INTERVIEW WITH

Dr. BRUCE GELLIN

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Bruce Gellin
Interviewed at Dr. Gellin's office
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Dr. Bruce Gellin: BG
Sheena Morrison: SM

BG: Another assumption: that we'd be able to tell early on what severity looked like. I may have talked about that a little bit, that there was this effort previously to look at something called the Pandemic Severity Index. And I think that we recognized even at the time that that was going to be difficult to make a call about how severe it was. And the likelihood, frankly, all along was that you would assess it as more severe than it actually was, because you would be seeing things that were the tip of the iceberg without seeing the base.

And that is essentially what happened in Mexico, is that you saw the sickest end of what was going on in the society, and it took longer time to have an understanding of what was going on at the other end of that curve of people who were less symptomatic or asymptomatic, but infected. And so, because of that, the relative number, the

proportion of people who appeared sick might seem greater, and therefore make you believe that what's happening is more severe than it actually is. So as a result of that, the response I think is appropriately designed to be, the response should be appropriate to the level of severity, but if you miss the level of severity then the response is not quite aligned perfectly.

So, I think that that was in part why (my sense is) the school closures in the spring were probably in some ways a victim of that, because it was difficult to tell which direction this was going. The indications, initial indications were that particularly young people were being hit by this more severely. I think that's why there was more interest in some of these other social distancing moves, because there was certainly no vaccine available, and the question was about the appropriate use of anti-virals in that setting. So, I think that the initial response to that, given what we knew at the time, was appropriate, but that we should have expected that it would be difficult to make a call initially and what that response should be. So, I think what happened over time is that there was an alteration in the level of response and the aggressiveness of the response that developed in

parallel with an improved understanding that it was less severe than it initially looked to be.

And again, I may have said this already, but I think that the problem was how do we describe this as, you know, 'mild'? And it's even continuing now. So, I think it would be interesting as you do this project, of how what the news of the day is over time. So, what I'm saying is, there was something even today about some look back, actually today's *Washington Post*, which was about WHO calling this a pandemic when it was only mild, and what that meant to people, and how it made people got scared because of that. So, I think it would be interesting to see how,(and I'll assume you'll do this,) not only the government documents, but whatever is the news of the day that's going on at the same time.

SM: Absolutely. That was part of the next question, because I asked you also, how did those assumptions change by the fall? And you said "Of course, we had to pull back because we thought it was somewhere else, it would happen somewhere else as opposed to on our own borders and"-

BG: What's the definition of 'assumption'? Fill in what you don't know? What's an assumption?

SM: Well-

BG: I'm saying that because they change when the data becomes available that says what you were thinking about before hand wasn't quite right.

SM: Right.

BG: So somehow there is this vision that somewhere between truth and assumptions is this gray zone, and depending on how much information you have your assumptions will be altered based on what the reality is.

SM: Absolutely. And that's how you responded. You stated that there was a huge contrast to the way that the virus behaved and the way that the seasonal virus behaved, and that you began two things simultaneously: enhancing your preparedness for a fall wave, and also trying to watch what was happening in the southern hemisphere.

BG: Again, all that was just trying to fill in whatever information we weren't able to glean from the spring here to try to think how that could better help us better understand what we might be facing in the fall. And I don't know how you do this or what other people you talk to, but it might be worth...there's a guy who Nicky and I have been speaking to who is the Chief Medical Officer of Australia, a guy named, Jim Bishop. And he's been a person that we've talked to many times and I may have even mentioned this previously. There was a time when in the mid summer I got a call from him when they were really at the peak of their epidemic, when they were having difficulties with lots of people coming into their intensive care units, and having people who were otherwise well with minimal risk factors becoming as sick as you can be. And they weren't sure what else they were missing, if there was something else about this disease that they weren't fully appreciating. And so here it was this summer when there was all this chatter here about whether or not we'd even called this right. There was minimal disease in the United States. And straight from the Southern Hemisphere you're getting what essentially is going on there, which is what you anticipate might be happening here with concerns about the most

severely ill people in a pretty sophisticated medical system. So, I think there was another disconnect there.

Actually I tried a number of times to get some of the media interested in talking to him, and vice versa, so that there could be essentially a different face for this disease, because it was seen as the springtime flu, a spring wave of a mild flu that wasn't particularly severe. At the same time you were hearing just several months later in mid-winter in the Southern Hemisphere of what it could look like. So I think that there was that disconnect of what this disease could actually be in affecting our preparedness.

