INTERVIEW WITH

JULIE SCHAFER

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Julie Schafer
Interviewed at Julie Schafer's Office
Washington D.C., U.S.A.
Interviewed on January 12th, 2010
H1N1 Oral History Project
Interviewed by Sheena Morrison

Sheena Morrison: SM
Julie Schafer: JS

Sheena Morrison: The following interview was conducted with Julie Schafer. It was conducted on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on January 12th, 2010, at Ms. Schafer's office in Washington, DC, and the interviewer is Sheena Morrison.

So, let's begin with a biographical question. What is your position here at the Biomedical Advanced Research Development Authority, and how long have you been in the current position?

Julie Schafer: Sure. I am the Influenza and Emerging Diseases Science Branch Chief for the Policy Planning and Requirements Division of BARDA.

SM: Okay.

JS: And I have been in this position about a year and a half. I've worked on influenza for as long as I've been in HHS, which is about 5 years.

SM: So this isn't the first pandemic?

JS: No, I've been following influenza. I've been following pandemic influenza--just different jobs, same subject.

SM: Can you tell me exactly, well, just tell me a little bit about what that means?

JS: Sure. I came to HHS as a Presidential Management Fellow in the summer of 2004 and was Policy Coordinator in the Executive Secretariat, which is kind of the position that doesn't exist anymore. I was there a few months, and my supervisor said that there was somebody who needed some help on a plan. And she introduced me to Bruce Gellin, who is the Director of the National Vaccine Program Office. He was working on a draft Pandemic Influenza Preparedness and

Response Plan, which was about 10 years in the making. That was in 2004. And so, we put that one out and then just kept writing plans and doing stuff.

SM: Okay. So you work closely with Bruce?

JS: I have for a long time. Yeah.

SM: Also, I was doing a Google on you, and I noticed that your name came up a lot for the vaccine safety--not vaccine safety, the advisory committee. Are you also a member?

JS: Well, no. In so much that I attend them and have for all related to influenza, but I'm not a member.

SM: Okay. At what point did you become involved in the 2009 H1N1 outbreak response efforts?

JS: From the very beginning.

SM: Okay.

JS: So, in April, I was at Sanofi Pasteur. I was at their manufacturing site to do a pandemic exercise. And it was that day that BARDA started making all the calls to the vaccine manufacturers to tell them that there was a virus that we were concerned about, and to kind of initiate that CDC was going to be making a virus reference strain and that we might kick it up.

SM: Okay. So who was there with you for the exercise?

JS: I was with our security person who has now left, Dave Bauer. And I was with Mary Beth Love who does a lot of the logistics stuff for the BARDA flu group. And we were just there to do--Sanofi was exercising their pandemic plan, which is kind of funny [laugh]. It went very well. So, yeah, it was a strange coincidence.

SM: So, you got the news from...it was passed on to you not in an official capacity, but because you were there and--

JS: No, well, I was there. And some of the Sanofi guys said, "Hey, did you hear about this virus? It's kind of

crazy. What do you think?" And then we started getting all the emails from our colleagues at BARDA saying, "Hey, we're going to call the manufacturers who make licensed influenza vaccine in the U.S. just to talk to them, and just to give them a heads-up that we're watching this one. And we want to know what our capabilities are if we have to make vaccine."

SM: What was your role after you learned?

JS: Let's see. Gosh, what did I do? Whatever Robin asked me to do, I guess [laugh]. I'm trying to remember now. So let's see, we did all of those calls. I'm a little hazy on the time lines, but I think it was really early that we started putting together papers and strategies. Like, if we're going to do this, this is what it would look like.

The other thing that was strange was that we were in transition with all of our leadership in that we didn't have a Secretary yet. We had an Acting Secretary. The senior people were not... There was a kind of a strange time because our ASPR, we knew he was on his way out, but we didn't have a new ASPR yet. We didn't have a Secretary,

and I don't think we had a Deputy Secretary at that time. It was a very strange time.

It was hard to know who to brief, and who was going to be making the decisions. So we started putting materials to brief people because we knew that it takes so long to do all of this stuff. To make a vaccine, it's moving large mountains, essentially. And also, it requires an enormous amount of money. So there was a lot that needed to be done--front loaded work.

SM: Was there a team?

JS: Almost immediately within BARDA, Dr. Robinson, the Director, kind of pulled together a team of people and said, "We're going to ramp up. You are the people who're going to...It's going to be clear to you what you're going to be doing." And so we started meeting. I think it was every day, early in the morning. There was just a lot of activity.

