health Organization, and the World Health Organization, which had from the mid ‘90s to the mid ‘00s “The Decade of Indigenous People”. And so, I got real involved with indigenous populations here in the Americas.

And so, for instance when Hurricane Mitch roared through Honduras in ’98, I went and helped with PAHO and the ministry of health in Honduras, and [undecipherable: los pueblos indegenas y Honduras?], the Indian people of Honduras. When the Kosovar folks were undergoing their genocide from the Serbs in ’98, ’99, then Secretary Shalala asked HHS to help deal with the health needs of those refugees, and so I participated in that as well.

Then you had WTC, and we had people on the ground. HHS sent teams to assist in health care there in New York City at the World Trade Center.

I went to Iraq in [undecipherable] in September of ’03 through March of ’04 to work with the folks at the ministry of health to create an Iraqi health system that they could direct, guide and facilitate to achieve the ends that they wanted for their people. Again, the Indian health experience--because we in fact have turned over 60% of the

resources to the tribes themselves to manage, and I was the lead negotiator for the Department on much of that early on--that experience of how do you facilitate a local population taking control of its own health system, I practiced in Iraq as well. *Ānā al-'Rāqy;* I am an Iraqi, you know.

And then shortly after that, you had the tsunami in Indonesia. And the navy wanted to do something, so they sent the Mercy out there. They weren't sure what they were gonna do with it, so I linked up with the navy surgeon general's office and his chief of staff. And I worked with NGOs to figure out an operational approach to how we could use the Mercy in responding to the issues in Acha province--Banda Acha--and on the ground there in Indonesia (largest Muslim country in the world).

And then that summer, we had Katrina and Rita. And in that context, then with the perceived failures in Katrina, Secretary Levitt needed to change direction for his activities. As I suggested, there was a whole set of activities in the winter of 2005 into the spring of 2006 re-examining what we could do. He asked me to come and lead that re-analysis. Then he asked me to take over as the

Assistant Secretary, then, for Public Health Emergency Preparedness. And then when Congress established ASPR, the White House nominated me because it became a senate confirmed position, again, not because of political affiliation or activity but because of the experience-based and demonstrated activities.

We took, from that point in late 2006 forward, the organization from a very small organization of 35 or 40 people up to 700 people, a budget that went up to about 6.5 billion from next to nothing. And we established a management plan: first we established a strategic goal; then we established the performance expectations for us to meet our customers' needs, the people we serve--the states, the locals; established our own internal quality assurance benchmarks, how we were gonna manage resources. We used what was called a balance score card to establish the management plan overall for the organization.

We took it to a very fine operational unit, recognizing that operations in public health domains still reside largely with CDC. But then, the medical support piece is in coordination with DOD, coordination with DHS because, remember, those are all federal elements in the public

health and medical response: doing coordinated planning for those folks; exercising with those folks; and then in events, being able to mobilize.

Before Katrina, we had almost 30 HHS people on the ground ahead of that storm. Two years later, we had Ike and Gustav. I had 1500 people on the ground three days before the storm at pivot points: Atlanta, Tallahassee, and over in Alabama, so I could pivot them depending upon which way the storm went. Now, that's a natural event, relatively predictable, which is very different than responding to a man-made event, or very different than responding to a pandemic.

Now, let me step away from ASPR a minute and set the stage for how we viewed pandemic. I think that our public health scientists here in the country recognized in the late '90s that the potential for a pandemic was something that we needed to anticipate. In part because we had seen so much change in the viral mix, especially the influenza A's and B's, and the simmering pot that was south China where you have this mix of birds, pigs, and humans that is an ideal environment for the development and transmogrification, if you will, of different viral species. The concern was that

sooner or later, we were gonna encounter one that would be like the 1918 event or like we saw in the mid-50s with those events.

And so, they began to think forward about how we're gonna deal with this. The World Health Organization queued up similar kinds of concerns, and by the time we got to 2004/2005, Congress had been educated sufficiently and seen enough disaster events occur that they appropriated funds to support the development of appropriate preparedness activities, including the development of more effective laboratory tools; the development of medical countermeasures; the acquisition of countermeasures--and in this case, countermeasures means vaccines, and it means antivirals, primarily.

Well, in 2004, we had a real shortage in influenza vaccines. I don't know if you recall that, but there are only two manufacturers that were able to produce the seasonal influenza vaccine, and we were short between 75 and 100 million doses nationwide. This too exacerbated Congress's concern, and they said, "Do something to fix our ability to produce vaccines."

Well, the dynamics there are--again this is a public sector counter measure that has no other market than the public sector, people aren't going out and buying flu vaccines on their own and being willing to pay significant amounts of money to do that. So the incentive for companies to manufacture these vaccines is pretty low. That's not to say that they don't view themselves as good corporate citizens, they generally do. But in the environment where they have a choice: "Do I invest in this or do I invest in that?" they're gonna respond to where the return on investment is higher. That's business. So this whole notion of public health as a public sector responsibility comes to a head in the production and distribution of vaccines as an example. Because good corporate citizens aren't necessarily gonna make that choice, the public sector has to step in.

