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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Interviewed on July 7th, 2010
H1N1 Oral History Project
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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, July 7, 2010, in Dr. Miller's office in Washington, D.C., and the interviewer is Sheena Morrison.

Okay. So, during the last interview we ended with the meeting with Margaret Chan, and you spoke about the characterization of the meeting, her purpose for being there, and how she was received.

Can we begin again with the International Health Regulations and pick up from how familiar were you and

others of the lead agencies with the international regulations which governed her declaration?

Daniel Miller: I would say that we were very familiar with the International Health Regulations because the U.S. was a major proponent and supporter and negotiator of those new International Health Regulations back in two thousand and--actually, it was a five-year negotiation. They were concluded in 2005. So I would say HHS was very, very knowledgeable about the International Health Regulations.

There was a little bit of confusion of some of the process at the beginning, in terms of this was really the first pandemic since the--or potential pandemic, because in those early days, we didn't know whether this was a pandemic yet. It was localized in Mexico and the U.S. It had not yet spread or was just beginning to spread to other countries, and so we really weren't clear that it was a pandemic yet, and it didn't meet the criteria of a pandemic yet. And so, there were some early processes in terms of we understood how we were supposed to report, which we did, because we were reporting other infectious diseases since 2005 that had--they were called public health events or emergencies

of international concern. So we had been reporting things routinely in terms of WHO, as we were required.

But in the nexus between the International Health Regulations reporting and the role of WHO's Emergency Committee to determine the pandemic phases, that was a little unclear about that IHR process in the pandemic phase process. And that's where we initially had some confusion in terms of we reported as we were supposed to, but then what would be the process by which WHO would declare or review the data to consider changing from phase 3 to phase 4 and phase 4 to phase 5? That was unclear. So I'm not sure that that was a confusion about the IHRs, as much as it was about pandemic phases, because that had never been tested, as far as I know, in terms of that. So our initial confusion was related to the process.

We knew that there was an Emergency Committee; we knew that there was U.S. scientist representation on the Emergency Committee. And there were some words on paper somewhere that described a consultative process with the reporting countries in terms of the process of determining if this was truly an international event, a public health event,

and also in terms of the process by which WHO would change the phase level from 3 to 4.

And the nature of the confusion was, let's say, some interpretation of the processes or some fuzzy wording. One interpretation was that the reporting country would have to provide consent for WHO to call together the Emergency Committee, and that was clarified by Margaret very quickly in terms of "No, we don't need consent. We just do it."

And there was some discussion early on in terms of, well, you know, this is not really a public health event of international concern because it's just the border between Mexico and the U.S. And at that point, it hadn't spread to--we didn't know that it was confirmed in New York yet. Because I think the concern was that as this had occurred in Mexico, their tourism dropped to 20 percent, and the concern was that there would be similar problems in the United States in terms of visitors to the U.S. So, it was swine flu in terms of pork exports, the economic and financial impacts of this, at the same time as an economic meltdown in terms of the recession. So, there were concerns about, well, you know, are we really sure that this is a pandemic?--blah-blah-blah-blah-blah-blah-blah. But Margaret

clarified, "I'm sorry, but we don't need your consent. We don't need anybody's." She was more diplomatic, and said basically, her interpretation of the wording was she would notify the reporting countries with 48 hours advance before the meeting of the Emergency Committee. The wording was interpreted as that they had to, the United States or the reporting countries would have 48 hours to provide consent or input or whatever. So, there was some nebulous wording that there was a little bit of friction there at the beginning.

And, once again, these were all new people, new administration. Some people had been on the job two or three days. Our Secretary was not even yet, whatever the word is--

SM: Sworn in.

DM: Sworn in, or approved by Congress.

So there was a lot of going back and forth internally in terms of what is it that we have to do. Well, we're clear on what we have to do. Now, how do we interpret this?

And so, within 48 hours, the Emergency Committee met. There was a change from phase 3 to phase 4, and there was discussion of, well, who was on this Emergency Committee? Maybe we should talk to them about what they're going to say. And the answer is the Emergency Committee, the names are not known because WHO does not want any kind of political intervention. It needs to be science-based. But, once again, all the newbies were saying, "Can we get to them, can we talk to them," and the answer is, "No."

SM: Okay. So that's how it was resolved?

DM: Yes.

SM: She said, "This is not--"

DM: "I know who's on the Committee, but."

SM: Okay. And so, it was very cordial.

DM: Yes, very cordial.