SM: Can you recall, what was one of the first projects that you had to take on?

JS: I think it was putting together the strategy--it was either the strategy or the time line, I can't remember which. But they kind of laid out, "Well, if we start doing things now, this is how it flows." There was a lot of information to share about, well, what does this really entail?

When you start something from scratch, it's getting all the steps: It's getting a virus reference strain; it's getting the virus reference strain to the manufacturers, and then they produce. At that point we were just thinking pilot lots. And that's really consistent with our National Strategy for Pandemic Influenza, that we said that we would create pre-pandemic vaccines for any influenza virus with pandemic potential. At that point we're saying, "Well, let's ramp it up to make at least pilot lots of vaccines", so, not hundreds of millions but enough to see what we've got and to run clinical trials. And then if we needed to, use it as a pre-pandemic vaccine.

At that time, I mean it's so hard to remember now, but we just didn't know what we were dealing with in April or May.

It was really unclear what was going on because we had what was going on in the U.S., which people were getting sick and they were recovering. Then we've all these reported deaths in Mexico, and it was really hard to understand what those meant.

SM: Right.

JS: Was that something different? It seems fairly mild in the U.S., but is it going to become worse any second now? What does it mean? And so, we're trying to make all of these big decisions in this total lack of understanding of what we're dealing with.

A lot of things, if you don't make the decision right then, you're going to be... We were also really concerned about--there's only so many vaccine manufacturers. Is everyone going to lock up the vaccine manufacturing capacity? Then we wouldn't be able to get any vaccine.

So, it's all this stuff swirling around. We don't really know what we're dealing with. How do we move forward? We don't really have a Secretary to brief. Who's going to make

the decisions? How are we going to get the money? What's going on? All that was kind of swirling around.

And so, I think all of us at my level were really being directed, as it was appropriate, by our leaders, like, "Write this paper," "Do this," "This is how we're going to frame this and move forward." Most of us were really just in charge of providing information to help brief the people who are going to make the decisions.

SM: What were some of the things that kept you up at night during that time?

JS: I think, you know, for someone who had worked on pandemic influenza for a long time, it's a strange feeling. I have talked to some of my colleagues in the interagency because I do a lot of the interagency work with the national strategy. I sat on interagency groups for the Homeland Security Council to really work through a lot of our policies for a big pandemic, a 1918-style pandemic that would be really disruptive to society. And it's funny talking about it because it was a little bit anti-climactic as time went on. I was like, "This is it?" Not that it

wasn't scary or anything, but it also just felt surreal to plan for something for that many years, then to have it happen. It was like, "Wow, I don't know." I thought it would feel different, I guess.

I think a lot of people were worried about 1976. And I think that that's always the thing you worry about: You worry about overdoing it. I think I worried about something going horribly awry with the vaccine and what it would mean. I mean, you don't want to hurt anybody. And I think that everyone--well, I shouldn't speak for everyone. I think a lot of us it was certainly referenced in a lot of meetings early on: "Let's not make the same mistakes." That's why Harvey Fineberg wrote "The Lessons Learned from 1976" so that these things wouldn't happen again. And I think the last page of that has this kind of summary, I think there's like 10 or so things that--

SM: Yeah, I've read it.

JS: Yeah. I looked at those a lot. Of course in my position, what can I do? But you know, it's scary when you see how easy it is to go down those paths. And I think that

that's the scariest thing. Actually, I think that that was the scariest thing.

SM: Well, you mentioned the meetings. Were these meetings solely BARDA meetings or were they--?

JS: No. No, I recall early on the Chief of Staff--I don't know when the Chief of Staff started her job, but she was there pretty early on, so I'm just not sure when she started. But there would be these meetings every evening.

SM: Every evening?

JS: It felt like every evening [both laugh]. I think it was every evening. It was most evenings anyway. And they would go on for a really long time. And she would lead them. Yeah, I think that's right. I don't remember Charlie being there--our acting secretary at the time--so I don't remember the timing of that. That's when a lot of the time lines and things like that would be discussed. I think I missed a few of the really early ones, and then somebody must have invited me. I got on some list, so there. But

yeah, I think that that was the collection of the senior leaders on this issue. They would meet.

SM: What was it like during the meetings? I have attended these meetings here with the current Secretary, but what was it like during that time?