And so, when Congress saw this problem, they provided $7 billion over a five year time span to try and improve that situation. And what that meant was investments through CDC and the more effective laboratory network; more effective tools for early identification of specific kinds of influenza viruses; acquisition materials for the stockpile Tamiflu in particular. And for BARDA, as part of ASPR, it was guided at "how do we develop a stronger

manufacturing capability in this country to assure that we aren't gonna run afoul of need and the ability to produce?"

And so, we began that investment process in 2005 with half dozen or so manufacturers, some of them big names, some of smaller organizations. Many of these medical countermeasures are being developed only in very small bio-techs. In the case of vaccines, that's not necessarily true, although some of the newer technologies for vaccine production that will shorten the time for production, increase reproducibility, decrease our dependency on egg-based solution and therefore the need to have 2 million chickens, which ASPR owns. [Both laugh.] So it's investment in a variety of fronts to try and develop the capacity to reduce our dependency on this kind of under-infrastructure, chickens, and to expand our capacity for production that is actual factories, if you will, that can go through the manufacturing process.

This doesn't happen overnight though. And in fact, the most significant investment in a cell based production capability which is more reproducible higher quality, et cetera, we couldn't target to open until 2010. It just takes that long to get the material. And given the money

that we had, and even if we'd had more money, there's a question of can you do it any faster, you know?--maybe a little bit, but not huge. The technology and the investment in physical plant construction and so on take time and money.

SM: Is that the plant that opened in North Carolina?

CV: Right.

SM: Okay.

CV: So these investments were being made. And in fact, we warm-based--warm basing meaning, you provide a contract to an entity to ensure that they have some level of manufacturing capability ready even though nobody's buying the product at the moment. But you want them to have that manufacturing capability in place and functional so that if you need it you can tell 'em, "Flip the switch and let's start running tomorrow, or next day," as opposed to waiting six months to turn the switch on for manufacturing. That still doesn't solve the problem of getting a good identification of the viral strains, getting a good match in the development of the antigen, and then turning that

antigen into a large scale production process that will produce a lot of vaccine.

So, on the front end, you have science and technology challenges that are unrelated to building buildings and hiring scientists, and so on and so forth. It has to do with the pace, the ability to identify cleanly, and then get a good match in the antigen and go to reproduction phase. (And this played in the H1N1, and we'll get to that in a moment.)

So, to summarize all that, there are developments around ASPR as a phenomenon in the department's capability to coordinate operations, response, preparedness and the development of countermeasures. And you had concomitant to this then investments in specific activities around influenza viruses and preparation for what we were concerned would be a potential pandemic. So that all had gone on before we got to the spring 2009.

SM: Great.

CV: That's a lot of stuff.

SM: It was good background.

CV: But I'm trying to keep it tight you know.

SM: Okay. Can you recall...? Why don't we start at what point did you become involved in the 2009 H1N1 outbreak response efforts?

CV: Well, the simple answer is I think activity began in the U.S. really in March, late March of 2009.

Again, given the context that I provided to you, one of the investments that BARDA jointly made was in the development of some laboratory screening tools that could be used on site in clinical settings to get an early set of identifiers in place for different strains of influenza. And we'd begun field trials of those laboratory tools in late 2008. One of the places that was employing it was this Navy South West Medical Regent based in San Diego, Balboa Hospital, and they were employing that tool. And so, we knew that they were doing these. They had the capacity now to do this.

And in March, what we began to see was that Mexico was beginning to experience an outbreak of a severe respiratory

illness that led to a significant number of hospitalizations and some deaths. Now, this showed up in the popular media in late March without any--they just reported that they were seeing this, and we knew that as well. And in fact, we had pretty good lines of communication with the Mexicans. And let me give a context for that.

SM: Okay.

CV: In the Bush Administration, one of the things that had been established was a North American Treaty activity. And the president of Mexico and the president of the U.S. and the premier of Canada met on a regular basis, and among other things, there were certain activities in health that the three of us began to work together on. And that enhanced a variety of communications that were going on, and that was very useful.

Secondly, Congress had established a Border Health Commission with Mexico in the late Clinton years. Essentially, the four U.S. states and the six Mexican states along the border identified individuals to participate in this Border Health Commission. The states

got to appoint one person. Then the presidents got to appoint one person from each state. And that began a dialogue on a variety of health issues, particularly communicable diseases, tuberculosis, et cetera, because in a border environment that's a significant challenge.

The goal for the Border Health Commission was to try and enhance communication, not just between the two national governments, but to enhance dialogue and shared skill sets between the states. And one of the bi-products of that commission was that--and this was best developed between Arizona and the State of Senora--they had absolute transparency of their surveillance data through a common website. So that Senora, which is the capital (there is [Emelsia? 37:20] and Dr. Lopez Lukovitch, who is the Secretarial, the Salud de Senora, and the folks in Arizona were wired together extremely well. And so their early warning systems in terms of surveillance were extremely tight. But across that border amongst those ten states there was improved dialogue, greater public health sharing of responsibility et cetera.