SM: So, can you tell me a little bit about the U.S. international vaccine donation effort and, let's say, what

did it entail? And then, how long did it take to get it up and running?

DM: We began receiving requests, immediate requests from countries for antivirals, from Mexico for hospitals and medical equipment and personnel, and that sort of thing. And everybody knew that there was no vaccine, and there wouldn't be a vaccine for four to six months. So nobody, there was, I think, one request for vaccine--it would be on that spreadsheet--early on. But we had already begun planning in terms of we needed to have criteria for responding to international requests. And so, Maria Julia and I worked on a policy-options paper that went to the White House in which there was high-level discussion and a decision about what criteria would be used to respond to requests for international assistance with antivirals. And then there was an offer of donation to Mexico as well as to the Pan American Health Organization. And then we had to go through the process of decision-making about every other individual request that we received, regardless of what they requested.

At the same time, we began teeing up. We said we need to have the same kind of discussion and process for criteria

for how we're going to respond to requests for vaccine, knowing, still, there wasn't vaccine.

So, in the midst of all this, at the same time--and I don't remember the dates--probably in summer, mid-summer, Maria Julia and I wrote an options paper about vaccine donation. Should it be bilateral? Should it be multilateral? Should it be to WHO? Should it be to PAHO--to whom? and the pros and cons of taking both of those approaches. Should it be one approach or two approaches, multiple approaches, a single approach? And that floated up to the White House, I recall, probably in late July or early August. My dates may be a little fuzzy. And then, when would we donate, and what would we donate? And that was all in the options paper.

And there was a high-level--it was presented to the President, and a decision was made that any donation of vaccine would be multilateral. We would not entertain bilateral requests for vaccine. And that's in keeping with this administration's priority on multilateralism--support of WHO because WHO had not been well supported in the previous administration, and that it was felt that that's the role of WHO is to meet the needs of member states.

And there was a lot of work to be done by WHO in terms of criteria, blah-blah-blah-blah-blah. How were they going to get this? There was concern that WHO may not have the capacity to mobilize this very quickly.

We also did not know when we would be able to donate because we didn't know when we would begin to get vaccine. There were endless challenges technically in terms of the vaccine. The virus didn't grow well. There were technological challenges in terms of the production lines. Two production lines of our suppliers broke down in terms that there were quality control problems. What came out was not vaccine, but crystals. So we did not know when we would begin to get our own vaccine.

And at the same time, there was a lot of data, conflicting data, in terms of how severe is this pandemic? The early data from Mexico was catastrophic in terms of what this looked like. But our own experience in the United States was different in terms of we don't have as many hospitalizations. We don't have as many deaths. So, what's different? Is it the same virus? Is it a different virus? What are the complicating factors?

So, at the same time as the epidemiologic investigation and trying to improve our understanding of what this pandemic was and how severe it is or was going to be, we were also dealing with technological challenges in the production of the vaccine. So we couldn't give a firm date to WHO as to when we were going to be able to donate vaccine.

And there was a policy decision that was on the options paper: do we donate as soon as we start receiving the first dose? Do we donate after we receive a certain number of doses or we begin our own vaccination program? And at what level: is it 5 million, is it 10 million, is it 100 million? What is it? So all of the policies went up, and the decisions came down in terms of we will donate once we have. There was a calculation made at that point in time--if we defined the high-risk populations as WHO and as the data was emerging--children under five, pregnant women, chronic disease. That was about 42 million people in the United States. So the decision was that we would begin our donation after we received 42 million doses, that we would meet those high-risk population needs first, and then we would donate to WHO.

That was controversial because there was pressure from all over that developing countries should get vaccine at the same time that developed countries are, not at some later date. And that was not necessarily an advertised policy. What was advertised is... Well, we didn't advertise; that was still internal.

Then on September 18th or 20th, President Obama announced that the U.S. would be providing 10 percent.

And that was the other question: how much are we going to give? Is it 1 percent, 2 percent, 10 percent, 20 percent, 25 percent? The Gates Foundation and others were saying 25 percent. That's what developed countries should be giving to meet the needs of the developing world.

And what about middle-income countries? That just focused on least-developed. What about middle-income countries? There's no vaccine to buy, so even if middle-income countries had money, there's nothing to buy. So, what do we do with middle-income countries? WHO isn't interested in middle-income countries; they're really focusing on the least-developed, as they should be.

So there were many moving parts in the calculus of trying to get to how much and when will the U.S. donate, and there was no public announcement until September 18th or 20th.

