INTERVIEW WITH

Dr. BRUCE GELLIN

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

December 15th, 2009

November 2010, National Library of Medicine Archives

Interview with Dr. Bruce Gellin
Interviewed at Dr. Gellin's Office,
Washington D.C., U.S.A.
Interviewed on December 15th, 2009
H1N1 Oral History Project
Interviewed by Sheena Morrison

Dr. Bruce Gellin: BG
Sheena Morrison: SM

SM: The following interview was conducted with Dr. Bruce Gellin, Director of the National Vaccine Program Office within the Department of Health and Human Services on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on December 15th, at Dr. Gellin's office in Washington, DC, and the interviewer is Sheena Morrison.

I started off informally asking you whether or not things have sort of petered off, slowed down a bit.

BG: I think that, again, I see this more of an inflection point that we've seen. We've been watching this since April. We saw things take off late in the spring, which was unusual, and that made everyone worried. And while people thought it went away, it didn't really go away during the summer, but just sort of tamped down a little bit, probably

mostly because of differences in social mixing, as people got scattered for the summer. And then the combination of fall activity, school and the like, and different patterns, and now with the weather, it's changed again.

I think what's striking, particularly if you look at this now, today, just in the past week, CDC had revised their estimates in what the impact of this disease had been. And you're looking at this from a historical perspective, so somebody is going to look back at this, and it will just be one other point on the curve. But essentially, at the same time that CDC was making these other projections about the impact that this disease had, and the increase there - and it was a combination of changes in the model - it accounted for another round of disease associated with morbidity and mortality. But essentially, the death count went up from 4 thousand to 10 thousand. The estimate is that now 15% or 1 in 6 Americans have been infected; part of that reflects what went on in October and November. But it was just striking that at the same time that that came out, that shows what the infectivity was, and the impact of this virus, there was a modeling paper that came out that said this is the mildest pandemic in history. So, I think that for the public, it's hard to put all these things together,

because both of these may be true, but people don't have a way to sort of assemble all this information.

So, I think that where we are now...and again, another piece of this is that it's now December. We know that the 'typical' flu season often, primarily, peaks in February, but that doesn't tell us anything about what we're going to be seeing from now until February, or beyond February. It's a great unknown, and I think it makes everyone quite uneasy. While some people think that, well, this is now behind us and we've bit the bullet and we're past it, I think that people just don't know just what to make of it, and want to stay prepared, don't want to incite too much angst in people, because they're seeing that we're just sort of revving things up. I think that people may then interpret that as, you know, we bought all these vaccines so we therefore have to use it, but we just don't know.

But we do know that if you just look at a couple of figures: if you look at the number of people who've been vaccinated, and the number of people who've been infected, those two together tell you the number of people who are theoretically immune protected, either from the disease, or from the vaccine. So, if your number is 1 in 6, 15% of the

population - let's just say 50 million people - have been infected, and another 50 million people have been vaccinated. They're round numbers; we don't have the precise number. That tells us there's still 2/3rds of the population still susceptible - subtracting off the elder part of the population. So if this virus still hangs around, and it still is infective. We know that it still is infectious. It just tells you that there's still people out there who could get sick, and who could suffer those consequences. So I think that's what's driving the public health approach, and the public health messaging, right now. It will be easier to look at all this in retrospect, but prospectively, it's more difficult.

So, while things are winding down – it's almost the holidays - people think that this is now maybe history; we've gotten over it. But nobody knows, we'll just have to continue to watch. And we do have two things: we know that the flu season normally goes throughout the early winter and into the spring, so we'll have to see what happens with that, with this virus, or other flu viruses. And we know that this is an unusual virus, and we just don't know how it will continue to play out.

SM: What about the uptick in New York?

BG: I don't know enough about that to speak knowledgably. I think the problem is that - it's like anything else - you get a national picture and you get some variability within that, so I don't really know. Again, I don't know enough about that now to speak about what that may or may not mean. But we do know that there have been (it's a similar situation around the world, where recently with other countries from the G7 plus Mexico, we were meeting in London), there are different experiences. So, in the same way, even within the United States, what goes on in some states is different than others. The same situation is going on elsewhere. Where some countries are suffering worse than others, some don't seem to have gotten much disease, and others have had a lot. So again, trying to get a snapshot of what's going on right now is kinda difficult, because there are different pictures in different countries.

SM: Well right now, can we talk about the international donations of vaccine and what your role is?

