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## **Press Briefing on the Avian Flu by Dr. Rajeev Venkayya, Special Assistant to the President for Biological Defense Policy**

Via Teleconference

 [National Strategy for Pandemic Influenza](#)

 [In Focus: Health Care](#)

1:45 P.M. EST

DR. VENKAYYA: Thanks very much, Trent. Again, this is Rajeev Venkayya, from the Biodefense Directorate at the White House Homeland Security Council. Thanks for joining today. I'd like to give you a little bit of background on the President's announcement today, and link between the strategy that he announced and the budget submission that is going up in parallel, as well as the legislative language that's going over to the Hill to support the goals of the strategy.

We released today the national strategy for pandemic influenza, which represents a comprehensive approach that not only the U.S. government, but we expect that all levels of government, as well as the private sector, individuals and our international partners will follow in their efforts on the avian and pandemic influenza front.

There are three pillars to this effort which cut across everything from the international spectrum, all the way to our domestic efforts, and from the federal government all the way down to the community. Those three pillars are preparedness and communication, surveillance and detection, and response and containment. As you look at the strategy, which was placed on the White House website at around 10:00 a.m. this morning, shortly after the President's speech began, you can see very somewhat detailed descriptions of the specific actions that are mandated in the strategy. And those actions stretch, again, across the entire government and across levels of government, and provide principles for which our international partners we believe should aspire.

We really view this as a threat that cannot be only addressed here within our borders; we see this as an international threat that currently resides overseas, but very well, with the passage of time, could be within our borders, within the animal population, and could reflect a more imminent threat to our population here with regard to animal-to-human transmission.

But since it is overseas now, we do think we need to have an aggressive effort internationally to provide early warning of human-to-human transmission, as well as a coordinated rapid response plan

that will, on the international stage, contain this to the extent possible and limit its spread to our borders. We do recognize, though, that we are -- while we can be hopeful that we will be able to contain an outbreak overseas, that we can never guarantee this, and so that we cannot ignore domestic preparedness, and therefore, domestic preparedness represents the brunt of the budget that was described this morning.

What I'd like to do is very quickly recap the budget for you at a high level, and then we can go ahead and open it up for questions.

The budget, itself, has been in the works for several months now. This overall process began back in the spring and proceeded through the summer, and led to a draft budget submission that crosses seven different federal departments, as well as the U.S. Agency for International Development. Those departments are HHS, Veterans Affairs, Defense, Agriculture, Interior, Homeland Security, and State, and as I mention, USAID.

If I can begin, first, with the international budget. We're looking at a total of \$251 million spread across USAID, HHS, Ag, and State, that is principally directed towards supporting the activities in the -- that are described in the international partnership, essentially activities to improve surveillance and early warning, scientific cooperation, transparency in nations, building up laboratory capacity, establishing emergency response plans in nations, and building up general capacity in these regions to not only respond, but also to produce their own vaccine, and perhaps someday their own antivirals to deal with the outbreak.

The international budget is also very focused on improving the relationship between the agriculture sector and the human health sector. We think that this is an issue that has come up time and time again, both across countries and in multilateral organizations that deal with those issues on the human and animal side, but also within countries where we see that the ag sector is not communicating as well as it, perhaps, ought to be with the human health sector.

Turning now domestically, we have HHS, VA -- actually, all seven departments have components of the budget. The lion's share is at the Department of Health and Human Services, about \$6.6 billion. But let me just quickly touch on what the other departments are contributing here.

First, the Departments of Agriculture and Interior are leading the way on surveillance, particularly of wild birds, but also of our domestic bird population here. They already do a fair amount of work in this area. Those departments have a lot of experience with low-path AI -- avian influenza -- as well as high-path avian influenza. And they had been doing surveillance before, but we've asked them to ramp that up, particularly in light of the concern that avian flu through the migratory bird population will come into the continental U.S. through Alaska, over the Bering Straits.

The other departments include the Department of State, health support for embassy and evacuation contingencies for Asian countries; the Department of Homeland Security to establish materiel to protect its first-line workers, particularly the border officials who might be the first points of contact for a flu that enters our country; and finally, Departments of Veterans Affairs and Defense are supporting the HHS/CDC activities in bio-surveillance by improving the quality and quantity and timeliness of data

that's going into the CDC BioSense system. And then, in the case of the Department of Defense, there's also about \$81 million devoted to purchasing unexpectedly available H5N1 vaccine from Sanofi. I say "unexpectedly" because Sanofi, through our discussions with them, has agreed to put off another project they were working on. That freed up their production lines to produce this vaccine, and the Department of Defense has purchased them.