JS: It was really different, then. It was also kind of adjusting. The previous Secretary had a very different style. And that's what they do, they all have different styles. It was also just kind of adjusting to a whole... And also, we're starting with scratch with people. He had a very hands-on style. He was very interested in influenza.

SM: Okay.

JS: So, he was very knowledgeable on these issues and had been very passionate about our preparedness. In fact, it was certainly a big driver for there being a national strategy. It was a passion of his. And so, we were really starting from scratch with people and also with OMB.

You know what? I think that the money issue--I'm sure everyone will talk about that. I don't know if we were just really naïve of how difficult it would be to get money, and how much time we spent trying to get money early on. When we did all these plans, as far as I can tell, I think that we thought the picture would be more clear. And it would be obvious to OMB and to the Hill that this was a huge deal, and that we needed money to get stuff to save people. That wasn't the case with this. I don't know how I could have blocked that out to not have mentioned it first. It was an enormous amount of energy.

JS: And doing things over and over and over again and writing the same thing, getting asked the same question over and over again. It was like, "I answered that." Well, "Answer it again." That really predominated the early days because OMB wasn't buying it. They didn't think it was a big deal.

JS: And what's really hard is that, understandably, they're reactionary. So when it became a big deal later,

they turned to us and said, "Well, what the heck guys, where is it all?" But we needed them to get behind us early, and it all worked out, but it was very, very difficult. It was incredibly stressful and time consuming, and a lot of us spent more time doing that than probably some other stuff that might have been helpful. I don't know what that would have been, right now, but it predominated the early days.

SM: And what was the process? How did it work in terms of requesting the money? Was it a joint meeting or did you--?

JS: The senior leaders would go to OMB, would go to the White House a lot and meet with them. And then, there'd be questions that would be transmitted. Then we'd be answering things, and then they'd go back. I think that our Chief of Staff, I don't think she slept. It was just a constant cycle, very stressful.

SM: What were some of the agencies that you guys worked with in the beginning?

JS: Within HHS?

SM: Yeah.

JS: Yeah. So, it's really the same as it was for planning too: It was NIH, CDC, FDA, ASPR. That's the core.

SM: And you guys met daily? You had the Chief of Staff meetings?

JS: Yeah. That's where the senior leaders would meet. But then, on different issues--for example, NIH and BARDA would be meeting about the early vaccine stuff in terms of the clinical trials, and then another part of BARDA and CDC would be meeting about, "Okay, if we're going to have to distribute vaccine, how are we going to do that?" Like that. And then FDA and another part of BARDA would be meeting with FDA because of FDA's role in the approval and licensure of vaccines and drugs. So, we all interacted. And I'm sure that they all interact with each other. All of us are interacting with each other and all together, and then in little pairs as appropriate all the time.

SM: Do you have any records or documents that would help me better understand the time line and the role of BARDA in the early days till now? Perhaps a time line or--?

JS: There is a time line. Are you going to meet with Robin Robinson?

SM: I have met with him and I will meet--

JS: Yeah, if you check with him because it was a document that was written for him. If he says it's okay for you to have, then. Or if he wants me to just take out the time line part and send it to you, that is totally fine with me. Yeah, I'm happy to do that if he's fine with that.

SM: Okay. Can we go back to the time at the manufacturer's when they first notified you? What was it like at the manufacturers'? How did they respond?

JS: They were just in and out. We were supposed to be in this all day exercise, and it was just like this constant people, everybody was in and out because they were taking phone calls. And so I think that it was just kind of, I

think that all of us were a little bit just in, not disbelief, but, really? [Laugh.] This isn't how we planned. It's in Mexico? [Laugh.]

SM: So, as someone who's worked on the plan for a number of years, in your opinion--I know you said that it was anticlimactic, but how do you think it went?

JS: It had nothing to do...it showed... This is I suppose when you're glad that something's going to hang out for five years before it's released. My personal opinion is that when the National Strategy was created, the creators became overly enamored with modelers and allowed the modelers to form a plan that wasn't flexible. And the National Strategy is not a flexible plan. And I think that we learned through the implementation of the National Strategy the need for a flexible plan. So, I think that we were getting there, but it wasn't there, yet.

We wounded up with this plan that had all of these assumptions, and 2009 H1N1 met almost none of them: It didn't start from someplace else; we found out it was impossible to understand the case fatality ratio. So, we

couldn't say, "Oh, what kind of pandemic do we have? What is its severity index?" Well, that wound up being impossible to know. And also, they had all these phases, these stages that they wanted everybody to have their plans around. And then they didn't implement it. So everyone's going, "Well, what have I done?" And I think that the root of it was that the plan wasn't flexible.