BG: Sure. And I think that this is a really important issue, and maybe the other theme we should talk about (if we can't do it today, some other time) is the whole vaccine safety: the concerns about vaccines, and vaccine safety in general; what they are specifically around this incident, what we're doing about that, what that may mean for the future. So, it's probably a separate one we should probably develop to capture it. 'Cause when somebody listens to this years from now, they'd be interested to know how that looks at the time, because we're struggling with some of those issues now - a combination of perception and unease.

But, on the international piece: this is one where, I think, for a long time, it's been quite clear - based just on the production capacity of influenza vaccine manufacturers globally - that there wasn't enough to go around, particularly at the same time. I forget the precise statistics, but the majority of the influenza vaccine manufacturing capacity in the world is either in Europe or North America (and probably we should clarify this). But probably, one way of thinking about it is: 90% of the capacity is in the countries where 10% of the world's populations live. So, that tells you right away that there's gonna be a disparity of vaccine around the world at

a time when you have a pandemic, which means that the entire world is, or a large part of the world is, susceptible. This is something that has been on the radar screens of the world Health Organization, and others in global health, for a long time.

Several years ago, the World Health Organization put us on something called 'the global action plan for pandemic preparedness'. It acknowledged where (I think that was 2005, 2007, I forget exactly when), but it sort of gave a snapshot of where we were at the time, and what was needed to improve that capacity. There were some short term things that were identified, and again, this was in the era of the H5N1, but it applies as well now: of beginning to have some stockpile vaccine (that has its own issues, but at least that there'd be something to have a running start); to begin to increase the use of seasonal vaccine that would then increase the overall base of influenza vaccine production capacity, on top of which there would be then ability to surge; and then there was a whole range of things that we were really promoting - new technologies. So, I think it was a short, medium and long term goal.

With that, I think what's interesting...we had a session last week at the National Institutes of Health. It was a chance to just focus on influenza vaccine development, research and development, technology, and production capacity. And that's something that hopefully will be available in the archives for a long time, but it was a series of talks that several people gave. I was there, Dr. Collins from the National Institutes of Health, Dr. Fauci, Dr. Hellman, Dr. Goodman and a few others, and Dr. Robinson - looking at where we are right now, and what's in the future. The themes were to look at the difference: there are production technologies, and then new vaccine approaches as well, and they are often confused. We're trying to think of how we can collectively increase overall capacity. So, while that's an overall goal - to have new technologies that are more nimble, that are scalable so you can make a lot of vaccine in a short period of time - in the short period, that's not the case, which gets back to the international issue and the recognition that there's not enough to go around.

Maybe there's no more stark example of the haves and the have not's than the influenza vaccine, because we know that in any one country, there's not going to be enough vaccine

at the beginning of a pandemic to satisfy that country's needs. That's really required countries to take a hard look at their values, and to try to have a sense, internally, of how they would prioritize vaccine as it becomes available. Does it go to the most vulnerable in society? Does it go to the most important in society? Does it go to the most wealthy, or whomever? So, we had a long exercise internally in the United States, particularly in a severe pandemic, of how we would allocate vaccine that was a scarce resource, knowing that not everybody could be first in line.

On a larger scale, when you look at that globally, while every country has to do that with their own resources of whatever vaccine they may or may not be getting, that also speaks to the international scene whereas just a few countries would have the ability either to afford to have vaccine and to have access to it. And then at the same time, recognizing that a large number of countries would not be able to, and yet, the people in those countries would be suffering the consequences of a pandemic. And in some of these countries where they have, you know, marginal health care systems and a whole bunch of co-morbid conditions, you could imagine that the outcomes of the pandemic would be far worse in some of these countries. A

look back of 1918 certainly showed that. And it's not a surprising story that where there are these kind of health disparities, they're going to be magnified in a pandemic.

So while this is a discussion that was held in international forum, and the World Health Organization had calls for doing something about it, it was always very awkward 'cause no one was quite sure how to start, and there were many discussions about it. And I think for the most part, in international situations, people would say, "Well, we're concerned about it; we're working with WHO about it; we're thinking about it." But no one was quite sure how to move forward, because if you're the leader of a country, you're going to recognize that by acknowledging that there is this disparity, and doing something about it you're taking vaccine away from your population to give it to somebody else, *that* is, obviously, a pretty difficult decision to make.

