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POLICY FORUM

BIOTERRORISM AND SMALLPOX: RING CONTAINMENT, MASS VACCINATION, OR INDIVIDUAL CHOICE?

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Featuring:

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P R O C E E D I N G S

MR. MILLER: Good afternoon.

Our forum today is "Bioterrorism and Smallpox: Ring Containment, Mass Vaccination, or Individual Choice?" We will be discussing smallpox, this old and deadly killer and what it poses in the wake of what we learned on September 11th and the direct mail delivery of anthrax last fall. We are also asking whether our national policy regarding access to the smallpox vaccine needs a shot in the arm.

The Federal Government has begun to expand its stockpile of smallpox vaccine, but it hasn't fully determined what to do with it as it has more of it. The general public hasn't received smallpox vaccinations for about 30 years in the United States. Recent policy has been that even in the wake of the new bioterrorism threat, the government would withhold the vaccine from the public and administer it only after confirmation that an outbreak has occurred, using a geographically limited ring containment strategy.

That policy is now under review. The Department of Health and Human Services and the Centers for Disease Control are planning to hold a series of forums later this month before announcing their final revised policy recommendations for smallpox vaccinations. The CDC's Advisory Committee on

Immunization Practices is meeting in Atlanta in a couple more weeks, and they should be finalizing the strategy coming out of that meeting.

But the first and foremost public form, of course, is right here at the Cato Institute. We will examine the risk assessment and the policy options for smallpox and bioterrorism, including greater individual choice in making those risk assessments -- a preemptive mass vaccination strategy or variations of the older ring containment strategy.

Our first speaker will be Dr. William Bicknell. He is Chairman Emeritus and Professor of International Health, of Sociomedical Sciences, and also Community Medicine at the Department of International Health as the School of Public Health at Boston University. He received his master's in public health at the University of California, Berkeley. His medical degree is from Duke University Medical School. Dr. Bicknell also has his bachelor's of science from Johns Hopkins University. He is the founding Chairman of the Department of International Health at Boston University. Previous to that he was the founding Director of the Center for International Health there.

And he particularly came to our attention with his excellent article in the April 25th New England Journal of Medicine, "The Case for Voluntary Smallpox Vaccination." He has been in some of the follow-up meetings since then.

Dr. Bill Bicknell.

(Applause.)

WILLIAM J. BICKNELL,

BOSTON UNIVERSITY

DR. BICKNELL: Thank you very much, Mr. Miller.

It is a pleasure to be here today. The other part of my background that may have some relevance is I was Health Commissioner in Massachusetts for a number of years in the seventies, and some of the strengths and limitations of health departments I am familiar with.

We are going to talk about uncertainty in the health system, and particularly choice, public health, and public policy. I would like to address the risk of attack; ring containment, can it work; vaccine risk; liability issues; and alternative options. But I think, before we get into that, we need to know something about what is smallpox, what about the vaccination, some basics.

I would like to get risk of attack off the table. I think it is going to come back on the table a bit later with another presenter. But what was the risk of 9/11 on 9/10? It was unimaginable. All I know is that every responsible person I have talked to who has any knowledge of smallpox at the Federal

level thinks that it could be outside the two repositories. The Russians think it could be outside their repository. It was weaponized there. So I think there is an unknown but not nontrivial risk of terrorist attack. Certainly we bought hundreds of millions of doses of vaccine, and other nations are doing similarly -- at least the U.K. is, and I think Germany. So we need to know about the basics.

It is a highly infectious disease. There has been some recent talk about, "Oh, it's hardly infectious at all." One person was quoted in Science a week or two ago saying that. That is dangerous and in error. The mortality ranges -- and it is rare to get as low as 5 percent -- but between 5 percent to 50 percent. It is usually between 20 and 30 percent. In kids it's higher. It is highest in young children. There is no specific treatment. In the U.S., about half the population is not immune -- everybody born after 1972. If you were born earlier than that, there is some residual immunity. Nobody really knows how much.

How does the disease work? I cough on Mr. Miller -- I'm a terrorist -- it's well known -- he does not notice much, and in six or seven days he starts to get sick and feels lousy and flu-like and feverish. He is really feeling badly, and then he starts to feel better. His temperature drops. And that is when he becomes infectious. He does have a rash. It is inside

his mouth and throat. He doesn't see it. Nobody else can. And only several days after that does the rash move to the skin and become the classic rash.

So it is a bit of a myth that you are so sick and it is so visible, you will be found and isolated or too sick to move around. That is just not correct.

And terrorists are motivated folks. I once had a fever of 103.5 and had to present to our university president, who was a bit of a bear. And I somehow dragged myself there and did just fine. I think terrorists could do similarly.

A good contact is within six feet. Think of the Metro in the morning. Think of airports. And let's find out, how easy is it to transmit? Let's take a look at some historical examples. This is a quote from Dixon's book from the early sixties, citing an event in 1913:

One person with smallpox arriving in the country, traveled by train... he was apparently in the initial phase of the disease, as nobody noticed a rash on his face. Almost everyone who traveled with him... contracted smallpox, the ticket collector and those who traveled in another train... Something like a hundred cases being infected from a single case.

Not so different from flying in from Europe, or Boston, down to here, where the air is recirculated. Take a train to the next city, et cetera.

Other examples. There was a very well-known case in Yugoslavia. No rash in the primary case, and no evidence of it when the person recovered. There are many examples of easy transmission. And there are also examples where it is not so easy to transmit. But I do not believe we should count on the "sometimes it's not so easy to transmit." Better plan for the worst and hope for the best.

If the disseminator is not a walking disseminator or a walking bomb and has an aerosol, it's worse yet. You will never find them.

This is a slide from Dixon. This is people in the community who were unvaccinated, the risk of getting infected. And here it is 15 percent. And between the ages of 10 and 25, somewhere between 30 and 50 percent of the people in the community -- not in the household -- got infected. This is the household ones, the dark lines. It is a pretty infectious disease.

There is the four-day window we hear a great deal about. Get them in the four-day window and you're safe. The actual hard evidence that I have been able to find is 21 cases from an epidemic in 1946, in Tripoli, where 21 people were

identified who had not been vaccinated, who were vaccinated within five days -- not four days -- all got the disease. None died. Most were a mild disease.

There is a lot of anecdotal evidence that if you vaccinate within four days -- from the eradication years -- the disease is less serious and might be prevented. That is the evidence for the four-day window. It is real, but it is very hard to get in that window. And it is by no means absolute if you do get in the window.

The vaccine, it works and it works well. There is now plenty for everyone, with dilution, and the new vaccine is being delivered as we speak. So there is not a vaccine shortage.

It does have more side effects, including deaths, than other vaccines currently in wide use. The people who die and have the most severe side effects are kids 9 and under. That is of use to us. Accidental inoculation and the consequences of that are most serious in kids. And what usually happens, you're playing in the sandbox or on the playground and it's kid-to-kid transmission. If you do not immunize kids 9 and under -- using the 1968 data, which is the latest data in the U.S. -- about 80 percent of the serious complications and deaths would be avoided.

There is evidence from recent dilution studies that a dressing that is kind of a clear dressing which looks like a clear band-aid, a double dressing prevents viral shedding. That

can protect the immunocompromised and it can protect others from accidental infection. Dermatitis is tricky -- that is, skin rashes in people. But the severe complications for people with dermatitis tend to be more in children than adults.

The new vaccine, people think it is going to have about the same complications. The people at CDC believe there is no reason to think that it is going to be much different in terms of complication than the old. And there is, for some but not all, complications, and a human blood product, a vaccinia immunoglobulin, that works for some, but not all, vaccine complications.

Our challenge is that we have limited current knowledge about smallpox. And there is not a person, to my knowledge, in the world who has addressed this issue of epidemic control of smallpox in the non-immune population experience. The trouble is we have people who successfully, triumphantly, and wonderfully eradicated the disease and who wish to apply disease eradication techniques to an epidemic exposure. And that is a serious flaw in my opinion.

The magnitude of attack -- plan for the worst, hope for the best. It is probably going to be malicious and well executed -- I think we should think that -- with multiple terrorists going to multiple cities. It is a race. Getting in the four-day window is extremely, extremely difficult. Let me

just give you an example of why it is so hard to get in the window.