SM: Can you tell me what role your office played in the decision to launch a national voluntary vaccination program?

BG: It's somewhat anomalous. So, the office, the National Vaccine Program Office had become the institutional home for a lot of the pandemic preparedness, as I mentioned before, because there wasn't another place that had sort of this cross departmental scientific orientation. A large part of that was overtaken by events and many more people.

This is a very small office, and at the same time I think it was important to keep the business of this office going, looking at other issues with the vaccine and immunization program, whether they'd be issues of vaccine safety or shortages of vaccines or working with the National Vaccine Advisory Committee to advance their agenda. So I was always sensitive to - with a very small staff of really less than ten in total - to try to keep the other things going when everybody's efforts were dedicated to H1N1. So, in part, that was when...so my role here versus the role of the office is a little bit different just because I've been doing this for a long time; so I was, I've been regularly pulled into these things.

SM: I'd like to hear both.

BG: So, I think that to a large degree, I try to keep this office on mission of doing its thing, which is what I referred to as the day job part, because there was a lot of the things going on that needed tending to. Because like the rest of society, there were other issues going on that required the other coordination of the kinds of things this office does around the immunization program, whether that was about, again, for example, managing vaccine shortages.

There's been a rabies shortage; there are a number of vaccine shortages. This office has been helpful in working with the FDA, the CDC, and the suppliers to try and think of how to help manage some of those things.

So, with some exceptions, the people have been involved in some of the pandemic preparedness, but the National Vaccine Program Office, as an office, has had little institutional role in a lot of these things. So, discussions about the campaign - I think that because there had been a lot of thinking by many of us about moving forward, I think it was just a natural that there was a discussion broader than here.

So, I think what began to happen (and it was before Dr. Lurie was in place) was recognizing that, particularly beginning in the summer, vaccines were going to be an essential part of the whole program. And with that, beginning with Craig Vanderwagen, what he called the Enterprise Governance Board - it was his construct of what you're seeing now with the chief of staff meetings - it was a way that ASPR as a convener would bring together the leadership of the department around key issues. Again that is what he was able to do in his sphere for a number of

things related to preparedness, and that gravitated, it fit most in that office.

So, it was at the time of that transition when, clearly, the vaccines were a key part of that. And that's when I became increasingly involved in that setting of trying to keep track of the vaccine program, because it was clear that it was going to change over time from the development aspects, which were largely the scientific part of getting the virus reference strain to the manufacturers, to the production aspects, which BARDA had began to focus on, to now, the delivery aspect. So, I think there was a desire to have a focal point, to a large degree, on vaccines that would manage to straddle all those areas. So it was in that setting, really, through ASPR offices that that's how I became more and more involved. Because I have awareness of each of those and an overview of each of those that not any of the programs do themselves.

So, I think that the gradual piece from CDC and the FDA, from reference strain to BARDA, and now again overall CDC, and working with the states on an immunization program, it's sort of the continuum from vaccine development to vaccine production to immunization. And so, that was the

way we talked about those things. Somewhere in your archives there's this picture on the wall of this graphic, we call it, which looks at these different phases. And essentially that outlines those phases of an initial development phase, production phase and now this implementation phase.

SM: So a lot of the work was sort of convened outside of the normal process?

BG: I'm not sure what the normal process is. I think that this is where ASPR took the overall coordinating role for H1N1, because there were gonna be many more things and I was just looking at the vaccine part. I got pulled into others because of my infectious diseases background and some of the other things I have worked on historically, but overall, all these things were anchored within ASPR. They were called the chief of staff meetings, in large part because that's the normal conduit for information to go to the Secretary and up to the White House, but in those settings, which had been daily. Now, there's still something going on almost every day that involves a multi-departmental discussion.

SM: How big a role did the medical emergency countermeasures enterprise play in the decision making process? Did they convene as well?

BG: Who is that?

SM: It's an agency that was created to, well, not an agency, an entity created to respond to the need for medical counter measures like vaccines.

BG: So who is that? I'm not sure. I'm sure that we're talking about the same thing but I don't know it by that name. Do you know?

SM: Okay. PHEMC? I know you guys are more familiar with acronyms.

BG: I don't know, what is that? Who is that, do you know?

SM: It's your office, ASPR, NIH, and FDA.

