Learning to Live in a World with the H1N1 Pandemic
Kaiser Family Foundation
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STEVE MORRISON: Morning, still morning. Good morning. Thank you all for joining us. I'm Steve Morrison. I direct the Global Health Policy Center at CSIS and we are delighted to be able to hold this event today with Dr. Phil Nieburg, Dr. Tony Fauci, and Dr. Harvey Fineberg on this very critical issue.

We are also delighted to be able to do this jointly among CSIS, Kaiser Family Foundation and the Congressional Caucus on Global Health, chaired and led by Congresswoman McCollum who is a close ally of ours and close friend and an activist on these issues.

At CSIS we have launched this Spring and will carry forward through the end of the year the Commission on Smart Global Health Policy cochaired by Helene Gayle and Admiral Bill Fallon and includes a number of prominent Americans trying to take a look at what a long term strategic approach by the U.S. and Global Health might look like and this issue of

preparedness for pandemic flu figures very strongly in our work and will figure as we go into the fall.

And so we are delighted to be able to associate ourselves with this event where we will bring together folks for an additional follow-on roundtable in mid-July. We haven't set the precise date but we intend to bring together some personalities, Gaudenz Silberschmidt from the Swiss Government who will be here in mid-July along with some U.S. officials and independent experts to look again at some of the questions having to do with WHO and the developing country response so keep your eyes posted for that.

I'm very grateful to Lina Choudhry from Congresswoman McCollum's office for helping to engineer this and for a number of folks at CSIS who put a very special effort in making this happen particularly Emily Poster and Daniel Porter and a number of our interns who pulled this together, so thank you very much and welcome.

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JEN KATES: Good morning. My job is very simple. I am also welcoming you here and echoing what Steve has said and thanking our partners in this event. This is also a very important part of what we are doing at Kaiser, in trying to bring people together to talk about issues that we are currently experiencing in the policy world.

And while we have had lessons learned and others taking stock, I think it's really important to have lessons learned and taking stock of events during the period in which something is occurring as opposed to the retrospective "what did we learn", "what do we need to know about that we didn't do last time?" So, this is more than timely.

I also wanted to draw your attention to one thing. We were struck just in thinking back just a couple of months to April when the government actually declared H1N1 to be a public health emergency how much activity has actually occurred in Congress and in the administration on H1N1 and pandemic preparedness. And

so we have a new tool online called the Policy Tracker, which tracks daily all of the movement on the Hill and in the Administration on different global health issues and we just pulled out the H1N1 information.

And you can see here how many hearings and legislative actions and reports and things were put out since just the end of April. So, we encourage you to take a look at that. I will stop here and thank our panelists for being here with us today and turn it over to Phil who is going to moderate and take questions.

PHILLIP NIEBURG: Thanks Jen and Steve and good morning everyone. I just want to add my welcome to theirs. Before turning the session over to our two expert panelists, I wanted to provide a bit of context by briefly noting the most recent H1N1 influenza numbers from the U.S. and elsewhere and then mentioning a few of the many important uncertainties about this new pandemic influenza.

First, one of today's handouts, and I think it's on your chairs, is a table of the most recently

reported pandemic flu data from CDC for the U.S. and from WHO for the rest of the world.And line one on that shows the U.S. numbers now more than 27,000 infections, 127 deaths reported by states to CDC.

The case fatality rate shown on the second column from the right is, that is the number of deaths, sorry the rate of deaths among people known to have been infected by H1N1 virus and at this point that number for the U.S. is 0.46-percent. It is a little bit less than one half of 1-percent.

The analogous numbers from Mexico and Canada, on the next two lines, and it is notable that the case fatality rate among Mexicans is just under 1.5-percent, that is higher than in the U.S. and that probably represents the initial discovery of this outbreak in Mexico and this kind of initial bias toward higher mortality numbers is very common and almost unavoidable with any new disease that sometimes has a fatal outcome, because these new pandemics are almost always identified when the most seriously ill people come to

the attention of the health care system. As the weeks have gone by, the case fatality rate in Mexico has progressively decreased as more mild H1N1 infections show up there.

WHO's global summary numbers on the fourth line now show more than 70,000 H1N1 infections and a little bit over 300 deaths. The global case fatality rate of 0.44-percent, that is again just less than a half percent.

And then on the next line I recalculated the global case fatality rate, taking out, that is without including Mexico's numbers and that number is 0.31-percent. On line six, you can see that in Sub-Sahara and Africa, a location of concern for influenza obviously, there are only six cases of H1N1 infections reported to date.

This low number is likely a reflection of two things, one is not much exposure yet, not much circulation of the virus, and also the inability of even sophisticated African laboratories to specifically

identify this virus without the newly developed laboratory materials that are now being distributed.

Finally, the last line, line seven, is the countries in the southern hemisphere, that is South America, New Zealand, Australia and South Africa have reported thousands of infections and their case fatality rate so far is the same as the rest of the world, if Mexico's numbers are not included in that calculation.

So, we are all facing a situation that is going to require a lot of decision making in the face of great uncertainty. We can't address all those uncertainties today and some of them can only be answered later through collaboration between local, state and federal officials. But what you are going to hear from today's presenters will help give you a sense of the scientific and policy complexity of the issues being faced.

There are really four broad and overlapping, partly overlapping categories of uncertainty, and for

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each of these we need to understand what we can learn from the new empiric data or from new empiric data we have collected and what we can learn from the lessons and the data of the past.

First, we don't know enough about the virus, the H1N1 virus itself. What do we know or what can we learn quickly about its biology, its severity and its spread within human populations? Will its continuing spread be accompanied by a change in the severity of illness caused?

Second, we can't be certain and these are just examples of the questions within the categories, we can't be certain now about the effectiveness of our responses. How can populations and individuals best be protected? What are the current plans and uncertainties for producing an H1N1 vaccine? What kind of information would be needed or used when deciding to go forward or not go forward with a mass vaccination program? Specifically, how does the current situation differ from the situation faced with swine flu in 1976?

Third, in the past we have seen shortcomings in lots of areas of public health and our methods of communicating risks and uncertainties, what is the best and most accurate way to transmit complex technical information from scientist to lay politicians or policy makers and subsequently from the government to the public? How can that kind of messaging be made more effective and what role should the media play in that latter effort?

Finally, although we are not attempting to address this issue in great detail and Steve alluded to it, it's not clear how the U.S. could best play a leadership role in supporting the work of WHO and in supporting the preparedness efforts of individual developing countries.

