

INTERVIEW WITH

DR. NICOLE LURIE

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Nicole Lurie
Interviewed at
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Interviewed December 9th, 2009
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Dr. Nicole Lurie: NL
Sheena Morrison: SM

NL: MJ, John Monahan, you should definitely try to capture. I don't know that it's gonna get captured otherwise, and it's really important. So I don't know if there was a place that you wanted to start today?

SM: Well--

NL: Or questions that you had, or--

SM: I do. First, it seems to me that we're approaching the end of the second wave, right?

NL: Uh huh.

SM: And so, I'd like to hear your assessment of how the overall implementation of the program has gone thus far, beginning with the aspects that have gone better than

expected, as expected, and then whether they have gone worse. So, if we could start with what aspects of the vaccination program have gone better than expected.

NL: So, I'm happy to do that. But what I'm feeling that I most need to get done in this project is some of the thoughts and decisions and all that stuff really captured. So, I assume that you're doing that. And our call's at noon, but there's an awful lot that's been happening offline that it's harder to capture. So I'm happy to talk about that.

SM: Well, why don't we start with some of the things that have been happening offline since the last time we talked, then. And that was at the point where states were just beginning to receive their--

NL: Offline, on the national vaccination program side, there has been a ton of back and forth with States. Whether it's about the projections, whether it's about shortfalls that happen, whether it's about "Can we start a PSA campaign now?", there's been a lot of active engagement with the States. There's been a lot of frustration and anger among the States when vaccine does or doesn't show

up. There have been times when we've had to do all of these back flips, including keeping the system open on weekends, when stuff didn't get to where it was supposed to in a hurricane, so that States could order. There've been a lot of interesting issues with (there's still active epidemic in the Northeast, but in the South, there's not so much,) can we reallocate vaccine from one place to another? We got health officers talking to their elected representatives who want to beat up on us about why we haven't done one thing or another. So, all of those very active dynamics have been constantly in play.

And there's a very interesting pull and push, tug and pull with states, and some states in particular, and with ASTHO about all of this. I mean, I think they finally understand we can't make vaccine come any faster than it's gonna come. There have also been some major challenges and problems in projecting the amount of vaccine that's gonna come, and some very big hiccups with some of the manufacturers.

SM: Right. That's what I wanted to get at. I know that there have been some challenges with supply and production, particularly on the manufacturer's end, and I would like to know how you were able to respond to that.

NL: I don't know if you watched any of the hearings.

SM: I've listened to some of them.

NL: Oh, good. So, on the one hand, we worked closely with the manufacturers. On the other hand, there have been a huge number of challenges here with coming to understand that most of what would have been put to me as agreements with manufacturers have no documentation, paper trail, or emails to back it up, no anything. It's just really been very freaky.

We've had a couple of major 'come to Jesus' things: One with Novartis about all of the issues, and a couple of calls that the Secretary had to make to the vaccine manufacturers, and more that I had. I had one with Novartis about, "What on earth is going on here?", and their needing to be more upfront about what their problems are, and then having to call them quickly when stuff didn't show up. And I think there's a better back and forth now, to be sure, but it's been pretty unpleasant.

And with the hearing, everybody agreeing to have a truce, and weren't gonna attack each other. Then they went and just totally attacked us. It was really inappropriate. And the money and the lobbying and all that stuff, it's been very interesting.

SM: Can you tell me, what were some of the issues with Novartis? I heard this company's name thrown around quite a bit today.

NL: Well, you know, they've been really, really late in getting stuff to us, despite all of these projections. I can't even remember. But then, when we went, they started with the stuff about, "Well our contract was to deliver 90 million doses of bulk vaccine to you. Oh, it translates into only 60 million doses of 'net' vaccine." It's like, give me a break! No, a dose is a dose! They tried all of this unbelievable weaseling to try to renegotiate the terms of the contract: "And you made us do this, this, and this, and use these reagents." Well, we made them do what they have to do every year, in every flu season. And what they tried to do was reinterpret the letter of the contract to advantage them, to make it look like it was our fault, or FDA's fault, or somebody else that they were behind and not

able to fulfill their contract deliverables. So, that's been a pretty unbelievable process, and a pretty unbelievable thing to try to disentangle and understand the various allegations.

And they would make these allegations, especially about FDA, and then nobody at FDA would have any idea that they happened. And then they'd say, "Oh no, in fact, we didn't really ask FDA for those things." You know, it was all of that kind of stuff. It was extremely slimy and unpleasant. And then really unleashing high priced, politically connected lobbyists to threaten us, which caused a couple of extremely unpleasant weekends. I'm sorry, but this isn't acceptable behavior.

SM: Were you able to reconcile the discrepancies in what the story was?

NL: Well, I mean, I understand what the story was. I understand that they made many attempts to shade the truth. I understand that we're completely dependent upon them to get vaccine. And I understand that we just helped them open a new facility in North Carolina, which, by the way, when they say its gonna make 150 million doses--they're on the

factory floor, and they're giving me this tour, and I go, "So we're talking about bulk doses or fill-finish doses?" They go, "Oh, bulk doses!"