Then the third thing that was going on was what was called the Global Health Security Initiative and the Global Health

Security Action Group. And this was a group that stood up in 2002 after the anthrax event here. And it involved the G7: that is U.S., Canada, the U.K., France, Germany, Italy, and they added Mexico to that and added the EC and added WHO.

And that group met on a regular basis; the ministers meeting once a year, and the senior staff, that is the counterpart to ASPR in those countries and with the EC and with WHO, met a couple of times a year. And they were working groups for various targeted activities that were working on projects throughout the course of the year with the goal to deliver products at the ministerial meeting on an annual basis, so the ministers could point to the improvements and changes that we've made through dialogue, through discussion, and through shared activity.

And pandemic flu was a major component of the GHSAG's activities. And it involved cross training and laboratory skills--shared laboratory information. It involved sharing operational planning for how we were going to respond to events, and in the case of pandemic, how we would respond to events and discussion of who's acquiring what. Because remember, the global supply of Tamiflu, the global supply

of vaccines are finite. And if the developing countries, and that's essentially what this group is, acquired all that material, no one else could have access to it. Or, we would be competing with each other, even in the developing context for that. So the dialogue around planning for how much Tamiflu we're gonna acquire and why, what was our plan for who was gonna get it, and when they were gonna get it and how much, and so on and so forth, were all part of the ongoing dialogue and joint planning effort.

Now, specifically related to pandemic, at the ministerial meeting in December of 2008 in Brussels, the ministers issued a statement saying that we would not close our borders; That the health and economic effects of border closure were adverse and would have more negative effect on our cultures, societies, and economies, not to mention health than if we maintained open border but did active surveillance, and so on and so forth. That was a major move, politically.

And it also was a very different approach than occurred in SARS. You recall in 2003 with SARS, people were closing their airports. It was finger pointing, blame placing, problem, problem, problem. So, the GHSAG was very helpful,

the Global Health Security Action Group, very useful in establishing an understanding of how we would be approaching these issues domestically but with an eye towards our world citizenship, and how we would engage with others in this process.

So, to go back to where I took off on this particular sidebar with Mexico, we had pretty good dialogue with them, great personal relationships:

Moritzio Hernandez is the Undersecretary for Health, for all public health and primary care responsibilities: Harvard educated guy, very capable, very smart; came out of academia when President Calderon was elected. His guy responsible for these activities is a young doc, smart as can be, very committed to the notion that the government exists for the people as opposed to as an opportunity to make money. Because there have been concerns about corruption in government, there are a number of young, very capable public servants in Mexican government right now who really are trying hard to overcome that sort of history and notion. And Hugo Lopez Gatell, who is the young man I'm describing to you, had responsibility for laboratories and the response, and so on and so forth. (And to Hugo, I'm

tio, I'm his uncle because I'm committed to supporting him and seeing him grow and develop for him personally certainly, but for the Mexican people. [Spanish] My family lives close to the border. I have in-laws in Senora, not my in-laws but my cousins have married in, and so on and so forth: *Es mucho importante ami*, to see their health improve, to see the system work.

So, in March, this was going on. Late March, had a communication with Moritzio and Hugo, and they thought it was influenza B that was going. They really didn't know that it was an influenza A, and in particular the H1N1. They did not have the laboratory capacity to do that level of typing. One of the things we've been working with them on the last three of four years is to try and build out a national laboratory that could serve that function, and they could do more of those tests for themselves as opposed to relying on CDC or Canada.

Well, in this event, in early April then, they had sent samples to Frank Plummer who's the chief scientist for the public health agency of Canada. He's based in Winnipeg, and their national laboratory is based in Winnipeg. And so they had sent samples up to Frank and his folks, and then a few

days later, they sent samples to Nancy and the folks at CDC. And before Nancy and her folks had confirmed that it was a new, a morphed entity, Frank and his people advised Mexico they thought they were dealing with a new, a novel virus. And then CDC confirmed that. So then, we get down to the week of April the 18th, 19th, and there was this preliminary read from Canada. They thought that it was a novel strain there.

Nancy and her people were working. And it seems to me that it was during that week that we got these two cases in Southern California: one in Imperial county and one in San Diego county, where the new lab piece that we were field testing there in San Diego picked up a novel virus. And so then, we realized we probably had a couple of cases just here in the U.S., and by the 23rd, 24th, Mexico had confirmation from Canada, and Nancy's people were close to confirming it.

I spent most of the night of the 24th on the phone with Hugo and with Mauritzio. I was out in Santa Monica because I was out at Rand Corporation; I was doing a presentation and speech out there, and Rand was doing some research out there for us on preparedness. Dr. Lurie actually was the

lead investigator [both laugh], and so I was out there with them. We conducted a variety of regional hearings. What we were trying to do is develop a national strategic plan, which was part of the PAHPA Act. It required ASPR developing a national strategic plan for health preparedness. Rand, who was conducting regional discussions for us--and this was the last one that was gonna go on--they were doing it in Santa Monica, and so I was out there with them.