So, with that, I would like to just briefly mention a couple of items, well actually let's just move on to the speakers. And really it is difficult to imagine a more qualified pair of speakers to discuss

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the technical and policy aspects and the uncertainties of preparing for this new pandemic influenza.

You have their detailed bios in the handouts. Dr. Harvey Fineberg came to his current role as president of the IOM after four years as Provost at Harvard University and preceding that, 13 years as dean of the Harvard School of Public Health. He has also served as president of the Association of Schools in Public Health.

Much of his professional work has focused on the development of health policy and specifically on medical decision making, the latter being a field that focuses on health decisions that are made in the face of uncertainty. He is an author of many articles and professional journals and is coauthor of several books including The Swine Flu Affair which is a fascinating analysis, really it's an autopsy of what happened in 1976 with the decision making. And I think we will hear something about that today. Dr. Fineberg received his doctoral degree from Harvard University.

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Dr. Anthony Fauci is the director of the National Institute of Allergy and Infectious Disease a position he has held at NIH since 1984. His work is focused on regulation of the human immune system as it affects the course of various infectious and non-infectious diseases.

Although much of his early work focused on the immune system's role in modulating noninfectious diseases, he is probably best known in the medical and public health world for his pioneering work in understanding how HIV progressively debilitates the immune system, and allowing an opportunistic infections to occur.

Dr. Fauci's many professional memberships include the Institute of Medicine, the National Academy of Sciences. He has authored or coauthored countless scientific articles and from a public health perspective he has repeatedly been the reassuring presence who helps the U.S. government explain complex new and threatening diseases in a way that the public

understands. Dr. Fauci received his medical degree from Cornell University Medical College.

The plan is to have Dr. Fineberg then Dr. Fauci speak in turn, and then we will move to the Q&A sessions. So, with no further ado.

HARVEY FINEBERG: Thank you very much, Phil. Good morning. Good morning to all of you. It's a pleasure to have a chance to be with you and especially to share today's program with Dr. Tony Fauci. I am going to talk to you a little bit about the background of influenza as a policy challenge using as a backdrop the experience of 1976 and then draw from that experience a few lessons that I think have relevance and significance to us today in facing the current H1N1 influenza outbreak.

This is a year when we are thinking about influenza, not simply as a historic problem but as a very present and threatening reality. It is not the first time since the great pandemic of 1918-1919, that

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swine flu has returned to be a major policy focus in the United States.

You may not be aware, as I mentioned the 1918-19 influenza pandemic, that that 12 month period represented the greatest natural cataclysm of the 20th century. A minimum of 25 million people died around the world. Estimates go up to as high as 100 million, and that epidemic period was a time of enormous disruption and great mortality, especially among young adults.

Typical influenza year in the United States today is estimated to cause 30,000 to 40,000 excess deaths, that is every year in an average year. Most of those deaths are amongst the elderly and the infirm. In the great 1918-1919 pandemic, a large number of deaths also were in young adults.

In 1976, in January, at Fort Dix, New Jersey, a military installation, a number of soldiers became ill with a respiratory disease. The leader on the base assumed that this was an outbreak of adenovirus because

they had actually isolated adenovirus from another military installation at Ft. Meade, but the commissioner of health in New Jersey to whom this outbreak was reported suspected it might be influenza and actually asked France to settle a wager. The base commander sent to the commissioner in the state some samples drawn from the patients, four of whom had been hospitalized.

It turned out that some of these were influenza A and some of those were untypable, meaning it was not of the type that they expected in the year of 1976. Those were forwarded to the CDC and at the CDC it was discovered that some of the isolates, including the isolate from the one of the four hospitalized soldiers who died, was actually a swine type influenza. Now this caused tremendous consternation and concern because it was the same type of virus that was believed to have caused that great pandemic in 1918-19.

It was also the case that a number of the great virologists of the day expected that swine flu might return and actually return around that same time. Just a few days before the CDC isolate, Dr. Ed Kilbourne, one of the great virologists of our time and a leading influenza expert, wrote an OP/ED piece in the *New York Times* that predicted the outbreak of a new flu because of the cycling of influenza that he had perceived and especially warned that it might be a return of the swine type. So, that was a prepared mind.

When the CDC isolated this virus, they called together their advisors. They thought hard about what to do and they developed a memorandum of decision making that outlined four options, three of which were designed to be rejected by the reader and one of which was designed to be adopted. The four included do nothing, have a minimal response, do everything just by the government, and the fourth was to mount a

nationwide public/private immunization campaign to protect the American public against influenza.

This was rolled up through the decision making to the White House. The president convened a group of leading virologists including Albert Sabin and Jonas Salk, the two great heroes of polio vaccine. If you know anything about the history of polio and polio vaccine, you know that Dr. Salk and Dr. Sabin did not agree on very much. In fact, the two of them looking at the same clock might disagree on the time of day. But on that day, with President Gerald Ford, the two agreed and recommended a nationwide immunization campaign.

That didn't last very long. Dr. Sabin soon had second thoughts about it but at the time by March of 1976, on the recommendation of the CDC, on the recommendation of the Assistant Secretary for Health, on the recommendation of the Secretary of what was then called Health Education and Welfare, President Gerald Ford announced that the United States would embark on a

nationwide effort to immunize everyone against this influenza, the new swine flu.

Then, more difficulties began. First, the manufacturers, who at the time rallied to begin producing vaccine, found that their ability to deliver the vaccine was inhibited because their insurers decided they were not going to be insuring the manufacturers.

The reason they decided they weren't going to provide insurance is that this was a vaccine that was going to be used for everyone and there had been a recent case that was decided that invoked what was thought of as absolutely liability on the part of the manufacturers, and the insurers felt even if the manufacturers aren't liable, there are going to be a lot of lawsuits.So, this was a great stumbling block by the late spring in June and July. It appeared that we weren't going to be able to produce this vaccine in a form that could be delivered to people until in August of 1976.

With the Congress deciding nothing yet about this liability, there was an outbreak of disease in Philadelphia. It occurred among attendees at a convention of Legionnaires, it was called Legionnaire's Disease. But for the first four days with people falling ill and even getting severely ill, no one knew what it was. And people started to think it might be influenza and that, even though it wasn't influenza, stimulated the Congress to get back into action to adopt liability protection and enable the manufacturers to proceed with packaging and distributing the vaccine.

