

INTERVIEW WITH

DR. DANIEL MILLER

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Daniel Miller  
Interviewed at Dr. Miller's Office  
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H1N1 Oral History Project  
Interviewed by Sheena Morrison

Dr. Daniel Miller: DM  
Sheena Morrison: SM

Sheena Morrison: The following interview was conducted with Dr. Daniel Miller, Director of the International Influenza Unit at the Department of Health and Human Services. It was conducted on behalf of the National Library of Medicine for the Making History: H1 Oral History Project. It took place on Wednesday, June 3, 2010, at Dr. Miller's office in Washington, D.C., and the interviewer is Sheena Morrison.

Hi. May I call you Dan?

Daniel Miller: Daniel.

SM: Daniel, okay. Okay, Daniel, how are you today?

DM: Good.

SM: Well, can we start with your giving me an overview of the International Influenza Unit's role in the federal government's planning and response efforts?

DM: The International Influenza Unit is a unit within the Office of Global Health Affairs, which is headed by a special representative or special advisor to the Secretary for Global Health.

The International Influenza Unit has been in existence for approximately five years. It was organized and developed in approximately 2005, late 2005, when the first human cases or the reemergence of human cases of bird flu occurred in Southeast Asia. At that time, there was grave concern, and there continues to be grave concern, about the potential for bird flu, otherwise known as H5N1, to mutate and to cause a major pandemic with high death rates similar to or worse than what was experienced in 1918 in terms of influenza.

At that point, Congress and the world were very, very concerned, and as a result, there was emergency funding that was appropriated. Actually, originally, the first

funding came as part of the tsunami relief emergency supplemental appropriation. There was a small amount of money for planning and preparedness for pandemic influenza specifically focusing on H5N1.

The following fiscal year, which was four or five months after that point, there was a large appropriation to HHS for pandemic preparedness; the concerns were so grave. A lot of that money went for developing and supporting the development of new drugs, vaccines; preparedness grants that went to state and local governments so that they could develop plans: continuity plans, inter-sectoral, multi-sectoral plans, continuity of business, energy, transport, et cetera. And there was a certain amount that was set aside for international preparedness, planning and preparedness for pandemic planning and response. And this office was set up by Dr. Bill Steiger, who was Director of OGHA at that time, to oversee how those monies were being used by our agencies, which primarily were CDC and National Institutes of Health.

And so the role of the office since 2005 has actually evolved dramatically. Where, originally, it was, "Okay, here's money. Where is it going, what is it going to be

used for, is it being spent?" It was more of a monitoring of how those monies were moving and the progress that was being made. But over time--and I've been here for two and a half years, almost three years--in that period of time, the last three years, the needs have increased dramatically in terms of it's not just monitoring where the money goes and how it's being spent. There are five or six areas of key functional roles that this office has assumed.

Number one is coordination within HHS. There are a lot of program activities and a lot of policy discussions about pandemic preparedness that are occurring and have occurred at CDC, at NIH, at Fogarty, at FDA, in ASPR. And there has not been a central location of coordination of information in those policy discussions, so our office stepped into the role of trying to coordinate program as well as policy discussion.

We also have done and continue to do a lot of policy analysis in terms of what are some of the barriers to effective pandemic preparedness internationally. And how can HHS and the U.S. government be more supportive and improve upon our support of the World Health Organization, of other organizations, of countries bilaterally, in terms

of their preparedness planning and response planning? So, program coordination between particularly CDC and NIH; policy coordination; policy analysis; representation in international negotiations. For example, there have been parallel international negotiations on the terms and conditions of the sharing of influenza viruses and the benefits that developing countries want and expect to receive as a result of them participating in this global surveillance network by providing their samples. Some developing countries, for example, want some of the vaccine that's developed as a result of them providing their samples. And there's been a three-year process of negotiations about the terms and conditions for the sharing of those viruses as well as provision of benefits back globally to developing countries who lack access to vaccines, antivirals, to laboratory diagnostic capabilities, et cetera.

So we also coordinate with other U.S. government departments. It's not just HHS that has been involved with pandemic planning and response. Other departments include the Department of Defense, the State Department, USDA, USAID, and those are the primary. And in some of these discussions related to benefits and sample sharing, those

have touched on issues of intellectual property rights, international norms and standards of intellectual property protection. So we've had to coordinate also with the U.S. Trade Representative office, the Office of the U.S. Patents and Trademark office. So there is a lot of interdepartmental coordination that has been necessary so that we are hopefully moving in the same general direction, even though our funding streams and authorities differ from department to department.

We also coordinate with other international organizations, primarily the World Health Organization, the regional offices of the World Health Organization, the World Bank, the Gates Foundation. There are a few nongovernmental organizations that have had interest and have been working in pandemic preparedness, but, once again, there hasn't been a central location for collation of information as well as reaching out to them for policy discussions and planning, coordination.