SM: This was in April, April 24?

CV: Yeah. So I got out there midday on the 24th, like in this flashing, you know, "Mexico needs to talk to you!" Yeah, yeah, you know. So, okay, well, anyway. What was going on was Mauritzio was going in and out of meetings with President Calderon, and Calderon was trying to decide do we shut down businesses and stuff. So, 1:00 o'clock in the morning of the 25th, the night of the 24th, however you wanna say it, I think they decided that they would wait until Sunday before they made a final declaration. And that would give them some time to configure themselves and do some preliminary informing of people, and so on and so forth, that they had a novel virus, and that they were

going to ask businesses to close for a week or 10 days. And for Calderon that was a tremendously challenging political move, just tough. And Mauritzio was sweating bullets: "Dr. Craig, What's your advice?" And I think they were talking to Rich Besser a little bit as well. I don't know that for a fact.

But at any rate, 24th, 25th, we realized we had cases. They were gonna make some significant public moves, and I think Rich had really started to ramp up the CDC folks to start to deal with this. Now, this wasn't *de novo* action on the part of CDC, or us. In fact, as recently as January 16th, we'd run a full day exercise with CDC, with DHS, with a few state folks--Julie and I in the driver decision maker seats--on a pandemic event. And I think that was about the third one that we'd done over the course of the previous two years, fairly large scale table-top and not actually deploying equipment and people, but really going through it.

Julie was gone by this time and Rich was acting, and Rich and I had a great relationship. I mean, you know there's a lot of tension between ASPR and CDC in that environment because CDC believes they own public health. At least in

that director's mind, they own public health, and what the hell were we doing? And so, there'd been a lot of tension going back and forth.

Their operations part of this was the dynamic of trying to change the department from a culture of subject matter experts and bureaucrats--both of which are necessary for this department to function, no question about it--but augmenting it with a culture of action: decision and action. Because this department has very little ability to make a decision and act because the SME culture is more about, "Well, we need more data", "Let's think about that a little bit more", "Maybe we need to talk to this one and that one about it", and so on and so on and so on. You know, the search for the perfect science answer inhibits their ability to make decisions on a timely manner. We need that science, we need those people, can't exist without them, but they're insufficient for these kinds of events, generally. And so, what CDC had done for instance was in their events management, they would identify an SME to be responsible for it, and it would be the expert in TB, or—

SM: SME?

CV: Subject Matter Expert.

SM: Okay.

CV: Rather than somebody who knew how to manage an operation. It didn't interface well with the other actors in events very effectively. The states had their problems with it, et cetera. And Julie, to her credit, was trying to create an operations center and to bring a more effective approach to managing operations. She hired some former army medical planners who know how to run operations, and so on and so forth, but the default was still "let's put our expert in charge", and the expert didn't know how to run an event.

We saw this with, you may remember, the XDRTB case with this guy flying all over Europe. Well, we had the expert trying to manage the operation, and they were dealing with their buddies, the other experts in other countries, but they didn't know how to run the operation. You gotta have them both. It's not one or the other. You gotta have them both.

And so what ASPR had to do was try and introduce that culture, and sometimes that meant being heavy handed. And that created animosity and jealousy and competition. I'm not a terribly competitive guy, but I had a mission to get done. And it wasn't about turf, it wasn't about ego, it was about, "Here's the strategic objective: Save lives and reduce the burden of disease and get it done now!" Rich, I think, understood that. And so, when he was Acting, he and I could operate from the same page. And because it was an infectious disease event, ASPR needed to let CDC be the lead, be the public face. That's their stock and trade, that's what they know: infectious disease. Now, the whole world isn't infectious disease and they don't always get that, but when it's an infectious disease event, they need to be the face.

Now, if a pandemic goes wider, and it starts to involve transportation and energy and other aspects of the economy, and it involves a heavier dose of medical challenge, they may not be sufficient to that and others would have to become the face. But in this event, at this stage, "Rich, you're the man. Go for it. And you be the public face. You do the White House meetings, and all that. We'll do what we need to do to make sure you get all the support you can

get." And so from April 24th, 25th forward, it was really about CDC dealing with the infectious disease reality and communicating with the public about that infectious disease reality.

Now, there are other players, there are other stakeholders. And one of the things that I think the President really wanted to do was have greater transparency; I have to tell you this: It's not totally true in the Administration everywhere. I think the President's goal is to have that. You know, the Chief of Staff's brother, an NIH employee, I think wanted that as well. And that's who the chief of staff was listening to. These things play.

Here I am, a Bush holdover; both Rich and I are Bush holdovers, right? I mean that's the way we're perceived. But we handled this professionally, credibly and gained the confidence of the infectious disease community out there. And those guys could really undermine like crazy if you didn't have them convinced--the pediatric community, because they're worried like crazy about how many kids are gonna die from this. Because remember, what we were seeing epidemiologically is the people who were dying were younger. They weren't 65, 70 year old, COPD diabetic person

that seasonal influenza usually kills. It was younger people; it was pregnant women.