In the meantime, the field trials of the vaccine were being carried out very expeditiously but with some severe disappointments. In particular it was found that one dose would not protect a child in a dose that was sufficiently low to have few side effects and therefore be acceptable. So, a second round of field trials had to be engaged in during the summer.

Finally, in the fall they were ready to begin to immunize and in the meantime throughout the spring,

throughout every month of the summer, looking hard in the rest of New Jersey, in the rest of the United States, in the rest of the world, there was not a single additional case of swine influenza unrelated to direct exposure to a pig, that is unconnected to human transmission.

So, by October with no transmission anywhere in the country, the campaign was ready to go forward, the vaccine was ready, and in the first 10 days a million people were immunized. After that 10 days, three elderly gentlemen in the city of Pittsburgh with heart conditions died the day after immunization and as a result the immunizations were suspended in Pittsburgh and in a number of other places while that was all sorted out and the CDC could come back with an estimate of 10 to 12 elderly people dropping dead every day with heart disease and restarting immunization around the country. It continued in a desultory way but ultimately in the next 12 weeks immunized a total of 40

million Americans, more than had ever been immunized at that time against influenza in any previous year.

But in December, a physician in Minnesota reported to the health authorities a case of what's called Guillain-Barre Syndrome which is a form of ascending paralysis often thought to be a part of a post-infectious syndrome, and reported it in connection to the vaccine. Now the reason he reported it is that he thought he had been warned to look out for it on an audio digest tape that was prepared by Dr. Paul Worley of California and he was listening to it in his car.

What Dr. Worley actually said on the tape is that on any given day, someone, somewhere in the United States, is going to be coming down with Guillain-Barre Syndrome and if that happens the day or the week after immunization, people are going to think that it is related. He was trying to warn about coincidence. The physician thought he had been warned to look out for Guillain-Barre. He did, he found it, he reported it and when the CDC investigated, they felt there was a

rise in the number of cases of Guillain-Barre relative to baseline, perhaps as many as one per 100,000, later adjusted to a level of about one per million additional excess cases.

And in the absence of any actual influenza from swine flu, the affect of a side effect of one per hundred thousand or one per million was enough to lead the health authorities in December of 1976 to suspend the immunization program.

What lessons can we draw from this? The first lesson is that as a policy matter, rolling up every aspect of the decision into a single go, no-go proposition, way back in February and March was premature and probably unwise and certainly unnecessary because there was additional information to be learned in the coming months that might guide and shape your policy decision. What was needed in February and March was a decision to start making vaccine, not more.

Related to this, as a policy matter, was the strategic error or flaw at the time, which was not

setting any moment or condition that would lead you to reexamine your decisions and ask what information might lead us to do something differently and what would that different action be? There was no opportunity, in other words, for resetting and reconsideration.

The problem that Phil mentioned of communication was a very real problem between policy makers and scientists and between everyone and the public. The Assistant Secretary for Health at the time, when asked in September, had anything changed, was able honestly to say no, nothing had changed compared to the spring. In the spring an epidemic was possible and in the fall an epidemic was possible, but the difference between possible at a level of 5-percent or 10-percent and a level of one or two per million is a big difference, even if the word possible applies to both.

The important lesson is that in 1976 the focus of policy makers and public health authorities was almost entirely driven by the worst case. Today, we

have to be careful not to make the complementary error of having all of our attention only on the most likely case. We need to have a capacity as a nation to deal both with what is most likely to happen and to be prepared in case it is worse to act and react responsibly so that we do our upmost to protect the health of the American public.

There are more lessons to be learned but in the interest of time, I will conclude at this point, turn the podium over to Dr. Fauci, and look forward to your comments and questions in our open discussion period. Thank you very much. [Applause]

ANTHONY FAUCI: Thank you very much, Harvey, Phil, it's a real great pleasure to be here with you now this afternoon. To just take up on what Harvey said so what I am going to discuss with you very briefly is Harvey gave you a magnificent history of an extraordinary period of time in the public health and public health policy era of our nation, really a defining moment. What I'm going to do over the several

minutes that I have is to talk about what's going on today and the analogy between what we are experiencing literally in real time on a day by day basis and what went on in 1976.

And I'm going to do that. Before we started Steve had asked me what is going to be the bottom line theme of what you're going to talk about? And it really is the relationship between what we experience every year in the seasonal flu and how we handle seasonal flu, what seasonal flu means, how viruses evolve, and the challenge that we are facing now with a real threat, with a pandemic influenza that we are experiencing right now.

So, starting off when you talk about seasonal versus pandemic flu, they are truly interdigitated. You cannot talk about seasonal flu without the possibility of pandemic flu and it's impossible to talk about pandemic flu if you don't understand what seasonal flu is.

So, very, very briefly, seasonal influenza is something that is exquisitely predictable. It occurs every year-let's take the northern hemisphere where we are right now-it occurs in the late fall and throughout the winter. In the southern hemisphere, it occurs during our summer and their winter. What it has, it has a characteristic that it generally, in a seasonal fashion, attacks a population that has a considerable degree of residual immunity to related viruses.

Now, that means that the virus changes a bit from year to year, the seasonal flu. It changes enough to warrant our changing the makeup of our seasonal vaccine, but it doesn't change enough to leave our population completely vulnerable to something that they've never experienced before.

To say it in another way that would be more clear is that we get vaccinated every year. We are vaccinating more and more people. We used to vaccinate tens of millions of people, now we vaccinate over 100 million people a year. If we did not vaccinate people,

heaven forbid that I as a public health person should say that, but if we did not vaccinate people, there still would be enough residual immunity in the population so that we would unlikely have a public health catastrophe, because the viruses that we experience this year are quite similar, not identical to, but similar to those that we would experience in the previous years. So, that is what seasonal influenza is. I'll get back to pandemic in a moment.

As Harvey alluded to, seasonal influenza is not something to be taken lightly. We have about 500,000 deaths globally, about 36,000 deaths a year in this country and about 200,000 excess hospitalizations.

However, as a nation, we generally, we're getting better at it now as we are bringing seasonal and pandemic flu together, we generally have not taken seasonal flu seriously enough over many, many years because people say well I have the flu. It doesn't kill a lot of people but in fact it does. It kills

about 36,000 people a year. We are getting much better at vaccinating people.

If you look now on the lower right of pandemic, what is that? That is something that is unpredictable and rare but the critical issue, it's new to what we call a naïve population. Mainly it's a virus that's new enough that the vast majority, maybe not everyone but the vast majority of the population has had not only no exposure to that virus, but they haven't had exposure to anything that's even related to that virus.