I go to the airport tonight and I bump into a terrorist. I'm infected. I'm in Boston. Seven or eight days later, I start to get flu-like. I first get the rash. Nobody thinks it's smallpox. Maybe 15 days from the moment of infection, my God, Bill has got smallpox. And I've now contacted any number of people in the last four or five days, before that diagnosis is made. The terrorist has contacted me and others. My four-day window is 10 days, 11 days before. Getting into the window seems to me, logistically, epidemiologically, biologically, virtually impossible.

Some very sophisticated modelers took a look at identical situations and compared the CDC approach, which they call trace vaccination, ring containment -- whatever you wish -- with mass vaccination. One thousand people in New York, with assumptions favorable to the CDC approach, they came up with these results. And both started at the same time.

If you did the best job you possibly could with ring containment, the best job you possibly could with mass vaccination, in New York City, ring containment gave you a growing epidemic at 100 days, with 300-plus-thousand cases, close to 100,000 deaths. Mass vaccination after the fact, it was all

over in a month or so, and the cases were a bit under 2,000, with more than 500 deaths.

This is information that needs to be seriously, seriously looked at and thoughtfully and openly considered and discussed by the Centers for Disease Control as they revise their approach.

This is a model of my own. This is a terrible case, and let's hope it never happens. This is 10 terrorists to five urban areas, 500 close contacts within six feet. You hang around National or the subway station until you have bumped into 500 people. A 40 percent infection rate, 30 percent mortality, 5 percent of the people who are contacted go to other cities, and then the rates of transmission beyond that are progressively lower but still high at 10, 7 and 4. By day 11, it is in 100 different cities and towns around the country. And by 45 days you have a million deaths. That is horrible.

This is a better case, in the sense of not such a worst case. Five terrorists to three cities, 200 contacts, 20 percent mortality, lower infection rate, lower transmission of secondary and tertiary people infected. Still, you are in 21 towns and cities by the 11th day, and you have 114,000 cases by the end of the month, and ultimately 22,000 deaths.

And the model, which I don't know if it is pasted and distributed there, but control isn't going to start kicking in until around day 15. And that's a problem.

Ring containment works for disease eradication, but it is not good for a mobile population, as we have now. The assumptions by CDC are unrealistic. In brief, it is a plan that probably cannot work. It is a plan that is inadequate for a mobile population, with low to absent immunity, and a malicious exposure in multiple cities.

The Feds have taken, I think, another approach which I find very disquieting. They will keep the vaccine and decide which States should or should not get it and where priority rests. But they go on to say that their capacity to be of help will be quickly overwhelmed. So CDC keeps the vaccine, and the States are left holding the bag. It is rather like saying, go out, fight the enemy, I'll keep the bullets.

If I were a State health officer, I would be very, very distressed. I would want to get access to my own supply of vaccine before the fact. And there may be varying approaches States may want to take. The risk and the definition of first responder might be different in South Dakota than Los Angeles or New York. States may want to give advice to their citizens as to their perception of risk, and they may want to define first

responder differently and have some variation in plans to reflect their own reality.

Who should decide what? Attack risk is unknowable, I believe, at the present time. Personal risk can be illuminated, as we are doing today. People, you and I, we make decisions about everything, far more difficult than should I get the smallpox vaccination or not. Informed consent for research protocols is everywhere, and that is very complex.

Do I want, if I am a woman, a C-section or a vaginal delivery? That is an important decision and more complicated than getting a vaccination.

Angioplasty, open-heart surgery, medical treatment -- all these things are more difficult and have really more risks associated with them than smallpox vaccination. So saying that this is too tough for you and I to decide I think is both wrong and arrogant.

Pre-exposure -- why? It decreases the consequences of an attack. The more people who cannot get smallpox, the fewer people who get it and the fewer people who will die. It is real simple. It may decrease the likelihood of an attack. It provides the best protection for the immunocompromised. You vaccinate in a non-panic situation. They are isolated and protected. And the people at greatest risk of both vaccination and smallpox are the immunocompromised.

It is low cost and easy to do as part of ongoing care. It recognizes the limited surge capacity of our medical systems and hospitals and the near impossibility of quarantine. If there is an attack, it makes containment and control easier. It decreases panic and it helps to maintain order, and it minimizes interruption of the nation's normal business. It is realistic. It is easy. It has face validity. And the more people who opt for it, the better it is. It will protect the most people at the lowest cost.

There are some other vaccine issues which we have talked about and alluded to. The immunocompromised, people say, my God, they're so bad off, but pre-exposure with forethought does provide a calmer atmosphere. Dr. Bartlett, from Hopkins, presented at CDC. And his point was that if your CD-4 count is above 200, it is probably likely that you are not at any more risk of vaccine complications than people in the general public. But even if that is not the case, you might not want to immunize anybody beforehand.

And let's say you exclude the immunocompromised and you use occlusive dressings, like described by Dr. Belshe, the immunocompromised can be very well protected without a doubt, I think. And in a crisis situation, there will be over-vaccination, inappropriate vaccination, and there will be more risk to the immunocompromised.

The accidental vaccination of contacts with vaccinees. It is rare. It is mostly in household contacts. It is mostly kid to kid. And the answers to all these things, I think, is pre-exposure. Don't do kids under 9. Use the dressings described by Dr. Belshe. And then I think you have the risk down to really low levels.

And to prove that, and before just going willy-nilly with the whole population, I will get to what to do. You want to inhibit the epidemiological pump. If people get sick, they go to hospitals and emergency rooms. So you want the people who work there not to be the transmitters. You want to let them be the treaters and not the transmitters. So you certainly want to immunize all the front-line health workers, hospital staffs, and the like, and some group beyond that. How far beyond that is a matter for great discussion. But certainly I would say you want to immunize enough people so you can keep civil society running, as a minimum. That is how I would define first responder.

Liability is something that people are not adequately talking about. It is outside the scope of my expertise, but there needs to be Federal legislation that protects everyone in the chain of delivery, from the manufacturer down to the person who is putting the vaccine into your arm, with transferred liability to the Federal Government, limits on that liability,

and provision for fair compensation, within limits, to individuals.

So, what to do? Careful guidelines to protect the immunocompromised and others. Vaccinate 100,000 first responders. Watch, see what happens. Ask them to give blood so you can build up the supply of vaccinia immunoglobulin. Then, based on what happens, if it works well, go to a quarter-million and a half-million. Watch. Do it again. Go to all first responders. Then, if that goes well, look at the results, revise the guidelines, and make vaccine widely available to adults and kids over 9. And that I think is a very sound, thoughtful way to go in terms of public policy.

We do not need to go into the details here. They are in front of you. There are some objections. Some people feel our medical care system is unfair and therefore the distribution of vaccine will be unfair. And until we have a just social order, we should do nothing. I don't think we can solve all social problems through responses to bioterrorism.

Wait for new or safer vaccines? They are years away at best. And there are some who feel that unless we are prepared to vaccinate the rest of the world, we shouldn't move ahead.

Voluntary vaccination here will give signals to others, which will suggest that we have smallpox as a weapon and we are about to do something. I think these are foreign policy issues

and I think the protection of our public takes some precedence over such issues. And I think they can be treated separately and they do not need to, if you will, contaminate each other.

It is not logical to say that this is so bad that no terrorist would ever do it, because it could boomerang. But terrorist logic is not our logic, and I don't think we can rely on that.

The likely results are we would have 50 to 70 percent of the adult population vaccinated. There would be very few complications and deaths. There would be much decreased risk to the immunocompromised. There would be vaccinators and supplies in place in case of an attack. Containment and control would be far easier. Hospitals and health care systems would not be overwhelmed. And you have a good example of sound, proactive public health.

CDC should do guidelines for pre- and post-exposure and provide technical assistance. States should address risk. Individuals should make their own decisions based on good advice from Federal and State government, opting or declining pre-exposure vaccination.