BG: Well, I don't distinguish it from the other one, and whether or not they are different. Maybe I'm in too many of

these conversations, which banner I'm under. But again, I think of them all as the leadership, the scientific and public health leadership of the department that convenes on a variety of topics, whether it has to do with vaccines or anti-virals or public health measures. So I'm not as familiar with that configuration.

SM: Can you recall when you first became aware of the possibility that efforts to protect the public from this particular virus would demand the kind of resources that is has?

BG: This particular virus, the H1N1?

SM: Yes.

BG: Well, I think that it predates this, because I think when we started with the H5N1, I mean really, from the very beginning, as I think I said really at the outset, anybody can have a little committee that meets together and writes a report. But if you're going to truelly have an impact on preparedness it was really going to require substantial resources. And one quote you probably heard from others is that along the way it was this discussion with President

Bush about preparedness and what it was going to cost, and at that point, I tell you, maybe I've mentioned it to you-

SM: You mentioned it to me-

BG: About him telling John Bolton to put his calculator away?

SM: No, no, you didn't.

BG: Did you hear this from anybody else? No?

SM: No I didn't.

BG: In fact, are you going to talk to Julie Gerberding at some point about all this?

SM: I am. I've spoken to Jessie and Dr. Lurie and you, and I have an appointment with Robin tomorrow or Friday.

BG: But Julie Gerberding is on your list somewhere.

SM: Yes she is.

BG: No, because there was a discussion, I think, when this was happening. This was the H5N1, and there was increasing concern about the threat that it could be and the need to greatly enhance our preparedness. And there was a series of briefings that went on, and I can't remember how many with President Bush, but at one point, and I think it was after, it was clearly after 9/11, and in the setting of Katrina, exactly when, I'll have to think about, I think it was after, what year was Katrina, 2004?

BG: Yes.

SM: It was after that. Because we clearly came up with...it was the summer of 2005, is when most of the big thinking and planning and the resourcing of a pandemic preparedness budget went on. But it was in that setting when we went with Secretary Leavitt to the President and outlined the problem, that's when he turned to Josh Bolton who was then head of Office of Management and Budget. Apparently, every time when people would talk about money, Bolton would pull out this calculator that he got at ToyRus with big buttons, and so basically it was this symbolism of saying, you know, 'this is going to be expensive!' And that's when Bush said "Put away your calculator, that

they'll tell you what they need." So, I think that was the indication that there was now an opportunity to take a serious look at what it was going to mean to invest in preparedness, and it wasn't going to be fast, and it wasn't gong to be simple, and it wasn't going to be cheap. But that's what developed into this budget of over $7 billion, and a large part of that was the vaccine infrastructure.

So, when you flash forward to H1N1 I think that that was essentially building on what was already in place. Now, while those plans that were begun in 2005 haven't yet matured, we're going to be going down next week to North Carolina to go to the opening of a, or to a ribbon cutting. They wont be making vaccine yet, but Novartis has built, with a lot of our investment, a new vaccine production facility making flu vaccine in cell cultures and not eggs. That, those are among the kind of investments that those billions of dollars are bringing forward. They're not ready yet, but the whole idea was that you needed to have a significant amount of infrastructure to be able to mount a response like that. This is just the vaccine infrastructure.

We've learned over the course of implementing the H1N1 immunization program that the decay of the public health infrastructure is working against us as well. And how, if you wanted to have a response like that and involve public health as a lead that they're not as prepared as they could be had there been similar investments to bring them up to speed, both in terms of their technical abilities and their manpower needs. So I think that when this one came up it was pretty clear what the range of things had to be. And I think, in some ways, the tricky part was gauging the appropriate response to the level of severity, but from the very beginning it was clear that a vaccine was going to be needed. So, that all started.

Then shortly after then came the discussion about what planning for an immunization program would look like. I was cautious to keep those two separate, and I think that among the many things we learned from the analysis of 1976 was, in 1976 there wasn't a time when people stopped and said "Take a deep breath, are we still going to, right, the same direction? Is this what we should be doing?" I think it was very clear that the development of a vaccine and the production of vaccine was a separate discussion from whether you have an immunization program. And so all those

things, the first things had to be going on, because you can't have an immunization program without a vaccine. But I think we were all schooled to understand that just because you had invested in a vaccine didn't necessarily mean you had to use it. So that's where we were in the summer, but as the evidence from the Southern Hemisphere came in, as we saw the virus never going away in the summer, and then particularly as you saw the disease reemerge in the fall, it was pretty clear that this was a disease that you'd like to get a vaccine out in front of. So that became our challenge of racing the vaccine and the virus, and the virus had a head start.