So, Rich stood up his plan B group, which was a group of experts from various domains. And we ended up standing up some of that as well within the ASPR world and the White House; a lot of the same people but engaging in different environments for different purposes.

For the White House, it was more about, I think, political cover. That's their job. And it's an inherently political environment. Not to say they don't care about people, they do. Not to say that they didn't care about the quality of the product, they do. But they're also looking for political cover.

For Rich and his folks, it was making sure that the science community that they engage and work with on a regular basis was comfortable. That they were doing the right stuff and if they weren't, CDC would change appropriately. CDC needed to have that.

And for us it was partly political because there wasn't a Secretary at the time, remember? But Secretary Napolitano

was gonna be our secretary in this event, from her view. And I know her going back a long time. Her dad was the dean at the University of New Mexico School of Medicine when I was doing my residency there, and I knew the family. New Mexico is a small place. People know people, right? And I worked with a lot of her staff on Indian issues at the health department there in Arizona, in addition to Border Health Commission, which I was real actively involved in-- again, the Indian play in that environment. The Border Health Commission was interesting. So, Secretary Napolitano was leaning in.

We needed, in the department, to make sure that we were getting good advice, and that we were responsive to people's concerns. So for instance, I remember one conference call we had with the pediatric community. We had 250 lines and they were all full immediately.

And so beginning in late April: CDC, you all are going to be the face for us on this activity. Our responsibility really was to move out on the vaccine production, assuring that we had the vaccine manufacturers lined and ready to produce when there was a virus and an antigen that they could develop their seed strains from, and develop their

product. So my guys were busy negotiating with the vaccine manufacturers--half dozen of them.

And at the same time, we're communicating about every 3rd day with our GHSAG colleagues to make sure that, again, we got some alignment here, and that the U.K. is not going this way, and we're going that way and all the hassles that that leads to functionally and politically--for them, for us, and for the Third World. Because remember there was this question about, "Well, if you guys buy up all the vaccine, what are we gonna do for the Americas, for Africa, for South Asia?"

And so, messaging; we didn't have a secretary there for a while messaging. And assuring that Secretary Napolitano, for instance, had a good health message to work... Rich was going to the White House and briefing the President, and that was perfect.

And our role in ASPR really was to pursue this vaccine activity, work with CDC around the distribution of Tamiflu, work with the states and locals around how they were gonna deal with the medical challenges. They were having problems with personnel. Numbers needed: Texas, for instance, was

looking for 40 or 50 laboratory assistants. And with our ability to draw down to NDMS and through the Commissioned Corps, we could assist in getting personnel, and so on; filling holes for them where they determined they had gaps and needed some support.

So, ASPR's role was lead in terms of getting to the vaccine production piece, but in strong partnership with Nancy and her folks because they were doing the strain identifications with NIAID. They had to stand up some testing because this was a novel virus. It was gonna be a new vaccine. How were we gonna test it working with FDA, coordinating with FDA around what their regulatory expectations were gonna be? So, it was coordinating those activities while the public face and the dialogue with the states was actively happening through CDC on those activities.

Now, I forget exactly which day she got confirmed, but in mid-may or so, we got a Secretary. Meanwhile, remember the department was in a bit of turmoil because, initially, in December, we were looking at Mr. Daschle.

SM: Right.

CV: And so he brought in his Chief of Staff. He brought in Bill Cord who was going to be the Deputy, but none of them were confirmed. Charlie Johnson was retained as the acting Secretary; he was a holdover from Levitt's group. He was the Assistant Secretary for Budget, basically. But I was the only political appointee still in place throughout that process. Everybody else was acting. And so by mid-May, it was kinda hairy: no Secretary; Bill was not confirmed; Mark, the Chief of Staff--because Daschle wasn't gonna play, he'd left--went to the Hill; Laura Petrou, who'd been on Daschle's staff, came as the chief of staff, but her whole time was getting the Secretary confirmed. (I knew Laura from the Hill because she was Daschle's staff, dealt with Indian issues, and I was the regional director out in the Dakotas and lived about 6 blocks from Daschle's parents, actually. So I knew Laura from that environment.)

So to me, you know, the victory here was a couple of things: One was we had done some preparation in terms of getting some infrastructure in place for vaccine production; we'd acquired Tamiflu; we had put some operational plans in place and exercised them and improved them, and people understood their roles. And in the face of

not having a Secretary, or anybody, we executed that thing to good effect.

In fact, the public health community out there just felt tremendously uplifted by the success that occurred in April, May, and into June in terms of their ability, and our support of them, to stand up and do education; to manage school closings; to manage illness where it occurred, et cetera, and then to anticipate the next wave coming in the fall.

So, if you talk to Susan Cooper right now for instance, who's the Commissioner of Health for Tennessee--she's a nurse by trade, and I just did a meeting (IOM had a meeting) here about a month ago and visited with Susan--and she was just so pleased with what they were able to do.