I will not go over the options in detail, but basically those to the left of the screen are not as good. Those to the right are as good. The more you do in advance and the quicker you respond broadly after an attack, the fewer side effects and

deaths you have pre- or post-attack. Of course, if there is no attack and you do nothing in advance, you have no side effects. But you are left with that uncertainty, which I think is not a tolerable uncertainty with our knowledge today.

This merely reiterates what I have already said. And I would say that what we need to do is be public, have open discussion, have an informed public debate. It is very possible that this can be a win for everyone. We can protect the public's health and strengthen the public health system.

Thank you very much.

(Applause.)

MR. MILLER: Thank you, Dr. Bicknell.

For a different viewpoint as part of this continuing public debate here, our next speaker is Dr. Richard Levinson.

Dr. Levinson is Associate Executive Director of the American Public Health Association. That is the oldest and largest organization of public health professionals in the world. It represents more than 50,000 members from over 50 occupations of public health.

Dr. Levinson is also an Adjunct Professor of Public Health at George Washington University. He has worked in State and county public health for 20 years, including serving as Director of both the Detroit Public Health and the Pinellas County, Florida Health Departments.

He received his doctor of medicine from the University of Illinois in Chicago, and his doctor of public administration from George Washington University. He believes that, in the current climate, more vaccination is better than less. And he will explain why we need to consider mass vaccination.

Dr. Richard Levinson.

(Applause.)

RICHARD LEVINSON,

AMERICAN PUBLIC HEALTH ASSOCIATION

DR. LEVINSON: Thank you very much.

I didn't know that the extreme position would be presented next, so what follows me will be a little bit downhill.

I think the excellent presentation we have just heard has laid out the facts as we know it about vaccinia, the vaccine, about the smallpox virus, about the nature of intelligence about terrorist activities, and so on. I would like to repeat certain statements which I regard as postulates for my position.

First of all, the nature of the virus. The 30 percent mortality rate figure is quoted for the virus known as variola major. There was another virus, closely related to it, variola minor, that had approximately a 1 percent fatality rate. Variola major, which was the virus that circulated from ancient times, as

far as we know, until practically the beginning of the 19th century, has the 30 percent mortality rate. I do not believe for one moment that the virus that terrorists would use would have a mere 30 percent mortality rate.

We know that the Russians, and undoubtedly others, have been working very hard, through widely available techniques in molecular biology, to heighten the virulence and the infectivity of the variola virus. They have also worked, it can be reliably reported, on chimera viruses; in other words, combining the smallpox virus with genes from other harmful viruses that have different attack sites, such as the equine encephalitis viruses that would attack the central nervous system, such as Marburg and Ebola viruses that produce a hemorrhagic diathesis. So that the virus that the terrorists would use would probably have a significantly higher mortality rate and it would be more infectious.

We do not know exactly how infectious variola is. We do know that when the virus was introduced to Colonial populations when the Americas were settled resulted in the epidemics that virtually wiped out the entire indigenous population. And we didn't have airplanes, we didn't have train stations, and we didn't have large hotels. It was very effectively spread. So this suggests to me, in addition to the more recent evidence, that we do not know the true infectivity or

basic reproductive number of this virus, but it is fairly high. If 10 to 15 means an uncontrolled epidemic, it's probably very close to that range.

The delivery devices are also unpredictable. We might consider that several terrorists, suicide bomber types, would be infected by the virus. And when they begin to develop the symptoms, and perhaps somebody would cue them to begin their work, when they have lesions in their mouth and nose, they would begin circulating in airports and so on, they could spread the virus to a large number of people. Surely they will not limit themselves to this rather crude device, but will use aerosols. And we know that the virus has been weaponized and can be used in an aerosolized device.

Can we respond to such an outbreak? I think the answer is unequivocally no. The country is not prepared to respond to a massive act of terrorism. Consider what happened in New York City when the West Nile virus appeared. The Centers for Disease Control's laboratories were virtually paralyzed by an epidemic that involved perhaps 80 people. And the entire City of New York's public health system, which is probably the most advanced in the nation, was totally involved in this relatively small outbreak.

If New York City began experiencing an outbreak of smallpox and you wanted to immunize the entire population of New

York -- I mean those that are actually in the city -- it is estimated that you would have to mobilize 20,000 people to begin giving immunization. There are not 20,000 people in New York City that can give the immunizations today, much less in the country.

My point is that the public health system -- indeed, the entire American defense against bioterrorism system, with all of its component parts -- is not prepared to deal with a massive emergency. So we have a likely epidemic caused by a particularly virulent and transmissible virus, spread by multiple devices in multiple sites, and we have a system that cannot respond to that emergency at the present time, or any time in the foreseeable future. Then what are you going to do?

You could wait, as CDC says, for the outbreak to begin, and then hope you can contain it. Operation Dead Winter, which was done in 2001, indicated that within nine months after an outbreak that was started in three sites, there would be at least 3 million victims, 1 million deaths, and at least 15 other countries would be involved. So that approach, the ringed containment approach, will simply not work; it wouldn't begin to work in such an outbreak.

What about making the vaccine available to people and let them discuss it and let them decide if they want it? I think that discussion is absolutely essential. I think that is the

American way. That is the way that I would like to see the whole world go. But I have no faith at this point that that discussion would be either informed or particularly relevant.

I would point out that our experiences with vaccines used against childhood vaccine-preventable diseases indicates this over and over again. If you look at the experience of England and Italy with regard to these vaccines, a number of parents -- I'm not talking about peasants, I'm talking about well-educated people -- decided that the complications which they had heard about this vaccine were unacceptable, and they induced authorities in both countries to give it up. What followed, quite predictably, were large outbreaks of whooping cough, with tremendous mortality rates, far greater than any that have ever been recorded as a side effect of the vaccine.

If you look at the discussion of the anthrax vaccine, I think you will see far more heat than light, with everybody claiming absolute knowledge about something that, at least the experts say, if you can believe them, has been fairly well settled. I think such a discussion would go on endlessly. I think it would be marked with massive misinformation, hundreds of Web sites in which people would speculate as to possible causes and outcomes. The result would be that a relatively small number of people would be immunized.

And would that be effective? My answer is no. Epidemiologists talk about herd immunity. Herd immunity from most transmissible diseases is somewhere between 80 and 90 percent of the population. If you immunize a smaller number -- let's say 50 million -- in scattered locations, this will not stop the spread of smallpox, not at all. It would be too little, too late.

Now, I am not preaching tyranny. I am not suggesting that we declare an emergency today and immunize everybody. But what I am saying is that I think there is a responsibility to inform the public about the danger of the situation, about the relatively high likelihood that it would be used in the worst possible scenario, and an understanding that if one is to respond effectively, the entire population must be immunized in some sense or other.

Perhaps we should have special provisions for the very young. Children under 2 are most susceptible, as we have heard, to the encephalitis complication. Certainly those who are immune-compromised and those who have any number of major skin diseases might suffer complications. Nevertheless, recognize that if there was a smallpox outbreak, the current accepted wisdom is that all of these people would receive the vaccine, despite the possibility of complication.

A final point. If everybody, every man, woman and child, in this country were immunized now, the speculation is we would have 300 to 600 deaths and maybe 50,000 complications. If you immunize 50,000 people, leaving 250,000 unimmunized, and you developed a mere 3 million cases, you would still have a million deaths. I would compare the two figures and, to me, that makes a convincing case for immunization of everybody as soon as possible.

Thank you.

(Applause.)

MR. MILLER: Thank you, Dr. Levinson.

We are next going to turn to the respective cases for I guess an ounce of caution versus an ounce of prevention. First, Jonathan Tucker. He directs the Chemical and Biological Weapons Nonproliferation Program at the Monterey Institute's Center for Nonproliferation Studies. Before joining the Center, he worked for the U.S. Government, in positions at the Department of State, Congressional Office of Technology Assessment, and the Arms Control and Disarmament Agency.

About seven years ago, in February 1995, he was an UNSCOM biological weapons inspector in Iraq. Dr. Tucker holds a B.S. degree in biology from Yale University, a Ph.D. in political science with a concentration in defense and arms control studies from MIT. Dr. Tucker literally wrote the book on smallpox. Last

year he was the author of "Scourge: The Once and Future Threat of Smallpox," published by Atlantic Monthly Press. He is also the Editor of "Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons."

