INTERVIEW WITH

Dr. JESSE GOODMAN

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Jesse Goodman
Interviewed at Dr. Goodman's Office.
Silver Spring, MD, U.S.A.
Interviewed on November 17, 2009
H1N1 Oral History Project
Interviewed by Sheena Morrison

Dr. Jesse Goodman: JG
Sheena Morrison: SM

Sheena Morrison: The following interview was conducted with Dr. Jesse Goodman, Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs within the Food and Drug Administration. It was conducted on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on November 17th, in Dr. Goodman's office in Silver Spring, MD. The interviewer is Sheena Morrison.

So Dr. Goodman how long have you been in your current position?

JG: Well, I came - it's a little complicated - but I was previously Director of the Center for Biologics at the FDA from late 2003 to the beginning of 2009. Okay. And then came to the Commissioner's office in January of 2009, and

have been in a couple of different appointments here. But in this position as Acting Chief Scientist and Deputy Commissioner – now, the title is somewhat different because of the result of an organizational change in the office, so it's actually Deputy Commissioner for Science and Public Health - but have been in that position (it's been a busy time, so it's a little hard for me to keep track of it), but let's say for probably about six months.

SM: Six months?

JG: Yeah. And then before all of this, I was previously in academic medicine, and was head of infectious diseases at the University of Minnesota.

SM: Okay. Well, as you mentioned you were also the director for the Center for Biologics, Evaluation and Research. Is there any overlap in the responsibility of the two positions?

JG: Yeah. So, the Biologics Center - and having directed that I think was really an important experience, both from what it brought to this response to the pandemic (some of the experience there - is responsible for licensing and

oversight of vaccines for the United States. So, it is the center that does that. Also, we serve as a WHO collaborating center for influenza and for biologics. So there's this very long history of intense activity on vaccine activities.

And then, particularly during my period leading the center, I would say, really, my highest, or one of my highest overall priorities was, sort of, I think, strengthening the vaccine infrastructure - doing what we could to strengthen the vaccine infrastructure in this country to develop and modernize regulatory oversight in a number of ways. And also to very explicitly see ourselves as a global partner and part of a global community. So we did that as a center, across our product portfolio. But that was particularly important in vaccines.

And, you know, another thing that I think was very - that I viewed as a high priority and that also has really helped us in this response - was that when I started I really looked at how do we enhance our interactions with sister agencies, especially NIH and CDC, to take a really public health oriented approach. And so, although all the agencies have somewhat different missions and somewhat different

cultures, we had put real energy - and I had put energy as CBER director - both into our global relationships pandemic preparedness in general, and also how we relate across the government as a team in responding to a public health problem.

So, one aspect of that response, for example, was how we had worked with CDC and also the private sector - in a sense, the blood banks, et cetera - in responding to a major threat to blood safety when West Nile virus emerged as a disease that could be spread through the blood supply. So, by bringing people together, both from the government and then having appropriate forward leaning interactions with the private sector that needs to develop and produce products, we had experience with a proactive rather than a reactive model in how to deal with an acute public health threat. And having the staff within FDA comfortable with taking that approach and building those relationships at every level, whether it's the leadership level or the staff level, I think, put us in a much better position to deal with a challenge like this.

Another issue that I dealt with that certainly has received a lot of attention then, and has been of interest and

relevance, is that I have to deal with what happened in 2004 when what was then Chiron Vaccines had issues with contamination in its factory in England, and both the public health response to losing nearly half of the United States' seasonal flu vaccine that year as a result. So, the public health response to that issue.

But also, again, that was an opportunity to help ourselves and the country look at, really, the weaknesses in our vaccine manufacturing infrastructure, and begin, as we started, as we were thinking about pandemic preparedness, to think about how do we help rebuild that infrastructure. How do we add more diversity to it, a sounder infrastructure? How do we make sure we are reaching out and communicating well with sister regulatory agencies throughout the world to identify problems, et cetera. So starting then, we really embarked on an effort both at FDA and with HHS to get more U.S. licensed manufacturers to strengthen the FDA's oversight of manufacturing quality. And as part of pandemic preparedness to say, you know, what can we do to really accelerate adoption of new technologies for influenza vaccine? And so, all of those things were given further impetus by that, as well as the importance of really a high degree of interaction with the manufacturers,

the sponsors, et cetera to get them to help us meet the public health needs. So, this combination of what I think needed to be strict and careful oversight, but at the same time with the need to really help them achieve success in building and strengthening the vaccine infrastructure. And also, with CDC paying much more attention to influenza immunization and immunization in general as really important to public health in this country. So I think there is a lot of work in the last few years on those relationships, on getting more manufacturers, on getting more capacity. And, you know, what we've tried to explain is that there is great deal further to go; there's still not enough U.S. based capacity, but there's much more than there was. So there's been progress, but there's a good way to go.