SM: I got an email today from an HHS bulletin about the FDA approving a new vaccine.

BG: Which one?

SM: It was just a headline. I saw it before I left and it said-

BG: So again, I'm not sure exactly which one that is. For flu?

SM: For flu, yes.

BG: For H1N1?

SM: Yes.

BG: So, the principle we had all along was that we would look at the vaccine companies that would be most likely to provide vaccine to the U.S. We stratified it in terms of those companies that already made a seasonal vaccine, and therefore, that would be the clearest pathway to developing a licensed vaccine for H1N1, companies that we were familiar with that had influenza technology but didn't have their vaccines licensed here, and maybe some novel products that weren't licensed but that we'd consider using since we had the experience. And so, that was how we looked at the different approaches. And then probably even a third tier of much more upstream technologies, more along the lines of biotech companies that had very interesting technologies that were not as mature as some of the other vaccines, but in a severe emergency you might look at them differently than you would without an emergency. So that was our approach initially to looking at these different vaccines.

And so with that, the main discussion has been about having the same companies that supply seasonal vaccines to the United States supply H1N1 vaccine that could be licensed. So, there are 5 companies now that provide seasonal vaccine, and perhaps, and I'm not sure what news bulletin you saw, but that may be the fifth. The four other vaccine companies' vaccines were licensed in September. There were some additional reviews that one of the companies needed, so GSK's, if that's the one you're speaking of.

The other thing that is also happening this week not related to H1N1 vaccine, the FDA's advisory committee on Thursday is going to be reviewing an application from one of these newer companies. A company that makes a new, a different type of vaccine. They don't grow virus in eggs, but they have a recombinant where they produce the vaccine in caterpillar cells.

SM: Wow!

BG: So this is a company that we've been very interested in - they have a very interesting technology - have supported along the way, and now, they are presenting their

information to the FDA for seasonal vaccine. The idea is that if they get a seasonal vaccine license then that then puts them in the sphere where it's then easier to then work with them to develop a pandemic vaccine, should that be needed. So we'll watch to see how that is taken to the FDA, but again that's another piece of news. It's not the approval of a new H1N1 vaccine.

The other news from the FDA, (and I think it would be interesting to look at all these pieces of early advances, and probably if you get a listing of all the press releases available in all the agencies you'll capture these,) the FDA reviewed data from another company recently from Australia. The vaccine is already here but the vaccine had been licensed only in adults. It was important for flexibility to have as many of these vaccines available to as many people in the population as possible. So we have encouraged these companies to do the kinds of studies that would license a product that would be for children as well as adults. So whenever it was, this week or last week, the FDA approved that amendment to CSL's license so it's a vaccine that can now be used in children as well as adults.

SM: So, once the momentum picked up and everyone was in gear, what agencies were you most engaged with, in the beginning? And who were the contact people?

BG: I think that the principle agencies within HHS have been CDC, NIH and FDA, and depending on the topic, it's different parts of those organizations, and maybe different people. And by the topic I mean, if you're talking about the vaccines you're talking to one set of people in each of these agencies; and if you're talking about antivirals you're talking about other sets; if you're talking about the epidemiology that's largely CDC; if you're talking about the immunization program, that's largely CDC and then ASPR, and then ASPR's got other people on the ground locally, some of the regional advisers. So I think that there's a number of these things that are all going on simultaneously: advancing preparedness for an immunization program, at the same time dealing with preparedness for dealing with disease in the community, working with hospitals so that they could figure out how to keep people away from the emergency rooms if they didn't belong there. So I think there were a number of these things that had to go on simultaneously.

SM: If you had to name six principle players in shaping policy around the pandemic response who would they be.

BG: So, I guess when you ask that question you should probably ask it pre H5N1 and then this one, because they are different, to some degree.

SM: Okay.

BG: To some degree. I think that there were, in terms of the agencies...but so you want people? Or you want titles? What are you looking for?