He is here to help us by suggesting a more cautious approach to distributing the smallpox vaccine is advisable.

Jonathan Tucker.

(Applause.)

JONATHAN TUCKER,

CENTER FOR NONPROLIFERATION STUDIES, MONTEREY INSTITUTE

DR. TUCKER: Thank you very much, Tom, for that introduction.

I am feeling a bit outnumbered on the panel today, because I think everyone else on the panel does support some form of immediate vaccination, either voluntary or mandatory, against smallpox. But I am going to present a number of arguments for why I think we should be more cautious in proceeding down that path.

For one thing, the description of ring vaccination, or at least the CDC's interim vaccination plan that we've received, has been somewhat oversimplified. It is not quite as rigid as is often portrayed and it is being continually refined. Initially,

the strategy was based on the fact that there were very limited stocks of vaccine available. By the end of this year, that will no longer be the case. In fact, we will be swimming in vaccine. So CDC has modified its strategy somewhat.

Instead of tracing contacts and identifying people who might be directly exposed by an infected individual, they have expanded that to include the targeted use of vaccination, including mass vaccination, in a localized area in which an outbreak has been detected. For example, if there was an outbreak in New York City, CDC would consider mass vaccination within New York City, but not in Kansas City, the idea being to put the vaccine where it's needed and to build firebreaks to prevent the spread of the disease from one area to another, while minimizing the risk of complications to populations that are not directly at risk.

As was mentioned earlier, the smallpox vaccine is unique among vaccines in that it can be administered up to four days after exposure but before the development of symptoms. That means that pre-vaccination is not essential as in the case of, let's say, the anthrax vaccine, which has to be administered over a period of 18 months, probably six or seven shots, before it produces a significant level of protective immunity.

However, the caveat is that a highly efficient mechanism for detecting an outbreak and responding very promptly

with distribution of vaccine has to be developed and tested. And I think this is one of the weaknesses of the current CDC effort. I will return to this point a bit later on.

Also, when CDC develops its new vaccination plan, it would be prudent to vaccinate the vaccinators, the people who would engage in triage and vaccination in an actual case of an outbreak. These people are unlikely to take the risk of going into an epidemic area unless they are protected themselves. But I do not support vaccination of the general public, at least at this time.

And why is that the case? First, the potential complications of the vaccine that have been referred to. The smallpox vaccine is associated with considerably more risk than any other vaccine currently on the U.S. market. And the general public is just not used to that level of risk.

Another factor is that unlike all other diseases for which people are vaccinated today, smallpox no longer exists in nature as an endemic disease or a potentially importable infection. So that the only potential source of exposure is through its deliberate use by terrorists. So the metaphor of whooping cough, for example, is just not relevant. This is not a disease that continues to pose a natural threat.

There is also a growing risk of complications in the U.S. population for several reasons. For one thing, we have an

aging population. And it has been shown in the past that the primary vaccination -- that is, the first vaccination -- if given over the age of 18, is associated with a higher risk of complications. There is also a growing number of underlying conditions in the U.S. population that would increase the risk of complications. These include, most prominently, HIV/AIDS, hepatitis C, organ transplantation, and cancer chemotherapy, all of which can impair or suppress the immune system. And it has been estimated that at least in a quarter of the U.S. population, smallpox vaccination would be contraindicated because of the very high risk of complications.

Even if these individuals can be excluded from pre-vaccination, it has been shown in the past, when we had mandatory vaccination campaigns before 1972, that a certain number of children with no apparent contraindications developed a complication known as vaccinal encephalitis. And there was no way of predicting this in advance. Another fact is that the available antidote, known as vaccinia immunoglobulin, or VIG, is not effective in treating vaccinal encephalitis. So we would have to deal with these cases, and there would be no effective treatment for them.

Dr. Bicknell also pointed out the problem of contagious spread of the vaccine virus by shedding. The smallpox vaccine that would be used today, or for the foreseeable future, is a

live virus vaccine. That is one of the reasons it is associated with a high level of complications. But it can also spread from person to person. Someone who has been vaccinated, if they do not effectively cover the vaccination site, can expose other individuals. And there have been cases, reported in the medical literature, in which an adult was vaccinated, spread the vaccine virus to a child, who then developed a severe case of vaccinal encephalitis.

In fact, one of the reasons the U.S. military stopped vaccinating military recruits on a routine basis in 1990 was the problem of person-to-person spread of the vaccine virus. And they concluded that they would have to quarantine people who had been vaccinated to prevent them from infecting others.

A second argument against immediate pre-vaccination in the absence of a more imminent threat is the nature of the threat itself. As I mentioned, this is no longer a natural infection. The only potential source of exposure would be terrorist use.
So, in attempting to weigh this policy question, which is probably the most difficult type of issue that policymakers will face because of the high level of uncertainty, we know that the vaccine is associated with a known level of risk, which is substantial, but the level of risk from terrorist acquisition and use of the virus is uncertain but appears very small.

From everything we have heard from the U.S. Government, which has been recently issuing numerous threats about every conceivable, possible terrorist attack, conspicuous in its absence has been concern about the possibility that al-Qaida or some other terrorist organization has acquired access to this virus.

Now, that may change. And if in fact the government assesses that there is an imminent threat of an attack, then that would warrant a reevaluation of the cost/benefit analysis. But in the current threat environment, it appears that the risks of vaccination would outweigh the risks of terrorist attack, particularly because it is possible to contain an outbreak after it has occurred with vaccination.

Finally, there are a number of political and strategic implications, both domestic and international, of a pre-vaccination campaign. First, the domestic factors. If the U.S. Government were to endorse pre-vaccination, either on a mandatory basis or a voluntary basis, it would indicate that the U.S. Government feels that this is an imminent threat, one that would warrant accepting a significant level of deaths and severe illnesses to offset the threat of an attack. That would definitely alarm the public. And it could well provoke demand for other vaccines against other putative biological warfare

threats, such as anthrax, tularemia or plague. So why just focus on this particular threat?

I would also like to refer to what I call a cautionary tale about when the U.S. Government tried to urge people to be vaccinated in the past against what appeared to be an imminent threat. This was back in 1976, when there was a strain of influenza, called swine flu, that many public health specialists believed was related to the 1918-1919 Spanish flu, which had caused somewhere between 20 and 30 million deaths around the world during that period. So the public health authorities believed that they should err on the side of caution, be prepared, by urging the entire U.S. population to be vaccinated against swine flu. But this turned into a public health debacle.

After vaccination resulted in some serious complications, including Guillain-Barre syndrome, and a number of deaths, many which may have been coincidental, among older people, sensational media coverage and an outcry from the general public forced the program to grind to a halt.

We have seen another case recently of how the public has reacted to vaccine complications in the controversy over vaccination of military recruits against anthrax, which has led to some high-profile cases in which members of the military have actually resigned and accepted dishonorable discharges to avoid being vaccinated.

I would argue that informed consent in this case would not be effective, because this, as I mentioned, is a hypothetical threat. It is not an imminent natural threat. And so if people start developing severe complications, including brain damage and death, from this vaccination, I think the government will have a major political crisis on its hands.

I would argue that we will only have one chance to pre-vaccinate against smallpox, and we better do it at the right time. Doing it too early, before the threat is really imminent, could result in a political backlash that would make it impossible to vaccinate at a future time, when the threat really is clear and present.

Under conditions of imminent threat, or if there are actually cases of the disease, people would be psychologically much more prepared to accept the risk of injury and death from vaccination than they would be if it remains a purely hypothetical threat.

Finally, there would be a number of international implications from a decision by the U.S. Government either to encourage voluntary vaccination or to require mass vaccination. We have to think about how this would be perceived internationally. A U.S. decision to pre-vaccinate would indicate that senior U.S. policymakers who have access to the most sensitive intelligence have made the judgment that there was a

real threat of sufficient magnitude to justify a significant level of mortality and morbidity from a vaccination campaign. This would be a signal to the rest of the world that the U.S. believes that this is an imminent threat.