SM: I see.

JS: I think it maybe would have gotten there, but it wasn't there. So it's impossible to know if the National Strategy was a good one because we didn't get the pandemic that it was written for.

So, all of those negative things said, there *were* so many things that were built because of it, and because of the money that was provided to do it that made this all a lot easier.

I think it's easy for me to forget that in 2005 when the National Strategy came about, there wasn't any real connections between public health and emergency

preparedness. The commitment of the White House (of that White House at that time) and the political leadership, and the commitment of the Secretary of HHS and the Secretary of DHS to work together on this issue--and then the funding behind it to build in states--that made really positive impact. And so, even though you had a plan that was not very easy to implement, some of the work behind it did do good things. I mean, it's impossible to know the counterfactual, but I'm sure it made things better than it would have been.

When I think about the 2004 plan, the draft plan that we put out there, gosh, it was so long. I don't really want to think about it, but it was a plan full of panic. I mean, it was really like 300 hundred pages of panic. Like, oh my God, we've got no drugs! We don't have any domestic manufacturing capacity! We're all going to die! [Both laugh.] You know?

And then, all of the things that attention and money fixed--in terms of, we got a huge stockpile of antiviral drugs that we didn't even really need to touch, and we made huge strides in domestic manufacturing capacity that we were

able to use. Well, we will have more in a couple years, but even now, we had a lot more than we did in 2004. We had all this attention to an issue that if 2009 had happened with the same capabilities that we had in 2004, I think it would have been kind of ugly. It would have been a lot of scrambling. So, I think in many ways, we all were just so... We'd had all these plans. I mean, I just don't know. I can't even imagine. We would have muddled through, but it would have been kind of ugly [laugh].

SM: Yeah. I wanted to go back to your last comment on... It escapes me, but I will try something else.

JS: Okay.

SM: Thinking ahead to the future, what kind of documents do you think we should archive?

JS: Documents from this experience should we archive?

SM: Yes.

JS: I think it'd probably be helpful to archive all of the decision memos and the papers that led up to the decision memos because I think you can really see a lot of our thinking and how our thinking evolved.

Even just doing my P-Map, which you know all federal workers have to do--our little, our professional assessment stuff, like, "oh, what have you done this year?" I just listed all of the ones that I either wrote or co-wrote because that was really what I spent the last couple of months doing, is writing these papers. And it was really just fascinating to go back to all of them because I had to open them all up. Wow. It's funny when you look at it from May to December, and how you can really just see how our thinking evolved and how the situation evolved.

I think that along with a time line, you can actually map it to the time line. You can see how it all... As an armchair quarterback, it's easy to look back and say, "Oh, that's where they didn't see the whole picture." You know what you know. And so, I think it would be easy for somebody with fresh eyes to go back and say, "That's where they miscalculated, or that's where--"

SM: What is your background, your training? Epidemiology?

JS: Epidemiology. Yes.

SM: Where did you go to school?

JS: Columbia.

SM: Oh, me too!

JS: Oh yeah?

SM: In New York? Well, yeah. So, let's see.

JS: Oh, you know something else? Something that we didn't anticipate that happened early is that from an ASPR point of view, the early response--the spring response--was completely run out of CDC, and there was a real lack of communication.

They were doing their thing and I'm not... They were doing a good job, but because it happened during a transition of

leadership, it didn't go anything like we thought it would in terms of how a pandemic response would go. It was really a hundred percent out of CDC. I think that was a little bit to the detriment of the response because they had their tunnel vision, which is totally... Everybody has tunnel vision.

But they had their tunnel vision. One thing that I thing would have been better is that… They were making tons of decisions in a vacuum, and if the decision making had been pushed up to get a little bit more oxygen and some people with some different perspectives, I think it probably would have been a little better. And I think that it's their inclination due to geography and the nature of their work to kind of go it alone. But I think that it was exacerbated by the strange timing of when it popped up.

SM: So was the director of CDC in yet, or?

JS: No. Rich Besser was the Acting Director.

SM: Okay. And so, acknowledging the fact that each agency has tunnel vision, and having experienced other incidents

like the previous pandemic responses, what was different about how they handled it?

JS: According to all the plans [both laugh], the ASPR is the lead for an incident of response like this. I mean that's how PAHPA is written--The Pandemic and All Hazards Preparedness Act. That's how it's supposed to go. And I have no visibility whether that was a CDC decision, just to kind of do their own thing, and say, "ASPR go take a break", or if it was our former ASPR just not wanting to engage. We would find out from the newspaper what CDC was doing.