SM: Can you recall where you were and what you were doing when it became clear that this novel H1N1 virus was highly transmittable?

JG: You know, I can't recall that. I recall the first emails about one or two cases of what seemed like a new flu virus. The initial, in a way, confusion about what might be going on in Mexico, the picture initially of what seemed to

be severe disease in the population in Mexico. So, that first few day period was a real blur. But as soon as - I can't remember the dates, but I think it was a Friday - we had heard about the initial cases and then within a couple of days realized (I have to go over emails) that there was an outbreak going on and that we were going to have to mount a very aggressive response. And within the same day, as it was clear to us that, or something like the same day, that there was a threat to U.S. public health, and clearly an epidemic going in Mexico, we recognized here that we needed to set up a very different emergency response structure to this. So, this concern - and I think some of this came out of the public health situation in Mexico, the stories of many hospitalizations and deaths, and the clear fact that the virus was here - there was a lot of uncertainty about how severe was this going to be. And so, we felt like we had to prepare, and start acting on potentially worst case scenarios to be ready for the worst.

So rather than saying, okay, we'll sit back, we'll wait until things come to us, we recognized the need from day one to begin to mobilize in case we needed to prepare vaccine, the need to mobilize antivirals, the need to support CDC and others in the overall public health

response. So, at the agency, we said we can't have little pieces of this going to multiple places in the agency, and we needed to bring together everybody across the agency from a logistics point of view, and also so that we were handling this as a emergency response in real time. So, we set up an incident management system with the right kind of support, with myself as the incident commander reporting directly to, at that time, Dr. Sharfstein, who was the Principle Deputy Commissioner. That was before Dr. Hamburg got on board. And we set up teams in each area where we knew it was likely we'd have to take actions. And this included teams for - and these teams were led by scientific experts often from the different product centers who were in leadership roles in the normal way that we would handle these things, but it brought them together into one team and into a command structure - so, a vaccine team, an antiviral team, a diagnostic team. I think we had a drugs shortage team, a communications team, a logistics team, and we had our Counter Terrorism and Emerging Threat Office provide logistics support for this whole enterprise, and help lead it in an effective way. And a legal group because we knew it was likely we'd have to deal with many legal issues, particularly with any emergency authorizations of products.

And we started initially meeting, getting the team together twice a day, and moving on some of the issues very quickly, including, again initially, CDC. And all of us together thought it was very important to get antivirals out to the states in case they were needed, because we couldn't tell the initial scope of this; to try to get a diagnostic out to the public health laboratories so you could identify where all the infections might be, and also identify patients who needed treatment at that time, potential isolation, et cetera. So all of that was mobilized very quickly. And CDC put together, very quickly, effective primers, PCR primers for diagnostic. And we worked with them to evaluate and feed their diagnostic to their entire laboratory response network, which was sort of the state public health and other major labs. So within days, there was a diagnostic out there to help track what was going on.

The antivirals were approved for use in a public health setting outside of the normal physician patient relationships. Drug, where the label had expired but we knew from scientific evaluation and or testing that it was still good anti-viral drug, we provided emergency use authorization to allow that to be used through the

stockpiles. The drug Oseltamivir or Tamiflu had not. There had not been enough data previously to approve its use either as clearly effective in either extremely ill patients or in infants under one. And our drug center, working with the CDC, NIH, and others, got the data together to provide emergency authorization for those uses, and got dosing guidances for the less than one year olds. So, this was a lot of work within the first few days that I think was pretty unprecedented.

And we were - for example, at every level I always meet personally with the people running CDC's emergency response: Steve Redd, Anne Schuchat, Rich Besser - we're on the phone day and night, sort of solving all the problems that come up with this. And there was also, I can't remember the structure, but there was certainly very frequent, for example, daily meetings of the different leadership of the different agencies across HHS.