But such action could be perceived by nations hostile to the United States or suspicious of our intentions that Washington, which has one of the official repositories of the virus, at the CDC, is preparing to use the virus offensively, as a biological weapon. Now, a number of countries, including China, have accused the U.S., and Cuba as well, of maintaining an offensive biological weapons program. So this is not beyond the realm of possibility not in my view but in the view of countries suspicious of the United States.

In fact, a few months ago there was an interview with an Indian doctor, by the name of Dr. Banerjee, in the British Medical Journal, in which he was referring to the upcoming decision by the World Health Organization to retain the stocks of live virus for defensive research. He maintained that in fact this was a smokescreen, and that the U.S. and Russia were using defensive research as a cover for offensive research on smallpox, with the intention of developing a super weapon.

So these ideas are definitely out there. And I think if we were to begin vaccination, it would trigger a domino effect, a series of decisions by other governments, including

governments hostile to the United States, to either vaccinate their senior political cadres or their entire populations. And it could create a psychology of a kind of biological arms race.

Already the Russian Ministry of Health has indicated that it is considering vaccinating its own population. Would we be comfortable, given Russia's history, or the Soviet Union's history, including the development of smallpox as a strategic biological weapon, with Russia vaccinating its population? How would we perceive that? And if that would make us uncomfortable, we have to think about how we would be perceived by other countries.

What would happen if Iraq, following our lead, were to begin vaccinating its senior political cadres? Would we perceive that as a potential threat, that Iraq, which we have assessed may possess undeclared stocks of the vaccine, might be preparing for offensive use of the virus?

In conclusion, I think I have pointed out a number of drawbacks, both from a public health and a political and foreign policy standpoint, to moving too aggressively with a decision to pre-vaccinate the U.S. population in the absence of an imminent threat of a specific outbreak. I believe that pre-vaccination is not warranted at current threat levels, but that the CDC needs to do much more in preparing for the possibility of a smallpox outbreak, however unlikely, by developing much better

epidemiological surveillance capabilities. That is, the ability to recognize an outbreak at a very early stage, when it can still be contained.

This involves training physicians and improving communications between primary care providers and public health departments at the local, State and Federal levels, and also establishing efficient mechanisms for distribution and administration of the vaccine. These strategies not only have to be developed, but tested repeatedly throughout the country to make sure they would actually work in a crisis.

Also, there is an ongoing effort to develop a next-generation smallpox vaccine that would not have the risks of the current-generation vaccine. It would probably not be a live virus vaccine but would be based on new technologies, such as DNA technology or recombinant DNA technology. So I believe that, in the absence of an imminent threat, it would be prudent to wait for the next-generation vaccine before we consider making the vaccine available to the general public on a voluntary or mandatory basis.

Thank you very much.

(Applause.)

MR. MILLER: Thank you, Dr. Tucker.

We finally turn to Chuck Pena, as our last speaker. Chuck has worked for several defense contractors with a variety

of government clients. He is Senior Defense Policy Analyst at the Cato Institute. He is the author of several studies on theater missile defense, national missile defense, arms control, the ABM Treaty and space policy, and, most recently, a Cato policy analysis which you have a copy of, responding to the threat of smallpox bioterrorism, "An Ounce of Prevention is the Best Approach," with his coauthor, Cato Policy Analyst Veronique de Rugy.

Chuck is a graduate of Claremont Men's College. He has a master's in security policy studies from The George Washington University. He is going to combine a choice-based approach with a national security-based analysis of policy options, including how we respond to present and future bioterrorism threats beyond smallpox.

Chuck Pena.

(Applause.)

CHARLES V. PENA,

CATO INSTITUTE

MR. PENA: Thank you, Tom.

Normally, in public speaking 101, you are supposed to say something humorous to break the ice, create some levity in the situation. And I thought about how to do that in this

particular context, but I honestly couldn't come up with anything, because this is such a serious subject. The only thing I could think of was, since we are talking about terrorism -- and this is something I follow and I don't expect that everybody else necessarily follows -- but, for the record, we are still on Yellow Alert, as we have been since the beginning of March, when the system was instituted by the Office of Homeland Security.

This, despite a number of different warnings, mostly vague, coming from the Federal Government. I don't know if that means imminent threat or what, but it does say that we are at a significant exposure to terrorist attack. So, that may or may not have some bearing on today's discussion.

I am going to try and provide some national security context to this, although, quite honestly, I think Dr. Bicknell did a wonderful job explaining the problem. We are not dealing here with natural outbreak of a disease that, indeed, has been eradicated from the world. So that if it shows up, it would be an anomaly in a natural sense. We are dealing with people who have nefarious intentions towards the United States. And while I cannot predict or assess and give you any real probability of what is the threat level that we face with regard to smallpox, I can tell you that there are basically three components that we need to consider: vulnerability, intentions, and capabilities.

Certainly, in an unvaccinated population, we are vulnerable, whether it is smallpox or any other contagious pathogen. I think September 11th pretty much demonstrates the intentions of al-Qaida. The real question that the jury is still out on is capabilities. We hope that the virus is contained securely at the two facilities here in the United States and Russia. There are some experts who are questioning that, and point to the fact that other countries may indeed have the virus.

If that is true, then there exists the possibility, however remote, that a terrorist group like al-Qaida may eventually get their hands on it. If they do get their hands on it, as Dr. Bicknell pointed out, if they get it in weaponized form, they could just try and use it, and find some way to distribute it, probably via aerosol. But they don't necessarily have to do that. They could infect themselves and spread the disease simply by walking around in the general public.

I just got back from a trip to England. I can tell you that airports are very crowded and people are making connections all over the place. It is not hard to imagine that the virus spread person to person would spread very far and very rapidly. And certainly we are dealing with people for whom suicide does not seem to be an obstacle and in fact where martyrdom is celebrated. So we cannot dismiss or discount those possibilities.

We have to understand this in the context that smallpox, if it was introduced into the population, would be devastating. And unlike the events of September 11th or other postulated attacks, we are never going to know what hit us. There will be no big bang, no explosion, no brimstone and fire associated with a bioterrorist attack. The pathogen will simply be released.

Now, if we get really, really lucky and they do it in some way that is observed -- for example, they try to use crop dusters and we notice crop dusters flying over heavily populated areas where there are no crops -- we might have some indication that we have been attacked by bioterrorists. But absent some specific anomaly like that, we will never know. We will know something has happened when there are enough signs that smallpox or whatever the disease might be has broken out.

I think almost everybody agrees that by the time that happens we will at least be too late, at a minimum, to help anybody who was initially infected. The four-day window will be gone, because it will be probably more like 12 to 15 days before we realize what hit us. So at least all those people who were initially infected you could write off. There is not much you can do for them. Why? Because we have a vaccine, not a treatment. And I am going to get to some of those issues a little later.

So then you have to play catch-up. How do you find all the other people who are infected? If we were living in a completely rural society or if we were in the Sub-Saharan continent in Africa, where a lot of people rarely travel more than a few miles from their village during their entire lifetime, it might be possible to use a ring containment, post-event approach to contain the disease.

Given the high mobility and density of American society, and in fact most societies these days -- I travel on the Metro to and from work, that means I come into contact with literally hundreds of people, standing on platforms, going up and down escalators on the Metro trains, a lot of people travel quite regularly for business, you are going to be in and out of an airport, having contact with airline personnel, security personnel, and then all the passengers on your plane, and who knows where they're going, they might not all be going to the same final destination you are going to, they will connect to another plane, and so on and so forth -- so the spread of the disease is likely to happen very quickly and very widely. And there will not be enough information for responders to try and figure out who to inoculate.

In fact, I would contend that even if you thought the outbreak was occurring in New York City and you had the ability to mass vaccinate all of Manhattan instantaneously, that still

wouldn't be enough. Probably the disease would have spread far beyond Manhattan, and you would not know where. Some of it may be to other parts of New York and New Jersey, but certainly some of it on people flying on airplanes going to Kansas City or to London, which is where I just came from.

So we have to consider all these possibilities and then ask ourselves: What is it that we should do?

It is also somewhat fortuitous that as we speak, going on up on the Hill right now are hearings, which look like it's going to be finger pointing between the FBI and the CIA as to who knew what and who didn't do what and what should have been done and who is to blame. That should give you some indication of our Federal Government's ability to respond to information.