We work with other multilateral organizations such as the Global Health Security Action Group, as does ASPR. One of our primary areas of cooperation and collaboration and coordination is with ASPR because they're in charge of

antivirals and the vaccines, and we're more involved... They're also involved in the policy discussions. We're also involved with policy discussions, and much more on the foreign policy. We coordinate with individual countries in terms of what they're planning to do and how both donors and recipient countries and developing countries...

And then the pandemic came, and so planning was finished. Now we had to respond. So all those different, that six-dimensional chessboard in terms of within HHS: coordination, coordination between U.S. government departments, coordination with the World Health Organization and outside entities, bilaterally, multilaterally, was just revved up even more in terms of who's doing what, what's the problem, where is it, how severe is it, is it early on? The information coming from Mexico was very scary in terms of how severe the illness was. And so we had more of a role of coordination. CDC certainly had the lead on responding from an epidemiologic perspective and laboratory perspective, but there still needed to be some air-traffic control.

For example, in the early days, Mexico requested approximately \$10 million in medical assistance in terms of

they needed 10 field hospitals, and they wanted 10 million doses of antivirals, and they wanted... Well, where does that request go? It came to HHS. So we became a repository for those kinds of requests coming in so that we could triage them and move them out to where they needed to go.

So, that's sort of the answer in terms of what the IIU is, what are its functions, and how that function really has changed from its inception. And today, we still do it all because the pandemic has not ended. The Southern Hemisphere is in sort of their second wave. They're just entering their winter and their flu season--second winter of flu season. So, domestically, things have kind of died down, but on an international front, it's still going. So we're still very, very active, and we have fine staff.

SM: Well, you said that you were in this position for three years.

DM: Two and a half, almost three years.

SM: But you were working in influenza internationally prior--?

DM: My background is I've been in Washington for 11 years. CDC is actually my employer, and I'm assigned here to the Office of the Secretary from CDC. So for the last 11 years, well, off and on for my entire 21-year career, I've been involved with international health. But this was the first work that I'd done with influenza specifically.

SM: I see.

DM: Prior to this, I was actually at the State Department, assigned to the State Department in their Office of International Health and Biodefense to provide, as a Senior Policy Advisor on international health, basically everything except HIV/AIDS because that was done by PEPVAR. And then I was there for 18 months.

Before that, I was congressional liaison here in the Legislative Affairs Office of CDC. So I was a congressional liaison to Capitol Hill on global health, working primarily on malaria, polio eradication, et cetera. Before that, four and a half years as a Senior Technical Advisor to the World Bank, working in Eastern Europe, Central Asia, and Southeast Asia, providing technical and policy support to

World Bank projects on global health, on health systems development, and that sort of thing.

So it's been a progression in global health. My professional background is I'm a family physician by training, so I've done obstetrics, gynecology, pediatrics, adult health, geriatrics, surgery. We did the spectrum. So my professional background is a generalist, and in public health at CDC, we all tend to be generalists. Unlike NIH, where you focus down and you make a career in one disease, in public health we have to deal with many things that come up.

SM: Okay. Well, because I've seen your name in different areas.

DM: Before that, I was Cancer Prevention and Control. So it's whatever is needed.

SM: A renaissance man.

DM: I don't know. I feel that old.

SM: Well, let's say the Harlem Renaissance then.

DM: Yes, that's right, that's right, that's right.

SM: Well, this is a huge portfolio for your unit, how did you facilitate this in your capacity as Director?

DM: I think the best descriptor is air-traffic controller; that I have, and had, a small number of staff. And because I'm the senior member (I'm senior staff from CDC in Washington), I've had experience in the distant past in other emergencies, humanitarian crises, in Somalia, Eritrea, Ethiopia. And I know the public health system backwards and forwards in terms of how to get things done. You don't necessarily follow the organogram. There's the official organogram, and then there's the organogram that you have in your mind of who you go to get things done or get information.

SM: I see.

DM: And that's the perspective that a senior public health person can bring.

In my role as facilitator, it was really directing more junior staff in terms of "okay, our major priority for today and this week is or are." Prior to the pandemic, I think it was more of the big picture: where are the gaps in our preparedness? Who is it we need to talk to in terms of relationship building, partnership building? Who is it we need to be developing better communication ties with at WHO? Who do we need to be negotiating with? What are those positions that we should be taking?

For example, in the international negotiations on sample sharing and benefits sharing--three years of negotiations of every four months--we're having international negotiations every six months. We had to write position papers that had to be reviewed and discussed and come to consensus positions within the U.S. government. We did that in conjunction with the State Department, but since we're technical and the State Department isn't, the State Department tended to a lot of the diplomatic piece. We did the technical piece in terms of "here are the options of what we can do in terms of sharing of samples. And this would be the repercussions if we agree to these kinds of restrictions."