I do think there was both extraordinary effort - in other words, the minute this started, basically everybody started working on it - and also extraordinary communications. And there were a million times where, if that hadn't been going on, things could not have been done as quickly. So that was

basically it. Then as things, as we began to have more of a sense what was going on, we were able to scale back these meetings to daily, to say, "What are the things we have to do in the coming weeks, et cetera, versus hours?" And I think particularly important, of course, was on the vaccine front, almost immediately, CDC was able to isolate a virus that went to all the different federal and other, and global laboratories, including ours at CBER, to make reference strains for potential vaccine use, et cetera.

The other thing I'm sure you've heard from others is that a lot of this was certainly enabled by pandemic planning and exercises we'd all participated in, but also by a lot of thinking many of us had done about what did we learn from previous experiences? Certainly, as an agency certainly responsible for vaccine safety, there was both in our agency and elsewhere, a lot of interest in what happened in 1976 with the swine flu vaccine. In the, I would say, four or five previous years, I personally devoted a fair amount of time to reading everything I could get my hands on about that. And, in fact, what were the lessons we had learned from that? I've given several talks about that, and always wanted to write an article, but had never had time. But what I was going to say is, the whole team from the

leadership of HHS, CDC, NIH, ourselves had thought and talked about some of these issues, and you know, some of the more important points were the transparency that was going to be important to have. The fact that we needed to not rush to judgment, but make decisions at the time that they needed to be made.

Certainly, with 1976, a big issue was the decision from early on not just to produce a vaccine, which was prudent and justified, but then to use it to execute an immunization campaign when there wasn't evidence that the virus was highly contagious or circulating in the population. Clearly, this emerged into a very different situation where the virus has spread widely and is very infectious, but even within that there was a deliberative approach to make each decision as we reach each decision point. For example, do we get a virus and try to create the reagents needed for manufacturing? Obviously, we decided from day one that there's enough of a threat that we needed to do that. But then at another point, do we ask manufacturers to begin to produce lots of vaccine? And again, I can't recall the dates offhand, but again we brought the whole group of senior scientists from the agencies together discuss that, made the decision to go

ahead and do that, but made clear that wasn't the same as saying that we're doing an immunization campaign, or we're doing full scale manufacturing, et cetera. So there was that consciousness.

I think another interesting issue about all this that I'm sure you've heard is that a lot of the planning assumptions had been around a very much more dramatic worse viral scenario like the avian flu, H5. So, in a sense, when this started to happen, that was the biggest fear. In a way the planning assumption, in a way the emotional assumption, is that well here this is and it's going to be absolutely terrible; there's going to be this high mortality. So, I think people had to both prepare for that possibility as we responded, but also begin to say, "Okay, how does the fact that this isn't this way affect what we do in terms of, for example, using unlicensed vaccine, adjuvants, in terms of the general public's health response? What are the recommendations about how you care for patients, isolation, et cetera?" So, I think that also is one of the difference. And in the public mind, and in the mind of the scientists, it's been a difficult calibration to sort of, not that different than seasonal flu, but to get people to take the

disease seriously, but not overstate it, or you know, base awareness solely on fear.

SM: Well as someone who sits in the meetings I see that delicate balance as you try and get the message out, but stay ahead of any sort of misconceptions.

JG: Yeah. Also, I think a huge factor here is the uncertainty. So, even right now, while we have a pretty good idea of how the virus is behaving now, there's concern still that could a future wave again occur, could the virus change, could this be worse? So, we just have to prepare for that. On the other hand, that's not where we are now. I think the other thing, certainly that FDA and CDC are very conscious of in all of this, is that this is all occurring in a background of at least a portion of the population that has had some uncertainty about the safety of vaccines in general, and a small and vocal minority that have been really just, you know, extremely concerned about vaccine, have raised various allegations about their safety going back 10 plus years, and probably really longer that that. So that we've all been very conscious that, number one, and this is our job, that because vaccines are given to large numbers of healthy people, including children, that we have

to do every thing we can to help them be safe. But also, that there's been this public strain out there that has questioned their safety, that's raised this specter that diseases like autism and their increase are related to vaccines, and how we have to be, to understand those concerns, be sure that we don't miss anything, and we address them from the scientific point of view. But also, the risk to public health if people don't understand the risks and benefits in a balanced way. And many people, I mean, everybody has to make their own decision about things like whether to get immunized, but if we can't effectively provide a balanced perception of risks and benefits there'll be a lot of people that could be hurt by, for example, not being immunized. So, there's been a real challenge to take the concern seriously, respond to them, and get that right.