I don't know when we would have enough information to say an imminent threat is imminent. I certainly don't think al-Qaida or any other terrorist group is going to advertise to us that Thursday we plan to attack, you have Tuesday and Wednesday to inoculate the population.

In fact, what September 11th shows, and as most terrorist activity shows, is that they will probe for weaknesses in our society, they will find those weaknesses, and they will act accordingly. So I don't know that there will be visible signs of imminent threat to give us enough strategic warning so

that we could engage in a pre-vaccination policy, knowing that there is a threat.

Therefore, I think the most prudent thing for the Federal Government to do is to make the vaccine available to the American public. First and foremost, the American public paid for the vaccine. It was your taxpayer dollars. So I am a little bit bothered that you paid for something and you can't have access to it; that the Federal Government would in fact dictate to you that you cannot have the vaccine.

A lot of people point out that the threat is remote. I saw concern on a lot of faces out in the audience during the various presentations. And it is important to underscore that nobody, I don't think anybody, is saying that this is a very high-probability threat. Nobody knows for sure. That in fact is part of the problem and part of the nature of terrorism. There is no way to predict it. But nobody is saying that al-Qaida has the virus and will use it. We just don't know.

The interesting thing, however, is that we are talking about maybe spending $500 million on a specific vaccine. And as others have said, we should have probably on the order of 400 or 500 million doses in the stockpile by the end of this year. The concern is while it is a really remote threat, therefore we shouldn't do anything about it. Let me contrast that to the fact that the administration seems to be very concerned about

ballistic missiles coming from lots of different countries, none of whom have ballistic missiles that can reach the United States. So we are not talking about Russia and China, but we are talking about rogue states, states of concern, axis of evil -- however you choose to characterize it.

We are going to spend, just this fiscal year, $6 billion to $8 billion on research and development on missile defense systems that we don't know if they will ever work, we don't know if the threat will ever materialize. And yet we are concerned about spending $500 million in making a vaccine available that we know works to the American public who paid for the vaccine. That strikes me as -- I'm not sure what the right word is -- but it strikes me as not right.

Why are we willing to invest $6 billion to $8 billion on technology that we don't know will work against a threat that we are not sure will materialize, but we seem to have a problem making a decision about whether to distribute a vaccine that will cost us at most $500 million, that we know will work, and we know we have a real enemy out there in al-Qaida? We just don't happen to know whether they have the virus.

So I would submit that we need to inoculate the population voluntarily. In other words, people should have personal choice. And I think that is the right thing to do, the principled thing to do. After all, we do live in a country that

is supposed to value individual life and liberty. It is the responsibility of the Federal Government to protect the population. This is one simple, quite frankly, no-brainer thing that the Federal Government can do.

Imagine a month from now -- the CDC is having their policy debates right now and hopefully they will change their policy -- but imagine that the policy stands, that the vaccine will not be distributed until after an event. And the event, as Jonathan quite rightly pointed out, is going to be an attack. The likelihood of natural outbreak is next to zero. Imagine the scenario where the government continues to hold on to the vaccine. We have had this discussion now, so this is not some sort of closed door, nobody knows anything about it. And three months down the road it happens. An attack happens.

Don't you think that it would have been incumbent upon the Federal Government to have done something about it beforehand if they had the capability? That is, after all, what the whole debate on Capitol Hill that is going on right now is -- what should the Federal Government have done beforehand?

I think this is a situation where we now have the luxury of time to make informed decisions, to educate the public, to educate the medical profession. Because, quite frankly, most of the medical profession is not terribly up to date on smallpox.

And why should they be? It's been eradicated for 30-some-odd years. You don't worry about dealing with it or treating it.

So let's take the time now both to engage in debate as we're doing here and to educate people, educate the medical profession, and then allow people to consult with their physicians so that they can understand the risks, whether they are at risk, do they fall into that group of immuno-deficient people, pregnant women, whatever the risk categories are, so that they can make an informed decision not in a state of panic, not "if I don't get vaccinated I'm going to die because the smallpox virus is out there," but beforehand, when you have time to make an intelligent decision.

We have talked a little bit about the risks. The number that seems to get thrown out a lot is possibly about 600 deaths, if we had mass vaccination, forced mass vaccination, of the entire population. To put that in a little bit of perspective, I would imagine that almost everybody here does not have any qualms getting behind the wheel of a car and driving almost every day. There are 40,000 deaths a year as a result of fatalities on our nation's roads. And yet people do it all the time.

It seems to me that the American public, and individuals, are smart enough to make those kinds of decisions

and balance risk. But we have to get the information out there. And it is not going to happen under the current policy.

So it seems to me we are talking about a relatively simple proposition here with the existing smallpox vaccine. And that is it ought to be made available to the public. I like the idea of the fact that you probably ought to have some sampling. The first responders make a good choice for who to do the sampling with, to see what the side effects are and were we wrong. Did we underestimate what the side effects and the fatalities would be like?

I do have a problem with only inoculating the first responders, as some people have proposed. Only because, why are they more special than you and I? Yes, they are important, and they will important if we need them to combat a potential bioterrorist attack. But why should they be more special? Why only them and why not you or I? And why not give you or I that choice?

All of this I think also points to a larger problem. And that is we have been talking today about a vaccine. Which means it has to be administered, most people say, within four days of exposure. It is not a treatment. It is literally a prophylactic. It can prevent the disease from infecting you, but you have to have been vaccinated. We don't have any way to deal with this issue post-infection, post-four-day window. And I

think that points to the larger problem dealing with the bioterrorism threat, not just smallpox. We need to start looking at that threat and understanding how might we respond and what do we need to do, knowing from the get-go that we will never be able to imagine all the various scenarios and all the various threats.

Cocktail viruses were talked about. There is probably an infinite number of ways that these things can happen and can come at us. Which to me I think points to the fact that we probably need to pay more serious attention to viable research that might lead to eventual treatment. Because if you have treatment, then you don't have to deal with the issue of whether it is voluntary or non-voluntary, trying to inoculate a large percentage of the people beforehand. You could in fact do a combination of both -- have people who choose to get vaccinated but also know that you can deal with the situation after the fact because you have available treatment.

To that end, I just want to touch briefly on some proposed legislation that is going on up on the Hill. And I am not here to endorse it, only to say that I have heard about it and talked with the principal author of that legislation. I know he is here today -- Chuck Ludlam, from Senator Lieberman's office. I think it has merit and I think it is worthy of further consideration and discussion.

The whole point of that legislation is to look beyond vaccines, to look at vaccines but to look at treatment and other countermeasures as it might be related to the threat of bioterrorism, knowing that we face potential bioterrorists threats other than smallpox. And because we are here at the Cato Institute, one of the appealing things about that legislation was that it has a very free market aspect to it, knowing that the only real market for any of these things, whether it is vaccine or treatments, really is the Federal Government. I honestly don't imagine that, given the choice, everybody is going to run out tomorrow and create a demand for any kind of vaccine.

Briefly, I am going to talk about this in very general terms, without the details. The purpose of the legislation would be to create tax incentives for research and development into bioterrorism countermeasures. It is not the government underwriting research and development, but providing tax incentives to companies. It establishes price and quantities to be purchased by the Federal Government from companies that come up with viable countermeasures. There are patent incentives, either patents on the countermeasure developed or patent extensions on other products that the company might have. And there is liability protection. Liability is an issue if there is the risk of side effects, including death.

So I think, in sum, we need to look at the smallpox vaccine issue in isolation. And as I said, I think it is a no-brainer. I am hoping, in two weeks, CDC turns around and changes its policy, sees the light at the end of the tunnel, and says, yes, it would make more sense to allow the American public to make the choice. I do believe everybody in this room is smart enough to sit down and talk with their own doctor and figure out what the risks are and whether they are willing to accept those risks, just as you accept the risk of driving a car every day.