Turning, finally, to the Department of Health and Human Services. As you know from the discussion this morning there is, as I mentioned, about \$6.6 billion there that is spread over vaccine, antivirals, surveillance activities, state and local preparedness, and general research and development. On the vaccine front, to accelerate cell culture technologies, we're looking at a \$2.8 billion investment that includes accelerating the culture, as well as building out search capacity.

The reason that we're focusing on cell culture capacity here is because, to use the current technology, which the President, I think appropriately, described as old-fashioned, based in eggs and flocks of chickens, is that it's very difficult to have surge when you're talking about eggs. In other words, in order to ramp up production quickly, you've got to wait until you have a lot more chickens and eggs to do that. When you take that in conjunction with the fact that it takes a lot more vaccine to produce an immune response in a person than we see with the typical seasonal vaccine, you quickly realize that you would need a lot of chickens and a lot of eggs sitting around month after month after month, just waiting for us to use them to produce vaccine.

Cell culture technology, which is, we view, the next wave of technology that's going to come through the influenza vaccine industry -- I think the industry shares that view -- allows us to build out capacity, essentially vats that would be mothballed -- I shouldn't say, "mothballed" -- they would be used to produce other vaccines, but then when we needed them, they would be available to quickly divert to producing large quantities of vaccine. And that's what that \$2.8 billion is for.

There's another \$1.5 billion that is devoted to producing vaccine that is created through existing technology; \$1.2 billion of that is to incentivize the vaccine industry to expand the current egg-based production capacity to produce 20 million courses of vaccine -- "course" here being defined as two doses of vaccine. So that means 40 million doses of vaccine. And then we also have additional funds invested at HHS and at the Department of Defense to buy, again, from the Sanofi excess capacity.

On the antiviral front, we're looking at an investment of about \$1 billion that is going to be spread across two antiviral drugs -- one called oseltamivir or Tamiflu, the other one called zanamivir or Relenza. We looked to purchase 24 -- sorry, a total of 44 million courses for the Strategic National Stockpile as a goal, with an extra 6 million courses that we would use domestically for containment efforts if we were to have an outbreak of bird-to-human that then became a human-to-human outbreak -- in other words, the initial spark, if you will, in a pandemic, domestically. The remainder, we look to the states to participate in the purchase of, and we would subsidize those purchases, to get us up to a total of 81 million courses of vaccine shared between the states and the federal government.

The remainder of the budget is spread across state and local planning -- \$100 million devoted to helping the states to wrap up activities that they've really undertaken over the past several years. And that's been funded through just over \$5 billion in public health and medical cooperative agreements

through the Department of Health and Human Services to do preparedness that is all, really, for the most part, directly relevant to influenza preparedness. It may be, in some cases, earmarked for smallpox preparedness or general bioterrorism preparedness or general public health preparedness, but if you look at the cooperative grant agreement guidance, you'll see that much of that is actually very relevant to public health preparedness for influenza.

So the \$100 million is to help states finish their pandemic planning efforts and to exercise those efforts. There's also very critical money in there for risk communication efforts and to expand the Strategic National Stockpile so that it includes more than, of course, vaccine and antivirals, but also personal protective equipment, additional ventilators or breathing machines, and masks, and so on.

With that, let me just stop. I've given you a lot of information. Actually, one last point, because this question had come up, and that is a better discrepancy between the speech and the fact sheet. In the President's remarks, he mentioned that there was -- he was asking for \$583 million for preparedness, and the fact sheet, in fact, said \$644 million. That reflects the addition in the fact sheet of two items that were not referenced in the President's speech. One is an advancement of general R&D efforts on human pandemic flu vaccine, both here and in partnership with Vietnam.

And then secondly, there is an additional \$30 million at the Department of State that I mentioned earlier for their emergency response to bring personnel back home. So that explains that discrepancy.

The second question that had come up was the mention in the speech of \$1.2 billion to buy vaccines, when the fact sheet says, \$1.519 billion. I mentioned earlier that there were two other vaccine purchases that are included in that \$1.519 billion that are not reflected in the \$1.2 billion, and those are at the Department of Health and Human Services to buy excess capacity from Sanofi this year, as well as the Department of Defense, another \$81 million.