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

JG: Well, I think, major issues included, again, understanding the severity and spread of the disease. You know, in some ways it was surprising to gradually find out, maybe it should not have been surprising, but understanding

what was happening on the ground in Mexico, for example, was very challenging to everyone. And I think Mexico was dealing with an acute public health crisis, was trying to put together its information, and our country was trying to understand what was going on. And because from the beginning this was a new epidemic, and it didn't behave as necessarily expected, and because you see the tip of the iceberg with more severe disease, it was hard. I mean, I think its been hard even in this country.

So, again it illustrates some of the, in a way, deficiencies of epidemiology and the public health infrastructure throughout the world. Even in a country like ours that has more resources, and certainly in countries with less resources, to some degrees the needs and the science, how can we much more quickly understand how many people are infected versus sick? And to understand the severity of disease, how can we much more quickly understand how the health care system and medical care can most effectively respond? So I think that was a challenge. It's been a challenge in many places. It's a challenge in this country, where you can see how as the science improves we have a clear idea of how many people are really getting infected, what is the rate of really serious complications,

et cetera. Now, on the positive side, I think it's also extraordinary how over the first couple of months we learned so much more, but I think there's still a lot of work to go there.

Other things that we had to deal with very quickly - I think this is more an issue for HHS and CDC - but certainly, how do we keep science, when we have issues of uncertainty, how do we make sure the best science drives the decisions? And so, for example, there can be a diversity of legitimate scientific opinions. CDC particularly dealt with this issue of, you know, border closings, school closings, all these various measures that may have their proponent. How do you make your best assessment, and your best decisions? I think one of the strengths of the response has been that - again there were always challenges in coordination and there were always people who go off and do or say something - but in general, both at the working level of the scientists and again at the scientific leadership of the agencies, there has been a lot of communication. And it's been so that the scientists and public health people have been able, at least in the setting of uncertainty, to come up with our best opinions and have those drive the policy. So, I think the fact that

the scientific community at multiple levels was the group taking these issues up and then bringing them up into the policy and political arenas has been important. And again, that was something I think we were all conscious of that was important to preserve based on 1976, and also, based on responses over the last several years to other public health issues across the board. So I think that would be another one.

SM: And in terms of safety and regulatory issues, like I know, for instance, that at one point the United States was considering the use of adjuvant.

JG: So I think there too, it's a very complex nuanced area, but we try to take a balanced view based on the science available, and also get the science we needed. So it was very clear to us that if this was an H5 type of situation, like with the avian flu, where a non-adjuvanted vaccine would take extraordinary doses to yield an immune response that wasn't even very good then, that we were going to need to go in the direction of adjuvants. So adjuvants had been stockpiled in the past, and also HHS had funded studies of adjuvants particularly in the H5 context and with the H5 vaccines. This is an area where the

European branches of pharmaceutical companies...the specific vaccine preparations could be available in Europe where there was much more clinical experience and safety information about those vaccines. The potential vaccines that could be available here were not identical from the start from what had mostly been developed by European branches of pharmaceutical companies. So, two of the major suppliers here, Sanofi and CSL, had done either not much or no work around using these novel oil and water adjuvants with their vaccines. So there just wasn't much data. The other major companies, Novartis and GSK had been very engaged in developing adjuvant, but using vaccine materials produced in facilities and using methods that were really licensed and intended for their European market.

So we thought there's a high likelihood based on the H5 experience, that if there was a bad immune response to a flu vaccine that these adjuvants might very well be helpful and important. But even for Europe, there was not the long decades use experience in hundreds of millions of people other than one vaccine, which had been licensed in the elderly by Novartis. So there's always much more uncertainty and lack of experience to balance against the potential benefits. Then in this country, there was either

very little or no experience with some of the possible vaccines that could be adjuvanted where we'd be using material from other manufacturing facilities where there was much less experience using it with adjuvants. So, there were more scientific uncertainty and unanswered questions.

But what we did from day one is, we said, "We don't know what are going to be the needs, don't know whether the vaccine will induce a good immune response without adjuvant." We thought it was more likely it would than H5, because H1s are things we have a lot of experience with. They circulate in the population, they're in the seasonal vaccine, and there's usually a reasonable immune response to H1 strands that aren't adjuvanted. But this virus could have been very different. So we said from day one, "Let's prepare as if we may need to use the adjuvants", that even if we don't have enough data to meet the normal standards of licensure, with safety and effectiveness data typically in tens of thousands for a vaccine like this, especially with new technology, lets be prepared to make an appropriate benefit judgement if we need to use it. And these emergency use authorization powers under a public health emergency from Project Bio-shield, put that option on the table. So we said, "Even if we have to go that

route, let's get as much data as we can." And so we encouraged both NIH, working together with NIH and the manufacturers to study their vaccines with and without adjuvant added to see what would be the benefits, to get more experience where they hadn't been used with specific products before, or where the experience was limited. Those data are still starting to come in.