Then, once we get beyond that, from a national security perspective and from the larger threat perspective, I think we need to start looking at how do we try and deal with the myriad of potential bioterrorist threats out there. And I underscore the word "potential." Nobody knows exactly what they are. I don't think there is anybody smart enough to predict exactly, if there is going to be a bioterrorist attack, what it will be and the manner in which it will come at us. Much like 9/11, it will be a surprise. That is the unfortunate nature of terrorism. And no matter how many preventative measures the government takes, no matter how much money we spend on this problem, it will never, ever be 100 percent perfect. So we have to allow for the possibility that a terrorist attack will occur and it might be a bioterrorist attack.

Let me end by saying this. President Kennedy once said, "Ask not what your country can do for you, but what you can do for your country." Let me say that with regard to the issue of smallpox, I think it's the other way around. I think we need to be asking what our country can do for us. And I think they can do a lot better than sitting on the stockpile.

Thank you.

(Applause.)

MR. MILLER: Thank you, Chuck.

We have been this afternoon probing for alternatives to some unappealing policy options for a smallpox vaccination strategy. "Anything that isn't mandatory is prohibited" sounds like some kind of old Eastern Bloc language. "You can't stop smallpox, you can only contain it" sounds like a Dan Patrick quip on ESPN about a suddenly hot ballplayer.

Let's go around the panel one time for a quick summary as to where we are and where we're headed. What is unlikely to unfold in the next few months? What kind of input is CDC and HHS receiving? How are they likely to respond? And then we will go to your questions in the audience.

MR. PENA: I know that CDC is having a series of open public forums in four or six cities, and I can't remember all of them. I know San Francisco and I think Los Angeles and St. Louis are amongst them. My hope is that there is good public turnout

for those hearings and that the public asks the hard question: Why can't I have the vaccine?

If enough people stand up, raise their hand and say, "Excuse me, we have vaccine, I would like to get vaccinated. Can you please explain to me rationally why I can't get a vaccine, especially if I consult with my doctor?" I think that might begin to push CDC in the right direction. This is going to be followed by some closed door session, and policy will get reported out.

I guess, realistically, knowing how slow governments and bureaucracies tend to move, I think that we are likely to see a policy that says we will inoculate the first responders but not much beyond that.

MR. MILLER: Other comments?

DR. BICKNELL: Yes, I would like to make a few points. One, I think the hearings that are going on now, they were announced with great speed, there is very little knowledge of them, they are in four cities around the country, they are for a very short period of time, and most of the public does not have the information in order to either attend or ask informed questions. So I think that it is an insubstantial and inadequate public comment process.

I should have started with a slide, quoting Dr. Tucker, which said that it is reported that North Korea and Iraq have

vaccinated and may be continuing to vaccinate their own troops against smallpox. That is kind of an interesting fact.

I want to point out the post-vaccinal encephalitis, in the latest data in 1968, there were five cases of that in 4.9 million children. They were all in children under 9, three under 4, and two in the 5 to 9 range. None were from contacts. And the risks to adults -- everybody born before 1972 has been vaccinated. The risk of re-vaccination, if you have already been vaccinated, is very, very low. I think the 600 number is actually high.

To the best of my knowledge, I don't think it is correct that CDC has changed their guidelines. They may be changing some of their internal discussion but, as yet, the guidelines have not been changed. And there are a couple of polls that suggest that around 60 percent of the adult population would elect for smallpox vaccination, knowing that it has serious side effects, including death. So I think we could go a long way. And the further we go, the better it is.

I am not sanguine about the outcome of the meetings this month. I think they are going to be timid and make a halting first step. I think that will be inadequate and is not responsive and is not responsible given what we know.

MR. MILLER: Jonathan?

DR. TUCKER: Just to respond to Bill's comment about Iraq and North Korea, there are a number of pieces of circumstantial evidence that are troubling, but I think vaccination in isolation does not really say very much, because we were vaccinating our troops against smallpox until 1990. And we stopped not because of a change in our policy but because there were concerns about spread of the vaccine virus to non-vaccinated family members.

Also, Israel, for example, vaccinated its troops up until 1997. And there we don't believe that they have any intention of using smallpox as a weapon. They're a friendly country. So that, in isolation, I don't think is sufficient grounds for concern. There are a number of other pieces of evidence, entirely circumstantial, that have raised concern in the U.S. Government about this as a potential threat. But no evidence that terrorists have gained access, just that a few governments, about which we have concerns, may have undeclared stocks of the virus.

In terms of your question, what you thought would happen in the next month, I would agree with the assessment of other panel members that we are not likely to see a dramatic change in policy. I think it is very possible that CDC will agree to vaccination of a subset of first responders. Of course, how broadly that category will be defined remains to be seen.

But at least people involved in triage and vaccination in the event of an outbreak would probably be vaccinated.

Ultimately, this is a political decision that will be made at a high political level. I think it will ultimately be made by the President, not by the Secretary of Health and Human Services. And it will only reach that level if there is a large amount of political pressure for a change in policy. But I think, as I pointed out in my presentation, the U.S. Government is going to be very wary about the political risks and costs of moving ahead with pre-vaccination at this time, because it could preclude a later decision, when the threat is more imminent, to vaccinate.

Thank you.

DR. LEVINSON: In response to the question, "What's going to happen next month?" I couldn't possibly say. At least I hope there will not be a terrorist attack during that period of time using anything, including smallpox. I think that we have heard an example today of how virtually the same data can lead to very different conclusions about what should happen. This reflects the complexity of the situation that is being discussed, the many, many nuances of it, some of which are known and some of which are not. The hope of better technology, which I think is forlorn any time in the next decade, but perhaps better technology for producing vaccines will come along. And the fact

that September 11th wasn't predicted either, it was something that could never occur but it did.

So I think, weighing all these things, nothing much is going to happen in the next month. I don't think that the hearings are going to be particularly persuasive or lead to any particular new conclusions. I think that a month from now, unless there has been an attack, we will still be debating this situation in much the same way. Somebody finally has to break the tie, and I presume that will come from the highest levels of government. And all I wish is that they have the appropriate wisdom and data to support whatever conclusion they reach.

MR. MILLER: Thank you.

We want to know your thoughts, comments and questions in this first town farm on smallpox vaccination. As Ted Koppel would say, I want to warn our affiliates that we may be running over. Wait for the microphone to come to you. Identify yourself. And since we already know we are in jeopardy, please disguise your commentary in the form of a question.

Sue?

MS. BLEVINS: Sue Blevins, Institute for Health Freedom. I have a question for the three doctors.

Has the smallpox vaccine, the one that is currently stockpiled that would be used or diluted, has it ever been tested in a randomized clinical control trial? If so -- and Dr.

Levinson is shaking his head no -- if so, did the researcher look at how that vaccine releases the vaccinia virus that would then contaminate others and where those research studies would be found or how I could get a copy?

DR. LEVINSON: It is not ethical to do an experiment giving people smallpox and testing the vaccine. So the only tests that are being proposed, in this country at least, are on the close relations to humans; namely, monkeys and the higher apes. How conclusive that test would be is hard to tell.

DR. TUCKER: I just wanted to make a clarification. The new vaccine that is being produced is the same old strain of vaccinia. It's just being produced in a different system, a cell culture system, instead of the old antiquated method, which was to scarify the skin of living calves, inoculate the vaccine virus until they formed pustules, and then harvest the pustular material. So, basically, the vaccine was semi-purified pus from cows. That is a slight exaggeration.

DR. BICKNELL: That's an extraordinary exaggeration.

(Laughter.)

DR. TUCKER: It often contained other viruses, cells, hair, other contaminants. For this reason, it is the same active ingredient, but just produced in a more sterile preparation.

DR. BICKNELL: I have one point to add there. If you contacted Dr. Belshe, who I think is in St. Louis, and he is one

of the authors of the New England Journal dilution studies, in terms of how does the vaccine get from me to somebody else accidentally, he has studied that. They have cultured above dressings, found what protects and what doesn't, and he could actually give you some information and data on that.

MR. MILLER: Yes?

DR. MARSHALL: Dr. Marshall, a private physician.

Dr. Bicknell, are there any blood tests available to determine if those of us who have been vaccinated years ago still have some degree of immunity, like we had with German measles?

DR. BICKNELL: I do not believe so. I think the short answer to that is no. And there is a lot of debate. My own personal guess is yes, probably some, but we don't know.