In the United States (and I'm sure it had similar optics in other countries,) that was a discussion we had over the summer that grew from our discussions about prioritization, domestically. Who would be first in line, to a question of, what are we gonna do for international...what are our

international obligations, recognizing we didn't have enough of our own? So there were a series of discussions over the summer (and I think that's worth getting the backup documents that went with those), that really were, as I saw it, the debate between those with domestic interests and those with foreign policy interests. And you could see those were convergent, because you could make the case on either side of this, and ultimately, there were risks in going in either direction.

I think one of the principles behind it, though, was working with the World Health Organization in the recognition of a multi-lateral approach. Because the products are going to be so limited (the idea of picking favorites, if you will), if we have countries for whom we have some special relationships, would we want to put our vaccine, our pandemic influenza vaccine into that mix or not? The way I see it, the opportunity was to create many more enemies than friends because you had such limited supply that while you could provide some to country x, you wouldn't be able to provide it to countries y, z, and many others. And I think that's why working with the World Health Organization to develop some kind of a scheme for

which countries with vaccine access could be providing to those without.

So, that was going on in parallel with our domestic discussion, and essentially, it came down to a decision by the President, as I understand it. I wasn't there at the time, but I think that's the way that this was clearly going, because it was weighing the domestic interests and the foreign policy interests. This went on over the summer 2009 while we were preparing for our fall wave. We had projections for how much vaccine we might have. Again, those didn't turn out to be fully accurate, but I think the principles were there about: what was the United States' obligation to the international community? The timing of this came down to the UN General Assembly meeting in September in New York, and the discussions were to be able to have a conversation about it there, and an announcement just prior to that. So, really, an effort that was led from the White House, to have a decision by the President (and that decision is another document that you should have), was a press release from the White House that talked about the United States and a series of partners (of donor partners,) were committing to this effort, recognizing that

the pandemics were not limited to any country, but were global problems.

I also think that this is where, and again, some of the discussions were, I think, the approach that the Obama administration wanted to take as far as global health and multilateralism. So I think those two things together are: the need to ensure that the developing world were ready to get vaccine in a way that wasn't trivial, in a way that wasn't seen as an afterthought. So, I think the driving principles were to work with the World Health Organization so that as developing countries were able to receive vaccine, vaccine would be there for them, but not to wait until the entire country's needs were satisfied, and then to provide vaccine later. The analogy that I use is that, you know, if your goal is to try and improve health globally and make a statement, you don't wanna...the equivalent would to come with your fire truck after the house has already burned down and say, "Okay, you know, we have some extra water, would you like it?"

So, the decision was about 10% of the U.S. vaccine supply in an ongoing basis - again, working with the World Health

Organization - when countries were ready to donate it. Prior to the announcement, there was an outreach that was done by the White House to enlist a number of countries as fellow donors, so that there were many like-minded countries. And I think the idea was in order to make a broader statement about the United States working in partnership with other countries (but also it made a stronger statement), particularly if, and when, there was a need to negotiate with other companies, it wouldn't be just a country and its wishes with a company, but many of the countries having the same values. 'Cause again, these are countries that have mature health systems. And I think it was an important way to have an interaction and a discussion with the pharmaceutical industry around vaccines.

So that was how it started, and that was the public face of it, with this press release, a series of brief meetings. Essentially, within the United States, it's divided between the Department of State who leads the diplomatic effort and was working on expanding the donor pool, and Health and Human Services who've been working on the technical aspects of all this. I think that one of the issues has to do with this larger effort, which is clearly global public health,

but it's also a foreign policy statement as well. So, I think that the partnership with the State Department really speaks to that.

It's now December 15th, and we've had many conversations with the World Health Organization, with U.S.A.I.D., with other donors. I think the summary is that this is incredibly complicated, and no one knew how complex it was going to be, both in terms of the logistics of doing this, as well as some of the legal requirements.

So I think that among the issues that came forward were just the legal basis on which you'd operate. So, the World Health Organization developed a series of template draft documents which were agreements between donor countries and the World Health Organization. And it turned out that the first round of those documents were not really in line with what people had envisioned. If you're going to be donating things you didn't imagine that you had a lot of other criteria that you'd have to meet. And I think that it took a while for us to be able to work with the World Health Organization to come up with documents that met our needs, as well as the World Health Organization's needs. So that

was a learning process for all of us, and I think that that's been simplified.

One thing that I don't have a clear window on is how all the different donors are interacting with WHO as well. It's been clear in our interaction with WHO, they prefer to talk to us - the United States - about these documents, and not to talk to a large group about them. I suspect it's because they prefer to have as little complication as possible, and would prefer to have a single document be the one document that all countries have signed off on. We have talked to some of the other donor countries around the edges and found they've had similar issues. In fact, we're still trying to get clarity on which countries, if any, have actually signed these original documents, or if they're negotiating something different.