And, just as history is, these discussions, policy discussions were going on in late July, early August. We heard nothing, nothing, from the White House or anybody until 15 minutes before they made the announcement.

So we, as the do-bees, knew nothing. I actually had someone from Canada call me and say, "What the **** are you doing? I just heard from our Ministry of Foreign Affairs that the U.S. is donating 10 percent of your vaccine. Canada is not on the partner list, why not?" We knew nothing. This was all handled out of the White House, John Brennan. He spoke with the ambassadors based in Washington, for eight or 10 developed countries, who obviously did not confer with the people who had the vaccine assets in their own country. And, as usual, they had 24 hours to sign onto this announcement or not. So there were key players who were left out: Canada, Japan, Germany. And so I get a call from Canada as the first I know that there's going to be a public announcement, and I call my boss at the time, John Monahan, and I say, "What the **** is going on?"

He says, “What do you mean?”

I say, “There’s an announcement, and I have to find out from Canada? We are responsible for implementing it, and we know nothing. I’m getting calls from our allies and close colleagues. What the hell is going on?”

He says, “Well, um, I just found out too.”

“Wait a minute. We talked about this six weeks ago.”

“Well, it’s been close hold.”

I said, “Okay. Has anybody called someone from Canada?”

“I don’t know.”

“Did anybody call someone from Japan?”

“I don’t know.”

“Anybody call someone from Germany?”

“I don’t know.”

And my response was, “Who the hell was in the room who knew anything about diplomacy when that decision was made?”

He says, “I don’t know.”

I was furious because decisions are made up there, and those of us who are responsible, the career people, to implement those policies and decisions are left in the dark, and we have to do the diplomatic cleanup. So I was extremely angry, but I’m not in the position to be angry in my position--we’re the do-bees.

So the announcement was made. We had to do the diplomatic cleanup in terms of the people with the assets in those partner countries didn't know what their ambassadors in Washington had agreed to. And there was no donor coordination other than John Brennan's office saying, "You want to sign on? Okay, good." "You want to sign on? Okay, good." "You want to sign on? Okay, good." No donor coordination in terms of what would be donated, when, how much, where, what's the process--no donor coordination. And, once again, those of us who have to implement these policies are left to figure it out and do it.

So, the vaccine--And so, that was September 20th. We began getting vaccine, the first doses, probably around that time or the next week. But, once again, what the manufacturer said, "Oh, you'll have X number by next week," never materialized because of the technological challenges. So, we began operating on the assumption, well, we will have 42 million by this date. Well, that kept getting pushed and pushed and pushed and pushed. We didn't hit the 42-million mark until the second week of December. So, our planning, those of us who have to implement the policies, our planning was "okay, we're beginning to receive, so maybe by

mid-October we will begin donating," because that's what the projections from the manufacturers were.

There was congressional pressure: So, where's the donation? I had congressional calls: Where's the donation? What do you mean you haven't donated anything? But nobody up there were taking those calls. They were all coming to those of us who hefted the work, with the same time as the changing evolution of the nature of the pandemic, the clear data about who's at high risk, how many doses do we really need, at the same time as mobilizing the domestic deployment of vaccine.

The states weren't ready to deploy either, so the balancing act of how much is coming in, who needs to be vaccinated as a priority, and whether the states are ready to actually start vaccinating.

So, what's left over? Can we donate this? No, we don't have 42 million. So when the magic 42 million is reached, then it's, "Okay, let's get this out the door."
"Well, you know, we're having a flare-up in this part of the country. We may want to hold on to that."

So it was continually evolving, the uncertainty about what was happening in this pandemic. And there's no way to get around uncertainty in a pandemic. It showed the flaws in our surveillance system. It showed the flaws in the distribution system for which there was, in many states, no distribution system for U.S. government-purchased vaccine. Most vaccine is distributed in the private sector in the United States, including seasonal flu, so this was a new government program to purchase all the vaccine and get it administered through state governments. And it wasn't until late that the private sector began to be brought in in terms of big-box pharmacies, of let's get them some vaccine because they have access to a population that may not be going to school-based clinics or may not be going to the doctor, or whatever.

So there is the whole domestic--all the challenges of domestic mobilization and deployment, with the challenges of the availability of vaccine from the manufacturers, which there were some manufacturers who met their projections every week and others that it was just toss a coin. "How much will you get this week?" "I don't know." "What do you think?" "I have no clue." Pick a number out of a hat, that'll be as valid as what they say they're going

to send you, which made our decision-making about donation even more complicated.