Some of the folks on the National Bio-Defense Science Board--which is a secretarial advisory group managed by ASPR but directed by the Pandemic and All Hazards Preparedness Act, so it was congressionally directed; we had to stand it up and blah, blah, blah--some of the folks on that group had been challenging me about why we were doing all this stuff (I'd raised questions about their

ability to be able to distribute), and you know, the Cheney-bogey-man-under-the-bed kinda worries, and blah, blah, blah. Well, in the middle of this event, one of those guys--a faculty guy, a big gun in the pediatric infectious disease community, on the National Bio-defense Science Board--said to me on one of these calls, he said, "Admiral," he said, "you know, you told us, and we weren't particularly listening, but you were right, and this is tough." [Laugh.]

SM: Their ability to rev up for distribution?

CV: Uh huh. Yeah. So I think my role was to act the ASPR part, and assure that we weren't interfering with Rich; that we were supporting the states; that we were responsive to their needs; that we were working on a vaccine development; that we were dialoging with our international partners, recognizing that I was a lame duck, a Bushie holdover, but we had to get this done.

SM: Right.

CV: And, you know, Laura, we met every day with her. She was sort of assuring that we were in line with, that we

weren't gonna run afoul of where the president and the administration wanted to go, and that they understood what we were, where the holes were, what the problems might be, and how that could be managed, and so on and so forth. I mean, it's a kind of weird situation. But on the other hand, I'm a career guy, and my attitude was, "I'm a career guy, let's get this done. This is the mission. This is what we've been practicing for, and working towards. Let's get it done."

SM: Can you tell me where you were and what you were doing when you realized that this was actually a highly transmissible virus, and that it would demand the kinds of resources that it has?

CV: Well I think the 23rd and the 24th were the turning points for me. Now, after I was at that regional meeting that Rand held up in Santa Monica, I went up to Sacramento over the weekend because my youngest son had just been diagnosed with ulcerative colitis, and he's going to law school in Sacramento at the University of the Pacific at the [undecipherable 1:09:04] Law School. So my choice was do I cancel that and run back to Washington, or do I

continue to just work it through email and phones and give my kid the support he needs?

SM: Right.

CV: Well, I opted for the latter. And so, I spent a lot of time on the phone on my blackberry over the weekend, even though I was in Sacramento having dinner with he and his wife, and this and that and the other thing. But it was pretty clear to me that this is what we were dealing with.

And there's always this challenge in the response community. FEMA is sort of the response community at the federal level. At the state and local level, the FEMA equivalent exists, and it's usually fire and police guys and retired military types, and so on and so forth. And they're used to sort of quick time response to fires, to hurricanes, and that sort of thing. And a pandemic is very different; it's a very sssslllooooowwww moving event, you know.

SM: [Laugh.]

CV: And these guys don't know how to cope with this. On the other hand, the challenges that were there in the public health community as I described them earlier were problematic as well because those folks didn't quite get how you engage with the preparedness people very well. But we had worked the pandemic stuff enough in exercises so that those tensions weren't huge, even though a pandemic, again, is a very different kind of response event than say a 9/11--or a hurricane, earthquakes, somebody set off a nuke down on the mall. Those are very different kinds of responses.

But a pandemic has the potential for much greater social disruption in the fabric of our society if, in fact, you lost 25% of the workforce due to illness, and so on, and transportation goes down and energy goes down, and that could persist for a while, and it's nationwide. It's not like if you had a nuke go off down here on the Mall. That's a real problem for the Washington area: How do we take care of the survivors who have blast and burn injury? How are we gonna deal with those who've been irradiated? How will we clean up the area and reuse it at some time in the future? It took up to two years to clean up Brentwood from that anthrax exposure. So, it could put Washington's physical

space and people out of commission for 2-3 years, like Katrina has done to New Orleans, but it's local. But here in pandemic, it could be the whole nation affected. And that's very difficult for people to get their mind around. How to deal with that?

So, there I am in Santa Monica then up in Sacramento, and I'm thinking, "Hmm [both laugh], how's this gonna unfold," you know?

And Vivian Cray--Admiral Cray, who's a vice-commandant at Coast Guard--was the identified national DHS pandemic coordinator. And we'd been working with her for two or three years and planning things, and so on and so forth. She's a coast guard pilot; her view is, "what do I know about?" Well, "But Vivian, it's not about the infectious disease piece of that. Yeah, that's an issue and that's a problem; we'll work that. What it is, is if energy goes down or transportation goes down and public safety is in question, how are you gonna manage that?" So I'm thinking, "What's poor Vivian thinking right now, you know?" [Both laugh.]

SM: Well, what were some of the mechanisms that you were able to put into place to coordinate things on a daily basis? I spoke with someone, and they mentioned a governance board and said that you were instrumental in putting that in place. Can you tell me a little bit about that?