So I think this whole...I think it's been very insightful about working with the World Health Organization on this. Hopefully, by the time people go back and look at this transcript, things will have changed, because I think that we've learned a lot about how to do these things, and we clearly have a lot more to learn about how to be most efficient in doing, in achieving these goals.

So, there's these series of interactions: between countries and WHO, between companies and WHO, between donor countries, between companies and WHO, and between recipient countries. Essentially, the biggest issue that I see is the question of liability, in the same way that in the United States, manufacturers who refuse to provide vaccine unless they were covered - except for negligence which they acknowledge they should be liable for - they had liability protection for creating a 'new vaccine'. And the PREP Act gives them that in the United States. But it doesn't apply to the vaccine that's donated around the world. It's only a United States issue. But from the company's standpoint, they have a huge risk in having their vaccine in some of these places if they have deep liability, so they've required liability protection. WHO can't assume that for them, and WHO has essentially been the broker between the recipient country and the company. That's been part of the complexity as well, because the recipient country needs to sign off on that liability protection for themselves, or they're not gonna get vaccine. So, I think that this is another one of these principles that has not been...You know, it's a complicated one to execute, and those are still being worked out.

So, of the many countries who are on the list that WHO has identified as in need, only a few have finished their paper work that would allow them to qualify to receive vaccine. So, that was one of the complexities that we've had to work with, again, just in getting the legal arrangements sorted out. I think that as you go through this, you probably want to have the annex of the documents and the various stages - the initial ones, and then the ones that are finally signed at each of those stages (the ones that are you are able to get). You may not be able to get them between companies and WHO, or recipient countries, but you can certainly get the ones that we have with WHO on the donor agreements. And again, this has been something that's been far more complicated. In fact, we're regularly talking to other donors to try to see what they're learning about these things and comparing notes. So there's the whole legal basis on which this happens.

There's the financial issues. Again, the purchases of the pandemic vaccine came as part of the supplemental funding. And while some of these purchases are allowed within that funding, we have the budget office here, OMB, taking a look at this to make sure that what we're doing is appropriate

for the language, and not overly costly. So, it had to continually have those discussions as well, of - who's paying for this, and how much, and why, and is this the right thing to do or not - at a time when we have overall budget issues, and don't need to be spending any money that we don't need to spend.

And then on top...then there are the logistics and regulatory issues. These are products that are not currently used in some of these countries; they don't have familiarity with them. They may or may not have a reasonable regulatory authority like their own FDA, so they don't quite know how to deal with some of these products, and I think WHO is right to make sure that they're protecting some of these recipient countries from products that may not be perfect, or that may not be adequately qualified. So if there's some product that's made by a manufacturer in some country where you're not quite sure that it's the best process they have, WHO is in a position to truly protecting the recipient countries to make sure that the vaccines that are ultimately shipped to them are of reasonable quality.

So there's a whole process called 'WHO prequalification' where they have to look at the data about how the vaccine was prepared, and does that meet the needs for which a recipient country can essentially use WHO's review as their own quality assurance for their own regulatory piece. So, there's a number of vaccines that have to go through that evaluation as well. It's got varying amounts of complexity to it, but its another hoop to have to handle.

Some of these countries have other regulatory requirements for the vaccine: they need to be registered in the country, some countries may require clinical studies. So, the idea that you're gonna give something away, it's not like you're gonna sort of drop in spam and say, "Okay, we know people are hungry, and we have some food for you." And I think it just speaks to the complexities of the regulatory apparatus. It's essentially designed to ensure that the products that go are what they're supposed to be, and not something else. So that's another piece of it.

And then finally, the logistics. From our perspective, since there is still more demand for vaccine than there is supply domestically, and recognizing that - we don't wanna, because of that demand - giving things to another country

will only increase the demand to supply, we don't want to have vaccine sitting around somewhere. So if it's gonna be diverted, if it's gonna be taken from the domestic distribution and put to the WHO distribution, that's fine (and I think that we've all agreed that that's what we should be doing), but we don't want that vaccine to get stuck somewhere. The analogy has been, you know, food in a family. You don't want to have that sitting on a loading dock somewhere while it's rotting, or someone is sorting out the paperwork. I think the analogy is relevant here, even more so, because vaccine that's not distributed in the United States isn't gonna vaccinate people in the United States. If it gets stuck somewhere else and it is not in an immunization program, it's not vaccinating people in that country either. And if it ends up sitting somewhere at the wrong place at the wrong temperature, it could be ruined for anybody.