A small percent of the population, usually older people who have a lifetime of experience of seasonal influenza, generally may have some residual immunity, which we will get to in a moment when we talk about why this virus seems to be selectively attacking young people and older people seem to be relatively, if you want to use that terminology, protected.

So, what does pandemic influenza mean to the population? We have a history of pandemic influenza.

In the 20th century, there were three. One was the catastrophe that Dr. Fineberg mentioned where anywhere from 50 to 100 million people succumbed to this brand new swine H1N1, but we also had two other pandemics in the 20th century.

One was in 1957 which was a moderate pandemic in the sense that one to two million people were killed whereas on a regular year about half a million people died. What H2N2 in 1957 did is it bumped out of the picture the H1N1 that we had been experiencing yearly from 1918 up until 1957. So H1N1 kind of disappeared in 1957 and only came back at the time that Harvey mentioned in 1976 as a new swine flu.

In 1968, we had another pandemic by definition. It was new and the population was naïve, but it wasn't at all severe. It was not much different than a regular seasonal flu but by definition it was pandemic because it was new. Now, Harvey described very well the issue and the situation as it existed in

1918-1919. That's the defining benchmark that everyone is worried about. So what happened?

A few years ago, all of you know and remember that there was the appearance of a new virus which is fundamentally an avian virus, H5N1. It had the characteristic of being new, it was fundamentally an animal virus, so if you were a chicken in Southeast Asia over the last few years, you had a real serious problem. However, it did not do very well in humans. As of just a little while ago, it was about 430-40 case in humans with a very high death rate of more than 50-percent.

The sobering news is that it was very severe disease. The somewhat comforting news is that despite tracking it for many years, it does not and has not efficiently spread from human to human, so it doesn't have the characteristic of a pandemic of being able to be widespread.

However, in preparation for that H5N1, a series of pandemic influenza preparedness plans were

put forth. Good idea because those are the plans that are now being implemented today as we face yet another challenge and that is the new novel H1N1 2009. And, hesitancy to call it a swine flu, but as a matter of fact, tipping the hat to the agricultural industry, it doesn't make pigs sick to our knowledge, it doesn't give you flu if you eat pork. I've said it.

But, it is a swine virus, in fact if you look at the genes, it is a multiple re-assortment of genes that are from swine both in Eurasia and in the northern hemisphere as well as bird and human viral genes. They have all re-assorted. The critical issue is that it has been in pigs for at least the last 10 years. We don't know how or where or when it jumped species, but if you do the molecular epidemiology, it has been in pigs for at least the last 10 years.

It started off with a couple of cases that were recognized almost simultaneously in Mexico and the United States because things were going on in Mexico and then things appeared in the United States. And on

this map you can see there were a couple of cases in April of ’09 that were confirmed in the United States.

And just like you would expect, unlike H5N1 which has a really tough time going from human to human, this new H1N1 doesn’t have a lot of trouble going from human to human, so it did what viruses, particularly influenza viruses, do. It spread very rapidly so that by just a few days ago we have over 28,000 confirmed cases. And as you read in the newspapers, likely more than one million because now if you go in a doctor’s office and you have what appears to be a swine flu, there are so many people that have it, that many doctors don’t even do a test for swine flu.

In fact, I didn’t show the slide but if you show the breakdown of the flus that are occurring now in June, the vast, vast majority, more than 90 plus percent of them when typed are the H1N1 novel. It is completely bumped off the H3N2’s which are mostly seen during seasonal flu. In fact, if you look at the far

right of this slide, what you see is that little blip that occurred out of season. So in many respects the H1N1 swine flu now is acting like a seasonal flu that is out of season.

It should not be taken lightly because there appear to be somewhat more deaths and serious disease among young otherwise healthy people. More than 80-percent of the deaths and severe diseases are occurring in people with a cascade of underlying conditions, infants, pregnant, 65 years of age or older, or underlying immunocompromised conditions, but there is a small fraction that we don't understand of people who are otherwise healthy, so we have to keep an eye out for that.

It is spread globally, as all good pandemics do. There are now more than 70,000 confirmed cases in 109 countries and as you know, WHO has declared a flu pandemic. Now, we should in the question period get to, I don't want to take any of the allotted time, to talk about what do you mean by a pandemic? I'd love to

talk to you about that during the question period because it's a very interesting semantic about what a pandemic is or is not.

So, getting back to this implementation of a very well conceived preparedness plan, it is in full swing, with public health measures which were actually very good and a lot of credit goes to the CDC, the Department of Health and Human Services, and the FDA for the work that they've done over the last couple of months. The public health measures that were put into place were quite sensible, namely keeping people out of school and work who were infected, public health, low tech approaches that you hear about that some people sometimes smirk about, about covering your face when you cough, etc, etc. Those all are very important public health endeavors that do work.

And the other thing is where appropriate to close schools and they did that in New York for awhile and it was appropriate to do that. There's also the development of countermeasures in understanding the

virus. Now I show this slide because as we are preparing with tangibles and by tangibles I mean antivirals and vaccines.

There is a lot of good work going on at universities throughout the country and the world because when the CDC isolated the virus as they did very well, they distributed to the NIH and the FDA. And we sent it out to our grantees and contractors who are studying now the evolution of the virus, the molecular fingerprints of what virulence factors are, what transmissibility factors are, so that we can now make some statements that it doesn't seem to have the molecular makeup of high, high virulence that the H5N1 has, and as a matter of fact, it is being true to that because it's not killing a high percentage of people. And the same thing holds true with transmissibility. So we are going to keep a very strong eye our for those.

With regard to drugs, as you know it's sensitive to also Talavir and Zanamivir. It is

resistant to the adamantanes, Rimantadine and Amantadine, and hopefully we can talk about how resistance evolves when we get to the discussion period. I don't want to spend any detailed time on that right now.

This slide shows you some of the drugs that are available, the adamantanes, but as I mentioned it's resistant to the adamantanes and the neuraminidase inhibitors, particularly Zanamivir and also Talavir as well as some drugs in the pipeline that are here. We are not going to be able to use drugs like T-705 or Fludase this fall because as they say, they're promising but they are not ready for prime time.

And then I just want to close up on something that is quite important to the effort against any pandemic as well as seasonal flu is the development of the vaccine. These are the five companies that the HHS has long ago contracted with to use their license vaccine again for seasonal flu and I want to get back

to the seasonal flu preparedness. So they are all geared up to do that.