When H1N1 hit, for example, we wrote the options papers for the White House and the National Security staff in terms of we're getting all these requests for international assistance. Now, what criteria are we going to use to respond, and who should be responding, and how? When vaccine became available, we wrote the paper, the policy options paper in terms of should we be donating vaccine? If so, how, when, how much? And so my personal role was to direct all of those spinning plates. And early on, it must have been in the first month or so, we were just completely overwhelmed--small staff, didn't have the infrastructure in place. Just communications of, I carried the Blackberry, and I was getting calls 24 hours a day because somewhere on the globe, someone's awake and is trying to deal with their crises.

SM: Right.

DM: And policy discussions at 11:00 at night because that's when people are available.

So we didn't have an infrastructure in place of people that were prepared for the pandemic in our own office and in the Office of the Secretary.

SM: I see.

DM: The Secretary's Operations Center was focused on domestic, so they have communications. They have people. They have protocols. For the international piece, we had been working for two years to develop the plan, and just as we were getting ready to have a final draft of that plan is when the pandemic hit. So we still don't have a pandemic response plan because we had to set it aside in order to respond to the pandemic. So we didn't have the people in place, we didn't have the communications. We didn't have the things that we really needed to be able to be efficient.

So, for example, in the first two weeks I realized that--of course, I was getting a thousand e-mails a day and couldn't spend all my time trying to get through the e-mails rather than trying to think about what needs to be done--and so what I realized was information and questions and requests were coming in from all over to everywhere in HHS, and CDC, at the State Department, and so everyone was sharing those e-mails with each other. So, there was no central location for those communications to come to that then could be

triated out, so the communications were multiplied by 10 or 15, unnecessarily.

So, the first thing I did was I went to the SOC and I said, "Can we please get a chair in the SOC?" and the answer was "No." Okay.

"Can we have people here?" "Maybe." Okay.

"Can we get a telephone line or an e-mail address?" "No, no, no, no. That would cost money." Okay.

So, we set it up ourselves. We set up a central e-mail account. It was [hhs.international@hhs.gov](mailto:hhs.international@hhs.gov), and then, as all these were coming in, we would be responding, saying, "For future communications, please send it to this central address." Then we would staff that e-mail account and do the triage of, "Oh, here's a request to USAID." We send it to USAID. "Here's a request to CDC for diagnostic kits." We send it to the CDC.

So that kind of planning was not in place when the pandemic hit. We'd always been focused on what everybody else needed to be doing their infrastructure planning, and we hadn't gotten to ours yet.

And early on, because of the overwhelming nature of the pandemic, I made a tactical decision in conjunction with ASPR and Maria Julia Marinissen where she had a group of people who were interested in international. She was becoming the point person on requests for antivirals and requests for vaccines. And so, we functionally merged our two teams into what we called the super-team, because then we would have a critical mass of people that we could work together because they had their equities, we had our equities, we could pool those resources and, more importantly, be in close communication and coordination with each other. As our requests for antivirals came from wherever, I made sure they went to her. If there was a request for, I don't know--I have so many e-mails, I can't think about what--she'd send it to me. And then we would get a weekend off once in a great while because then I would say, "I'm done. You have the Blackberry this weekend; I'm going to sleep."

But even in terms of having standard operating procedures and tracking mechanisms, we had to set that all up while we were doing it. So I used the metaphors that we were trying to repair the engine while we were flying the plane, and that was very difficult because we had so many requests

that were so complicated, and we took on the responsibility to track those requests through to completion. So, if it was a request coming for personal protective equipment, that was USAID's responsibility, so we would send it to USAID. But then we would follow up with USAID, "Did you send it?" because our concern is--our office and the Office of Global Health Affairs--our concern is not just the technical piece, but the diplomatic piece and the international relations piece. How awful would it be to send something to the U.S. government for which you'd get no response, or you don't get what you ask for or at least an explanation of why you didn't get it?

And we worked through the State Department because they were very adamant that any communication with the government has to be through the embassy. Okay, right, that's fine. So our spreadsheets of tracking of incoming requests--primarily the biggest requests were for information. But since the pandemic started here and in Mexico, we were overwhelmed with requests: What's happening? What's going on? And, once again, internationally, we didn't have a central location set up that those communications could come in or go out. Domestically, yes, they had the media room. They had the

spokesperson already set in terms of who's going to be talking to the domestic media. And CDC has their Emergency Operations Center with hundreds of people, and at some point a thousand people working on it. We had five.

SM: In my interview with Mary Mazanec, she mentioned a matrix, and that this was a matrix that was created to actually manage this. Can you tell me more about it? Is this what you're talking about where it monitored the requests? It seemed similar.

DM: It's a spreadsheet. Yes.

SM: Is that something that we might be able to keep for the archives?