SM: Well, there is a lot of deliberation--everyone at the table, a consensus has to be reached, at least in the meetings I've been attending.

JS: That was not true in the beginning.

SM: Okay.

JS: Yeah.

SM: Okay. So, the Chief of Staff meetings, the earlier meetings were largely attended by people here at ASPR and--?

JS: Yeah. And whatever our money group is called now. ASFR?--the money people.

SM: Uh huh.

JS: Yeah, so--ASPR, the money people, and then FDA, NIH--the same group.

SM: Okay. And so, the papers that you mentioned that you use, you could see a trajectory over time. Are these the papers that Robin asked you to...? So, I would be able to see your--?

JS: Actually, you're on the meeting invites. So you actually could just go through your emails and the attachments to meetings.

SM: Well I didn't come on until October, September.

JS: Yeah, but you know, Casey Wright and Amanda Smith have them all.

SM: Okay, alright. And I will interview them as well.

JS: Yeah, yeah, definitely.

SM: Okay. Let's see. I know you gave me an hour. What kind of other mechanisms were in place to help (that you witnessed) co-ordinate the response with the other agencies?

JS: Well, something that I don't think worked so well was these pillars that were stood up at ASPR. So, there was this H1N1 response plan. Well, I don't remember--framework, sorry--framework that the White House created. And this was again, fairly early. This was to work on over the summer, essentially. And in response to that (I guess this is when Nicki came on,) they stood up these pillars, and that's where Captain Helminiak was put in. It just didn't work. And I was one of the pillars; I was the antiviral pillar.

JS: No one knew what it was, and then they were having to report. The whole thing was to report things to the White House because the White House wanted to make sure we were doing our homework.

I should go back and say that I was the person responsible for reporting all of... HHS had a couple hundred actions in the National Strategy for Pandemic Influenza Implementation Plan. I was the person who collected all of them and put in reports and would send them forward to the White House. That was my job for a couple of years. So I'm very familiar with this [laugh]. But what enabled me to do my job was that I had--when it became clear that we'd have to do all of these things, the Assistant Secretary for health at the time, Admiral Agwanobi, had a big meeting of everyone who'd be involved in HHS, and said, "This is what we're going to do. This is how we're going to do it. And basically, when Julie asks you for something, she's asking for me."

JS: And so, even though I was very junior to be doing that, it was no problem because everyone knew that I was doing it for him. It was very difficult. It was an enormous amount of work for everybody, but everybody understood.

There was nothing like that for this framework. There was no sense of this is who you're doing it for; this is why I'm asking you for this; this is how it all connects to the bigger picture. That was never given to anybody.

For me, I was talking to people that I'd worked with for years, so they were fine with it. It was like, "Okay, that's fine." But for a lot of the other pillars, they were brought in brand new. There would be all these tight deadlines: "I need this by noon", and it's 10:00. And they would have to go ask someone that they didn't know for something, essentially, demand it. And the person would reasonably say, "Who are you, and what do you need it for? And why are you asking me? I've got a million things to do." So, it was just totally set up to fail. It was so ineffectual.

SM: So the idea of the pillars came out of the White House?

JS: No. I guess it was the ASPR's idea. I don't know. I'm sure you're going to talk to Captain Helminiak. Maybe, she

understands better. And it's no fault to any of the people involved. It was just this structure was totally set up to fail. And in fact, all it did was add an extra layer of ridiculousness. I mean, there was already a million things going on, and then you add in this whole layer of people. It was a mess.

Yeah. I mean, I understand we had to report all these things to the White House. And then, in the middle of doing a million things, we have to report to the White House that we're doing a million thing. And that's always time consuming and difficult.

SM: And just to better understand, these pillars were conceived of so that the White House--it would be a direct channel of communication?

JS: So, well, that would be smart! But that isn't how it worked either. It was just this way of collecting information. The pillars would have to go report to this person who was writing reports, who would send it to the White House. But the person writing the reports didn't have any...so would kind of change things around. So sometimes,

wrong information was being sent forward. Or it was changing in between. When the pillar would drop, it would hand it off to the person writing it. Then, the pillars would see reports that went to the White House and say, "That's wrong. Who did that?" And then, "I don't know." So, it was just this layer of bureaucracy, which didn't make anything better and in some cases made things worse.