Now, let me stop, and if there are any questions, feel free to pipe in.

Q Thanks for taking my question. And I just wanted to get back to the antivirals. If you could go over the number of treatment courses again that are going to be purchased at the federal level, and then the number that are going to be purchased at the state level. I just want to double-check those numbers. And I have a question for you on that, which is, could you be setting up a situation here inadvertently, where you get disparities among the states? In other words, some buy and others don't buy?

DR. VENKAYYA: Well, to run through the numbers very quickly again and then to get to your latter question, the goal now for the federal stockpile is a total of 44 million courses plus an additional 6 [million]. The 44 million courses comes from recommendations of the National Vaccine Advisory Committee that peered or prioritized the groups that would receive antiviral therapy.

We would not necessarily -- I want to qualify that by saying that I think in an actual pandemic, we're not necessarily suggesting that we're going to strictly follow that list of prioritization. I think there are a number of different factors that would have to be taken into account, not the least of which are the characteristics of the virus that is actually produced in the pandemic.

But the goal now is 44 million courses in the stockpile, plus an additional 6 million. Why the additional 6 million, that is to handle two domestic -- attempt to contain two domestic outbreaks of human illness. In other words, if we have, for instance, a single case that arrives on a plane in a community and we believe that we have human-to-human transmission that's now spread to our country -- a spark, if you will -- we would follow the guidance that comes from scientific modeling in peer review literature to flood that community with antivirals -- we're looking at 3 million courses -- in order to attempt to contain the infection to that region. It is not a strategy that we can say with certainty will work, but it certainly is something that we must endeavor to accomplish, because if it does work it can save many lives and reduce illness significantly.

The remainder, then, 31 million courses we would look to the states to purchase with a federal government subsidy, and that would take us up to a total of 81 million courses.

Q Is that roughly a quarter of the population?

DR. VENKAYYA: That's right, that's roughly a quarter of the population.

Q Yes, please go on.

DR. VENKAYYA: Now, to your point about disparities and state and local preparedness, I think this is a function of the federalist system that we have, and that is that we think that the -- the federal government clearly is shouldering a tremendous amount of the responsibility of protecting the American population. I want to make that very clear; we take that very seriously. But I think that we certainly view preparedness as a shared responsibility. And I wouldn't limit that to a shared responsibility between the federal and state government; I would

view it as a shared responsibility across sectors of society, which includes the private sector and individuals and communities of families. So this is one example of that, where we look to states to shoulder part of that responsibility.

Now, what I think we'll see -- and this is per -- Secretary Leavitt's thoughts is that this will generate discussion in states about preparedness for influenza. And we think that's important. So we think that the side benefit will be that we'll stimulate that discussion.

Q Okay, but just a quick follow-up. Don't you think the Feds could get a better deal on the price than 50 states plus territories going in on their own and trying to do it?

DR. VENKAYYA: Well, I think that's a good point. And this is why we would look at this as a partnership. In other words, we would -- I'm not sure how this would work out, leave it to the attorneys, but I think that we would look to have the states get the same deal, if you will, that we're getting, to the extent possible. But, again, I'm not somebody that negotiates those kinds of deals.

Q Doctor, I was wondering if, in fact, you had a timetable for how long you anticipate it taking if Congress moved as quickly as you would like? How soon can these measures be implemented so that

-- I know for this flu season, we would be in trouble if the outbreak hit this season. But do you anticipate these measures would help for next flu season? The flu season after that? And how long will it take to get these antivirals purchased and in hand, knowing that we're behind so many other countries in line for those orders?

DR. VENKAYYA: To your question about flu seasons, let me just clarify that. Are you referring to our ability to deal with the annual flu next season? Or are you talking about if a pandemic hits next season?

Q If a pandemic hits next season.

DR. VENKAYYA: Well, the answer is it depends on which investment you're talking about. And these things are going to come in -- the rewards are going to come in, in phases. There are certain things that we can do today that are going to make a difference tomorrow. And when I -- and those are specifically the procurements of additional vaccine that are using the existing technologies. We've already got egg-based technology in place, proven technology. It's simply a matter of getting more eggs and flocks in order to expand our production capacity for the vaccine that we're already making -- the H5N1 vaccine, that is.