DM: Oh, yeah. At this point, we haven't had formal requests for assistance in months, so we actually closed out the files and archived it ourselves. And every request says "file closed, file closed, file closed." So if you just send me an e-mail, I can get that.

SM: Great. That would be great.

DM: And those are requests for assistance.

We ended up not tracking, not being able to track requests for information because they were just overwhelming. But the requests for assistance, requests for antivirals, requests for vaccine, we tracked very carefully, and we have all of those, yes.

SM: And they came from all over, as you mentioned.

DM: All over, developing countries, developed countries. We'd get requests from developed countries that, "We need to vaccinate our pregnant women, but we aren't scheduled to get any vaccine for another two months. Can we borrow some from you and pay you back later?" And then the least-developed countries, "We're never going to be able to get vaccine. Can you please donate some?" So it's the full spectrum of kinds of requests.

SM: And so these queries, they came directly to you because of your--?

DM: They came from all over.

SM: Oh, and they were just forwarded to you?

DM: Yes.

SM: I see.

DM: Since those communication channels were not set up, in the first few weeks, most of my job was just monitoring, okay, "Oh, here's something from Chile. Oh, let me pull that down and see what it says." "Here's a request from Kyrgyzstan. Okay, let me pull that down and see what that says," because we hadn't set up those--we had to focus so much on domestic that we hadn't focused on what we needed, even in terms of roles and responsibilities. Who in the Office of the Secretary was responsible for responding to international requests? Is that written anywhere?

SM: So, tell me, what--

DM: In draft form, yes, but in terms of being in place, no.

SM: Is there anything being done today, now, as a result of, first, the H1N1, and then right on the heels of that

(although it's not related to influenza,) then there was Haiti, and then the tsunami. So has this sort of stirred the pot?

DM: Very much so. Things have quieted down some. As I said, we have this lull between the Northern Hemisphere and Southern Hemisphere winters. And so we have resurrected-- the ASPR has the lead on, it's called the International Emergency Response Framework. It's an all-hazards approach to how do we respond, how will HHS respond to international emergencies? But the first case study is pandemic influenza.

SM: I see.

DM: So that's where we were before the pandemic, just as the pandemic hit.

And just going back--sorry if I digress a little bit--part of my role, our role, was the State Department was also writing their own plan, and USDA had their own plan, but there was no pulling them together as to what's the common plan for the U.S. government. And there were conflicts in terms of who's responsible for what and what will be the

standard operating procedures. So, we were in the midst of negotiating that when the pandemic hit. Well, now we're picking it up again and we want to finalize. And we certainly now have the benefit of the H1N1 experience to better inform what really was theoretical and hypothetical. It can be much more reality based.

So, for example, a lot of our planning early on was for containment, the idea that this would come, arise in Cambodia and we'd send a SWAT team out there to try to contain it before it got out. Forget that! If we weren't able to do that in North America, where we have the best surveillance systems and the best public health response networks in the world, it's not possible. So that process is starting to get, in terms of getting a new response framework.

SM: Okay. So let's go back to the beginning.

DM: Yes.

SM: Can you recall where you were and what you were doing when it became clear that this novel virus was highly

transmittable? And at what point did you actually immerse yourself into the response?

DM: I don't remember the exact date. It was sometime in April of 2009. Because I work for CDC, I have a very close communication with the Influenza Division in CDC. So when anything unusual, for example, since I've been here, anytime there was a new case, a human case of bird flu, we would communicate about it in terms of they would tell me, particularly in Indonesia where they were no longer reporting the cases, but they were occurring.

"So, what do you know?" This is what I heard, because the higher-ups were very concerned about these three cases in Indonesia: "Are they real? Are they a cluster? Is this the beginning of the pandemic?"

So, I was in very close communication. And somewhere, as part of that sort of routine--it happens this day, it happens that week, the week before, the month before--that communication was already in place.

Then, one day, I heard the media reports of what was going on in Mexico, and I called immediately and I said, "What is this?"

And the Influenza Division said, "Well, we're not sure, and it's an unsubtypable."

And then the next day or so, they said they'd gotten...It was just...

"Okay, who's getting the samples? Because I have to report to my director, and the director reports to the Secretary what's going on." And so I said, "Okay."

So they said, "We're sending people down. They're going to help."

"What's the status report? What do you know? Where are the samples? Who's testing them? What are the results? Call me with the results."

And they called me saying, "This is unsubtypable." That it's influenza A, but it's unsubtypable.

Okay. There was this diplomatic row with Canada because some of the samples went to CDC, and some of the samples went to Canada.

And I was asked, "Why did they go to Canada?"

I had to go back and say, "Why did they go to Canada?"

And it was a miscommunication, because CDC, for example, by their strict criteria for samples, they want samples within 72 hours of the occurrence of fever. Well, Mexico had samples that were beyond the 72-hour window, and so my

understanding is that a low-level person said, "Oh, well, we don't want those."