Now, the good news there is that the non-adjuvanted vaccine in normal, or perhaps even lower doses than normal, is inducing a very good immune response. The big challenge though, and that has still raised questions globally and in the U.S. is, could adjuvant, given the supply challenges and the production challenges, could adjuvant allow for more vaccine to be available that could be effective?

SM: And that's something that's still being tossed about.

JG: Right. So as we get more...again that decision had been continuously revisited, and the feeling, again, among the senior scientists across HHS has been, we're seeing the severity of the epidemic, which obviously, it's a concern, it's causing mortality and morbidity, but it's not an H5 level kind of severity. Based on that, and the really good

immune response to the non-adjuvanted vaccines, that right now people are comfortable pursuing continued production and use of the non-adjuvanted vaccines doesn't mean that it was unreasonable for Europe with somewhat different vaccines to make somewhat different decisions.

But, you know, still, the government went ahead and put a certain amount of adjuvant into vials. And I think we're still looking forward and saying, "Well, what would happen if there were other challenges, if the virus changed, if there were other supply challenges?" We don't wanna, again, not have that option. We have seen a lot of suspicion from the public about adjuvants, and this has been seen in Europe too, and it's not necessarily scientifically founded, but again, it goes back to people's concern about vaccine safety. So, we've tried to let the science drive our decisions, but it's important to realize in making those decisions too that the less experience and information there is about something, the less comfortable people may be with it.

SM: Well, in general, the public seems to be uncomfortable with this particular vaccine, and do you have any opinions as to why? Can you speculate?

JG: I think you would need a lot of really detailed polling and focused groups to understand this more clearly. But having looked at both the advocacy groups that are just very concerned about vaccines in general, then looking at what's sort of the discussions and then comments by people around the current issue are, I think that there are number of things that are...it's a very interesting phenomena. What you see is it looks like maybe half the population really, really wants this vaccine and they're standing in line for it. Even though there's forty plus million doses that have been available now, there's a lot more people that want it than that. So there's a group of people that sort of seems to understand that this vaccine, as we've repeatedly tried to message, is made identically to the seasonal vaccine, that we're expected to have an excellent safety record - although there's always some uncertainty, so its being very carefully monitored, et cetera. So there's a group of people who seem to have realized, number one, that even though the disease isn't a plague like H5 could have been, that it's significant, that it's a threat to certain patient populations: in particular children, pregnant women, young adults, people with underlying

medical illnesses. And so many of those people are seeking vaccine.

On the other hand, there seems to be a population that a number of perceptions contribute in varying degrees to them not seeking vaccine, or being suspicious. One that I think is interesting is the idea that this is a new disease and a new vaccine and it wasn't tested. So that despite saying that every year we make new flu vaccines the same way, people have that concern. I think that that's compounded by what happened 40 or 35 years ago with swine flu where there was another virus with the name swine flu attached to it – a very different vaccine industry, but absolutely true, another national campaign to face a new virus, and that there was an unexpected increase in this unusual neurologic complication, Guillain-Barré syndrome, probably in about 1 in 100,000 recipients. That was a real problem given that there was no epidemic at the time people were immunized. So that concern that, could this vaccine be like that one, is there. And it's not.

And then, also, in some of these people's minds, they don't see this as a severe epidemic, because we and others have not overplayed it and if you haven't seen your loved one or

neighbor or some really heartbreaking story about some of the tragedies that have occurred in the media with people who've gotten this infection and lost their pregnancy or their loved one, or whatever. So, for the people for whom that's not that personal, they look at this as not that severe. ...Uncertainty about the vaccine safety and something new and novel about the virus, so maybe that means that there's something new and novel about the vaccine.

And then I think underlying a lot of this too is that there is some distrust clearly of the pharmaceutical industry. Will the government tell the truth? So, I think when all these things play together, there are more people than one might suspect who are suspicious or worried about the vaccine or not convinced it's for them. Now at the end of the day people have to make their own decisions.