A similar statement can be made about antivirals -- the Relenza and Tamiflu, if you will. Now, I have to say that -- you made a comment about other countries being well ahead of us -- other countries have put in their orders, but it's absolutely not the case that all these countries have received and have in their stockpile the amounts of their orders. And I think that the timing of that delivery is certainly -- I'm not in a position to share that information, nor do I know it all. Some of that is commercial confidential; some of it they just -- we just don't have. But the bottom line is that we, once Congress approves this -- presuming they will -- will work diligently with the private sector to ensure that they are able to deliver what we need as quickly as possible, and to the extent possible -- do that with domestic production capacity.

Q But at this point we don't have -- you don't have an estimate as to how soon those medications could be delivered?

DR. VENKAYYA: Well, I mean I have to tell you it will happen as fast as possible. I am reluctant to commit to a time frame until we actually know that this is going to make it through the Congress, and that we can begin those discussions. Those are procurement-sensitive discussions, if you will, particularly on the antiviral side.

One last thing I'll point out that could pay out big dividends soon, and that is the studies that we are proposing in the budget to look at dose-stretching therapies, or adjuvants, which are materials that can be administered along with a vaccine that rev up the immune system, if you will, so that you need less of the vaccine to protect a person, to make them immune to the virus. If those studies show that we have effective materials to give with the vaccine, we'll revolve these rewards much more quickly. In other words, every dose we have will go much further along and we'll be able to treat all the American people more quickly than we had originally anticipated.

Q So the money that's going for development of cell culture technology, is that going to the NIH, industry, a mixture of the two? Also, I'm a little unclear on the -- still on the number of courses for the antivirals. There's a statement from Senator Schumer today saying that this plan only covers 7 percent. Are you -- is the 44 million number covered completely by the money that you're announcing today? And, lastly, I just wanted to get a sense of the difference between what the President has talked about today and what HHS is going to be outlining tomorrow.

DR. VENKAYYA: Okay. So just real quick, the first question was on whether this is going to NIH, or industry, or both. The second question was, is the money for the 44 million courses? And the third question is, how does today's announcement differ from tomorrow's?

Q Right.

DR. VENKAYYA: To your first question about NIH or industry, the answer is that majority of this is going to be to actually get vaccine and get capacity on line to produce vaccine. When you say NIH, one of the thoughts that comes into people's mind is basic science research. And while basic science research is critically important and we actually do have part of this budget devoted to developing new vaccines and antivirals, the majority of the vaccine investment is to get the private -- to incentivize the private sector to establish the -- to advance the technology to be able to produce influenza vaccine using cell culture methods, and to get the production capacity in place to produce vaccine for the entire American population within months of the recognition of a pandemic. So the majority of this will be to incentivize industry.

There is money, though, in the budget that is for advanced development, if you will, which is to bridge that gap between basic science and the point where you actually have a product that is licensable, and we have a few hundred million dollars that is -- \$200 million, in fact, that is directed to advance development of common flu vaccines that cover all influenza A strains, so that we don't have to -- someday we'll no longer have to change our vaccine out every year, that we might have a common vaccine that covers all those strains. And then, secondly, the advanced development contracts for those dose-stretching techniques that I mentioned.

On the 44 million -- the \$740 million -- there is \$740 million that we're asking for to take us from our current goal of 20 million courses of vaccine up to a total of 44 million, so it adds 24 million courses to what we've currently planned for.

And then your third question was about the difference between what was announced today and what's to be announced tomorrow. What was announced today is the broad framework for how we think about, prepare for, and how we plan to respond to pandemic influenza. It is a comprehensive strategy, and as I mentioned at the beginning of the call, covers not only many departments in the federal government, it also covers different levels of government, every different level of government, and it also includes international efforts. It includes N1 human health efforts and, finally, the role of entities that are outside the government that the success of our efforts is predicated on. And those are efforts by the individual, their families and the private sector.

Today is a broad context, the big picture, if you will. Tomorrow's effort, or tomorrow's announcement is

by HHS and that is going to be focused on the human health side of the equation -- and, principally, the domestic human health side of the equation. The HHS plan and strategy is going to be announced tomorrow and distributed, and the brunt of that is very specific guidance for state and local health officials on how to get their -- how to prepare and what they should do to respond to a pandemic.

So today is the big picture; tomorrow is human health.

Q I had a couple of questions. One is how much of this was already in the pipeline, administratively, or in legislation in Congress, versus how much that the President announced today is brand-new? And then my second question is the waiving of -- or shield liability for manufacturers essential to all this happening?

DR. VENKAYYA: So when you say "brand-new," the first part of your question, can you clarify that?