SM: People. I mean, because you have your day job but you're obviously working-

BG: I think, for example, like when you go back to the initial days of trying to craft a policy, at that point, I mean, Secretary Leavitt was really quite involved. When he first came to the department was when this stuff was starting to hit and the H5N1 was heating up, and I think he saw this as something that he didn't intend to deal with on

his watch, but it was something that he might well have to. And I think that at that point he had a very interesting approach to, sort of, policy management. For example, it was in discussion with him came, I think, this notion of shared responsibility, the recognition that a pandemic is different than an incident. Or, an incident is something bad that happens in some fixed place in some period of time, then you deal with the after effects; the pandemic was going to be the inverse of that, where there's a lot of things going on and that there's no way the federal government could be in all places at once. It just wouldn't happen. His chief advisor was Dr. Bill Raub, R A U B (who is somebody else you should talk to). He was probably the most, within the department throughout the development of pandemic preparedness, he probably was the sage, as far as keeping an eye on the larger picture of what the philosophical and underpinnings of preparedness would be. So I think he was probably the most important person to influence overall policy development. But again, he was appropriately deferential to the Secretary, would tee up issues to be able to take the pulse of the secretary.

I think that the agency heads were always critical. Particularly, again, in the H5 era, Dr. Gerberding and

Steve Redd. Steve was probably the person who was dedicating all of his time to this. The FDA was primarily Jessie Goodman throughout this, and I think that at the NIH, primarily Dr. Fauci. That's changed somewhat with the way that, particularly the CDC, has structured things for H1N1, but I'll get to that in a second.

But I think, initially, that some of the structures were really very important, that there was also a structure that still persists, which is looking at the oversight of the Pandemic Preparedness Supplemental Budget. And so, there was something that was referred to as a contract steering committee. Now its referred to as a Countermeasures Steering Committee that was chaired by the Budget Office, by ASRT, and that continues as a almost a biweekly meeting where there's a review of the overall preparedness funding that has come from congress, and how that's been allocated, and then make decisions about how to move forward that involves the approach we've taken for vaccine development and infrastructure development, for antiviral purchases, for diagnostic development. A little bit for the state and local allocations - not that that group made decisions about that - but recognize that that was an important slice of the funding.

Some of the international work, and I think that that is another place where, if you look at this whole area through the budget line, it will teach you a lot about how decisions are made. That'll probably be another way to look at where the priorities were set, and how money was spent.

So along that time is when BARDA emerged. So, I think that the development of BARDA as an entity over that period of time was important. I'm trying to think of who I'm forgetting, but those are some of the principle architects of that initial philosophy.

Now, its been a little bit different because I think that there has been a lot of understanding about preparedness; there have been a number of exercises that have helped us think through how we would respond to such things, and there are a whole set of different structures in place. Now, CDC's got a pretty elaborate infrastructure, again, Steve Redd of overseeing the entire operation. They've brought in Jay Butler, who was in Alaska. They brought him in to oversee the immunization portfolio, and all the things contained within that. Anne Schuchat has emerged as a public health leader and CDC spokesperson, then again,

still with Jessie Goodman and Tony Fauci. So I think that the rest of the structure has been the same - the substitution obviously of Dr. Lurie instead of Dr. Vanderwagen - but otherwise, the changes have been primarily the assignment of various responsibilities within CDC, and depending on what's going on when you talk to different people.

SM: Okay. Many of the federal agencies moved from a transitional leadership in the spring to its current leadership in the fall. What kind of impact did this have on efforts to develop and procure H1N1 vaccine?

BG: What was the first part of that?

SM: That many of the federal agencies moved from a transitional leadership in the spring to, was there any-

BG: I don't think so. I think that the new people have somewhat of a learning curve, but I don't think that that affected, I don't think that that changed the pace of anything. People recognized that we're gonna need these things, and you're gonna have to, and the virus wasn't gonna wait, and production timelines had a certain amount

of time and somebody had to figure out how to make a decision. Because I don't think you can think any time was wasted along those lines even though there was a transition in leadership, as people recognized that these things needed to happen. And I think that some of the people who were new to the department understood that there was already a system in place to bring these things forward. It just needed to be positioned in a way that they could, they're the decision maker, they just needed to be teed up to them. So I think that that happened pretty smoothly.

I think was some uncomfort at the fact that this was all heating up at a time that we didn't have a Secretary in place. That changed, obviously, quickly in April and since then, nobody's looked back over that. But I think there was that period of time in the early spring when there was a little bit of angst that not all the players who should be here were here. But it didn't really affect anything when you had people like the Chief of Staff going to cabinet meetings; there was clearly representation of what the agency was bringing forward.