This is a flow chart of where we are in the process and I want to emphasis something that Harvey said which is absolutely critical to the process. If you look at the far left, the virus was isolated by the CDC for us. It was grown in what's called a C-virus to be able to distribute it to the different companies to make pilot lots. They make the pilot lots, they've done it, they're getting ready now and have already done it, given it to the different companies who will then start on producing it.

The NIH is responsible for doing the clinical trials that are going to ask some important questions. Now there are multi steps to this. There is the clinical evaluation, the development of a vaccine, and then you have the vaccine in your hand. The clinical trials will be conducted in sites in the United States that traditionally every year do this, not only with

influenza but with other viruses that we develop vaccines against.

So, what are the questions we are going to ask: Is it safe? Does it induce an immune response that you would predict would be protective? What is the dose and the number of doses? Will we have to use adjuvants? We may. That is going to be important and we can discuss that in a minute or so. And what about the response in special populations, like infants, pregnant women, the elderly, etc?

Importantly, and Harvey emphasized this, the decision to test, the decision to produce and the decision to administer are completely uncoupled which is different from 1976, whereas Harvey said so accurately, in one day, in one room, the decision was made to make and administer with no exit ramps on that approach. So, that even though we were seeing that there were no cases of swine flu throughout 1976, the train was out of the station. Right now we have

multiple steps along that way in which we can stop or go.

And I end with this last slide because everything that I've said is applicable to how we approach any influenza and when we get to the day and I hope it will be not too far from now, where we actually virtually universally vaccinate people for seasonal flu where the whole population is protected, we will already have the wherewithal to do the same thing if a pandemic came as opposed to putting it on emergency mode when you have a new virus.

So, I'll stop there and I'll be happy with Harvey to answer any questions you have. Thank you. [Applause]

PHILLIP NIEBURG: Well thanks to both of our speakers for a crisp explanation of what we know about what happened in 1976 and what we know and don't know about the current situation. So now we're ready for the comment period. The questioners' or commenters' microphone is over on my left, your right, and so

people should cue up there. Please identify yourself and I think what we'll do—

ANTHONY FAUCI: Can we stand there because I don't think all the people over there can see us. Maybe all of us can stand up and we can answer the question and you can just direct it at who ever you want to direct it at.

DAVE MCCONNELL: Thank you. Dave McConnell with WTOP Radio. Dr. Fauci, based on what you've just told us and all of the preparations being made and the analysis being done, what can you tell us about this fall? I mean how prepared are we for the worst frankly or whatever's going to happen down the line? What should we look forward to?

ANTHONY FAUCI: Well that's a very good question. What we will be looking at very carefully, which will inform the decision about whether to widely administer vaccine and if so, in what kind of a rush, mainly September versus October, etc. will depend on two things. What goes on right here in the northern

hemisphere between now and our fall because this virus has not gone away. There are still outbreaks in camps. There were outbreaks in certain schools and we're hoping but it could be that when the children go back to school, we're going to see that but importantly what's going to happen in the southern hemisphere, in Australia, New Zealand, Chile, Argentina, South Africa.

Having said that, we are now prepared to manufacture enough vaccine that we hope, and again as Harvey will back me up, when you're making vaccines, it's a soft science in the sense that a lot of things can go wrong, but if everything goes right, we hope to have vaccines so that you can be able to start vaccinating people if the decision is made to vaccinate people that we could start in the fall and vaccinate throughout the fall and get as many of the people, particularly in the high-risk groups, protected before we have a fall season with this.

DAVE MCCONNELL: But we're able, you're confident, we're able to do that?

ANTHONY FAUCI: As confident as you can when you're dealing with biologics. We have five companies that know what they're doing. We have a seed virus that's growing. We have experience in making H1N1 vaccines. Nothing is guaranteed but we're on the road to that.

MARGARET MCCLUSKEY: Margaret McCluskey, USAID. Thank you so much for what a wonderful historical perspective. Now let me ask you, we know viruses change quite a bit and I wondered, Dr. Fauci, can you address the likelihood of this virus and its' mutagenicity and the possibility that as time evolves that we might have cross-protection from seasonal flu vaccine and this potential new vaccines that we'll have for this. I know that's possibly unlikely but it would be a great advantage if that could occur. Then you sound a little worried about adjuvants. Can you go ahead and address that?

ANTHONY FAUCI: Well the data that we have right now indicates that vaccination against seasonal

H1N1 does not provide cross-protection against pandemic swine 2009 H1N1. However there is an interesting observation that hasn't been definitively nailed down but you cannot ignore it, that older people, people who were around 30 years ago, 40 years ago seem to have one clinical relative, I wouldn't say protection because that's too strong a word, less susceptible to this current H1N1 and if you look at antibodies in their serum, there's about 30-percent of them are cross-reactive with the H1N1 current virus. Whether they got that through exposure of H1N1 vaccines over several decades or whether they got it through exposure of H1N1 virus over several decades, we don't know but there's no cross-protection against the seasonal H1N1 versus the new H1N1.

With regard to adjuvants, we don't have, except for Allum, a FDA-approved vaccine that is using the adjuvants that are currently been used in Europe, the ASO3 and the MF59. So whenever you're dealing with a new product that hasn't gone through the FDA's

scrutiny over many, many, many, many people it isn't that you're worried about it. You just are less confident because there's some unknown there. The data from the Europeans looked pretty good with regard to safety. Most of it is in people older than 65 and not younger people. so I wouldn't say Margaret that I'm nervous or concerned about it but we watch it a little bit more closely than something that we've given every year for 50 years.

MARGARETY MCCLUSKEY: And pontificate, if you will, about mutations of this virus.

ANTHONY FAUCI: Well yes, the one thing you can say about influenza that's very predictable is that it's unpredictable. So can it change to the point of veering away from the vaccine we're making? Yes. Is it doing it? No. It has been remarkably constant from April when we first recognized it until now that when you isolate viruses, the molecular fingerprint of the virus is remarkably similar and unchanged. Does that mean that it won't? We don't know.

I think, as an immunologist/virologist, one of the reasons that that likely is the case is that viruses change when they have pressures, evolutionary pressures, to make them change. You treat them with a drug, they become drug-resistant. You make an immune response against them and they tend to try and escape that by mutating. Since the population is essentially totally virgin and naïve to this, there's no evolutionary pressure to make the virus change but that is not going to be that way forever.

MARGARET MCCLUSKEY: Thanks very much.