Q Well, I mean, I know that, like, I think Bill Frist and maybe some on the House side had some shield legislation for vaccine makers, and I know that there's been a number of bills by Republicans and Democrats that would address little bits and pieces of this. I'm just not an expert, I'm not a health writer, I'm a politics writer. I don't know how much of what he said today is out of the blue, versus how much of what he said today is just kind of wrapping up things that we already knew about that are already out there.

DR. VENKAYYA: Well, we applaud the efforts that have been underway in the Congress recently. I think that they're all headed in the right direction. I think there are a number of -- the Hill has shown great interest in doing something about this. Let me just rewind the tape a bit here. We actually went to the Hill in anticipation -- in September -- in anticipation of taking up this package which we had had in the works for several months, back in September, in order to, first, before showing the package, briefing them on the threat, if you will, on what we need to worry about with regard to avian and pandemic influenza.

Within 18 hours, I think it was, the Hill introduced a \$3.9 billion package to address this. And so I think that it looks like we were successful, and we applauded those efforts. But as far as whether this is new -- this is something that we have had in the works for several months. And then, if you could just repeat your --

Q Let me just clarify that one. The \$3.9 billion that they had already undertaken, is the \$7 billion. whatever that the President announced today on top of that, or is it partially already including some of the elements that Congress is looking at?

DR. VENKAYYA: This is all brand-new.

Q So if this was all done, plus some of the stuff Congress is looking at, we'd actually be spending like \$11 billion?

DR. VENKAYYA: No, no -- I see, I understand your question. No, I think that Congress has put forth --

there have been a couple of proposals that have been put forward to address the avian/pandemic threat. They have done some of the things, I think put forward some approaches that we include here. In some cases, they've not included the approaches that we have included here. This is a comprehensive package. We wouldn't propose that we do this on top of whatever is on the Hill right now.

Q There's some crossover, there's some stuff Congress is already looking at, but they'll probably now look at it in the context of the President's package?

DR. VENKAYYA: We would hope so.

Q I'm sorry I took up so much time. Just technically, is this either going to move in the appropriations bills, or as part of budget reconciliation, or a little bit of both? Is that probably the way it happens?

DR. VENKAYYA: I have to defer that question. I'm not sure we know the answer to that yet. It was -- simply because it was just announced a few hours ago, and I think we need to talk with our colleagues on the Hill to --

Q -- but hopefully, by Thanksgiving, right about the time they're trying to wrap up all the money stuff?

DR. VENKAYYA: I think the sooner, the better.

Q Then my second question was, how crucial is the lawsuit shield to this being effective -- can this actually really work? Can you stop a pandemic flu from -- can you contain a pandemic flu?

Q DR. VENKAYYA: Well, that's two questions, which is okay. The liability side of this we think is very important. I mean, I think that we've -- we rely on the private sector to do a lot of these things in this country, and the private sector has not responded. In this case, we've sort of had a guess-timation, if you will, of the vaccine industry in this country for a few reasons, but the principal one being, in our view, this issue of liability. And the fact that we, as of today, recognizing that we have an imminent -- let me rephrase that -- recognizing that we have a threat, an infectious disease threat, and we only have one vaccine manufacturer that produces, licenses influenza vaccine domestically represents to us a huge problem. And we need to fix the climate to allow vaccine manufacturers to get into this business and stay in the business.

As far as -- and then you had also asked, how much of a threat is this, really. And to -- that's a broader question that it's impossible to answer, but I can tell you that we view the risk of a pandemic to be greater today than it was before 1997, or 2003, when we really saw avian flu take off. The fact that we now have this new virus that has developed in birds, that has shown that it can infect people and produce lethal disease in human beings, and that it shows no signs of stopping in its progression in birds and in other species around the world, makes us very, very concerned -- that taken in the context of the fact that the last three pandemics were caused by viruses that were either completely bird viruses, as in the case of the 1918 pandemic, or had parts of bird viruses in the virus that caused the pandemic in 1957 and 1968 makes us -- makes us concerned that this could be the harbinger of another pandemic.

But we cannot say for certain that this virus is going to be one that causes a pandemic. That's impossible to say -- which is why everything that you see in this budget is designed to provide universal preparedness for influenza, irrespective of which virus poses a pandemic threat.

Q I actually have more questions, but I know other people do, too, so I'll wait.

DR. VENKAYYA: Thanks.