SM: You've been in the role of readying the country for the influenza pandemics prior to this current outbreak. Has

there been much difference in the degree of senior level and White House involvement in the response efforts, say when compared to the Government's strategy to deal with the H5N1 virus?

BG: At the top levels, it seems about the same. I think that there were different things that were, are going on that probably keep people awake at night in different leadership positions, but I think that this is something that's been recognized, not only at the top level of HHS, but beyond that, was gonna be important. And so I think that there was, if anything, there's probably, there's maybe been more regular involvement at the White House. And I think that maybe that's just...I don't know what that means. The fact that this White House is dealing with a real pandemic, and the last White House was preparing for a pandemic, was a different level of intensity and urgency in sort of the management of day to day issues. But ultimately, I think it's a...the level of involvement and the level of trying to stay on top of this thing, at least, it seems about the same.

SM: Traditionally, there's been little interest in late season vaccination. Do you think that this is something

that should be promoted in light of the manufacturer's delays in production as well as the unusual wave activity?

BG: So, I think that you have to take a second look at this question. The 'traditional' lack of interest in delayed late season vaccination is about seasonal vaccine. And that's mostly because people have been locked into the idea that you get your vaccines before thanksgiving. Even though seasonal influenza doesn't usually show up until January or February, we've never been very good about telling people, after thanksgiving when they're doing other things, that if you're still susceptible and haven't yet gotten the vaccine, it's still worthwhile to do it. I think that there was still effort to try to improve that because there was increasing amount of vaccine that was being produced for an even increased number of people who were being recommended for it.

Somewhere in here you should get this slide the CDC has about the number of people for whom seasonal influenza vaccine is recommended. I forget the number, it may be about 220 million people. So 2/3rds of the country or more is recommended for seasonal vaccine, and the companies in aggregate have never made more than 120 million doses, and

even at that they'll probably throw some out. So there is this disconnect between the number of people who it's recommended for and who actually get it, year in and year out. With increasing interest in influenza, I think that an increase in manufacturers...and I think that part of this was pandemic preparedness. And I think there's more recognition that more people could benefit from a vaccination, and that it would improve public health and improve preparedness to have more people vaccinated. And that was the creation of this National Influenza Week sometime in early December to try to remind people that after thanksgiving, it's still a good time to get vaccinated if you haven't been sick yet, and you haven't been vaccinated yet. So that still persists now. And all that before the seasonal peak would begin.

This is different, because now, we have a situation where the virus got in front of the vaccine - the seasonal vaccine is the other way around where the goal is to have vaccine in front of the virus - and now what we may see is that vaccine will continue to come when the virus may taper off. And now the big question I think, and this will be the next chapter of your book, is what will happen in the late fall and early winter when there will be more vaccine,

because it is still gonna be produced. And if the disease is on the wane, will there be any interest in ongoing vaccination of people who haven't yet been vaccinated? We'll have to see what happens. Nobody can predict the future.

Nobody knows what this virus will do, but there's been a lot of attention paid to 1957 where there was a similar pattern when there was a lot of disease in the fall that tapered off late fall, but then recurred in the spring. So while no one can tell you with any assuredness that that's gonna happen again, if it does, you have a second chance to get people vaccinated and therefore protected before some next wave.

The other thing you could accomplish with this - and I think we'll have to look at what the final selections are for the vaccines for next year - is that, at least for the Southern Hemisphere, we know that this H1N1 virus has been recommended to be a component of a vaccine for the Southern Hemisphere. Assuming that's the same for the Northern Hemisphere, and we'll just have to wait and see, but I would think that that's likely. That means that the sooner people are vaccinated, the sooner they can be protected

even against next year's virus. And again, this is a virus that's behaved differently, whether it goes away in the spring, who knows. It didn't go away this last spring, and there's no way to know what its gonna do this next spring.

SM: So its keeping everyone on their toes.

BG: And the problem is everyone's got a different crystal ball, and nobody has a real one so. And you just have to try to make the best judgement with whatever information is available at the time.