On the other side of it was WHO was not ready to receive any vaccine. Even though we hit the 42-million mark in the second week of December, the first vaccine from the U.S. going to WHO didn't go until March because WHO wasn't ready. They had a whole series of steps that the years of pre-pandemic planning, nobody had thought about deploying vaccine or planned for it. Individual countries did not have vaccine deployment plans.

So even if we had gotten them vaccine on December 17th, they had no mechanism and no plan to administer those vaccines, and no resources. There was no plan to transport the vaccine. It was unclear, WHO wasn't clear as to whether they were going to receive the vaccine in a central location or four regional sites and then dole it out, and then they would have to store it and all that sort of thing. Or would the vaccine have to go from us, or whoever the donor was, directly to the country? So there's a period of negotiation about what the process is going to be, and decision-making at WHO about what they were going to do.

The decision was no central storage, that it would have to go directly from the donor to the recipient country. Well, who's going to pay for the transport? Everybody donated vaccine, not money. So, WHO had no money to transport. Well, we kind of assumed that the donors would pay for it. Oh, really? We don't have that kind of money.

As it turns out, USAID declared that they were willing to pay for the transport for a certain portion. Well, at the very beginning it was, "Oh, yeah, we'll pay for the transport of the U.S. donation" out of their funds. Great. So then it was doing the financial arrangements of moving money from USAID to WHO so that they would have money. Okay.

So, WHO didn't have any contracts in place for transport, so they had to negotiate within the U.N. system. Was it UNICEF, who does this all the time? UNOPS got the contract. Why? UNICEF is transporting vaccine all the time. Why didn't...? Not our business. That's the U.N. decision. UNOPS had never transported this stuff before, didn't know what to do. So there were no deployment plans in each individual country.

WHO's lawyers insisted that there needed to be a signed agreement, legal agreement, between the donors and WHO that would hold WHO harmless from any adverse events that would come from administering of this vaccine or any screw-up in the transport, and blah-blah-blah. The lawyers also insisted that the recipient country accept all liability for the adverse events, which was the first time that ever had required that. There are donations of vaccines and medications all the time. Never had WHO required release of liability.

SM: What do you think that was about?

DM: The lawyers. Get two lawyers in a room and it complicates everybody's life.

The issue is, with a pandemic vaccine, it doesn't have years of experience to know whether the Guillain-Barré or there's a rare event that would cause us not to use the vaccine. It has to be administered to millions of people to be able to detect severe adverse events, so you can't define that or predict that up front, and companies were unwilling to accept the liability. So even companies'

donation, they weren't going to donate a thing unless they were freed from liability. The U.S. lawyers, you get our lawyers involved, they're not going to put the U.S. government at risk for any international liability, period. So we had problems that the U.S. would not sign the letter of agreement, the recipient countries wouldn't sign the letter of agreement, and until the lawyers got it all together with the two WHO lawyers for a hundred recipient countries and 14 donor countries--two lawyers--you can imagine the backlog and the time it took.

It took us, I can't remember, maybe six weeks to hammer out a method by which the U.S. would agree to donation. And as it turned out, it ended up that we never signed a legal letter of agreement as a U.S. government, that we went and revised our contracts with the manufacturers, and the manufacturers would donate the vaccine.

There were also other various options that really held us up, that were just fruitless, going in circles. There were some people who just come from academic backgrounds, and so they were talking about the .1% possibility of something. They wanted to discuss that into the ground before any decision could be made, while those of us who work in the

real world were more interested in what is going to get us where we need to go the soonest, even though it may not be perfect.

"Well, we could release our contract here, and WHO could find somebody with money to buy that, and we could reduce our cost from our contracts, say thanks for your money, and we could do this, and do this:" weeks of that kind of discussion in terms of what we were going to do and when. "It's capacity, not vaccine." And people would change their mind: "Oh, no, it needs to be vaccine." "No, no, it needs to be capacity." "No, no, it needs to be the vaccine."

And, basically, my unvarnished opinion is, you know, when you don't make a decision, events just overtake you and that becomes your decision. And we ended up having to, because the legal complications, the logistical complications of saying we are going to release our contract for X million doses to this company—"Okay, company, you need to give that to WHO,"--we had no legal basis to tell them what to do with their product if we were releasing the contract. They could turn around and sell that to somebody else. They had no legal obligation to give it to WHO as we instructed.