Q Can you give some details of what the incentives are going to be for vaccine makers, and can you give us a few more details on what the cell culture preparation is going to be, what exactly you're talking about -- buy the vats, or what?

DR. VENKAYYA: Well, I think that I need to defer that question because I think that needs to be figured out. The bottom line is that we can't have all that detail until we actually sit down with the manufacturers and have discussions about what can be done and how to do that.

We do not intend to go off and build factories. Just to be clear, that's not part of this plan. What we plan to do is get the private sector to step up -- as they said they would when they met with the President -- to step up and meet the requirements to protect the American population. And we just need to figure out the right packages of incentives to both get the technology to advance, and then have the production capacity in place to meet the needs. But, unfortunately, at this point, I can't give you much more detail on that because we don't have it.

Q So how did you figure out how much money to appropriate to that area if you don't really quite know what it is you're going to do?

DR. VENKAYYA: Well, I think that was based on -- there have been efforts to -- there have been RFPs that have gone out on the cell culture front. And we have a fair amount -- we do have a fair understanding of what kinds of things the industry -- what kinds of methods we can use to incent the industry to advance this technology so this was not done in a vacuum. I guess, what I'm saying is that I can't tell you that we have a list of incentives that we're ready to put out there that we're going to use.

Q Can you give us, like, for instance, what kind of thing it might be -- chocolate sent to their desk every day?

DR. VENKAYYA: That would be an inexpensive approach, and if we could use that, we would. Unfortunately, I don't think I can give you much more detail than that right now.

Q I was wondering if you could give me a few more details about the \$1.2 billion -- or \$1.12 billion purchase of additional H5N1 vaccine, presumably from Chiron and Sanofi. Over what time frame are you talking about purchasing this? Would it be in bulk? And I think previously we were talking about \$165 million in purchasing; that would be 20 million doses. But it seems like a lot more now.

DR. VENKAYYA: Well, the 20 million estimate that was generated before was based on projections of how much vaccine would be needed to take care of a population of 20 million individuals. Based on the clinical trials, we now know that it takes more vaccine than originally anticipated to vaccinate 20 million people. And so that number -- immediately once we add that data, it went up significantly.

The actual -- I mean the investment, the \$1.2 billion in egg-based capacity and 40 million doses of egg-based vaccine using today's technology, that will be done using the companies that are already in the business, that are already doing -- have shown that they can create licensed vaccine using egg-based technology. And I guess, I can't -- I can't tell you much more than that. We're going to use the companies that are already doing it to produce more of what they're already making. And the difference in price reflects the difference in the amount of vaccine that it takes to produce an immune response with this vaccine versus the traditional trivalent vaccine.

Q But no idea how soon this vaccine would be in the storehouse?

DR. VENKAYYA: Well, I think that we're going to start to see this come online immediately. We're looking to have this in our stockpile by '08, '09.

Q '08, '09.

DR. VENKAYYA: Wait that would actually -- I would say '09.

Q '09, so the calendar year '09?

DR. VENKAYYA: That I can't tell you.

Q Okay. And then, talking about the antivirals, could you clarify again that some of it is going to be Tamiflu, some of it is going to be Relenza? Is that a three-quarter, one-quarter break? And will this policy permit states or the federal government to purchase these products from other than the patent holders?

DR. VENKAYYA: The breakdown of Tamiflu and Relenza has not been determined. I wouldn't want to signal anything on that front.

On the issue of procuring a drug from non-patent holders, I think that there are a variety of trade considerations there, safety considerations there that have yet to be determined. The bottom line is that we don't -- there is no such company out there now, and I think that -- as of today. And I think that would just have to be addressed once such companies were actually in existence.

Q With the states having to purchase 40 million on their own to get this 80 million course goal, I envision the states being somehow in competition with the federal government over the same production capacity, which all indications are, are vastly below that level right now. I'm just wondering how you possibly -- there has got to be a plan. Can you give a sense of how you would boost that production capacity?

DR. VENKAYYA: No. There clearly is a plan to expand production capacity. And I just can't give you details on that because these are things -- this is information that is commercial confidential, and I just can't speak to what companies might have in store to expand their capacity.

But to your point, which is I think a very good one, that we don't want to -- this incentive out there and encouragement for states to stockpile antivirals and then go out and compete against it, nobody wants to do that. And we would work with states and companies to make sure that, in fact, was not happening, that there was an equitable distribution of any buys that came from the United States across the nation.