SM: Can you explain the significance of bulk versus--

NL: You don't have that part down yet? So, bulk doses are these things where we're really hung up in the beginning, when you first started. This is the stuff that comes out of the big vat, but then has to get put in vials and syringes, and then lot released, and that's another four to six week process. So, if they're gonna make a 150 million bulk doses in six months, then it's 7½ months till we have a snowball's chance in hell of seeing a dose. And they only have a pre-filled syringe line there; they're putting nothing in multi-dose vials after all of the crap they gave us about how pre-filled syringes take so much longer. And they're just gonna contract out the multi-dose vials to somebody else. Well, did anybody have any understanding of that, about how we proceed within a public health emergency? Well, no.

So, there's all that stuff. Then, there's all the stuff with Sanofi and Mexico. So, Sanofi came to us early and

said, "You know, we need to help Mexico, blah, blah, blah," and we kept saying, "You know, your first contracted obligation is to us," and they said, "Yeah, but we're building a factory in Mexico, and we have to. We're getting a lot of pressure from the Mexican government, and all this stuff's going on." And we kept saying, "No, you've got to deliver doses to us." They got behind in some of their doses for us. They had all these issues. And we said, "Are you guys taking out doses to go to Mexico?", and they said, "No". "Are you having a manufacturing problem? "Well, no". Next thing you get is a clip from some international news wire that says the first 800,000 doses have just arrived in Mexico.

SM: How did they explain that?

NL: Well, it was really horrible. It just happened over Thanksgiving. And so we kind of said, "What's up?" And this is like after they're telling us to our face that, no, they weren't doing this. So, then, they admitted that they sent six hundred and something thousand from here, and another two hundred thousand from their factory in France. I had to write back and say, "I'm really flabbergasted." Oh I know! We called them, finally, the Tuesday before Thanksgiving.

They said, "We're doing better." They were way behind. And I said to them "If you can hit 10 million doses next week, I feel like we're going to be in a position to talk about Mexico." And they said, "That's great, we've actually been thinking a lot about Mexico, too." And I said, "We've been thinking a lot about it, because I really want to help them." And they said, "Next week or the week after, we'll be in position to propose a plan to you about how we can help out Mexico." I said, "Great." It was that night that we got the news clip. So, they never said a goddamn word about it. I mean it was really unbelievable. So then we sent them this email, we told them, "Look, I needed..." Their vice president called me up, and I said "I need a commitment for no more doses leaving the country." He couldn't give me that commitment; he said "I've got to check with the others." I said, "I want there to be a moratorium on leaving." Then we had to...and they made an accusation about somebody here giving them permission to do it, throwing somebody under the bus, which turned out not to be true. I said, "Even if this person told you, you know that person doesn't speak for me. You know that person doesn't speak for the Secretary. So, get off it." I mean, it was really amazing behavior.

SM: Can you speculate on what their logic--

NL: Oh sure, I can totally speculate on what their logic was. So then, right after thanksgiving, their CEO and their national CEO, everybody came in here. They were very contrite and apologetic. And you know, it's been really, again, a fairly unbelievable [laugh], really interesting, but a fairly unbelievable, scene. Yeah, so, they're building this company in Mexico. They have to show the Mexicans that they're working in good faith. The head of the plant down there is the brother of the deputy health minister.

SM: Okay.

NL: [Laugh.] And they just thought they could get away with this and we wouldn't notice.

SM: And so they have a plant here and a plant in Mexico, both opening around the same time.

NL: No, no, no, they have a plant here that's been open, that we've invested a lot with them to help retrofit. And then they started giving me this stuff about, "Yeah, but

we're a global company, and so our commitments to you don't really matter that much." And then, when they came in, they sort of ate those words, but--

SM: Okay, and what about the CSL? I just know that they fell short really early in a big way.

NL: They just fell short really early in a big way, because the Australian government used the equivalent of their Defense Production Act to basically say the vaccine needed to be domestic. That's so they couldn't send us anything. And then they started to try to send us doses later, but as a result, they haven't finished their bulk. We don't need the stuff anymore. You heard today. So, they're really in violation of their contract in every set of terms. And I feel bad, because this was the Australian government doing it to them. Not us. By the same token, one of the things that we understood is that there was a bunch of fill-finish vaccine made in Australia that wasn't being used that we couldn't use here, because it wasn't made in a licensed facility. But then, we could buy from part of our international donations, so we didn't have to take the first bunch off the States. And we've been waiting for a month now. They had to get clearance from the Australian

government. We've been waiting a month for the Australian government to say okay. And finally, you know, moved on. But they're getting completely screwed by the Australian government coming and going here. I feel bad for them, but I can't help it. I want to work in good faith with the manufacturers and live up to our commitments, but they also need to live up to theirs. And at some point, I can't help the fact that they had certain circumstances that kept them from living up to their contract. I shouldn't be \$150 million in the hole for that.