Well, the higher-level person would have said, "Oh, yeah, whatever."

But what got communicated to Mexico was, "Oh, we don't want those samples."

And Mexico was saying, "What?"

So that's a diplomatic problem where Mexico, another country is asking for assistance, and someone down here is saying, "No, we don't want those." So I had to find out what happened, report back, "that's why those samples went to Canada."

But it ended up fine because then you had two separate, independent laboratories confirming that it was influenza A, unsubtypable. Well, that's of concern.

And then, within a day or two, we heard of influenza in San Diego. I immediately called up and said, "Okay, we need to have a conference call with CDC and ASPR." (Was it ASPR? I don't remember.) And I said, "Okay, what is this?"

And they said, "Well, it's unusual. It might be in the same family. But we also, that family... There's another case in

Texas. It might have been that they were on the same airplane. We don't know."

And I remember asking, "So, is this in any way related to what's going on in Mexico?"

And the answer was, "I don't think so, but we don't have enough information from Mexico to know." And the rest is history.

And this is typical for any new outbreak. There's always uncertainty. You don't know what it is, and then you don't have all the information you need to be able to have a complete picture.

The San Diego, we were able to have a clearer picture because that was within the context of an actual scientific study. CDC was testing a new diagnostic kit, and it came up positive. And it happened to be in kids which ended up having H1N1. If they hadn't been testing that diagnostic kit, it may have been a week or two weeks later, through the usual public health system, that those discoveries might have been made. But it was in the context of a well-controlled, highly monitored, scientific project of testing this new diagnostic kit. And what they discovered was, with

this kit, it comes back as influenza A; with this kit, it's untypable. So, that's how they discovered it.

And in Mexico, because their surveillance system has a few challenges, it took a month before we really knew what was going on in Mexico. Even the federal government in Mexico couldn't find out what was going on because they're so decentralized, and they're federalized in terms of their relationship with the states of Mexico. So, that's my memory.

And then it was just full speed ahead from that moment on in terms of, because then, when that hit the press, then the European Commission calls and says, "What the heck is going on? What do you know?" I'm not talking to the Commissioner of the European Commission; I'm talking to my counterpart in the European Commission, saying, "What do you know?" And then everybody's calling saying, "What do you know? What's going on?" and then it just accelerated from there.

SM: Can you tell me about some of the major issues that you immediately had to contend with?

DM: As I said earlier, typical in any outbreak of an infectious disease, the uncertainty of is this influenza, is it SARS, is it some, especially if it's unsubtypeable, if you can't type it with what diagnostic kit you have, what is it? And since it was occurring in another country, you can't just swoop in and take what you want and need to get the information. So the uncertainty was difficult.

The other major challenge I would characterize is we had done so much work on making sure that everybody else was coordinated, and that everybody else had their plan, and that everybody else had their standard operating procedures, we didn't have ours in place. And, as I explained, we didn't have communication, we didn't have telephones, we didn't have a central e-mail account, we didn't have any standard operating procedure of, as these requests come in, who do they go to, and putting together the contacts. Who at USAID is the right person in the Office of Foreign Disaster Assistance that we should be calling? "Oh, no, don't call us until it's phase 6."

"Well, then, who do I call?"

"Well, call that person."

"Well, no, they're not here. They're traveling."

Well, then, who do I call? So having those things preset was extremely stressful because, as I said, early on, the fear factor was very high because what we were seeing and hearing from Mexico was very, very serious. And so it was extremely frustrating to not have that.

And then, of course, I kicked myself. Why did I spend so much time thinking about everybody else? Why didn't I think about what we needed to do in this office in terms of having-- I had to wait four days for a Blackberry, which means I was chained to my desk and cell phone at home. I didn't have access to all the files I needed from home because I didn't have the key fob. You know, it's just, we were not ready for an international response in the Office of the Secretary.

SM: And who was responsible for coordinating the communication between the international community and the various government agencies?

DM: We had to make it up as we went along. That was part of the planning that, for example, part of the negotiation in the pre-pandemic draft was the State Department saying that they would coordinate and communicate with the World

Health Organization. And we, as a technical agency, said WHO was a specialized technical agency; HHS will be the one to coordinate on operational issues. And that was a disconnect, policy-wise. And that is what we were trying to negotiate, to get clarity on that. And as it turned out, this was, of course, also in the early days of the new administration, which was on top of that. I knew who to call in general at USAID and the State Department, but many of the higher-level positions were empty or new people who, one, didn't know what we had been negotiating in terms of policies and procedures. And so, on top of that, you're trying to brief them on, "oh, this is the way we're supposed to be doing it." Or, there's nobody there in terms of empty chairs.