Q One last question because I know a lot of people have them. Is there somewhere published a sort of priority list over who should get what available antivirals are out there first, and for that matter, vaccines?

DR. VENKAYYA: The prioritization on antivirals, there is a set of recommendations out there that the National Vaccine Advisory Committee has put forth. And we have looked at that to establish some of our baselines, as far as what -- our targets, if you will, for the stockpile.

I want to be very clear, though, that we are not saying with certainty -- those are simply guidelines -- we are not saying that those are the individuals and groups that are going to get antivirals from the federal stockpile and that that's what we'd recommend for states if a pandemic begins. That's going to be -- that is being refined, and it will have to be refined further if and when a pandemic begins.

On the issue of prioritization of vaccine, that is something that we are currently working on. And I don't have a final answer for you except to say that this is something that's receiving the highest attention right now, given that we are -- we do have a nascent vaccine stockpile currently. But the general guidance is that vaccine needs to go to those individuals that are at greatest risk for exposure, and those are the people on the front lines. And the obvious examples are health care workers, people working at the borders, people that may be working on aircraft that are coming to and from our country, people that are working in the agriculture industry -- if you're talking about an outbreak that arrives here through animals. So those are the kinds of folks we would look to having that vaccine go out through first.

Q Why is so relatively small a portion of this budget going for the international cooperation when it seems to me the surveillance and the help that we could give to foreign countries, specifically the seven countries that are the focus, would be the first line of defense for Americans?

DR. VENKAYYA: Well, David, thanks for that question. I think it's a good one. I wondered that at one point when I was first looking at the way this budget was playing out. The bottom line is that the -- we think, first of all, that the international -- we agree with you that the international piece is critically important in all of our efforts. What I would say is that \$251 million sounds like a small amount of money in the context of a budget that totals \$7.1 billion. I recognize that. Realize, though, that the lion's share of that budget is devoted to expanding our countermeasure production capacity, building up our stockpiles, and advancing the R&D to produce better countermeasures, which, by the way, would benefit the entire world.

So it seems small in light of that, but if you look at it against the other parts of our domestic budget, I think \$250 million is a significant international investment, and I think you'll see that as you look at what other countries are doing. We here in the United States had invested \$25 million earlier this year as part of the tsunami supplemental and international efforts, and this is tenfold that. And it provides significant support to multilateral organizations, such as the WHO, FAO, OIE, as well as to bilateral support to nations -- affected nations that are particularly challenged by the issues presented by this.

So I actually don't think it's a small budget. But I agree with you that it seems small when you match it up against the significant investment that we have to make, this crash program, if you will, and a countermeasure development.

Q Thanks for taking my question. I have two questions. Number one, could you tell us the -- if a pandemic does strike, a part of the plan is that the administration would have enough vaccine within six months of a pandemic. But when -- how do we reconcile it with when the 1918 flu swept the Earth, it did most of its -- actually, all of its killing in the first six months? That's the first question.

Second one, could you give some specifics on the common vaccine, or the universal vaccine?

DR. VENKAYYA: Well, let me start with the latter one first. The common vaccine is -- there are a couple of companies out there that are working on -- actually, more than that -- that are working a vaccine that would not be strain specific. In other words, it would work against all H3N2s, and perhaps might even work against H3N2s, as well as H1N1, as well as, perhaps, H5N1. This is basic R&D that's currently underway, and I don't think -- it's something that we're investing in, but I don't think we're close enough to say that we've got something that's going to work.

Q What are the companies?

DR. VENKAYYA: I can't get into that on this call simply because I don't have the list of those, and I don't want to -- I don't want to just mention the one or two that I'm thinking of and shouldn't miss anybody.

On the issue of the 1918 pandemic, realize that things are very different today. That goes without saying, but specifically on the early warning front, that we have very different ways of looking at -- looking for disease early, both in animals and in humans. We have ways of following the evolution of the virus, and we now have the benefit of knowing what happened in 1918 with that virus, the specific genetic mutations that occurred that contributed to virulence and pathogenicity and infectiousness and transmit-ability and so on. So we do have significant tools at our disposal that are going to give us the kind of early warning of the outbreak that was not available. In other words, the start point, presumably, today will be upstream of what it was back in 1918.

The second point is that we have very good infection control measures, we understand a lot about infection control that we would put in place immediately. There are a series of things -- the bottom line is today, as it was back then, the best way to prevent yourself from getting this infection is to prevent exposure to it. The next best way, using today's technology, is to have a vaccine in hand. And so there

are a whole host of things that we can do to limit transmission of a pandemic virus, once it begins, that would further slow the spread.