CV: Well, one of the things that we had done with ASPR, we conceptualized the ASPR activity as a whole enterprise, okay?--from soup to nuts, from putting people on the ground in a response to doing this science advance development manufacturing piece. That's a big enterprise: lots of moving parts, lots of different pieces owned by a lot of different people just within the department, you know. NIAID owns the sort of research environment; FDA owns the regulatory environment; CDC thought they owned public health. So, just within the department alone, it's bringing those people together to develop a common strategic or policy understanding of what it is we're trying to accomplish, and how do we prioritize?

I mean, if we had 15 national planning scenarios for events, from anthrax attack to a nuke with all the in-betweens--the hurricanes, the potential man-made small pox,

to a pandemic, to all this--what are the priorities? What are the operating plans for each one of those scenarios? What are the counter measures that need to be developed, and so on and so forth?

DOD owns a lot of this because they're worried about their war fighters. They're invested heavily in infectious disease concerns because those are tools of war--chemical tools of war, tactical nukes tools of war. So, they have a concern about the very same issues but targeted at the 2.5 million people in uniform and then, if you wanna widen it, to their dependents.

DHS thought they owned everything, right? The Executive Order 5 said, "DHS Secretary is in charge"; that's the incident commander for the federal government. So, how do you bring these people together to get some coherency to the process? And remember, I grew up in tribal culture that's built around consensus, and consensus is arrived at through the talking circle. You pass the feather around and people say their piece, and you come to a decision point. Somebody's got to make a decision; you hope to have consensus, but somebody's gotta make a decision. Well, in this case--for the enterprise, for the public health and

medical, for the counter measures--ASPR had to be a decision maker to the Secretary. The Secretary signs it, but the Secretary expects to be able to say then, "Here's the options. Here's the decision."

So, what we did was we stood up, early in 2006, an Enterprise Governance Board. We chartered it, named the membership, voting, blah, blah, blah. We had an infrastructure underneath with subject matter experts to do all the subject matter expert work and provide us with the best science and bring to us, "Here's your options, and the best science says, blah, blah, blah. And here's the decision point for you to discuss as a matter of policy."

And so, Julie and Andy and Elias (although more often it was Tony because a lot of this was in Tony's domain—Fauci) were the prime policy maker participants in that Enterprise Governance Board; DHS, in the person of Jeff Runge who was their Assistant Secretary for health issues, and DOD, in the person of the assistant secretary of defense for health affairs, ASDHA. And they have an ATNL, which is an acquisition's planning group that funds a lot of their development. So, you had the dark side in the ASDHA, and you had the ATNL, which is the procurement science guys.

And we would meet on a regular basis to try and come to a determination: Should we buy this new anthrax vaccine or shouldn't we? Should we acquire Tamiflu? What about pediatric dosages, how much?--to discuss those kind of policy decisions.

And so, we had that as an operational reality going into this event, the most natural thing to do to assure common communication, understanding of what the critical policy decisions were; to get a sense of where (the non-existent secretary initially, and then a new secretary who really didn't know anything about this,) to assure that we were coordinating these things; developed a relatively rational understanding of what it is we were gonna do next, recognizing that there are operational things that are built into the plan, that we're executing against the plan.

But we had all these new policy players to educate and inform as well. And so, what this enterprise activity became as much as anything else was an opportunity to educate and inform some of the new players: the Secretary's counselors--Dora and John Moynihan, and Laura and these folks so that they would understand what was going on, that

they could tell us when they thought they couldn't live with that. But as much as anything else, to reassure them that we know how to communicate with each other, we're making that effort. It's less than perfect, but things are going along. So it had a variety of uses in the mix.

SM: Did it meet regularly during the first phase?

CV: Oh, it got to where it was daily because there was a lot of anxiety on the part of the new policy players, as you can imagine. For a while, we were doing daily secure video conferences with the White House every morning at nine o'clock. So, we all go into the ops center and look at the big screen and have our dialogue with what the day's plan and activity was. And then, we also had like a noon meeting once Laura sort of got on board. We got a noon meeting with she and others. So yeah, it was maximal transparency as a process for these folks. And while we did well, I think they needed to put a little Obama stamp on it too. And I get that. That's—

SM: Politics.

CV: Right. But my attitude is I don't care who gets the freaking credit. Let's just get it done, you know, and get it done well. And in that sense, I think we met the President's expectations. I work for the President. Even at that point, I was a Bush holdover, but they were keeping me in place, therefore I work for the President.

SM: Absolutely.

CV: And I work for the people of this country, that's who I work for. So, how do we do this right, get it done right, and assure the stakeholders involved that the new policy players are getting informed on how the usual processes go, so they can change it to meet their goals, their expectations, you know?

SM: Can I ask you about the tension between CDC and ASPR? Was that something that was always present in terms of who owns public health? Is that something that has always been there in terms of the culture of the two agencies?

CV: Well, yeah. I mean, I think there's a natural tendency. I don't think it was always there, but I think there's a natural tendency that CDC is distant, and "it's

all those Washington people. What the hell do they know?" Conversely in Washington environment, which is dominated more by the political process, it's like, "those freaking isolationists down there in Atlanta."