PHILLIP NIEBERG: I just wanted to take the moderator's prerogative to ask Dr. Fineberg a question as a follow-up to what we just heard. That is we've talked about uncoupling the decision to make the vaccine from the decision to administer it. What kind of changes, what would make a decision to administer the vaccine more likely? In other words, what kind of increase in mortality or what kind of increase in attack rate do that and what can you say about

translating, having scientists translate those numbers in a way that policy makers can make good decisions with?

HARVEY FINEBERG: Thank you. The next few months will tell us a lot and especially about the pattern of this virus and disease clinically in the southern hemisphere of the countries that Tony alluded to in his comments. One of the things that will need to be decided about the administration of a vaccine is to whom do you target in the first instance? In the usual flu season, we're especially concerned about the elderly.

Dr. Fauci's already mentioned that in this type of influenza, there's some reason to believe that the elderly, I include those over age 60, may be relatively protected as compared to a standard flu season. Keep in mind that when you have vaccine and the manufacturers provide it, they're not going to have delivered on September 15 or October 1st, the entire

[1] The Kaiser Family Foundation makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

six months' supply of vaccine. They're continuing to produce. They'll continue to deliver.

Very important decisions are going to have to be made about how to deploy the earliest batches and to utilize them in what particular populations. So that's among the critical choice points that we will learn a lot about and help in shaping choices over the next couple of months.

I might just add one final note. From my vantage point, the greatest vulnerability that we have in the entire process is the highly variable capacity to deliver large amounts of vaccine to targeted populations in specific areas of need in a timeframe that will protect the population optimally. If you think about it, if you administer 100 million doses over six months, what different do you need to do to be able to administer 200 million doses in two months? Will the standard mechanisms suffice? Do we need to take new kinds of steps for implementation? Those decisions also will be unfolding over the coming months

and I think very much informed by the scope and nature of this epidemic over these months especially in the southern hemisphere.

SUSIE PEALE: Thank you very much. My name is Susie Peale and I work on health communications. I heard very clearly Dr. Fauci saying there's H1N1 seasonal and there's H1N1 swine. From a communications point of view, it would be awesome if like certain groups, we could call it SO H1N1 as opposed to H1N1 or some denomination that allows the wider public to distinguish between these because I know they have different characteristics.

Then I wanted to take sort of enter into discussion with Phil Nieberg actually, you were talking about complex technological information transfer from gentlemen such as our speakers to the political community to the general public. I would like to counter that the information will actually be held in the community.

People will know who is getting sick in the classrooms, the teachers, the school nurses, the moms will be talking to each other and is there not a way to focus, as we did with Obama for America or with, you know, twittering, which I don't know anything about, and all of that but social networking because that's where it's going to be happening and we need to be communicating from the edge to the center just as much from the center to the edge. Thank you.

PHILLIP NIEBERG: Well I guess my only comment on that is that there are a number of different efforts under way to look at new ways of collecting data surveillance essentially on diseases in terms of exactly what you're talking about, local community numbers in terms of using communication modalities such as twittering and other electronic means. So obviously particularly because our public health system has been under funded for a while, we're going to need help from as many different directions as we can get.

SUSIE PEALE: I'd like to just put out there the notion of a social vaccine since we'll be waiting for the adequate number of doses if we can get people adequately informed and prepared on social distancing. We've got the hand washing down. We're not too clear on masks and how to cough and sneeze but the social distancing and the trigger points for closing or not closing schools, I think, we could do a lot more in that area. Thank you.

GENE BONVENTRE: Good afternoon. Gene Bonventre from CSIS. A question mostly for Dr. Fineberg. Indonesia has expressed concerns about sharing samples of the H5N1 vaccine. Nigeria has expressed concerns about the polio vaccine, which have been addressed. But to what extent do you anticipate similar problems with the H1N1 pandemic and to what degree has the medical community engaged the diplomatic community and the religious community to address those issues.

HARVEY FINEBERG: I think the acceptability of vaccine and willingness to undertake immunization is a

very real concern both domestically and internationally. I feel that one of the things that is different to 30 or 40 years ago in the United States is that there's actually now a significant movement of resistance to vaccines and particularly in childhood vaccines and particularly because of the concerns about autism and its' alleged connection to vaccines.

So we have a serious need for communication and understanding domestically in the first instance as well as global communication with countries around the world. When you get to a policy challenge like influenza, one of the great dilemmas, I think, will be when a policy maker might be convinced that it's sufficiently risky that people should now be immunized and protected ahead of where the public is convinced that it's sufficiently risky to me that I and my family should now be immunized. This is going to take a continuing communication.

I love Susie Peale's point about it as a two-way communication from the field and families to the

public health authorities and the policy world as well as from the public health leaders out to the public. If we can do that domestically, we then still have to face the challenges you described of global understanding. This gets to a point Phil, that you'd raised just briefly, and I'd love to hear Tony's comment on it as well, which is how the United States should position itself in the global struggle of protecting against a pandemic, which is after all by its' meaning.

And Tony, if no one else does, I'm going to ask you what you mean by pandemic, which you can also comment on. But how do we help the world prepare? What's the role of US? And I think that would get to the other part of your question. Let me invite Tony, if I could, to comment.

ANTHONY FAUCI: Well first, thank you Harvey. Two points, the idea about what our responsibility is, we do feel an important responsibility on a global level because we have become increasingly aware of over the past couple of decades that we do live in a global

community and we have responsibilities to countries that are less fortunate than we.

We have a primary responsibility to the United States of America since we're the public health system of the United States, but the idea, and I think the best way to do that Harvey, that we're trying, is to help build in-country capacity for those nations that don't have it rather than always giving them vaccine or giving them drugs to give them a sustainable capacity the way we have tried to do in other areas like HIV and malaria. So that's going to take years. It's not going to happen this season but I think that's the most important thing that we can do. A—we have the responsibility and we can do it by helping the countries help themselves.

The issue of what a pandemic is the reason I somewhat tongue-in-cheek, mention that when I was giving the formal presentation. As you know there was some concern about the delay on the part, if you want to call it a delay, of the WHO of going from pandemic

level five to pandemic level six in which that's a real pandemic, which got a lot of us to try and ask, so what do you mean by a pandemic?

The WHO definition was really one of geographic spread. It didn't address the number of people infected nor did it, in any way, address severity of infection. So a level five means you have sustained community spread in two nations within one region. The two nations were Mexico and the United States. The region was the western hemisphere.