But that's kind of theoretical, you know. From the very beginning, in fact, the original option recommendation that went to the White House is donate vaccine. It's quick, it's simple, you get it done. It took months of going around and around and around and around and around and around and around and around and around to get a decision, and it was because events overtook us. And the company said, "No way are we going to. That's just not feasible," and that was the decision. It took somebody else saying "That's not feasible" to get a decision. So angry. I'm telling you the unvarnished truth. This is how it went.

SM: Unvarnished is good.

DM: So, finally, WHO. There were a lot of questions about WHO's capacity, which I think was valid in terms of if we ship them vaccine. And there were concerns among the politicians in the administration of, "You're going to take vaccine out of the arms of American children and send it to some developing country where it'll sit on the dock and be wasted because it won't go anywhere, it won't be used, it'll spoil, it'll expire? You're going to do that?"

"I'm sorry, but the President's already decided that we're going to do that."

Well, that kind of dialogue internally didn't help us move towards the implementation of the policy decision. It was, "WHO isn't capable of doing this. We should ship it directly. We should get on the ground and we need to do the analysis of whether these countries are ready."
"Wait a minute. Maria Julia and I are going to do this? We're going to go to a hundred countries and assess?"
"Well, get USAID to do it."
"USAID's role is to assist the country in writing the deployment plan. USAID's role is to provide cash for the per diem for the vaccinators. The USAID role is to provide syringes and safety boxes. That's their role. It's not our role to tell USAID, to go out there and say, 'They're ready.' That's WHO."
"Well, they don't have the capacity. We can't do this, we can't do this."
"The President said we are; we are going to do this."
But those of us who were in working positions were not political, so we have a hard time telling the politicals what to do. We've got to manage upward as well as this way and this way.

So, admittedly, WHO was not ready. We didn't have any plans in place, logistical plans of how we would donate. We had the plans for which vaccine we would donate, which was the nasal spray. Recipient countries didn't want it. They're used to the injections. They wanted injections. And there were problems in the middle of the initial deployment domestically, that the manufacturer of the nasal spray said, "Oops. It's not going to last as long as we thought it was going to, so the shelf life is only half," which automatically eliminated it from consideration from the donation. Because if it doesn't have sufficient shelf life, send it to a developing country that is going to need at least two months to get it into the arms of people, if you're shipping it when there's only three to four weeks left of it before it expires, don't do it, it's useless.

So there were technological problems that continued. WHO wasn't ready. The legal agreements were a major stumbling point. They didn't have the logistics figured out. They didn't have contracts in place. They didn't have any procedures in place. It all had to be made up scratch. We didn't have anything in place for that either in terms of the concept of donating vaccine. Yeah, yeah, from a policy,

that's a good idea, but how are we going to do it? Are we going to move it from our site? Are we going to have the manufacturer move it? Are we going to truck it, are we going to fly it? I mean, what are we going to do? We didn't have those in place.

So, just as WHO was trying to figure it out from scratch, we were too. And having to keep the higher-ups, who were micromanaging every step of the way in terms of, "No, no, we can't do that."
"Then what's the alternative?"
"I don't know, but we're not doing that."

SM: What ultimately was the process?

DM: It was, ultimately, the process depended on the manufacturer. For one manufacturer, we paid, we added to our contract with the manufacturer to ship directly to the recipient country. That came out of HHS resources. With another manufacturer, USAID paid WHO, who contracted with UNOPS, who subcontracted with DHL to move the vaccine from the manufacturer's warehouse to the recipient country. But they couldn't move it directly from the manufacturer's warehouse. They moved it from the manufacturer's warehouse

to an intermediary warehouse, because Sanofi--not Sanofi, whatever the company was--wasn't going to do the packing because they didn't want to be responsible if the packing was done incorrectly by DHL. So they had to truck the...in cold storage, at a temperature--you can't let it freeze and you can't get it too low, you can't get it too high--truck it to another facility where it's packaged by the air carrier, by DHL, who has a subcontract with commercial airlines. So they pack it in the ice packs, but you can only do that within 24 hours of wheels-up because you have a 72-hour window for the cold packs; 73 hours, you can't use any of the vaccine.

So all of that logistical--you know, when do you have confirmation from the airlines that they can take this cargo? Back it up. Twenty-four hours before that, you have to move the vaccine from the manufacturer's warehouse to the DHL warehouse; the DHL warehouse to package it, put all the ice packs, the cold packs and put all the temperature gauges, monitors, et cetera, into it, and then move it to the airport, get it on the plane, and then it has to go. And you have to take into account, how long is it going to take to get there? You have 72 hours. And sometimes the temperature in the airplane cargo is not controlled

properly. So none of the U.S. shipments... But there were two shipments of WHO through this program that froze, so none of the vaccine was usable once it arrived.