I think the other issue here is the internet, the adversarial nature of journalism, politics, et cetera, where these issues become either sensationalized just for the sake of sensationalizing something, or become pawns in larger battles. So, of course, historically people will look and see that there were people saying we don't want to

trust the government about health care reform, so therefore we're looking at this through that lens. I mean, I'm actually impressed that for all the noise, there are substantial numbers of people who seem to have gotten a balanced view of this and say, "No, I realize the sky isn't falling right now. On the other hand, I have confidence that it might be reasonable to immunize my loved ones or my children." So I think there are a lot of people who are appalled that there is as much concern about it as there is. And, I think, just like the vaccine manufacturing infrastructure in this country, the trust and confidence of people, and being able to explain scientific and medical advise to the population in ways where they can make good decisions, you know that's gonna be a huge lesson and challenge.

I think, also, a whole other dimension of this is, different cultures view these things differently, are concerned about how they're being treated by the government, may or may not more or less have distrust about the pharmaceutical industry. And so, again, I think we're in the position of having to provide a balanced and truthful view. So, I saw an article today that said something about the safety of the vaccine, and then it

ended with, "Dr. Jesse Goodman of the FDA said" "you can never rule out", or something like this: "a rare and unexpected serious adverse event could occur with any medical product." Well, it would be irresponsible not to tell people that, but it results in us trying to give balanced messages, while practicing responsible advocacy for what we think is right. Which is that, especially if you're in a risk group, the benefits of the vaccine are way, way likely to outweigh any unknown risks. So, how do we give people good advice but also stay fully transparent? I think that's a big challenge.

SM: And as someone who sits in the meetings as a historian, and then as a private citizen, I see that everyone in the room spends a good deal of time, I'd say an equal amount of time, dealing with transparency and messaging as the actual practical implementation of the program. You can see there's this tension all the time.

JG: I think that's right. We didn't really touch on the whole thing, but I'm sure others will. But again, a major issue here has been the issue of even though half the people or so don't seem to want the vaccine, those that do want it expected it more to be available sooner and are

frustrated by that. So, some of this says something about a national moment in time and a national environment, and certainly, cultural and scientific challenges, and all these things coming together at once. You know, I do believe, it's been an extraordinary public health response that in the face of a lot of uncertainty – we'll see – but I think people have made reasonable decisions.

I think we need to know much more; we need to improve our vaccine infrastructure; we need to improve our public health infrastructure; we need to improve our ability to communicate with people – scientists aren't very good at that. We need, you know, to have much more, we need to revolutionize the technology behind vaccines, and if adjuvants can provide a tremendous benefit, then have confidence in that. We need U.S. based manufacturing capacity. We need to effectively connect public health to the health care system, who is faced with the brunt of delivering all that. So the needs are huge. But the collaboration and the fact that working with manufacturers, there is a vaccine; if we could have that be four months earlier the public health benefits would be tremendous. So that's what we should aim for.

On the other hand, a success at this level, and getting antivirals out and getting people treatment, all these things are to some degree accomplishments of people working together across and outside of government. Of course, we should always look at how we could do better, but on the other hand, there's also some level at which people don't seem to recognize sometimes that we don't control a virus. We don't control how it grows in eggs; we don't control how it spreads among people. What we do is try to marshal people together to say what can we do with what we have to help people?

But I do keep coming back to, that this is a teachable moment. We'd be a lot worse off if we hadn't had the preparedness, and if we hadn't done work on the vaccine infrastructure. On the other hand, clearly, we ought to get it to where we have the science and the capacity to respond much more quickly, and where we have a communications environment where people really do even better understand benefits risk in an environment of trust. It's not just a U.S. problem. We're seeing the same thing all over the world. And again, what a great opportunity to say how do we build that global science and collaboration? This country

needs to take a look at these things and say okay what have we accomplished well? Where do we need more work?

End of Interview

Broad Themes

- Biologics Center – responsibilities of
- Vaccine Manufacturing infrastructure – strengthening of
- Public health Oriented approach to response
- Chiron vaccines – factory contamination
- Incident management system
- CDC Laboratory Response Network
- Diagnostic primers
- Communications
- Pandemic planning exercises
    - Planning assumptions
    - 1976 Swine flu vaccine
    - H5
    - Decision making
- Uncertainty
    - Future wave
    - Public skepticism
    - Decisions based on science
    - Mexico
- Use of adjuvanted vaccine
- Public skepticism – of pharmaceutical industry
- Internet – adversarial journalism

- Responsible advocacy for vaccine use
- Challenges of preparedness

Follow Up

Names: None

Documents: None