When you had an additional country in which there was community spread in a different region then it automatically becomes level six or a true pandemic. Now that really is semantics because was it Spain that kicked it over or was it another country that kicked it over? It really is almost irrelevant to what we did in the United States because we were gauging what we do on the severity and the main purpose of the CDC was to mitigate the severity and to treat people and try and

prevent spread from person to person within the United States.

So get back to the definition of a pandemic. You could really bring it down to almost something very simple. If an epidemic is an outbreak and the definition of epidemic is much more clear and crisp than the definition of a pandemic. The definition of an epidemic is an outbreak of a disease over and above the baseline of what you see that disease in the population. So you can have an outbreak of measles in New York or you could have an outbreak of RSV in Pennsylvania. So a pandemic is a really big epidemic. So that really is what you can say it is mainly widespread.

A lot of people have secondary type definitions. Should you include severity in it, I believe you have to include some degree of severity because you could have an epidemic of body lice throughout the world or a pandemic, would you really call that a pandemic? It doesn't even have to be an

infectious disease. We talk about the pandemic of obesity, yet it doesn't spread from person to person. So there's a lot of iffy things. Mostly it's a widespread outbreak of disease throughout the world.

MARY PENDERGAST: Mary Pendergast, Pendergast Consulting. First, I'd like to ask a question about antiviral therapy. Assuming not everyone is immunized or assuming some people have breakthrough disease, what is the government thinking about in terms of monotherapy, drug resistance, multidrug therapy, how are you approaching this in terms of what you've learned from HIV, hepatitis, and other viral diseases? We've seen the beginning of resistance to monotherapy in regular seasonal influenza. What do you anticipate happening in the future?

ANTHONY FAUCI: Well I'll start off. With any virus, particularly a rapidly replicating RNA virus, you will inevitably have resistance if you treat widely and if the pandemic pans out as it is having now throughout the world, there will be widespread

treatment. So I would not be surprised if there's not the emergence of resistance against the one class of drugs to which the swine H1N1 is sensitive, namely the neuraminidase inhibitors, Tamiflu, and Relenza or Zanamivir.

It is already resistant to the adamantanes. The question that you ask is an important one. Like all other rapidly replicating mistake-prone viruses like RNA viruses that if you treat with a single drug, you will select for resistance. The favorable situation that we have with HIV is that we have 30 FDA-approved drugs that you can give in combination usually of three. So the reason why we're so successful now in 2009 with HIV is that we have drugs that hit multiple targets: reverse transcriptase, protease, integrase, binding fusion inhibitors. So it's easy to let that virus get suppressed without selecting for resistance.

The problem with influenza is we fundamentally have ready for primetime, namely that you could actually use, we have several in the pipeline, two

classes of drugs. The neuraminidase inhibitors and the adamantanes. They're already resistant to the adamantanes.

So by definition, the only combination that you can give is two of drugs of the same class or there's one now that is an old drug but it's a polymerase inhibitor, Ribavirin, that has been used for other viruses but which is somewhat toxic. So the bottom line of what I'm saying is we don't have many options. The answer to avoiding resistance is combination therapy, good news. Sobering news, we don't have a lot of combinations to use.

So the principles are there but we can't practice the principles because we don't have a lot of drugs that we can use in combination.

MARY PENDERGAST: Thank you and I have one question about the swine flu from 30-odd years ago when I was in the public health service working on the adverse events side of it. You made an intriguing suggestion that maybe it wasn't the swine flu that

caused Guillain-Barre' or we're not 100-percent certain. What do you know some 32 years later about the adverse event profile of that swine flu vaccine and what do we know about the immunology of adverse events with respect to this type of vaccine?

HARVEY FINEBERG: One of the oddities about the Guillain-Barre' association with the swine flu vaccine of '76 is that when a similar association has been sought with flu vaccines of other years, it has not been found. About five years ago actually, the Institute of Medicine had a group convened to reassess the evidence and they're overall assessment was that there probably was, not with certainty, an elevated risk but more likely at the lower level of one per million.

Guillain-Barre' itself is a very intriguing ailment because of its' presumed association with prior infection. Many people who contract Guillain-Barre' appear to have recovered from an earlier viral infection. So there is that kind of loose connection,

which makes the vaccination plausible but the fact that it's the only flu vaccine that appeared to have this excess association leads to a degree of skepticism because it's possible by chance simply to get that level of excess association.

Now having said all of that, it's very important to track the profile of side effects from a major vaccine program. You have huge numbers of people who are exposed and even a relatively rare side effect, therefore can loom large in the case of a widespread immunization program. The truth is if there had been a swine flu outbreak in 1976, the one in 100,000 or one in a million case of a condition that was one in 20 fatal would have been background noise against the value of the vaccine.

Finally, keep in mind that under usual circumstances, the flu vaccine even when it is prepared against the best judged virus of the winter is probably, on average, 60-percent or 70-percent effective in the next flu season in terms of reducing

the burden of illness compared to the population that's not immunized. Now that's a very important degree of protection personally but also for reducing the likelihood of spread in the community, but this is not a perfect vaccine even under the best of circumstances. Do you agree with that Tony?

ANTHONY FAUCI: Absolutely.

HARVEY FINEBERG: Yeah. Okay.

JULIE RONES: Hi, good afternoon. My name is Julie Rones and I'm with the House Oversight and Government Reform Committee and we actually had a briefing on H1N1 last Monday. We had a briefing with the vaccine manufacturing companies, four out of the five that you listed, and we learned a few lessons. I want to just ask you about some of the things that they brought up in that briefing as well as I have a two-part question.

I guess in terms of the vaccines, there seem to be questions regarding timing, regarding regulatory needs, and also in terms of collaboration. What they

had said was that two of the companies had patents for adjuvants. They offered to work collaboratively in terms of increasing the capacity in the United States to produce the vaccine but suggested that there was a need to get together on a regulatory effort to maybe trigger emergency use authorization.

I wondered what your thoughts were about that. Also to the degree of talking about the differences that you see in terms of using a live culture, which I understand, doesn't need to have adjuvants - you can take it nasally - and also a DNA approach to perhaps rapidly being able to increase capacity over a short period of time and do so in a safe way.

The other part of that is the HHS Secretary has indicated that she thinks that adolescents need to be a priority targeted population because of the indications and she has started meeting, I understand, with the states about using schools as a source of giving the vaccine. If you could talk about your views on those two aspects, I would appreciate it. Thank you.