The third thing I would say is that we do have containment strategies that we have -- we're talking about with our international partners, so that wherever this begins we do think that while we may not be able to stop it in its tracks, that we will have a very good shot at slowing, limiting or otherwise containing its spread to that area, or slowing its arrival here to the U.S.

And the fourth thing I would say is that everything that we're talking about with regard to ramping up production is phased. In other words, it's not like you go six months without any vaccine and then all of a sudden, boom, you've got enough for the whole population. This is something that would begin -- the production would begin immediately and you would get vaccine online over the course of months.

And then the final thing I'll say is that the whole point of having a standing stockpile of 20 million courses of vaccine against the most likely pandemic producing strain of virus is so that we do have something that's ready to go at time zero when we recognize that a pandemic virus has emerged.

Q One follow-up. How do we plan, specifically, to require transparency with the countries we're working with?

DR. VENKAYYA: Well, we -- I can't say we "require," that makes it sound legal, but it's strongly encouraged. Now, the international partnership that was announced on September 14th has a set of core principles, one of which is transparency, timely reporting, scientific cooperation and so on. And if you want to be a country that's part of the partnership, you have to demonstrate that you -- and we are putting in place with our partner nations ways to track implementation of these measures -- you have to be willing to sign up to those principles.

Eighty-eight countries have signed up to the principles of the international partnership, including many, many affected nations. And so while we can't "require," because that sounds like it's a legal instrument, we can strongly encourage, and we can also bring to bear all of the diplomatic pressure of our international partners, the other 88 nations that are part of this, to make sure that those nations do the right thing if something develops within their borders.

I'll take one more, then we'll wrap it up.

Q You mentioned earlier about the responsibility of all sectors, including the private sector. I'm just curious about your thoughts of whether there is any preparedness going on in the private sector, other than the drug and vaccine industry.

DR. VENKAYYA: I think there is. But I think that the private sector is interested in having guidance on this issue. And we're going to provide it from the people that do it best -- the health experts working in concert with people to understand the private sector, so that a business, a private sector entity will know what it needs to be thinking about with regard to pandemic preparedness and what specific measures it can take to be prepared.

Let me just elaborate briefly on that. The bottom line is that while a pandemic is not like a hurricane, it doesn't knock down telephone polls and destroy roads, it does produce severe absenteeism, such that a business could be attempting to function with only 60 percent of its employees, or 50 percent of its employees in place. Well, that, if it's not managed properly, can result in the same thing as a hurricane, by preventing the people that need to maintain the infrastructure, take them out of the equation, if you will, so that you can't deliver fuel, you can't maintain your telecom networks. We worry about that a lot. And we think that people in the private sector, businesses, need to be thinking about how they can maintain their essential functions in the face of a 30-percent to 50-percent absenteeism which might last a few weeks.

And there are things that businesses can do. First of all, businesses can prioritize what those essential services are. Secondly, they can determine staffing plans that would allow them to make sure that they can maintain those essential services in the face of absenteeism. Thirdly, they can take specific measures to reduce infection transmission in the workplace, and there is a whole list of things that the CDC and I and others could tell you about that would facilitate that.

And fourthly, they can put systems in place so that even if people have to stay at home because they are either ill or because they have to take care of a family member who is ill, or because the public health officials are just saying you should stay home, companies can put in place mechanisms for people to work from home. And if they're not working from home, if they're coming to work, well, maybe it doesn't make sense to have your shift change happen all at once, maybe you ought to stagger those shift changes. And once people are at work, maybe they shouldn't meet in rooms, maybe they ought to just meet by phone. All of these things and many others are steps that a business could take to prepare for a pandemic influenza.

And by the way, every single one of those things I just mentioned will also help any business during the annual flu season when we know businesses already suffer some degree of absenteeism that affects their bottom line. And so we think that there is a critical role for the private sector, as well as critical infrastructure entities to play in preparedness. And we intend to fully engage as we move forward with this pandemic planning process.

MR. DUFFY: Okay, we're going to have to stop it there. The Doctor has run out of time. Again, I'm Trent Duffy. You can reach me for any further questions through the White House Press Office which is 202-456-2580. And we'll be around, as well as other folks in HHS to answer other questions.

Thanks, again. Bye.

END 2:34 P.M. EST

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