SM: I was interviewing Dr. Goodman today and one of the things I commented on was that being the historian for the project, and being a private citizen sitting in the meetings, that one of the things that I see is that there is as much time spent on transparency and getting the information out to the public as there is in the actual practical implementation, and that there is this constant tension of trying to do both at the same time. And then to hear, to see in the news, or to hear the common person speak as if there's a conspiracy and there's so much deliberation going on behind closed doors that it's...no one has any idea.

BG: It's true. And my hope is that the rest of the Government works this way. I don't know how the rest of the Government actually works, but I read the newspaper and I have my own questions about what actually happens. At least, having now seen it at this level and I never expected to be playing at this level, you see that these are people who come to these jobs because they're wrestling with tough things, and they're trying to do their best with the best available information and trying to then provide it to people so that they can then make their own decisions. I think that, I hope that that's true of the way the rest of the Government works. I don't know.

I mean, there are a lot of people who have a lot of different views about what the government does and doesn't do. You run into it everyday about some conspiracy this or that. There's a book that's just out now called *Denialism*. It's about people who have their own version of the facts, and so I think what people often say is, "It's okay to have a difference of opinion, but you shouldn't have a difference of the facts", and that's why people have a sort of different factual basis. And then there's always the agenda that may be behind it.

So, I think, I'm encouraged by the discussions that we've participated in, at least seeing what that process is like, and particularly when you look at the people who are leading these discussions. And I know its not easy for people who are in these meetings, but they're basically saying, "Does anybody else have anything that they've got to say?" And I'm really impressed to hear that at the end of a discussion, because it basically says, "Okay, you heard this, are we missing something?". And I think that's what people are sensitive to, because I think there is always the concern about group think, that you come to some conclusion and it's then therefore hard to bring up a different idea. But I've been pretty encouraged that there seems to be a fostering of that idea of throwing stuff out there that may sound stupid or maybe wild or maybe way out of, but just to say listen have you thought of this? And then to have some discussion about whether or not that does or doesn't make sense.

SM: Yeah, I'm encouraged also.

BG: It is interesting for that. And particularly for people, and then there's other parts of it that, you know,

there's a whole range of things as well, and there are things that definitely could be better. And I guess the hope is that somehow out of this process there is this understanding that people have taken this seriously, and they've done everything that they can to try to think about all the contingencies.

SM: How much more time have I got?

BG: Five minutes now.

SM: Okay. Well, what are you contending with right now. Where are you in the process?

BM: So, right now it's shifting into...the implementation continues. People are still struggling to get vaccine, and wish that they had already gotten. I think we're going to start seeing that come up with second doses in kids, of people that had a hard time getting the first dose, and how they're going to find their second dose. And there'll probably be a bunch of issues about getting a vaccine that may not be exactly the same as they got the first time. Now that there's been a lot of vaccine that's been out there (there were probably around 50 million doses), I don't know

how many of those have been given. It would be better to know; it would be nice to have a better finger on the pulse, to know of the doses that have been produced, how many have actually been administered.

Increasingly, we're going to be looking at: what the impact of vaccine has or hasn't been - and that is on a big picture. Whether or not it has any impact on the overall trajectory of the disease, what happens as vaccine continues and disease goes away independent of the vaccine, or because of the vaccine? In either case, there's likely to be increasing amounts of vaccine, and at some point decreasing amount of disease. Then this whole issue about vaccines, how well they perform, both in terms of, are people gonna say, "I got vaccinated and I still got sick"? Are they gonna say, "I got vaccinated and nothing happened"? Are they gonna say, "I got vaccinated and something bad happened to me"? We know that the latter is gonna happen, because if you have millions of people who received something, then some of those people are gonna have some problem that's related or not to the vaccine, and sorting through that is gonna be a complication. We've tried to anticipate that. And among the things we tried to do is to improve the vaccine safety monitoring system by

building on the system we have now, and putting other things in place primarily designed to try to pick things up sooner, and put them into detect patterns sooner than we might otherwise. But you can also see how the same people would say, "If the government is going all that effort to look for these bad things, they must know something bad is out there and they're just not telling us." So there's always wrestling with that, of trying to do something that's going to detect things.

And I think we ran into this same issue with the clinical studies. Normally, for seasonal vaccine, no clinical studies are required for the vaccine; it's all done based on experience with the process by which they're developed. But because we wanted to make sure we knew how these vaccines were formed, and particularly in some of the populations that we're most concerned about, we're in the process of continuing to look at clinical studies. Somehow, that's confused. As we're doing vaccines, we haven't finished the studies yet. So is this some big experiment? I think we haven't communicated that as well as we should have, and I think we still have to deal with that.