So I think those are part of the logistics that we're working out, and to try and streamline, as vaccine is coming off the manufacturing line, and trying to figure out what's the last possible time when you can make a decision whether it goes into the United States, or goes to the World Health Organization in a way that there's enough lead

time to be able to execute that. And when you think about sending these vaccines to places where you wanna make sure that they have the systems in place to receive it, they have the storage requirements, they have the people who can sign off on it, both the regulatory, the legal, and the logistical: it is immense.

So we've got a number of people working on that with us. The companies have some familiarity with parts of this, but not all. The USAID, the Agency for International Development has a lot of experience, and they're working with us as well. There's a series of hand offs of responsibility: from the manufacturer, to HHS, to USAID, to WHO, to developing country. And that's before it even starts the program. So we'll see what happens. It's now, again, December 15th,and no vaccine has yet been received by developing country from this donation pool, but it should start happening soon.

SM: Who knew?

BG: It's incredible. I mean, everyone wanted to do the right thing, but having it happen is really far more complex than anybody would have imagined.

SM: And one of the shortfalls in vaccine here is actually related to a country's taking care of its domestic responsibility first?

BG: Right.

SM: Like in Australia, if I understood it correctly-

BG: That's right.

SM: ...in the meetings.

BG: Well, that was another...Again, another piece to that was the recognition that decisions are made that trump other decisions. We had contracts with 5 different manufacturers. The manufacturer in Australia, CSL, that was a vaccine that we're expecting to be receiving early on in our scheme, and weren't fully aware, at least I wasn't aware, that the Australians had a contract in place that would have allowed them first rights on their vaccine from that same manufacturer, before it left the country. So as a result of that, that contributed to some of the early delay in receiving vaccine. There were other things that affected

the overall vaccine supply and the timing of the supply, but that was one of them.

As we've had these conversations subsequently, and thinking about vaccines that we would donate, we started by looking at the list of vaccines that we'd otherwise be receiving. We have vaccine from 5 companies. So, early on, we were looking at some of the vaccine from CSL and Australia until we then learned there were conversations with the manufacturer. But then, those turned into conversations with the country, because Australia essentially had to approve the release of vaccines from Australia to leave Australia - whether they were gonna come to the United States or go to the World Health Organization. And you can imagine the same sets of issues were in play there. And essentially, we've been discussing this with Australia for some time. We've made a decision to move on for the first round of vaccines, just 'cause that was too complicated. And we didn't want to continue to dependent on Australia's decision to make our decision, at the time that the World Health Organization needed to make their plans.

So as a result of that, we've now decided - at least for the first round of vaccines - to use vaccine from Sanofi-

Pasteur as the first round of what we're gonna donate. So our overall pledge is for 10% of the vaccine that we're going to receive. At the time, when we talked about that, we had planned that we could receive in the United States as much as 250 million doses of vaccine. So, 10% was 25 million doses. And while it's likely that we're not going to take all those 250 million doses, given our conversations with WHO, given the interest of the global community, given, I think, some of the State Department foreign policy issues, that 10% is now sort of locked down. Essentially, 25 million doses is what the U.S. donation will be to the WHO effort. So we've got the first five million teed up. We're anxious to identify the next twenty million, and to have those into the system sooner rather than later. So, it's available as soon as countries are ready to use them.

SM: And how did the 10% come to be?

BG: I don't...You know, that's a good question. I think that people looked at a number of different things: they looked at what our supply was; they had a sense of what the demand might be; I think they wanted a sense of what kind of a statement you would make at one number versus another

number, and 10% seemed one that was a reasonable number to make. I can't tell you if there's any magic calculations of things, But I think it was meant to be significant that that was a large commitment that would turn, from the United States perspective, into a large number of doses. But part of the idea was that other donors need to be involved and do a similar thing, because WHO had identified a much larger need than just the United States. So there are a number of donor countries that are donating either money or vaccine. There are companies that are donating vaccine. WHO is still trying to increase the number of vaccines that would be donated over time. But again, the program has been quite complicated, in, it's now just coming to the point where vaccine will soon start to move. And I would expect that we start seeing it by the end of the year.

SM: How much time have we got?

BG: If we can, maybe another 5 or 10 minutes.

SM: Okay.

BG: And then, separately, we'll have to do a whole thing on safety, because I think that will be important.

SM: Let's see.