So in terms of communicating, coordinating in the international community, I would say that CDC had the lead on operational issues. And that's appropriate because early on those technical issues were paramount in terms of what do you know, where is it, how bad is it, what's the virus look like, what do we need to be doing, where do we need to be shipping people, where do we need to be shipping antivirals?

And then there were just a lot of requests for situational awareness from all the other countries around the world who did not have any influenza yet, but they wanted to know minute-to-minute what was happening. We did not have a central location, and we kept referring them to WHO because that is the appropriate source, because they have to have the big picture of what's going on in the U.S. and Mexico, and then it was in Singapore, and then it was here, and then it was there. We are not going to be able to keep track of that.

So we referred people to WHO "if you want information about what's going on internationally."

So, one of the chairs that was empty was OGHA. So a lot of that responsibility ended up falling onto Jerry Parker in ASPR because Nicki was--I'm trying to remember whether Nicki was on board yet. I think she was. I think she was, yeah, but she hadn't been confirmed. It was just the worst time for a pandemic to start. Actually, it would have been worse if it was January 21<sup>st</sup>, but it wasn't much better.

So, in terms of coordinating communications with external international, the State Department tried to take on some

role in terms of talking with what was called the IPAPI core group, the International Partnership on Avian Pandemic Influenza. ASPR talked informally with members of GSAG, the Global Health Security Action Group, G7 plus Mexico. The communications folks, Bill Hall's group, actually had a working group within GSAG that was very, very active in terms of coordinating the kinds of communications that the G7 countries plus Mexico--and that was the result of a lot of pre-pandemic planning and preparation for that. So that was a very active group.

But a lot of it was hit and miss. We didn't have a specific spokesperson for international. It ended up, a lot of that was done by CDC. I remember Ann Shuchat was asked to make a presentation by videoconference to an international meeting of APEC (Asia-Pacific Economic Cooperation) in Bangkok to give an update on what's happening in Mexico, what's happening in the U.S. So it was really quite mixed as to who was--the very public figures were probably at CDC, and I think that's appropriate because they have the technical part. But more of the informal, Maria Julia did it, I did it; we are joined at the hip in terms of who did you talk with. "Oh, I talked with so-and-so at PAHO." "I talked with

so-and-so in Euro." "Okay, well, what did they say, what did they want?" So that's how a lot of it got done.

The State Department I would say was, in my opinion, dysfunctional. Pre-pandemic, with the previous administration, they wanted to be the center of the universe in terms of intra-U.S. government coordination across departments on all policies. And with the change of administration, change of personnel, then when the first time I made a phone call and said, "So, when are you going to pull together an interagency coordination meeting?" "Oh, we're not going to do that." They set up there what they call a task force within their Emergency Operations Center at the State Department, but their primary purpose was to serve the information needs of Secretary Clinton.

So, pre-pandemic, this task force, what we were negotiating with them about was the State Department wanted to be the coordinator between all the departments. But when the-you-know-what hit the fan, they backed away. And then guess who it falls to?

On top of that, in the pre-pandemic planning, at the very beginning of our trying to develop a U.S. interagency

pandemic plan of how we were going to respond and coordinate for the international aspects, USAID had been around the interagency table, and we said, "Well, you know, OFDA, Office of Foreign Disaster Assistance, they do this all the time: Haiti, earthquake there, hurricane there, boom! They have an operations center, they have people, they have contracts already in place." And USAID said, "But that's only when the pandemic becomes phase 6; up until, between now and before phase 6--not our job."

So, Maria Julia and I said, "Okay, we'll work with that." And so we had to put together a policy paper for the White House saying, "Okay, who's responsible for flow of communications within the U.S. government and with the White House up to phase 6, before phase 6?"

"HHS."

You know, we had all the diagram of how it all flows in, and there's this sub-IPC and this policy decisions and discussions, great, great. Well, phase 6 gets declared. We said, "Okay."

We call up USAID and say, "Okay, we're ready to transfer our files, our spreadsheets," and blah-blah-blah.

And they said, "Why?"

"Well, you said that you would take over at phase 6."

"Well, it's not as severe as we thought it was going to be, so no, we're not going to do that."

"Really?"

Well, then, who does it fall back on? So all that pre-pandemic planning I wouldn't say was for nothing--there were good things that we did. But in terms of some of the critical roles, clarification of roles and responsibilities, it had been on a trajectory of this is what it will be, but because of transition of administration and the pandemic hit before interagency consensus, there was no consensus. And that--

So, once again, we repaired one of the engines. Now we have to go repair the other engine on the plane that we're trying to fly.

So for me, personally and professionally, I think that that what was most stressful is that we had been operating under a draft of "this is the way it will be." Even though we didn't get final approval from the White House on this plan, everybody had been around the table, and we were coming close to a consensus on all the little details. And when the pandemic hit, some of the senior people were no longer there, and the people who were left behind backed

away. So, given that it was a health issue and it was international, boom, it's on our plate, Maria Julia and my plate.