SM: Wow!

DM: And there were cases in which the airline, they're not in it for humanitarian purposes, they're in it for money, and there were several cases where, en route, the U.S. donation got bumped for more lucrative cargo.

And we had to track that every step of the way because the scrutiny we were getting in terms of where is it, what's happening to it, was intense. So we, every, twice a week, sometimes there times a week, we had to report to Assistant Secretary Lurie where it is, what's happening to it, if it's on the ground, it's not on the ground.
"So, is it being administered?"
"That's the ministry's responsibility."
"Well, why don't you have someone"--it's not Nicki, someone else in HHS.
"So, we have to know it's being administered."
There are limits to what we can do.

But the political sensitivity of taking them out of the arms of American children and having it sit on a dock somewhere were so intense that we had to track every single step. We had to know the unknowable, and I've never done logistics in my life; I'm a medical epidemiologist. I went to medical school, two residencies, and graduate school. What do I know about a pro forma invoice? Zero.

So, we didn't have our systems in place. We had no logisticians. The problem was that we had been planning what we would do in an international response, and I think I said this before, it wasn't finalized before the pandemic hit. So, none of this was in place. If this were in place, we would have a contingency contract for logistics, and we would hire somebody to do all this. But in the midst of the battle, you do what you've gotta do.

SM: How much was eventually delivered?

DM: We're still delivering.

SM: You're still delivering?

DM: Mm-hmm.

SM: I see.

DM: We have delivered about 16 million. The pledge was 25 million because it was 10 percent of what our overall contract was to companies for 250 million, 240-something million, and so it's 10 percent of that. And then, along the way, it was decided, "Oh, we're not going to purchase that."
And then there were those bean counters who said, "Oh, good, that means we only have to donate 14.7 million."
"No. The pledge is for 10 percent. The intent was for 25 million. Just because we didn't purchase 250 million doesn't mean that our pledge is going down."
"But, but . . ."

SM: What about the other countries? Did they also not sign an agreement, the other donor countries?

DM: I don't know.

SM: Okay.

DM: We have no visibility on that in terms of how the vaccine is being used. So we've already shipped--and it has been received and accepted--about 16 million of our 25 million. We have another four million or so, four and a half million, close to five million that is in process. And, once again, it's because recipient countries weren't ready.

WHO was also managing pledges of 200 million doses. So, just because we were ready to donate, well, so was Canada and so was Australia and so was the U.K. So, they couldn't just take our donation in preference to everybody else's donation. So, WHO is having to juggle what's available, when; what product has to be matched with a recipient country, but then has to review all the safety and efficacy information to register it in their own country. It's like an FDA approval for a new drug, except it has to be done in a hundred countries. But it's on an emergency basis, but that takes time, the logistics.

I mean, the volcano erupted, shut us down, because many of our routes had to go through Europe. If something was going to Africa, it had to go through Europe; shut down. So, in all of this, it's Murphy's Law. Whatever could go wrong,

did in terms of... But the positive side is we have mobilized 16 million of the 25 million. We're probably close eventually to 21 of the 25 million.

The demand has fallen off. The demand is mostly in the Southern Hemisphere now. There aren't that many countries who want vaccine now. It's unlikely that we're going to mobilize the entire 25 million for all these factors combined together. And we're still doing it. We have conference calls with WHO, UNOPS, DHL, BARDA, CDC, HHS, the manufacturer, twice a week, trying to mobilize the last amount.

SM: And what's the epi like in the Southern Hemisphere?

DM: It's still the beginning of winter there, so, so far, what they're experiencing is a late flu season. In general, there is not a lot of activity in the Southern Hemisphere, there's some. So, once again, the demand isn't real high right now.

And the other influenza viruses are also circulating, so it's not just pandemic H1N1, but influenza B is also circulating, so we still don't know. In the first two

waves, so to speak, the other types of influenza were crowded out by the H1N1, but that pattern is looking a little bit different now with the second wave in the Southern Hemisphere. And the predominant circulating virus in China and Southeast Asia right now is influenza B, so the pandemic vaccine isn't going to help them because it's not effective against influenza B.

India is having, in Kerala, the southern part of India, a lot of activity with highly publicized deaths in the usual--young children and pregnant women--so there are pockets here and there, and it's like...