BG: Actually, on the international thing, I will say that like everything else, it's been quite dynamic. And so, while there are all these discussions about supply and demand, we've also seen from other countries where, depending on what their projections were, what they anticipated, some now have more vaccine than they think they're gonna be able to use. And so, now we have a combination of countries who are either donating to World Health Organization, or selling that vaccine to other countries, who otherwise wouldn't have access to it.

With the WHO approach, WHO is primarily looking at the countries with the least access to vaccine, and no one faults them for that. But it turns out that in looking at the overall sphere, as I mentioned, most of the vaccine production capacity is in a few parts of the world. That still means that the middle income countries don't have - while they may be wealthy enough to be able to purchase vaccine they didn't get - they didn't have contracts in

place, and they don't qualify to be on the WHO list. So there are a number of middle income countries who have been trying to get hold of vaccine now, and I think that some of these other countries that have 'surplus vaccine' may find a place for it in some of these middle income countries. So if you look at the wealthy, the middle income, and the poor countries, WHO clearly is looking out for the poor; the wealthy countries are looking out for themselves; and now, I think there are opportunities for the middle income countries to get something. But clearly, this is all gonna need to be taken a hard look at this in the future, because you can invent this every time, and the needs are going to be the same every time.

SM: It's not too much different than the economy with the poor, middle class and upper class.

BG: No, I think that's right. It's funny, I think, that's the analogy. The middle income countries are sort of like the underinsured. You know, they're not poor enough to qualify for other programs, but they don't have enough to be able to get what they need.

SM: So, and your office, your role in all of this, can you give me some (phone rings), some-

BG: So, my role in this is somewhere between ad hoc and opportunistic: Because I've been doing a lot with the World Health Organization; in part, the Global Health Security Initiative, which is the initiative of the G7 countries plus Mexico, the EU, and the World Health Organization; I've been co-chairing an international...the Pandemic Influenza Working Group with the U.K. since 2002. I've gotten quite familiar with these issues on the global stage, and have been a consultant to the World Health Organization, and worked with their strategic advisory committee that works on vaccine issues.

So, because I knew both technical issues and some of the global public health issues, I was essentially asked to be the point person at HHS for the vaccine donation. Clearly, many other things need to happen, but this falls within the sphere of the ASPR and OGHA. And so, I think that they together felt that there needed to be somebody who was paying attention to this full time. So, they've constructed a small team that comprises people from each of those organizations within HHS, and have asked me to essentially

be reportable to them, to John Monahan and to Nicky Lurie on these issues. And needless to say, this is something that is of quite importance to the White House, so we have regular discussions with them as well. So that's how I got to do this. And it's been quite a lesson in all the things we've talked about from the legal, the regulatory, the logistic and some of the other sort of interesting negotiations.

So again, I think that we're learning a lot about how to formulate the needs here. I'm hopeful that this will be on a model of how to move forward. And again, we'll see what happens.

But one of the issues for the National Security Council is on the Global Health Initiative, and global health security. I think one of the things that's been identified is: in the future, how is the global response to pandemic improved? And so, I think this is among the things that will be a piece of those lessons learned that we can build from.

SM: And this is like your 4th job.

BG: I don't know. You know I have lots of jobs or no jobs, depending on who you talk to. And my mother says, "Well, how come you're not in the newspaper?" Or, if you're in the newspaper, "Why isn't your picture in it?"

SM: Okay, we're gonna stop here.

BG: Okay.

Broad Themes

- Late spring wave
- Statistics of disease impact
- Modeling paper – on mildness of pandemic
- Number of population in U.S. immune protected
- International vaccine donations
- The Global Action Plan for Pandemic Preparedness
- Discussions about domestic prioritization and international donations
- Debate about domestic and foreign policy interests
- Principle of working with WHO
    - Multilateral approach
    - Legal basis of WHO donations
    - Liability issues

- Financial issues
- Logistical issues
- Regulatory issues
- Domestic demand and supply
  - 10% - 25 million doses

- U.S. demand and supply
  - Australia/CSL and first rights
- Middle income countries access to vaccine
- Role of Gellin – technical and international consultative
- Future of global response to pandemic
- National Security Council

Follow Up

Names: None.

Documents:

1. Back-up documents on discussions about domestic needs versus international donations.
2. Decision/Press release from White House on donor/partners on international global pandemic donations.

3. Paperwork required from recipient countries to receive vaccine in various stages of process, including drafts and final documents.

4. Donor agreements between U.S. and WHO – drafts and final copies.