SM: So you guys were essentially the point people for the international community in addition to the different agencies?

DM: I wouldn't say the point person. We were the air-traffic controllers, because my acting boss would get information that he would funnel.

SM: And who was that?

DM: That was Jim Kulikowski.

SM: Okay.

DM: Nicki would get information, or Dr. Parker would get information, and he would funnel that to Maria Julia.

Dr. Parker probably had more of a leadership role in convening. Mary Mazanec also, in terms of they were trying to get themselves identified as contact points. But because

we didn't have that all set up, it came in from all sources. I would get e-mails from the CDC Emergency Operations Center saying, "Oh, my God, we just got this from this country. What do I do with it?"

I'd say, "Okay, I'll take it, triage it, follow it through to the final disposition."

We would get requests. CDC was sending out the diagnostic kits. We would get requests directly, by e-mail or by phone call or by, you know, the friend of the friend of the friend, and we would direct those to CDC. So, initially, there was a lot of that, just air-traffic control and triage. And it was unnecessarily duplicative and unnecessarily inefficient because we hadn't done the level of planning that we needed to do, because we had been, quite frankly, trying to move the ball on getting everyone else to agree on what their roles were. When it came time, we weren't clear on what our roles were, partly because that was sort of going to be the next step. But also because there was a lot of backtracking in terms of there was no interagency consensus, so there's no plan.

SM: Right. You mentioned a little bit about some of the agencies that you communicated with, but can you tell me

more about the agencies, international and domestic, that you were most engaged with in the beginning, and perhaps who were the contact people?

DM: Domestically, no one, because anything that came domestic I automatically transferred to CDC or to the SOC because I was very clear on what was not my job.

Outside of U.S. government--is that what you're referring to?

SM: Right.

DM: Okay. Outside of U.S. government, the primary contacts and people that I would work with would be my counterparts in Canada, Japan, Australia, France, U.K. At WHO, it was Keiji Fukuda, who is now the Assistant Director-General. He was Director of the Global Influenza Program at the time at WHO.

With PAHO, Maria Julia primarily did that because she's a native Spanish speaker.

So, it was through our work through these international negotiations and the years of getting ready to plan for a pandemic that I already had my go-to people in each of those countries. And they weren't necessarily *the* coordinators, but they were my entry points. And so they would get the information or refer me to the right place. They would call me for information. And Maria Julia has her own contacts, and so we merged our information together so that we had a common picture.

Who would be some of the others? Mexico. CDC did most of that. Since it was heavily in Mexico, CDC really took the lead, so I didn't get involved with contacting people in Mexico because they were being overrun with people from all over Mexico, outside North America, U.K., the European Commission, France, Italy.

Then, as we started getting the requests for antivirals and access to vaccines, then it would be on whoever the requester was. So, antiviral requests were coming from...I'm trying to remember some of the lists. Sorry, I'm just blanking. It's there in the documentation, but I just can't remember off the top of my head. It seems like it was a year ago, but it seems like it was years ago.

SM: I'm sure.

DM: Years ago. So I guess those are the primary ones. I'm trying to think if there's any other--

There was some contact with the Gates Foundation in terms of their concern about the vaccine, whenever it would become available, and in terms of the principles of equal access by developing countries, that they should get access at the same time that developed countries do.

Gates, WHO, PAHO; I think those were the primary ones.

SM: Were you present for the meeting when Margaret Chan came for a visit to HHS?

DM: Yes.

SM: How would you characterize that meeting?

DM: I have to think about that answer.

SM: Okay. Take your time. Like, how was she received?

DM: Oh, very cordially. It was in the very early days. I think it was like the 28<sup>th</sup> of April or something like that.

We still didn't know what was going on exactly. And the issue at hand at that point was whether the United States was going to report and declare a public health emergency of international concern. And the issue whether Margaret was going to convene a meeting of the WHO Emergency Committee to review the status in terms of potentially changing the pandemic phase from 4 to 5.

So I would say that my memory of that meeting is that Margaret is very charming, and the agenda was really not supposed to be focused on influenza, but because of what was going on, she just swept aside her itinerary. She was here for her, I think, polio meeting, and she just swept aside her itinerary in order to meet with the U.S. She said she had just gotten off the phone with the Ministry of Health in Mexico, trying to get more information, trying to work out where the samples were going, et cetera, et cetera, et cetera. So there was a lot of information going back and forth.

I recall that because Mexico was experiencing, at that point, a bottoming-out of their tourism industry, and empty resorts and enormous economic impact, there was concern in the United States that there might be a similar impact. So, I recall that there was some discussion with her as to whether the U.S. needed to report a possible PHEIC, because at this point, it wasn't. I don't know what the logic was.