And this is typical because you have flares up here, and then it will die down. It will flare up over there and it'll die down. A pandemic is not everything at the same time everywhere. It is really a series of rolling epidemics where it's here, flare down; flare, flare down; there, flare down, and that is the typical pattern. Unlike the first time, the first wave, where it was a big peak almost everywhere because it's the first time it's been introduced in the population. Now, even in the Southern Hemisphere, people have been vaccinated, people have already been sick, so they're immune. So what we're seeing now is more

sporadic flare-ups and then, of course, attention gets really panicked over this flare-up, and so it just continues.

So, in terms of the vaccine donation, I would say that we've learned a lot. I'm just hoping that in terms of that we will have the opportunity to finalize our international response plan for pandemic influenza and take into account the lessons that we've learned, of which there are many, both technical, logistical, and political, because unless we incorporate and learn those lessons, it may not be influenza that we're dealing with, it might be SARS, it might be some new organism that will...

I've been in government for 22 years, and what I experience is reinvention of the wheel, especially on humanitarian assistance. This is the same situation we had in X country 15 years ago. Why are we doing it all over, I mean, reinventing everything? Didn't we learn anything from the first time? Didn't we make any changes structurally or logistically?

SM: Many federal agencies moved from a transitional leadership in the spring to its current leadership by the

fall. What kind of impact--and you've already expressed some of the problems--but what kind of impact did it have on your ability to engage the international community once it was clear that the virus was highly transmittable?

DM: I think the engagement in the early days was when we had the most instability in political leadership--not instability in the sense... It's just that we didn't have, I mean, John Monahan had been on the job for a week. Our secretary hadn't even been confirmed. But most of the engagement was at the technical level, and that was seamless. The movement of viruses, the movement of samples, the movement of information, the movement of genetic sequencing from the U.S., Canada, and Mexico to WHO and to other researchers in other collaborating centers around the world was seamless. There were a few glitches here and there, but it was rapid, unprecedented, and that was really the most important engagement at that point in time.

The political engagement is politics, and I think that when it came early on, the kind of international engagement was really communicating about the epidemiology and what are your policies. I think on the epidemiology, we were in conference calls with PAHO, with the European Commission,

and it was really, "Okay, how many cases do you have?" "Is this the same virus as Mexico?" It's really on the technical level. Well, that's what career people are for, and there was continuity in that. As best we knew the information, we were able to convey that. And the politicals, many of them knew nothing about, some of them don't know anything about health, much less influenza, and so we were having to brief them about what this all was and what this all meant and what the policy implications were.

So we had the double burden of not only did we not have new policies that as new situations arise for which there needs to be a policy decision, we were having to brief the new politicals in terms of what are the policies, and why are those the policies that we have, at the same time as you're trying to respond. That was very challenging internally.

In terms of engagement, I think that there's a natural tendency for new politicals to want to be the spokespeople. And some were very good about saying, "I'm over my head, you handle it, but let me listen," and others that insisted that they needed to be the spokespeople and they needed to make the connection with whatever political on the other side. Okay? But then there's clean-up.

So I think that in terms of the international engagement, probably some of the planning about the antiviral mobilization, the donor coordination between the donors and some of the planning for a vaccine donation might have gone more smoothly if it hadn't been an administration transition because people would have been familiar with the issues, familiar with the usual points of contact of people that the usual working relationships would be clearer. So I think it would have been smoother if this pandemic had occurred in the second year of an administration. I think it had some impact in terms of adding some confusion and chaos to those of us who have to get the work done, but I don't think it affected public health so much.

SM: Was there a common message that was coming out of your office to the international community?

DM: Luckily, we had, in our pre-pandemic planning, that kind of decision making about who would be speaking, and messaging was pre-decided. Particularly between Canada, the U.S., and Mexico, there had been the Security and Prosperity Partnership under the Bush administration, now called the North American Leaders' Summit, as well as the

Global Health Security Initiative with G7 plus Mexico where, in the pre-pandemic planning, already the communicators, the communications experts, had a working group that got together and said, "In the event of a pandemic, not only what are the key elements of public communications and media communications, but how are we going to communicate with each other to coordinate our messaging?" And so I think that that was one of the...

Not to say that there weren't glitches. I mean, little things like--what was it?--oh yeah, little things like the U.S. decides that it's going to declare a national emergency, but nobody bothered to call anybody in Mexico to alert them. And, once again, who has to do the clean-up and answer the questions in terms of why is it a national emergency? This has been going on for two months now, why is it a national emergency?