ANTHONY FAUCI: I have to have a good memory here. Okay, so vaccine companies, adjuvants, etc. So the companies that were, first of all, an excellent question because these are things that are not particularly well understood. The companies that I mentioned, if you use unadjuvanted antigen from H1N1, these companies already are licensed for influenza A as well as B to make for seasonal flu. So the transition from getting those companies to use an unadjuvanted product that's now being grown up for pilot lots and being tested is going to be a smooth process because they're already licensed for doing it.

We're going to have to do some clinical trials because unlike the real seasonal flu, the thing we don't know is what the right dose is. 15 micrograms per dose in a single dose in seasonal has been well established. We hope and we think it's going to be that for the H1N1 but we don't know but once we get that and some reasonable safety data, it's a smooth transition to get product available for administration.

The point that the companies were making about adjuvants is that we don't, in contrast, have an FDA-approved adjuvanted influenza. So the FDA is going to need to combine the safety data that we accumulate - close examination of the safety data that's been accumulated in other countries - to make a decision as to whether or not they're going to officially approve it as a vaccine.

So let's fast-forward to September or October. Suppose we get to September or October and things are really bad - the multiple scenarios that we map out every day on conference calls. So suppose we get there and things are bad? School is starting. The children are starting to get infected. We don't have enough vaccine. We may need to use adjuvant.

If, in fact, the adjuvant has not been officially approved, we can use it on what's called an emergency use authorization or an EAU where the FDA has the authority, through the Department, to say that the risk/benefit for giving a product that isn't fully

approved yet, because we don't have enough data, weighs heavily in favor of using it on an emergency use authorization. That's all that means. So we may or may not need to invoke an emergency use authorization but it's there in case we need it.

SUSAN OKIE: Hi, Susan Okie. I'm a freelance medical journalist. I heard Dr. Fauci, I heard you say that there's some immunity in the population of those of us who were around enough years to have been exposed in 1956 to H1N1. There was some cross-immunity. No?

ANTHONY FAUCI: The '50s was, '57 was H2N2. H1N1 was around up to '57 and then disappeared until '76 and then '76 on.

SUSAN OKIE: Okay. So pre-57?

ANTHONY FAUCI: Yes. So it's either pre- or beyond '76.

SUSAN OKIE: I guess my question is since you said you would favor going to universal immunization, seasonal immunization for flu, as a population, would we lose anything by not having as many people naturally

exposed to the infection on a seasonal basis? Would we eventually be in a position where cross-immunity in the population would not be as good? Do we know that?

ANTHONY FAUCI: Well Susan, you can't have it both ways but if you vaccinate enough to protect against infection, you're good to go. if your vaccination isn't covering it as well and you get people naturally infected, they then are naturally protected. So if you add them both together, the ones that you protected are actually immunologically immunized in the sense of being protected. There will be a certain percentage, even the best of worlds, as Harvey mentioned, you're not going to get everybody protected.

You may get, in elderly individuals for example, it's 50 to 65-percent protection. In young, healthy adults, it could be as high as 95 but probably somewhere around 80. So even in the best of possible worlds of universal vaccination for seasonal flu, you'll have a varying proportion of the population who

will be susceptible because the vaccine did not protect them.

DAVID DIXON: Hello. I'm David Dixon. I'm with LaRouche Political Action Committee and perhaps this was taken up in your part of the panel, I wasn't here for that, excuse me, but my concern is with the implementation of vaccination. This was partly taken up in the last question. As you guys know, the French government is taking measures for universal vaccination or whatever that does end up covering but should we be concerned because I'm not exactly sure of the mode in which we usually administer vaccination but if that mode is through regular health care providers like HMOs, PPOs, should we be concerned with the level of drop offs due to the unemployment rate and the overall 26-year low of enrollment in HMOs period?

HARVEY FINEBERG: Well my answer to your question, to the basic question is yes but not for the reason that you pose. That is, I believe we should be concerned about our nation's ability to immunize the

right people in sufficient number in a timeframe that's sufficiently focused to provide protection against a threatened pandemic especially if it is at the more severe end of spread and severity.

But, the reasons why we should be concerned aren't specifically drop off and enrollment to HMOs. It's that today in the U.S., we have a very diversified mode of administering of vaccines. We use the private sector. We use the public sector. We do some immunization in places of employment but not everywhere. We do take advantage of practices like HMOs that are large practices but we don't generally organize to have people on a regular schedule assigned to come to get their immunization. We expect them to come on their own.

Using schools as a base and a vehicle for immunization against influenza would be a new use of the school-based population that is, in some sense, available so that you could immunize large numbers in a

relatively concentrated time with relatively concentrated resources.

So the big challenge, I feel, is getting organized throughout the country to administer what we'll need to administer especially if it's a bad case and to do it in the timeframe that will protect the public. Do you want to add anything to that?

ANTHONY FAUCI: No.

PHILLIP NIEBERG: Okay. One last question.

BEN SHEPPARD: Ben Sheppard from the Institute of Alternative Futures. To what degree are your discussions focusing on risk communication to ensure that the public understands messages regarding the safety and efficacy of the vaccines? You've touched on this a bit earlier particularly on social networking websites and also the aspect that you may need to use an emergency use authorization, which makes some people believe that the vaccine's probably not safe to use. If you are requiring people to go for second dosage, which would be effective, and they choose not to do so, you

may have more of kind of a complicated situation on your hands. What do you do?

ANTHONY FAUCI: Yes. You are absolutely correct [laughter].

HARVEY FINEBERG: The communication is going to be very complicated and it has to be simplified. it needs to be direct and meaningful to each of us as a citizen, as a family member, as a part of our community. We are going to have to work very hard as a community of public health specialists and physicians and other caregivers to reach out to people to hear their concerns and to be able to convey what the tradeoff of risk and uncertainty is for each individual and lead people to make an informed choice.

For most people, if there's a very widespread disease that is threatening especially young adults or children, I think most people will want the immunization. They'll want to gain the measure of protection that they can. They will want to do that knowing what the tradeoff of uncertainty and risk is.

But it's up to the authorities and the leadership in the health community to convey as accurately as we can exactly what that tradeoff is and give everyone a chance to make his or her own decision.

PHILLIP NIEBERG: Okay, well with that, actually I would like to thank first, the audience and then I'd like to have the audience join me in thanking Dr. Fineberg and Dr. Fauci for giving great presentations today [applause]. Thank You.

[END RECORDING]

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