SM: And of all the companies, which company is the one that we have the best relationship with as a result of this?

NL: I don't know. There's challenges with all of them. Every single one of them has had a set of issues. I've learned so much about the manufacturing process.

So, when you say to me, what's gone well and what hasn't? Last week I went to Europe to this meeting of the G7 or whatever it was, plus Mexico. The Global Security Initiative. And when you stand back and you see the problems that other countries are having, how little

vaccine they have, how little uptake there is, the problems that we're having pale in comparison. And then, zero understanding of any of this stuff about the manufacturing process. What they could have done to get...I mean, we were really aggressive about working with vaccine companies to deal with fill-finish capacity, to deal with all these other problems they had no understanding of. So, the Mexicans are still there saying, "Oh, can you help us get vaccine?" Look, the first thing you need to do is figure out, has the vaccine that's been promised you even been formulated? Is there enough filling line capacity in the world for whoever company to fill that vaccine for you? If not, we're getting pretty good at running the speed dating service between contract fill-finish lines and manufacturers, and we'll help you find a fill and finish line. First step. 1. But nobody has any understanding of this. And it turns out, a lot of countries have signed exclusive agreements with manufacturers that preclude them from buying from other manufacturers. So, it's kind of amazing from that perspective.

Then there's all of these pretty unbelievable intellectual property issues that are just starting. You heard them on the phone today, some of it.

SM: Related to the-

NL: The reverse genetics strain. Yeah. So those are also pretty amazing.

SM: And we've come out ahead in--

NL: Well, it's not a matter of us coming out ahead. The reverse genetics, the methodology, was originally funded by NIH, and so part of intellectual property agreement that got ultimately hammered out had to do with, we don't have to pay royalties on that vaccine. But it has all kinds of other completely screwed up implications.

SM: The media will look at the campaign and they will dissect it for holes and gaps, but as the lead agency and the go-to person, you have a better idea of the successes.

NL: Well, we'll see. There have been a lot of holes and gaps. There's been a lot of frustration. It's also the case that when there's a perceived shortage, it really drives demand. And so, as unpleasant and as bumpy and as hard as its been, it will probably be successful getting more

people vaccinated because we had all those problems. But we'll see. I mean, did I wish it had gone this way? No, I wish it had been a little smoother. I wish, you know, as one of the locals said, we didn't plan for a trickle when this vaccine first started. We didn't start a huge vaccination campaign with a few million doses, which is what we did because we couldn't ethically sit on it. Did any of us have any understanding of the manufacturing problems that might occur? No. Did the manufacturers have the understanding of this? No. Did they act in bad faith? Largely not, other than some of the things that I just described to you, which, yes, I think they're acting in very bad faith. But you know, that's not by and large why vaccine is late. I mean, it wasn't that they were trying to pull one over on anybody. Everybody's had problems and challenges. I think we've learned a lot about our gaps and our vulnerabilities. By the same token, if you said, "At the start of a pandemic, would you have eighty million doses out in eight months or sixty million doses in six months, or whatever?" No, way in hell. So, if you can step back and take the long view and step away from the sausage being made everyday, I think it's pretty amazing.

SM: I don't have access to the--

NL (Mutters: I need to go here and prep.) But yeah, you don't have access to what?

SM: I don't have access to what goes on on the weekends or late night evenings, but I know that as someone who sits in the meetings, to me, the program seems to have gone as predicted, and, I mean, with some bumps, but would you say overall that it has been pretty much on target?

NL: Uh uh.

SM: I would say so, and I'm asking.

NL: I don't know. I mean there's a lot of late vaccine, a lot of canceled clinics, and that stuff. And that was frustrating.

SM: Are you about to leave for your appointment, or do I have--

NL: You have one more minute. I'm late already.

SM: Alright.

NL: But my time is starting to get more flexible again.

SM: So I'll be able to--

NL: You should get on my calendar. I'm gonna take a little bit of time off just before Christmas.

SM: Oh yeah, I will also, but I'll call in for the meetings. Okay. Acknowledging the success--

NL: I got the hook, acknowledging the success, what?

SM: What aspects of the development and production phase have gone worse than expected or planned? Acknowledging the successes because they're...I mean the fact that you were able to get the eighty million from scratch.

NL: Yeah, well, lets pick up with that next time because it's too long a--

END OF INTERVIEW

Broad Themes

- States - Back and forth with
 - Vaccine shortfalls, distribution, projections
 - ASTHO
- Vaccine Manufacturers - supply and production challenges
 - Paper trails - lack of
 - Novartis
 - Congressional hearings
- Novartis
 - Mexican Government - relationship with
 - Vaccine supply - shortfall for U.S.
- CSL
 - and Australian Government's use of Defense Production Act
 - U.S. purchase of international donation from
- G7 + Mexico meeting
 - Global Security Initiative
 - Manufacturing process - knowledge of
 - Filling line capacity
 - Vaccine formulation
 - Exclusive buying agreements
- Reverse Genetics Strain

- o Intellectual property
- o NIH - funding of