It was an administrative move in order to...as we were concerned about surging of patients. It meant that hospitals would have some break in terms of the procedures they had to follow if they needed to set up a tent outside the emergency room for triage, that they could still bill Medicare. Without that national emergency declaration, they

wouldn't be able to do that. It permitted use of an experimental drug, the I.V. Peramivir, to actually be utilized in patients for severe cases. So there were administrative reasons, not because there were any change in the virus and the severity. Nobody thought to call Mexico. Who gets the phone call? Once again, what the **** are you doing?

"I thought we had an agreement that, in terms of communication, you all would tell us before you made big changes and big moves?" Well, a new administration doesn't know what the previous agreements necessarily were--bad politics.

And what that resulted in is big headlines in Mexico, big headlines, and a political backlash in terms of the U.S. just declared a national emergency. Why isn't Mexico doing the same? Destabilizing their government just because someone didn't pick up the phone--it didn't occur to them.

SM: How was that resolved on our end?

DM: All I could say was, "I'm sorry." And it came back to haunt the higher-ups: When the Secretary met with the

minister of health in Mexico the first time, he was not a happy camper, not happy.

But in terms of the communications with the public, the media, there was a network already in place, and they called each other and worked amongst themselves. And so I think that that really worked well as a direct result of the pre-pandemic planning and networking that was done. But our office, the division of labor was very clear: We don't do communications.

I only have about five minutes left.

SM: Okay, sorry. Let's see. You've been in the role of readying the country for influenza pandemics prior to this current outbreak. Has there been much difference in the degree of senior-level or White House involvement in the response efforts when compared to the government's strategy to deal with, say, H5N1 or other threats?

DM: I was here for both administrations, for the H5 and the H1, and I would say that the attention by senior officials, both in HHS and at higher levels in other departments and in the White House level, were very intense

in both cases. It's, I would say, a little more intense and time-urgent in the middle of an outbreak in a pandemic in terms of updates, updates, and the issues that are having to, that are the unknowable and the unpredictable, and dealing with those; whereas, in the previous administration, we were still planning, but they were very, very attuned to--we need a plan, we need the deliverables, we need to see what the progress has been made in terms of domestic preparedness.

On the international front, that's what was prompting us to try to get this international response plan put together. That was one of the things that was really not getting enough attention, and the White House was clear: this needs more attention. So both the State Department and HHS, our office was trying to bring those to what were independent, non-communicating processes together in terms of, let's have these be harmonized plans. And then we moved this way and got so far, and then the pandemic came.

But I would say that the interest level, the commitment level, certainly in terms of resources and oversight and interest, very high in both. I would say more so in the

acute phase in terms of that you have to be dealing with urgent issues every day.

SM: Okay. Well, thank you.

END OF INTERVIEW

Broad Themes

- International Health Regulations
- Declaration of Public Health Events of International Concern, and U.S. concerns
- Pandemic phase process
- International requests and donations
- Challenges of vaccine donation
    - Production lines
    - Severity of pandemic
    - Key players left out of White House decision making – career staff, Canada, Japan, Germany
    - Evolution of the pandemic
    - High risk data
- Decision making on domestic versus international obligations

- Low versus middle income countries

- Surveillance system, flaws in
- Distribution system, flaws in
- Domestic mobilization and deployment
- WHO preparedness
  - Deployment and distribution
  - Transportation
  - Legal liabilities
- Manufacturer's donations
  - Legal liabilities
- Vaccine safety and manufacturer liability
- Contracts for U.S. donations
  - Legal and logistical challenges
- Transportation of vaccine
  - Challenges with airlines, cold storage
  - Political repercussions
  - Icelandic volcano, 2010
- Pre-pandemic planning for international donations
  - Logistics not finalized
- Epidemiology
  - Southern Hemisphere
    - Kerala, India

        - Second wave – predominant and secondary influenza viruses
    - International collaboration – continuity of career staff
- Effects on response of transition of administration
    - Technical aspects of international response – seamless
    - Antiviral mobilization, donor coordination – challenges
    - Effect on public health
- Messaging to international community
    - Security and Prosperity Partnership, AKA, North American Leader's Summit
    - Global Health Security Initiative – G7 plus Mexico
- Declaration of national emergency
    - Use of Peramivir
    - Relations with Mexico
- International Response Plan
- White House attention to response

Names

- Margaret Chan – Director General, WHO

- John Monahan – Counsel to the Secretary of HHS

Documents

- Options paper on donations written by Marinissen and Miller