I think it was because it was one of those things that were popped up to try to deal with a problem, which is, "we've got all this reporting, and we're trying to get our job done." But it was not good.

SM: Is that still in place now?

JS: No.

SM: How long did that last?

JS: Too long! [Both laugh.]

JS: I think it stood down a couple of months ago because it was really supposed to be for that preparedness time

during the summer, before the fall wave. It really I think had largely stood down by the peak of the fall wave. But it was just one of those things. This was one of those things that start with all of the best intentions, but good lord!

SM: So what kinds of things are you working on now?

JS: Now, within BARDA, we're working on our after-action report while it's still fresh for all of us.

You know BARDA is a fairly new organization, and this is our first response. It's the first pandemic we've had, obviously. It's our first pandemic, many of us. Actually, all of us, it's our first pandemic, but learning, kind of refining.

There are a lot of things that we did that we absolutely worked exactly how we thought we're going to do, and that's certainly in large part due to Dr. Robinson. He had a vision of what we were going to do, and we did it. And then there's all these things that popped up that we just didn't anticipate, so accommodating for that. And how to execute

in an environment where the money and the decisions are very fluid? So that's what we're doing now.

And then, we're also working on our ramped down plans. How are we going to finish the vaccination program?--our part, obviously. CDC's part is huge for that, but we supply the vaccine. So, how we work with the manufacturers and--

SM: What were some of the issues that you are considering in the after-action that you would like to refine?

JS: Hmm. I think respiratory protective devices are a great example of something. They are the hardest because they're a countermeasure for which there isn't a huge amount of data that says that they're useful. I think that most of us have an intuitive sense that they're useful. The idea of covering up your nose and mouth for respiratory disease intuitively makes sense. But I think what's really tricky about them is that we don't know what's the best. Will a surgical mask suffice, or do you really need a N95 respirator, which are uncomfortable, more expensive, and they have to be fit, which is a huge issue. So for us, when we wear our advanced development hat, one of the things

that comes out of here is that "Gosh, we've got to find a better way for these respiratory protective devices." We've got a whole bunch of them in the SNS that most the hospitals aren't fit tested for.

JS: There's a real mismatch right there. So, for us, the respiratory protective device part was just really difficult because there's different policy ideas from Department of Labor and CDC. They had to take it to IOM, Institute of Medicine, to work it out. Within HHS (because of a lot of political stuff that's not worth getting into,) our own worker preparedness was at its infancy. They were trying to make all these decisions in the middle of this, and that didn't go well without a lot of good data to support.

It's very difficult to discern; what's the best path forward in terms of what people should be wearing? Should they be wearing anything on their faces? But then, if the decision's made that we should, well gosh, we really need something better than what we've got because all of this stuff is just--it wasn't designed for respiratory diseases. It was designed for people laying, putting up dry wall and

stuff. So really, it's not like we didn't know this. It's just that it brought in the unpleasantness of working it all out in the middle of it; reminded us all that we really need to resolve this issue.

And I think it's really galvanizing. We already were very committed to faster vaccines, and vaccines with less unpredictability, and it's certainly a good reminder. So I think, how do you remember all these lessons, and how do you build on the momentum? Like, you know why we need to invest here is because--remember how frustrated you were waiting for that vaccine?--that kind of thing.

SM: Okay. Is there anything else you wanna tell me?

JS: I don't think so.

END OF INTERVIEW

Broad Themes

- Advisory Committee

- Pandemic preparedness exercise, Sanofi Pasteur, 2009
- Response to virus
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    - Strategy papers, briefs
- Transition of administration
- Response team in BARDA
- Vaccine manufacturing
    - Reference strain
    - Pilot lots
- National Strategy for Pandemic Influenza
    - Modelers
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    - Domestic manufacturing capacity
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- Disease severity in U.S. versus Mexico, decision making
- Interagency meetings
- Chief of Staff meetings, pre-Secretary Sebelius
- OMB – money issues,

  - Difficulties
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- CDC's role, early response
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- Pandemic and All Hazards Preparedness Act, PAHPA
- White House framework
- Pillars
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Names

- Dave Bauer, BARDA
- Mary Beth Love, logistics, BARDA
- Dr. Robin Robinson
- Casey Wright
- Amanda Smith
- Dr. Captain Helminiak
- Admiral Agwunobi

Documents

- Draft Pandemic Influenza Preparedness Plan, 204
- Timeline
- Decision memos, briefs, strategy papers