MR. MILLER: Yes?

MR. ISENBERG: David Isenberg, Managing Editor, Homeland Security Monitor.

I'm wondering what the panelists think of the argument that the vaccine stocks that we expect to be swimming in by the end of the year, even if they are 40 years old, courtesy of Aventis Pasteur, should not be used for a vaccination program for the following reason: namely, that they may be needed to be held in reserve against the possibility that a smallpox outbreak would take place elsewhere in the world, outside the United States, and therefore, given the globalized world we live in, people can come

into the United States as easily as people can leave the United States and go to England, for example, that we would need to rush some of those stocks over there in our own defense to prevent any outbreak from spreading outward toward the United States.

MR. PENA: Most of the evidence, at least to date, shows that if we are talking about al-Qaida, that we're the target, that they don't seem to be terribly interested in getting to us via another country. That does not mean that they might decide that maybe a better way would be to infect a bunch of people in Western Europe, for example, knowing that they travel here to the United States.

It's a sticky question. Should the American taxpayer underwrite the vaccine, and then should we basically give it away to foreign countries to use? My initial instinct is to say that if we vaccinate the American public, and we do it voluntarily, that we don't have to worry about the scenario of it coming to us from abroad, because we will have inoculated our own population. I think that is the first and foremost responsibility of the Federal Government.

So I would say that if we have the vaccine, let's make it available to the American public. And that precludes all the scenarios. It takes care of all of the scenarios. It takes care of the scenario where the bioterrorist attack occurs here on American soil. It also handles the scenario, at least if we are

concerned about what happens here in the United States, of a bioterrorist attack emanating in another country and then migrating to the United States.

DR. BICKNELL: There will be, I believe, a couple of hundred million doses extra very shortly, when you take what we've got, dilute it, and the stuff that is being produced now and being delivered. So I think you can have your cake and eat it too in this situation. You would have some substantial, or nontrivial, surplus to distribute, or not, as one wishes.

MR. MILLER: Chuck?

MR. LUDLUM: Chuck Ludlum, with Senator Lieberman's office.

On the question of how a ring vaccination would work, I think people don't look at the implications of it. Assuming you knew who was inside the ring -- obviously that is a major question -- even if you knew that, you would have to define the ring, vaccinate people on sort of the donut part of the ring, tell the people inside that they're not going anywhere, enforce it with military or police, probably with "shoot to kill" orders or something tantamount to that, tell them that they are in trouble but that we are going to vaccinate people around the outside.

Doesn't this mean that all of this focus on vaccines, even if you have a vaccine, is drastically less important than

focusing on treatments? If you have treatments, you can say, get to a clinic, get on the drug, stay on the drug, we'll tell you when to get off the drug. You don't have to worry about the quarantines, defining the area, and it is a totally different situation.

DR. BICKNELL: One problem there is the biology of developing antiviral drugs. That might be true in 5, 10, 15 years. It might never be true. It might be true in three or four. The vaccine we have today works, and it is a highly infectious disease. So, throwing money at developing treatments will certainly stimulate a lot of research. Whether it will lead to timely availability of treatments I think is a very open question.

MR. MILLER: Yes?

MS. SAXTON: My name is Olivia Saxton. I have a question for Chuck Pena.

One of the problems or one of the objections is that the other countries will think, oh, no, we're vaccinating ourselves so we're going to attack somebody else. How would you deal with that situation?

MR. PENA: Quite honestly, I'm not sure that I really completely understand the argument that if we vaccinate our own country, other countries are going to get worried that we might choose to attack them with smallpox.

MR. MILLER: It would be like the ABM debate all over again.

MR. PENA: One, if they had vaccine, they could vaccinate their own country. And quite frankly, what do I care whether they vaccinate their own population in response to the fact that we vaccinated ours? I guess the bigger concern is, if we vaccinated the U.S. population, would we be tempting another country to strike at us somehow with ballistic missiles or whatever?

Again, I have a hard time with that scenario. I can't imagine that just because we vaccinated the population, that somebody is going to engage in a preemptive first strike against the United States. And if they were to do that with the smallpox virus, we've vaccinated the population. So I'm not sure where that argument leads to and what the real concerns are.

So what if we touch off a massive inoculation of the population worldwide. That's less targets for al-Qaida. It probably creates some deterrent value against a terrorist attack. If they know that the populations of the world are immune to smallpox, they are less likely to engage at least in that particular activity. It certainly won't stop them from trying anything else.

MR. MILLER: Yes?

MS. SERAFINI: I'm Marilyn Serafini, with National Journal.

Once we create the stockpile and have the number of doses that ideally should be in the stockpile, what is to stop the private sector, the vaccine manufacturers, from then producing this vaccine privately and selling it to the public as we do many of our other vaccines? Is it a liability issue?

DR. BICKNELL: Yes. There are a number of issues before you can bring a drug to market. It has to go through the FDA approval process. And these will go through that approval process. And then guidelines have to be developed for its use. But I think there could be pressure and that could happen.

I am not certain of the following statement: I don't think there is extra production capacity now beyond what the government has ordered.

DR. TUCKER: Well, there would be two problems from industry's perspective. First, because the U.S. Government has such a huge order, there would be a tiny market for this. So it wouldn't really be worth the effort involved in research and development and marketing for industry, and also there would be a huge liability risk. So, unless they had assurance that the government would waive their liability or assume their liability, they wouldn't get into that business.

DR. BICKNELL: I would just clarify one thing. The liability, I agree with. But there would be no research and development costs because it is already developed and produced. It's there.

MR. PENA: I think if the private sector thought there was demand for this, you would see them cranking out vaccine. And the fact that they aren't is a big indication to me that there is not a natural public demand for the vaccine. And partially that is because the government is already buying it up.

MR. MILLER: We are going to take two more questions and then break for lunch.

MR. BOURGE: I'm Christian Bourge, with UPI.

I'm wondering if you can speak at all to the issue of looking beyond the standard epidemiological model in terms of attacking this problem. There is some research going on in terms of developing computerized artificial societies that the Office of Homeland Defense has undertaken at Los Alamos. There are some other people who are looking at it in terms of mobility, different ways of attacking the disease and developing policies along those lines. Can you speak at all to that as a possibility of a policy response in the near term to long term?

MR. PENA: If you're talking about policy responses post-attack, it seems to me that there are only two real choices. You can either try the ring containment and hope that it works --

and it probably isn't going to -- or you have mass vaccination. because you cannot be assured of where the disease has migrated to. And I don't see much room in between for post-attack policy options. I think the purpose of today's discussion, and hopefully -- I'll keep my fingers crossed -- ongoing discussions, is to assess what should be some of our pre-attack policy options. Quite frankly, the government is really only thinking, as best I know, in a post-attack mode. And that has serious consequences.

Again, we are not saying that this is a high-probability attack. But I think what people do need to understand is that if it were to occur, however remote the possibility, the consequences are catastrophic.

DR. BICKNELL: You might want to contact Edward S. Kaplan at Yale. He is a sophisticated modeler. He is aware of all the various modelings. I think he could give you a rich, informed and broad answer in response to your question.

MR. MILLER: The final question here.

MR. WILCOX: Jordan Wilcox, for the Nixon Center.

I would like to ask someone who is medically qualified to know, how comprehensive and universal is the vaccine in response to alterations that al-Qaida or someone qualified might make on it? In other words, if we started a vaccination program, a pre-vaccination program, could this not trigger or prompt

al-Qaida to genetically modify the virus so that our vaccine was no longer useful? So, therefore, could we not end up in a situation even worse than we started in?

DR. BICKNELL: I think the answer to your question is the current vaccine is useful for the current virus. The more it is modified and genetically different, the more risk there is the vaccine won't work. But it is also not easy. It is very tricky to do this. It is not, oh, you've got this, I'll just add some oregano and I'm home free. It's a hell of a job.

MR. MILLER: Now that we've set your minds at ease, let's thank our speakers for this thorough discussion.

(Applause.)

MR. MILLER: And join us upstairs for a slightly more relaxing lunch.

(Whereupon, the Cato Institute Policy Forum was concluded.)