At that point, I would say that there was concern about the economic impact and some reluctance to maybe jump the gun or declare something that we weren't really sure was a true emergency yet. And there was, I think, some difference of opinion, but very cordial in terms of whether Margaret had the authority to declare a Public Health Emergency of International Concern. What happens is, under the International Health Regulations, countries are supposed to report information to WHO, and then the Director General makes a decision as to whether it's a public health emergency of international concern. We don't declare it, she declares it, but we report the information. So it wasn't that we weren't going to report, it was the question of whether she was going to declare this a public health emergency of international concern.

And I think there was some discussion about whether it met criteria to be a public health emergency of international concern, and the potential impact that that would have if she did. And there was some lack of clarity because it was all new people on the senior level here, and I don't recall whether Secretary Sebelius had even started yet. Maybe it was her first day or second day or third day. And there was a question as to whether the Director General of WHO could convene this group without consent of the reporting country, or whether consent was needed or not--not without, but whether consent was needed. So I would say that there was some reluctance to jump into this as a major problem, and she just went ahead and did it anyway.

SM: Well, it seems that people may not have been all that familiar with the International Health Regulations.

DM: John Monahan, I think it was his first week, and he was not familiar. And he was quite reluctant for there to be a declaration given what we were seeing in terms of the economic impact in the resort areas of Mexico. He didn't say it, but...

SM: Okay. And the other people at the table, was this a consensus, or was it open for discussion?

DM: It was really open for discussion. John was taking the lead. It was Margaret Chan, her Special Advisor, Ian Smith.

Once again, I'm trying to remember whether Nicki was on board then or not. I think she was not then. She hadn't been confirmed.

I'm trying to remember who else was around the table. It was Kulikowski, Monahan, Mazanec, and I don't remember whether Parker was there or not, and then Margaret and Ian and one or two other people from her entourage. And then the rest of us were sort of standing around. It was in 640H, so there weren't enough chairs. So we were standing around the edges and running out to get the latest on what was going on. So, that's my memory.

SM: I see. So, the main purpose of the meeting was for her to discuss the latest news that she had and what she was considering.

DM: Correct. Her trip here was polio, but she swept it aside and met with us. She had a meeting, supposed to have a meeting anyway. But we, just folks, "What's the update? What's the latest?"

SM: And what were your immediate concerns at that time, right then?

DM: Right then?

SM: Yes.

DM: My concern was this was the big, this was the real thing, and it was going to be devastating, devastating! I was quite frightened by what we were seeing.

END OF INTERVIEW

#### Broad Themes

- International Influenza Unit - within Office of Global Health Affairs
- Congressional appropriation for H5N1

- Congressional appropriation for pandemic preparedness
- Functional roles of International Influenza Unit
  - Coordination within HHS
  - Policy analysis of effective pandemic preparedness
  - Representation in international negotiations
  - Interdepartmental coordination with other U.S. government departments
  - International coordination with WHO, regional WHO offices, World Bank, Gates Foundation
  - Bilateral and multilateral coordination - e.g. Global Health Security Action Group, and individual countries
- Career trajectory of Dr. Miller in public health, international public health
- Role of Director of IIU - Facilitator
- International negotiations on sample sharing and benefits sharing
- International pandemic response plan, unfinished
- Infrastructure for international response
  - Communications - central email account

- International Influenza Unit and International Partnerships and Initiatives Team merger into super-team
- Standard operating procedures and tracking mechanisms
- Requests for information
  - Matrix - tracking mechanism
- International Emergency Response Framework
- U.S. Government preparedness plan
- Diplomatic row with Canada - virus samples
- Untypeable virus - California, San Diego, Mexico
  - Uncertainty
- Coordination of communication between international community and U.S. government agencies
- Situational awareness, international requests for
- International communications
  - State department - International Partnership on Avian Pandemic Influenza - IPAPI
  - SPR - Global Health Security Action Group - GSAG, G7 plus Mexico
- State Department - task force within Emergency Operations Center
- Responsibility for interdepartmental coordination

- U.S. interagency pandemic plan, pre-pandemic
  - Coordination of international aspects - USAID, OFDA
  - Transition of administration - lack of continuity, incomplete plan
- Role of Miller, Marinissen - triage, facilitators
- Major international agencies, engaged with - WHO, PAHO, Gates Foundation
- Meeting with Margaret Chan
  - Declaration of PHEIC

Names

- Dr. Bill Steiger - former Director of OGHA
- Bill Hall - GSAG
- Margaret Chan - Director General, WHO
- Ian Smith - Special Advisor to Margaret Chan
- John Brennan
- Jim Kulikowski
- Dr. Parker
- Keiji Fukuda - Assistant Director General, WHO
- Mary Mazanec

Documents

- Policy options paper on vaccine donations
- Option papers for the White House and the National Security staff on requests for international donations
- Matrix - tracking mechanisms