And we have got this whole thing about the perceptions of safety, of whether or not there are things that are gonna happen to people. And we encouraged a group to put a paper together that was published a couple of weeks ago about background rates. Essentially, in the practice of medicine, bad things happen to people; and when they happen to people, when they go see their doctors, we wanted to take a look at the statistical likelihood of what any of these things might be, particularly the things that are often alleged to be caused by vaccines - neurological syndromes and auto-immune kinds of things. At least those are the things that people seem to be most worried about.

So we put a paper out that looks at those, that tells us, without an immunization program how often you're gonna see Guillain-Barré, how often you might see lupus, how often you might see miscarriages, how often you might see medical events happening to people, particularly in the populations for whom vaccine is recommended. And that doesn't mean that any of these diseases might or might not be triggered by a vaccine, but I think it's important to have that in perspective, so that not every bad thing that happens or every death that's reported is attributed to the vaccine.

I think explaining that is going to be very complicated, because while there's an effort to look into each of these cases, those are primarily done to define what the problem was. Did this person have a stroke, or was it Guillain-Barré? If you want to look at the relationship of vaccine and Guillain-Barré, you don't want to look at a vaccine in a bunch of people - some have stroke some have Guillain-Barré - 'cause that would give you a different assessment. There are other systems in place that will monitor that. The answers will come after the allegations. And I think we're always gonna have to deal with that, and particularly if there's some clustering of things. If there are five people who have a heart attack in the same town in the same day, what's that gonna say? Then the question is, would that have happened without a vaccine? So, I think that that whole issue is going to be important, because I think that will have a lasting effect on people's confidence in immunizations at large.

And that brings me back (and I'll have to end for now) to sort of my day job of how much of what's going on now can affect the future of vaccines and immunizations in either a positive or negative way. And the last thing for this chapter I'll tell you is that we're in the process of

updating the national vaccine plan. I don't know if I've talked about this before.

SM: I've heard you talk about it in the meetings.

BG: And so, we now have this plan that we put out a year ago as a vision for what we think the vaccine immunization program should be in the United States for the next decade. We floated it a year ago, with a lot of thinking primarily from the department; we brought it to a national advisory committee; we brought it to the Institute of Medicine. In the coming weeks we're gonna hear back from the Institute of Medicine about what they think we should be doing. So, I think it's going to be interesting to watch that, as an opportunity to say, "Here's what we think as a placeholder; here's what we think should be happening; here's what we think the goals should be; here's what our priority should be." But in the setting of all this about H1N1, I think it will get a different attention than it might have otherwise. So, again, I think that's where there's both the opportunity to do good and not so good, and to take advantage in a good way of what we've learned here to try to build a better system.

SM: Thank you, Bruce.

BG: Okay.

End of Interview

Broad Themes

- Pandemic planning assumptions – of severity, susceptibility of the young.
- Jim Bishop – Chief Medical Officer of Australia
    - Disease severity – Southern Hemisphere
- Role of NVOP – as institutional home of response
- ASPR – as institutional home of response, overall coordinating role of H1N1
    - Enterprise Governance Board/Chief of staff meetings
- Phases of vaccine response – Development -> Production -> Immunization
- PHEMC – Medical countermeasures enterprise
- John Bolton – ToyRus calculator
- President George Bush - $7 Billion budget for preparedness
- Novartis facility, NC
- Public health infrastructure investment
- Planning and immunization program
- 5 vaccine production companies
- GSK review
- Recombinant vaccine production in caterpillar cells
- CSL's vaccine license for children

- Principle agencies in HHS
- Principle players
- Structure
- Pandemic preparedness supplemental budget
    - Countermeasures steering committee
- Transitional leadership
- Senior level White House involvement in response
- Delayed/late season vaccination
- National Influenza Week
- Government at work
    - Complacency
- Implementation – second dose, number administered
- Impact of vaccine
- Vaccine safety monitoring
- Perception of safety
    - Background rates study
    - Background rates publication
- Updating of National Vaccine plan, vision for next decade

Follow Up

Names: Dr. Bill Raub, chief advisor to Secretary Levitt.

Documents: Slide the CDC has about the number of people for whom seasonal influenza vaccine is recommended.

Graphic of phases of vaccine production.