Some of this stuff clearly got exacerbated by Tommy Thompson. I mean, let's call it like it is. Thompson, he was used to being the king of Wisconsin, and you know, he was the king of the department, and he just couldn't stand the idea that these people down in Atlanta were running their own ship. And he did some stupid things. After the fact, I think he would even admit that. And this is a guy I didn't know before, but was emailing me when I was in Iraq all the time. At any rate (and he and I get along well), he's sort of the classical plains populist at some level too. Remember Robert [undecipherable 1:23:56] and that whole Wisconsin populist mindset? He's got a lot of that in his behavior too. And I can relate to that part of it--not the king of Wisconsin. But he got in some trouble with the anthrax stuff, and the CDC folks exacerbated it by essentially saying the Secretary doesn't know what he's talking about.

SM: I see. Okay.

CV: And so, this particular Humphrey Building crowd, if you will, and CDC had real... And for us, in establishing ASPR and trying to bring a more operational capability to it, there was some inherent challenges, as I said earlier, about the culture of subject matter experts versus an operational culture. They've always handled disease outbreaks in a certain way, and now that's a 20th century paradigm, early 20th century paradigm. And there's some merit to it, but things have changed to a certain degree in terms of social cultural realities, of states and localities and competencies, and so on and so forth. And this idea of this vested expert from Atlanta coming out telling the states, "Hi, I'm from CDC; I'm in charge here," I mean, it came to a head with a particular state had an outbreak in a location, and they called us because they didn't want the freaking CDC coming down and taking over.

SM: I see.

CV: Because our attitude with them was you guys are in charge. How can we help? Whether it was a hurricane, anything else, where we engaged with the states, we work for them, they don't work for us. But that wasn't

historically CDC's attitude. And I can tell you, that goes back 50 years. My dad was the chief Vetinarian for the state of California. He dealt with a lot of disease outbreaks in animal health. Newcastle disease in chickens, cholera, and there was nothing those guys hated more than when the folks from the National Center in Colorado which is a CDC group came out and took over. And so, in one sense, the Secretary had created that tension, the stand up of ASPR created that tension in terms of the authorities and the responsibilities that were given to ASPR. "Cause it said in charge of public health and medical response. And also I was not unwilling to tell 'em, you're not serving the states well, you know. And if they call us, okay, I see the freaking mushroom cloud down in Atlanta because Colorado called us, not you guys on an infectious disease outbreak, but by God if you're gonna go back to the state and say to them well, if you don't need us to help you with this, then maybe you don't need the money for this. That creates problems, okay. So there's a lot of reasons for why that tension was there. And the other thing is I think that there is this natural division that people have had historically that says well it's all policy here and all operations goes on out in the optives. And the way PAHPA is structured put it both in ASPR. Okay. Now, clearly CDC has

expertise and capabilities that are, they are extraordinary, world class. Stay out of the way when it's something where their tools play, but they don't know the limits to their own tools either, and that's the role that, part of the role of an OS function is to say to the optive, you're exceeding your limits here. And you know, when you're a world class operation you don't want anybody to tell you you've got limits. So there's an inherent tension there too. But I think that policy in the abstract is always problematic. It's not beard-stroking thinking and then laying out a policy, it has to be engaged with the people who live with that policy and the only way you engage that is by being operational at some level, and being in constant communication with the people who live with that outcome. So that I spent a ton of time out in the states, I was probably a quarter of my time on the road, in the states, because that's where the reality is that we're dealing with.

SM: During the first wave?

CV: No, no, throughout my tenure as ASPR, but then on events, oh yeah, on the ground. Because that's where reality is, and I mean that was in part, when I was with, and I learned that in Indian Health, because we have our headquarters here in Washington, but the reality is out

there in Indian country, and the tribes would never let us sort of just sit in Washington and do Washington things, we always had to be out. And for good reason. I internalized that and believe it, you know. And so I felt like with ASPR, that was what had to be done as well because it didn't serve the Secretary or the President well, if in fact there was a ground truth being reflected back to them in the policy advise and direction being offered from the ASPR environment. And to say that the state relationships only reside with CDC, or the research community dialogue only resides with NIH or the industry dialogue only resides with FDA, that does a disservice to those stakeholders and to the decision maker in the Humphrey Building or at the White House. And that too created tension because certain elements at CDC felt like they owned the state dialogue. You know and who are you? You know. Well, who I am is, I'm their proxy here in Washington, in effect. I'm their advocate and if I'm not living with them and discussing with them and seeing what they see, then how can I be an effective advocate for their issues and shape the federal capability to be responsive as opposed to 'hi, I'm from the government and I'm here to tell you how to fix it, you know. Which is the perception of CDC."

SM: I see. Thank you. Well, I, this has been.

CV: What time is it?

SM: It's a quarter after eleven and I don't wanna keep you here forever, but I have lots of things to talk to you about.

CV: I've got a conference call I got to get to, so.

SM: Okay. May I reschedule another appointment with you to continue?

CV: Sure. Let's see, what does next week look like?

Broad Themes

Follow Up

Names:

Documents: