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TWENTY-FIRST CENTURY BIOLOGICAL THREATS

HEARING

BEFORE THE

SUBCOMMITTEE ON BIOTERRORISM AND PUBLIC HEALTH PREPAREDNESS

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

ON

EXAMINING TWENTY-FIRST CENTURY BIOLOGICAL THREATS, FOCUSING ON DUAL-PURPOSE PREPAREDNESS AGAINST NATURAL AND DELIBERATE MICROBIAL THREATS

MAY 11, 2005

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TWENTY-FIRST CENTURY BIOLOGICAL THREATS

WEDNESDAY, MAY 11, 2005

U.S. SENATE,
SUBCOMMITTEE ON BIOTERRORISM AND PUBLIC HEALTH PREPAREDNESS, COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:03 p.m., in Room 430, Dirksen Senate Office Building, Hon. Richard Burr, chairman of the subcommittee, presiding.

Present: Senators Burr, Hatch, and Enzi.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. We are going to call the hearing to order. I know that some Senators are scattered around trying to reconstruct, I think, today's earlier schedule. I think for those that may not be accustomed to being on the Hill that might be with us today, this is one of the unfortunate things that we react to post-9/11. It is a reminder to us, really, as to why we are here and we take very seriously the work of not just the subcommittee, but the full committee.

I want to take this opportunity to thank those for attending the second hearing of the HELP Subcommittee on Bioterrorism and Public Health Preparedness. I certainly have enjoyed working with the chair of the full committee, Senator Enzi, and the ranking member, Senator Kennedy, and all the members of the subcommittee. I believe those that follow the work of the subcommittee, you will be busy trying to keep up with the subcommittee as this year goes on.

Since our last meeting, there has been much legislative activity in the area of bioterrorism. Senators Hatch and Lieberman have introduced their bill, S. 975. I want to thank them and their staffs for the substantive contribution and simply say that we will be considering it along with S. 3, Senator Gregg's bioterrorism legislation, as we evaluate additional measures that are needed to ensure our Nation has the kind and quantities of safe and effective medical countermeasures to meet the challenges of the future.

The future is really the subject of the hearing today. As we prepare to look at what additional legislative measures might be needed to develop countermeasures as well as reauthorize the Bioterrorism Act of 2002, I thought it would be useful to step back a bit and to look over the horizon to understand the nature of the future bio-

logical threat and how that helps us consider what kinds of countermeasures we may need in the future.

This hearing today represents the first of several events we have designed to look down the road and appreciate where technology, information, Mother Nature, and other current and future adversities may be heading.

We have invited Porter Goss of the CIA to brief this subcommittee later this month and give us his assessment of the current and emerging bioterrorism threats.

For the record, the Bioshield Act of 2004 has already yielded a number of important countermeasures that are being added to our strategic national stockpile. HHS has announced purchases of the next generation of smallpox and anthrax vaccines using the Bioshield authorities. Bioshield is enabling the purchase of therapeutic treatments for anthrax and botulism toxins, as well. I commend HHS and DHS for moving out smartly to implement Bioshield.

As evidenced by the two draft bills I have mentioned, there is a sense that more incentives and other provisions may be needed to mobilize the pharmaceutical and biologics industry to work on countermeasures. I look forward to working with my colleagues in this subcommittee, the full committee, and other interested members to ensure that we enable the private and public sectors and the Federal Government to meet the challenges confronting our Nation.

Today, we will hear from our panel of experts about the diversity and challenges and opportunities we face. Besides terrorists, we are frequently reminded that Mother Nature can be counted on to serve up some challenges. Infectious diseases happen. And if that isn't enough, human error occasionally does occur, also. Witness the recent shipment of the H2N2 influenza around the world. Situations like this bring to mind the old Pogo cartoon strip, "We have met the enemy and he is us."

These realities reaffirm for me that our Nation needs a strong biodefense to address deliberate, accidental, and natural biologic threats. It also highlights that unlike the old adage, "All politics are local," infectious diseases are global and we must understand there is no border between the domestic and international when it comes to contagious infectious disease.

I want to thank our panelists today. We are honored to have such an excellent group of experts that span the disciplines of national security, medicine, science, and public health. As a freshman Senator, I recognize that many Senators before me have worked very hard strengthening our country's defenses against bioterrorist attacks. I am humbled to have the opportunity to work with them, many of whom are members of this committee and subcommittee.

On our first panel today, we have Dr. John Deutch, now Institute Professor of Chemistry at MIT, but significantly the former Director of the Central Intelligence Agency and former Deputy Secretary of Defense. We will hear this former national security practitioner's views on biological threats our Nation faces. We greatly appreciate your appearance today.

Our second panel will have Dr. Harvey Fineberg, President of the Institute of Medicine of the National Academies of Science. He is also the former Provost of Harvard and former Dean of the

School of Public Health. The Institute of Medicine has played a vital role in helping the Nation understand the complex nature of infectious disease as it relates to both emerging and reemerging events, as well as deliberate acts of bioterrorism.

Joining Dr. Fineberg is Dr. Craig Venter, President and founder of the Venter Institute. Dr. Venter has played a central role in decoding the human genome. We will hear his perspectives on the potential peril and promise of advanced biological techniques.

Joining us via video teleconference from Geneva, we have Dr. Guenael Rodier, Director of Communicable Disease Surveillance and Response from the World Health Organization. Dr. Rodier will give us an international perspective of today's infectious disease challenges.

And last but not least, we have Dr. Shelley Hearne from the Trust for America's Health who will give us a vision of what our public health infrastructure should look like in the 21st century. I would like to note that her recent report, "Ready or Not: Protecting the Public's Health in the Age of Bioterrorism, 2004" was a valuable, comprehensive assessment of the preparedness of the States to deal with bioterrorism. It is a matter of personal and professional pride to note North Carolina was cited in this report as one of two States scoring the highest in their assessment.

Again to our panelists, I thank you for your time and thank you for your input.

Mr. Chairman, do you have any remarks you would like to make?

OPENING STATEMENT OF CHAIRMAN ENZI

The CHAIRMAN. Mr. Chairman, I do have a full statement that I would like to be part of the record.

Senator BURR. Without objection, so ordered.

The CHAIRMAN. I do want to congratulate you for holding this hearing and the other hearing that you held and the forums that you have held and the personal meetings that you have held in your office with different people that can provide a perspective on this. You have really taken a vigorous role at making sure that we are safe.

You mentioned in your opening statement that you are a freshman here. Well, one of the great things about you coming over to the Senate was you already had a tremendous institutional memory from the House. You probably know more about this area than any other Senator, so we really appreciate having that. I am more than willing to defer to you on all of these things so that we can get the best possible bill. I liked your comments about the consideration that you are giving to the two draft bills that have been put in there.

I know from talking to you before that there are some things you are very definite on, and one thing we don't mention a lot around here is staff. Excellent staff play a superb role in anything that we do, and I want to congratulate you on the people that you put together to be on your staff. A little experience goes a long way around here, and you have got people who have a lot of experience, so I have a lot of confidence that we will come up with some really good things as a result of your work and as a result of the testi-

mony that we will have today, and yes, there will be a real disruption in the work because of the disruption this morning, besides a lot of other things going on.

I do appreciate everybody turning in their testimony. I think that one indication of people not being here, again, is the confidence in the chairman and his staff on being able to cover this. It is a very bipartisan issue. It is something we are all concerned about and something we all want to solve.

Thank you for your efforts and your tremendous diligence on the committee and the subcommittee.

Senator BURR. Thank you, Mr. Chairman, and by unanimous consent, all members who want to enter into the record opening statements, that will be made available.

[The prepared statement of Chairman Enzi follows:]

PREPARED STATEMENT OF SENATOR ENZI

I commend Senator Burr as Chairman of this subcommittee for holding today's hearing so we can better understand the biological threats presented by both man and animal today and in the years to come. I look forward to working with him to lead the HELP Committee in developing the legislation we need to respond to the ever-present danger of a biological outbreak or a bioterror attack.

Very soon, we will be outlining our principles and our process for crafting legislation that we will bring before the HELP Committee this summer. This hearing is critically important to alert us all about the nature of the threats we face, and to remind us of the potential consequences if Congress fails to act.

Over the years, time and technology have both conspired to change the nature of the forces that can be used against us to challenge the security of our Nation and the strength of our economy. Unlike the old weapons of war, "bioterrorism" and "pandemic" are issues that we now must be concerned with for the sake of this Nation's health and our economy. The military threats of the last century came from countries that could easily be identified. Attacks of bioterrorism and pandemic, however, can come from any part of the world and appear in forms that have never been seen before.

Though we've made remarkable strides to identify our Nation's weaknesses with regard to biological threats, the fact remains that our defenses on these fronts are far from perfect. Despite the best efforts of Congress and the Administration, there still are holes in our biological defense that must be filled to ensure the safety of public health as well as national security.

Clearly, we have the scientific knowledge, the technology, and the resources, including access to the World Health Organization, to face this challenge. What's missing though, is a comprehensive plan to rally and coordinate these resources to strengthen our overall defense against biological threats and bioterror attacks. Senator Burr and I are committed to making this mission the number one priority of this subcommittee.

Since the beginning of the 21st Century the threat that we face from infectious disease has become clear. In the recent past we have seen the U.S. Capitol attacked with anthrax by terrorists, the emergence of a never before seen disease, SARS, which infected thousands and rapidly spread across the globe, and more recently,

the emergence of a horrifically deadly Marburg Hemorrhagic (hem-or-adg-ick) Fever. In addition, the news regularly contains stories about the emergence of a deadly strain of avian flu. Taken together, these incidents have changed the way we view disease surveillance and they compel us to take a new look at the way in which we view our national health preparedness. It is clear that infectious disease can be a weapon and protecting our Nation's health necessarily involves worldwide disease surveillance.

To help us consider these issues I appreciate Professor Deutch's appearance here today to help with our discussion of the threats of the 21st Century so we may better understand how we might best be prepared for any eventuality. As Professor Deutch is a professor of Chemistry at the Massachusetts Institute of Technology and a former Director of the Central Intelligence Agency, I look forward to hearing about his assessment of the threat we face and what needs to be done to mitigate that threat.

I also look forward to hearing from the witnesses on our second panel. Dr. Rodier of the World Heath Organization will share his view on the role that organizations like the World Health Organization play in detecting outbreaks as they occur and marshalling the resources that are needed to meet these challenges around the world. His perspective will be interesting to hear and vital for us to consider. I also look forward to the testimony of Dr. Venter, Dr. Hearne, and Dr. Fineberg who will further describe the nature of the threat that we can expect to face and what our response should be.

Whether the threat is made by man or occurs naturally, we need to be prepared. That's why I look forward to working with Subcommittee Chairman Burr, Ranking Member Kennedy, and my fellow subcommittee and committee members to develop legislation this year to create a viable and innovative industry to supply us with the countermeasures, antidotes, and detection tools we must have if we are to ensure the safety of the people of our Nation and the world.

Again, I thank Chairman Burr and the other members for coming here today to engage in this discussion of the threat that lies before us. I look forward to working with this subcommittee to do what is needed to build a strong national biodefense.

Senator BURR. Again, I apologize for members in advance that they will be coming in and probably leaving as they try to reconstruct today's schedule, but with that, let me welcome and recognize Dr. Deutch.

STATEMENT OF JOHN DEUTCH, INSTITUTE PROFESSOR, MASSACHUSETTS INSTITUTE OF TECHNOLOGY; FORMER DIRECTOR OF INTELLIGENCE; AND FORMER DEPUTY SECRETARY OF DEFENSE

Mr. DEUTCH. Thank you very much, Mr. Chairman. Mr. Chairman, thank you for the invitation to appear in front of you.

Bioterrorism is one of the dangerous threats facing this Nation and this committee is to be commended for devoting the attention and the energy to helping solve this problem. I hope today to briefly give you my assessment about the nature of the bioterrorist

threat and some recommendations on measures that should urgently be taken to prepare our Nation to defend itself.

My views are based on my experience on following subjects and weapons of mass destruction, including biological weapons of mass destruction, chemical, and nuclear since the mid-1970s in a variety of positions. My views on the severity of the nature of this threat, I think align closely with others who have studied it, and I may mention that this January, I appeared on a panel at the World Economic Conference with Senator Frist and I found that our views on this subject were very closely similar.

Let me begin with my assessment of the threat. First, terrorist groups with international reach, such as al Qaeda, have shown an interest in biological agents and biological weapons. The technology for producing biological agents and dispersal mechanisms is well known and easily within the capacity of terrorist organizations. Thus, the threat is real. Moreover, several states around the world have biological weapons, programs, or capabilities and there is always the possibility that these technologies will be clandestinely or through theft transferred to terrorist groups.

In my judgment, we are fortunate that the United States, that our allies, that our deployed military forces have yet been subject to a large-scale biological attack. The likelihood of an attack, our vulnerability to an attack, the need to prevent catastrophic consequences means that biodefense should be a top national priority here.

Despite many warnings and some progress by the many government agencies involved, including Health and Human Services, the Centers for Disease Control and Prevention, the National Institutes of Health, the newly formed Department of Homeland Security, our territory, citizens, agriculture, livestock remain unacceptably vulnerable to catastrophic biological agent attack. State and local governments cannot possibly deal with such an event without significant and financial help from the Federal Government.

In the near term, in my judgment, the agents of greatest concern are anthrax and smallpox. In the long-term, it is entirely possible, and indeed, I should say likely, that new classes of pathogens will be developed based on modern molecular biology and biotechnology techniques. They will be much more virulent and much more difficult to detect and to treat.

Finally, to my knowledge, no comprehensive, multiyear plan exists that integrates the efforts of the various agencies of this government to improve our Nation's biodefense posture. So that is my assessment of the circumstances in which we find ourselves today.

Let me now mention several recommended actions that I believe need to be taken or pursued more aggressively in combating this bioterrorist threat.

First and foremost is improved intelligence on bioterrorism. It is a vital way of protecting our country because it offers the prospects of disrupting development efforts in terrorist groups or countries around the world, intercepting equipment or materials intended for hostile recipients, interdicting an attack before it occurs.

However, bioterrorism intelligence is a demanding intelligence task because so much of the technology and activity is dual-use in character, possessing both legitimate and illegitimate purposes.

This committee should urge the Director of National Intelligence, John Negroponte, to undertake periodic, thorough, all-source reviews of our capacity for collection, analysis, and dissemination of intelligence on the biological interests and activities of terrorist groups and nations of concern.

Second, I believe this Nation should reinstitute the practice of smallpox vaccination for the entire population. I recognize that smallpox inoculation carries a small but definite risk, so there are important issues of indemnification for drug manufacturers and health professionals and the issue of fair compensation for those injured need to be addressed. But smallpox vaccination is the single step that will best protect the American people from the catastrophic consequences of the most likely infectious agent that a terrorist might use today.

Third, the Nation needs a plan that aligns resources against the prioritized needs to address all aspects of biodefense. This includes efforts to improve the capacity of first responders to cope with an attack. This means providing adequate equipment, facilities, medicines, and importantly, training to local first responders. Emergency policies and procedures for controlling epidemics and establishing quarantines in the case of attack need to be set forth. An aggressive research and development effort to improve biological agent detection and treatment is necessary. In the absence of an integrated plan which covers all these activities of the several agencies involved, the President, Congress, and the American people are not able to measure the progress we are making in improving our biodefense preparedness.

Finally, the Nation urgently needs a robust research and development program to develop vaccines and drugs to combat both known biotoxins and to provide protection against virulent new genetically engineered organisms. The 2004 Bioshield Act is an important step in this direction.

These last two recommendations, the call for an integrated plan that covers the various agencies involved and the need for a robust research and development program, points to an important linkage that deserves mention. As the Nation strengthens its capacity for the public health system to deal with the extreme situation of a biological attack from an infectious agent and to develop the means of combating the most virulent agents imaginable, these capacities should also serve to improve the day-to-day functioning of our health system for our citizens.

I do not suggest that biodefense funding should be used to support unrelated but perhaps worthy public health improvements, but I do believe that those enhancements should compete on their own merits. But I do suggest that an intelligent design and execution of a biodefense program can and will improve the capacity of our Nation's health care system to operate under normal circumstance. This committee is in an ideal position to encourage this dual benefit.

I find that the accounts of horrendous consequences of biological attack, whether in fiction or whether in the media, often leads to the opinion that it is impossible to protect the country and its citizens against this kind of a catastrophic event. I do not believe that this is true. While perfect protection cannot be guaranteed, a meas-

ured government biodefense program can reduce the possibility of such an attack and vastly reduce the consequences and casualties of suffering should it occur.

I thank you very much for your attention. I am pleased to address any questions the committee may have, and let me just summarize by saying this threat is real and our country should be doing more about it.

Thank you very much, Mr. Chairman.

Senator BURR. Doctor, thank you very much.

[The prepared statement of Mr. Deutch follows:]

PREPARED STATEMENT OF JOHN DEUTCH

Mr. Chairman, Senator Kennedy, members of the committee. Thank you for the opportunity to appear before the committee. Bioterrorism is one of the most dangerous threats facing this Nation, and you are to be commended for devoting attention to this problem. I will give you my assessment of the bioterrorist threat and my recommendations on the measure that should urgently be taken to prepare our Nation to meet this threat.

I base my views on my experience as Director of Central Intelligence and Deputy Secretary of Defense in the first Clinton administration, as a member of President George H.W. Bush's Foreign Intelligence Advisory Board, as chairman of the Commission on the Organization of the Government to Combat Weapons of Mass Destruction, and from the mid-seventies, my service on many Defense Science Board and other government advisory committees, that addressed various aspects of the weapons of mass destruction threat.

My views align closely with most who have studied the threat of bioterrorist and our biodefense preparedness. At the World Economic Conference this January I served on a panel with Majority Leader Frist, a member of this subcommittee, that addressed bioterrorism and I believe our views on this important subject are quite similar.

My assessment of the threat is as follows:

• Terrorist groups with international reach, such as al Qaeda, have shown interest in biological weapons. The technology for producing biological agents and dispersal mechanisms is well known and easily within the capacity of terrorist organizations. Thus the threat is real.

• We are fortunate that the United States, our allies, and our deployed military forces have not yet been subject to a large-scale biological attack. The likelihood of an attack, our vulnerability to an attack, and the need to prevent catastrophic consequences, means that biodefense deserves to be a national priority.

• Despite the many warnings, and some progress by the various involved government agencies, including Health and Human Services (HHS) and its Centers for Disease Control and Prevention (CDC) and National Institutes of Health, (NIH), and the new Department of Homeland Security (DHS), our territory, citizens, agriculture and livestock remain unacceptably vulnerable to a catastrophic biological agent attack. State and local government cannot possibly deal with these events without significant technical and financial help from the Federal Government.

• In the near term, the agents of greatest concern are anthrax and smallpox. In the longer term, it is entirely possible that new classes of pathogens will be developed based on modern molecular biology and biotechnology techniques that will be more virulent and more difficult to detect and to treat.

• To my knowledge, no comprehensive multiyear program plan exists that integrates the efforts of the various agencies required to improve our Nation's biodefense posture.

Here are some *recommended actions* I believe need to be taken or pursued more aggressively in combating the bioterrorist threat.

• Improved intelligence on bioterroism is a vital part of protecting our country, because it offers the prospect of disrupting a development effort, intercepting equipment or materials intended for a hostile recipient, or interdicting an attack before it occurs. Bioterrorism is a demanding intelligence task, because so much of the technology and activity is "dual-use" in character, possessing both legitimate and illegitimate purposes. Director of National Intelligence Negroponte should be encouraged to undertake periodic thorough all-source review of our capacity for collection, analysis, and dissemination of intelligence on the biological interests and activities of terrorist groups and nations of concern.

• I believe that this Nation should reinstitute the practice of smallpox vaccination for the entire population. I recognize that smallpox inoculation carries a small, but definite risk, so the issue of indemnification for drug manufacturers and health professionals and the issue of fair compensation for those injured, need to be addressed. But smallpox vaccination is the single step that would best protect the American people from the catastrophic consequences of the most likely infectious agent that a terrorist might use.

• The Nation needs a plan that aligns resources against prioritized needs to address all aspects of biodefense. The plan should include: (1) efforts to improve the capacity of first responders to cope with an attack. This means providing adequate equipment, facilities, medicines, and training; (2) emergency policies and procedures for controlling epidemics and establishing quarantines in the case of an attack; and (3) an aggressive R&D effort to improve biological agent detection and treatment. In the absence of an integrated plan, the President, Congress, and the American people are not able to measure the progress we are making at improving our biodefense preparedness.

• The Nation urgently needs a robust research and development program to develop vaccines and drugs to combat both known biotoxins and to provide protection against virulent new genetically engineered organisms. The 2004 Bioshield Act is an important step in this direction.

These last two recommendations hint at an important linkage that deserves special mention. As the Nation strengthens the capacity of the public health system to deal with the extreme situation of a major biological attack and to develop means of combating the most virulent and infectious agents imaginable, it is possible that these capabilities will also improve the day-to-day capacity of the public health system to serve our citizens. I do not suggest biodefense funding should be used to support unrelated, but perhaps worthy, public health improvements. Such enhancements should compete on their own merits. But, I do suggest that intelligent design and execution of a biodefense capability can and should improve the capacity of the country's health care system to operate under normal circumstances. This committee is in an ideal position to encourage this dual benefit.

Superficial accounts of the horrendous consequences of a biological attack too often lead to the opinion that it is impossible to protect this country and its citizens against a biological attack. I do not believe this to be true. While perfect protection cannot be guaranteed, a measured government biodefense program can both reduce the possibility of such an attack and vastly reduce the causalities and suffering that would accompany it.

Thank you for your attention and I will be pleased to address any question the committee members may have.

Senator BURR. If I could, let me ask you to expand as much as you are anxious to as it relates to the comments on smallpox vaccinations. Clearly, that was a difficult measure that we undertook here. We clearly learned a lot about the process in that one issue. Why so strongly do you feel that smallpox is something that we should focus on?

Mr. DEUTCH. I believe that smallpox is the single infectious agent which is most easily and reliably obtained by terrorist groups or by hostile nations, that its infectivity is enormous, especially against populations such as ours, which has not had any inoculation for a generation. I believe that it is the single greatest likelihood of really creating tens of thousands, if not hundreds of thousands, of casualties, and we should get about protecting our American people from that single greatest threat.

There will never be a way of understanding or apologizing if we get hit with a smallpox epidemic and have not taken measures that could have been put in place throughout our Nation. I know that we had a small outbreak of smallpox, I guess, in 1947 in New York City and it was contained. But should it not be contained, we will see tens of thousands of Americans die, maybe hundreds of thousands. All the exercises that have been taken show what a smallpox attack might do.

Now, there is an argument which says we shouldn't—we should wait until a better vaccine is developed, or we should wait until the full spectrum vaccine is developed, which might protect us against smallpox and maybe other things, as well. But my view is you should take the measures today we can know will protect us against catastrophic consequences of a biological attack.

Senator BURR. I think many Members of Congress were shocked in the days, weeks, and months after 9/11 when we began to look at our health infrastructure and we found that clearly over a third of our public health entities across the country were not electronically connected to the CDC, that the notification of an outbreak, the notification of an attack, were it needed to be disseminated in that third was made by the telephone or by the fax.

Do you envision any successful response program that we can come up with that does not address a clear, engaged, robust public health infrastructure?

Mr. DEUTCH. No. I think you are quite right in pointing to a public health infrastructure where pharmacists, where emergency rooms, where police, all know what should be done if an outbreak occurs. That means you have to have the capacity for response in this country throughout our public health system, and it is a major challenge, but that capacity will also serve us in normal times to improve the health care which is provided to our citizens.

Senator BURR. In your testimony, you highlighted the need for improving intelligence collection and analysis for the biologic threat. Is this an issue that deserves special attention with the creation of maybe a bio-issues manager to be assigned under Ambassador Negroponte's staff and possibly the creation of a BW National Intelligence Officer or National Intelligence Council?

Mr. DEUTCH. Well, I believe that the—currently, there is a single person responsible for all of the weapons of mass destruction categories and that national intelligence officer should be seen, in my judgment, as being an issues manager for all different parts of these weapons of mass destruction threats. It is possible to put, in my view, either a separate National Intelligence Officer for Bioterrorism or to assure that the current responsibilities for all weapons of mass destruction is organized under that individual to give adequate attention to bioterrorism.

So I don't think that the identification of a single individual is important. It is just to make sure that the current National Intelligence Officer devotes the attention to it that is needed and that the community responds as a community.

Senator BURR. Dr. Deutch, I certainly agree with your major recommendation that we must align our public health efforts to address the bioterrorism threat and that will improve our overall ability to handle the routine issues. Given your background in the Defense Department, what lessons or observations do you have that might be relevant to the public health community?

Mr. DEUTCH. My first year in the Clinton administration, the first Clinton administration, I served as Under Secretary of Defense for Acquisition and Technology, so I tend to look at these issues, the one you have addressed, as an acquisition problem, as a full-spectrum attack from research all the way through procurement and making sure that you have an industry able to produce,

develop, and deploy the capacities that are needed to improve our biodefense.

Today, I do not see that acquisition ability in any of the agencies that are addressing this problem. The Health and Human Services or DNS, I don't think have that acquisition capacity that is needed to do the full spectrum attention, from first responders to an R&D program, that are needed to meet this threat over time.

Senator BURR. A last question and then I want to turn it over to Senator Enzi. Any time you undertake something new, like the creation of the Department of Homeland Security and all of the different funding streams that we have out there trying to address things, you get some things right, you get some things wrong. You find even if you did everything right, you would still have criticism on some things. I think you probably agree with that.

There has been some national debate on whether there was a need to spread this first responder money around the country or whether it should be targeted in just those high target areas. I remind people when we have the debate that when a community is decimated on their ability to respond to their own incident, it is, in fact, those that are trained from the surrounding State and States that, in fact, provide them the law enforcement and the first responder capabilities.

Do you have any observations, regrets, on how we have tried to upgrade the entire country's ability to respond and to train those first responders?

Mr. DEUTCH. Well, I think that the Department of Homeland Security is still getting its bearings. I should tell you, sir, that I was at the Department of Energy when it was formed in 1978, and so I could tell you it takes some time. But I do not think that these early programs have maybe been as effective as they might have been.

Now, on the balance between local and national programs, that I leave to your judgment, to Congress's judgment. As of now, I think there is a lot left to be done.

Senator BURR. I thank you for your observation and assure you that we are still trying to fix some of those things at the Department of Energy.

[Laughter.]

Mr. Chairman?

The CHAIRMAN. Thank you. This may be one of the most high-tech hearings that I have been at. I have never seen a Harry Potter-type thing where your picture, your moving picture is hanging on a wall halfway across the world and coming back to you.

[Laughter.]

So I want to congratulate you on that part, too.

Dr. Deutch, in your testimony, you mention that terrorist groups such as al Qaeda have shown interest in biological weapons and that the technology for producing the biological agents and dispersal mechanisms is easily within their capacity. Could you give us a better feel for the sophistication of facilities and personnel that are required to make this interest a reality? Are we talking about a kitchen meth lab or a Level 4 containment facility or something in between?

Mr. DEUTCH. There will be individuals on the panel following me who could address this much more authoritatively than I can, but let me just say that surely a fairly good undergraduate training at any leading U.S. university in microbiology would permit you to undertake the manufacture, the growth of these kinds of bugs. I might say that how much safety you have for your workers depends a little bit upon the attitude of the group. You may lose a few workers. But the answer is it is well in hand, sir, well in hand and quite easy to do.

The CHAIRMAN. To do this work, where do you think their technical experts would come from? Would they be ideologues or mercenaries or where——

Mr. DEUTCH. I mean, here again, the understanding about how to do the microbiology involved here is so widespread that you could probably do it with people in the related communities that these terrorist groups live in. It is unlike the nuclear situation where there is a key element of finding enriched uranium or plutonium. In this case, the biological agent, the biological material that you need and the know how is completely out there. So I think it could come from any one of the communities, any one of the communities in which these—and, you know, al Qaeda operates worldwide, so they operate in many parts of the world where they have access to good education.

The CHAIRMAN. Since your testimony says that, and I really believe that, the threat is real and we have been fortunate that there hasn't been a large-scale biological attack, given that the technology is relatively simple and the knowledge is pretty widespread and the terror benefit is so great, what do you think accounts for our good fortune to date?

Mr. DEUTCH. This would be a longer discussion, but I do believe that these highly organized international terrorist groups, as al Qaeda was, it may not be quite that formed today, also have very serious political objectives and they have to always balance whether they are accomplishing their political objectives with the level of terrorism that they want to inflict.

So it is a delicate balance with terrorist groups about how big an act do they really want to undertake. One of the greatest, in my view, limitations on why we haven't had an attack is because terrorist groups still have political objectives. Their only intent is not to kill Americans. Their intent is to achieve things in their own communities and countrysides and they balance the risks and threats to us by that. But it may happen, sir. It may happen.

The CHAIRMAN. My time is almost expired here, so——

Senator BURR. Mr. Chairman, I thank you——

The CHAIRMAN. [CONTINUING]. And we have a vote going on——

Senator BURR. We do have a vote going on, and Dr. Deutch, I hope you will be available for any written questions that Senator Kennedy or others might have.

Mr. DEUTCH. Certainly. Certainly, Mr. Chairman.

Senator BURR. Thank you for that. Thank you for your willingness to come in.

The chair would announce at this time that we will adjourn for the purposes of this vote. It is my full intention to be back here in about 10 minutes, if I can expedite my travel over. Our next

panel, Dr. Fineberg has a 3:00 need to leave for flight purposes and I assure all that he will have an opportunity to give his opening statement before that 3:00 magical time comes.

Once again, Dr. Deutch, thank you.

Mr. DEUTCH. My pleasure. Thank you.

Senator BURR. The committee stands in recess.

[Recess.]

Senator BURR. I would like to call the hearing back to order.

At this time, the chair would recognize and welcome Dr. Fineberg. I came close. I gave you 9 minutes. How about that?

STATEMENTS OF HARVEY V. FINEBERG, M.D., PRESIDENT, INSTITUTE OF MEDICINE, THE NATIONAL ACADEMIES; GUENAEL R. RODIER, M.D., DIRECTOR, DEPARTMENT OF COMMUNICABLE DISEASES SURVEILLANCE AND RESPONSE, WORLD HEALTH ORGANIZATION; J. CRAIG VENTER, PRESIDENT, J. CRAIG VENTER INSTITUTE; AND SHELLEY HEARNE, EXECUTIVE DIRECTOR, TRUST FOR AMERICA'S HEALTH

Dr. FINEBERG. That is perfect. Thank you very much, Mr. Chairman.

Senator BURR. Your microphone, please.

Dr. FINEBERG. Good morning, Mr. Chairman, and thank you very much. I do appreciate your consideration and, most importantly, this opportunity to testify before you today.

The main idea that I wanted to put before your consideration is that when it comes to bio threats, biological hazards and biological threats, a dual-purpose strategy in responding to those threats makes a great deal of sense, and by dual purpose, I mean a response that is comprehensive, strategic, and simultaneously deals with the hazards which come from acts of terrorism intentionally and which come from acts of nature.

I believe that you will find as you go forward that many of the elements that ought to make up a protective strategy for our Nation simultaneously will serve both purposes, and I would go further. I would say that it is by undertaking actions that do both, we actually do each better than we could do if we do not have this dual-purpose idea in mind.

I want to just hit briefly on five basic ideas. The first of these is that the emergence of new diseases and new biological hazards from infection is not a transient phenomena. It is not an aberration. It is not a temporary condition. It is an enduring and continuing part of the way we live our lives today.

Second, I want to point out that our vulnerability to infectious agents, whether by nature or by deliberate intent, is exacerbated today by a number of factors, the growth in resistance to antimicrobials, the declining availability of vaccine manufacturers, and the very few genuinely new agents to treat infection which are, in fact, in the pipeline.

Third, I want to point out that many of the means that protect the public, preventing these conditions or responding when they occur, are steps that need to be taken regardless of whether we are preparing for a threat from terrorism or a threat from nature.

Fourth, I do want to emphasize the point that was brought up earlier today that the weaknesses of our public health infrastruc-

ture are a fundamental problem and an inhibition to our ability to respond. If you had a rickety bridge in town over a stream, if nobody ever drove on the bridge, you might not know that it couldn't sustain the weight of a vehicle. It is only when you have the need to use it that you discover its inadequacy, and that is what we are discovering and what we have learned about our current public health infrastructure.

And finally, I just wanted to make an observation that whether we are talking about many of these natural hazards or the terrorist hazards, we are dealing with a family of problems that are what I describe often as low likelihood/high consequence. They are not very likely in any given year to occur, but if they did happen, they would have terrible consequences. And when you are facing a situation like that, the problem you have as a policymaker is that no matter what you do, you are going to be subject to criticism. If you take action because it is low likelihood and it probably didn't occur, you will be subject to criticism of doing too much. But if the event does transpire, you are going to find that you never will have done quite enough to prepare for such a devastating possibility.

The only approach to dealing sensibly, strategically with those conditions first require detailed planning and capacity building. Second, what I think of as contingent authority, that is the ability to act quickly but contingently on conditions as they develop. And finally, without the means, the financial and technical and human capacities to deal with these low-likelihood but high-consequence events, you cannot have any legitimate accountability for dealing with them.

So with that background, sir, I would be very happy to respond to any questions that you may have and appreciate this opportunity to put before you and the committee the testimony.

Senator BURR. Thank you, Dr. Fineberg.

In an effort to keep everything from a standpoint of the time frame that we have allotted on time, I want to ask you if you would also open yourself to written questions from not just me, but from other committee members, and with that, at your leisure, you can depart based upon—your flight today will probably be a little chaotic regardless of where you are flying out of.

[Laughter.]

I would imagine things are backed up a little bit. But we do want to make sure that you hit your time frame.

I want to thank you for your testimony and for the insight that you have been able to provide for this subcommittee.

Dr. FINEBERG. Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Fineberg follows:]

PREPARED STATEMENT OF HARVEY V. FINEBERG, M.D., PH.D.

Mr. Chairman, and members of the committee: I speak to you today as president of the Institute of Medicine of the National Academies. (The National Academies are a congressionally chartered, independent adviser to the Nation on matters of science, technology, and health. The National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council comprise the National Academies.) Before taking up my current position in July, 2002, I served as provost of Harvard University for 4 years, following 13 years as dean of the Harvard School of Public Health. Earlier, with the late professor Richard E. Neustadt, I co-authored a report on lessons learned from the ill-fated swine-flu immunization program of 1976 (R.E. Neustadt and H.V. Fineberg. *The*

Swine Flu Affair: Decision-Making on a Slippery Disease, Department of HEW, 1978. Subsequently re-published with additional material as *The Epidemic That Never Was*, Vintage Books, 1983.) A couple of years ago, I served on the Expert Committee charged with reviewing experience in coping with the SARS outbreak in Hong Kong. In recent years, the Institute of Medicine and the National Research Council have produced a number of consensus studies and hosted a variety of workshops that bear on the subjects of microbial threats, bioterrorism, and public health. For your convenience, I have listed a number of these reports in an attachment to this testimony. Their findings, conclusions, and recommendations cover many areas that I hope will prove useful in your deliberations.

The main message in my testimony today is the value of **a comprehensive preparedness strategy that simultaneously protects the American people against microbial threats that are natural, accidental, or deliberate in origin**. Experts in terrorism refer to dual-use technologies, meaning ones that can be used for legitimate scientific research and commerce, or turned to the nefarious purposes of terrorism. When it comes to bioterrorism, the soundest national response is a dual-purpose defense that would deter, detect, and respond effectively to microbial threats from either natural or intentional sources.

In briefly elaborating on the case for a comprehensive, dual purpose strategy to protect against both naturally occurring and deliberately inflicted microbial threats, I will touch upon five points:

1. We can expect and should prepare for continuing changes in the appearance, severity and incidence of microbial threats.
2. Our vulnerability to microbial threats has been exacerbated by the rise in drug-resistant organisms, the decline in the number of vaccine manufacturers, and a shortage of new antimicrobials.
3. Many of the same means of prevention, detection, response, and management apply to both natural and intentional microbial threats.
4. Deficiencies and variability in the public health infrastructure across different national, State and local jurisdictions represent a particularly severe gap in our Nation's capacity to respond.
5. Microbial threats from any source that are relatively unlikely, but very severe if they occur, pose a particularly demanding challenge to decisionmakers.

New and Newly Emerging Microbial Threats

Species survive not because they are stronger or more intelligent, but because they are better suited to their environment. Micro-organisms have been adapting and surviving successfully for hundreds of millions of years longer than plant or animal populations on the planet. In terms of sheer number, range of habitat, and total bio-mass, micro-organisms are the most abundant and versatile species on the planet. In fact, life as we know it on earth would be impossible without the positive contributions of innumerable microbial species to plants and animals. The gut of each human adult, for example, contains about two pounds of bacteria—more than 15,000 times as many individual bacteria as there are humans on earth! These internal cohabitants aid in digestion and absorption of essential nutrients, and play an important role in the development of our immune systems. Only a tiny fraction of the world's microbes constitute a threat to plant, animal, or human life, but some of these threats are truly fearsome.

Recent decades have witnessed the appearance of dozens of infectious diseases that were previously unrecognized or that attained new geographic reach, incidence or severity. These encompass newly resistant conditions such as some forms of bacterial pneumonia, malaria, and tuberculosis; threats such as West Nile virus that have spread across the United States; and new global catastrophes such as AIDS. The conditions favoring emergence of new diseases are neither transient nor aberrant; they are intrinsic to modern technology and ways of life.

Among the forces promoting new microbial threats or increasing human vulnerability:

- **Increasing population size and density**. Population growth is most rapid in low latitude countries. Large and growing cities in tropical or subtropical developing countries are frequently surrounded by peri-urban slums that lack clean water, sanitary disposal of waste, and access to medical care. Growing populations drive the need for more food, including animal protein, and closer proximity of human and animal populations, often with both occupying the same, limited space.
- **More rapid and frequent travel**. Almost 2 million people cross international borders daily. In the year 2000, an estimated 400 million international travelers entered the United States by land, ship, or air. Every human traveler is a potential conveyer of infectious organisms.

• **Increased number of vulnerable individuals.** Older individuals tend to mount less vigorous immune responses to infection, and the aging of the population increases the proportion that is susceptible to infectious diseases. Growing numbers of immunocompromised individuals—due to HIV infection, radiation and chemotherapy treatment for cancer, or immunosuppressive therapy in conjunction with organ transplant—also contribute to a population that is more vulnerable to infections.

• **Growing global commerce**. Trade involves living and dead animals and animal parts shipped for food, pets, research, and by-products. Mosquitoes that are competent to transmit human infections have been introduced into new geographic areas via trade (breeding, for example, in tires on ships). Food imports have been associated with outbreaks of unfamiliar infections (such as cyclospora in the United States and Canada from raspberries imported from Guatemala). Non-food imports into the United States in 2002 included 47,000 mammals (including 28 species of rodents), 379,000 birds, 2 million reptiles, 49 million amphibians, and 223 million fish. Most of these animals are wild caught, not screened before shipment, suffer high mortality in transit, and gain exposure to the public. Monkeypox was imported into the United States in a shipment of African rodents to be sold as pets in the United States.

• **Mass production in agriculture**. Large concentrations of genetically similar plants and animals render agriculture vulnerable to large scale outbreaks of infection. Large, high-density populations of poultry, hogs, and other animals are similarly susceptible to infectious diseases.

• **Widespread antimicrobial use and misuse**. Antimicrobials exert selective pressure on bacteria, viruses, fungi, and protozoa, leaving resistant strains able to survive, replicate, and, in some instances, be transmitted and become more prevalent. Approximately 40 percent of antimicrobials in the United States are used in sub-therapeutic doses to promote growth in farm animals, in aquaculture and in cultivation of fruit trees. Such chronic use of low-dose antimicrobials is especially favorable to development of resistant strains. A substantial fraction of prescribed antimicrobials are unnecessary or misused. Incomplete treatment of tuberculosis facilitated emergence of multi-drug resistant strains of the infection.

• **Changes in land use and human habitats**. Construction, agricultural projects, drainage, dam construction, and other alterations in land use can change the ecology for disease vectors and for reservoir and intermediate animal hosts. Human development breaches traditional biophysical barriers, such as rivers and mountains. Logging roads in Africa facilitate bushmeat trade, a source of human exposure to novel pathogens. Urban habitats can facilitate the spread of infections, as occurred with air conditioned buildings and legionnaire's disease in the United States, and with SARS and the high-rise Amoy Gardens in Hong Kong.

Many newly acquired infectious diseases in humans derive from an animal source. This includes HIV (from primates), SARS (from civet cats or other animals), avian influenza (from birds), variant Creutzfeldt-Jacob disease (from cows infected with bovine spongiform encephalopathy), and Nipah virus (from fruit bats). When the ancestor virus to HIV adapted to spread from person to person, the results were devastating. Globally, to date, 20 million persons have died of AIDS, and approximately 40 million are living with HIV infection.

The greatest natural catastrophe of the 20th Century was the influenza pandemic of 1918–19. In the space of less than 12 months, more than a half million Americans, many young and vigorous, lost their lives to the flu, and this was at a time when the total U.S. population was around 100 million. Worldwide, the great influenza pandemic killed at least 20 million; some estimates are as much as five times higher. The specific viral culprit was later identified as a form of influenza A that probably originated in birds. Even in an average flu season, influenza accounts for an estimated 30,000 to 40,000 deaths in the United States. Because of its ability to undergo rapid genetic change and to move across species (such as birds, pigs, and humans) the influenza virus is a formidable pathogen. The shadow of the great pandemic of 1918–19 darkens every discussion of the threat of influenza, including the pandemic potential of avian flu.

The natural reservoir for influenza A is aquatic birds that carry and excrete the virus, but do not experience disease. The virus periodically infects other hosts, including other kinds of poultry and mammals, which may suffer disease or death from infection. A highly pathogenic form of avian influenza is now endemic in bird populations in parts of Asia where 30 percent of the world's human population live and where contact with poultry is common among rural residents. Sporadic human cases have proven fatal in more than half the clinically evident cases, although the number of sub-clinical human infections is unknown. The major concern is that mu-

tation or genetic re-assortment may produce a viral variant that is efficiently transmitted from person to person, sowing the seed for a global pandemic.

The currently prevalent form of avian flu has shown increased severity of illness in poultry, an expanded mammalian range, and excretion of highly pathogenic virus by apparently healthy ducks. One worrisome development is the appearance of clusters of human cases, suggesting the possibility of human to human transmission, as appears likely in at least one reported instance. Efforts in some areas to monitor infection in animals and to track changes are hampered by local conditions, limited capacities, and concerns about commerce and tourism.

Early vaccine trials are underway as is research on more efficient ways to produce influenza vaccine and on the potential transmissibility of avian flu variants. In addition to this current research, a concerted strategy to cope with avian flu would incorporate intensified bilateral and multi-lateral international efforts to monitor and cull infected animal populations, accumulation of larger reserves of anti-viral drugs that may reduce the severity of a disease outbreak, and detailed plans for international sharing and domestic deployment of drugs and vaccine if and when they are needed.

Drug Resistance, Vaccine Manufacturers, and New Drugs

Drug-resistant microbes are a serious public health threat. The CDC estimates that approximately 2 million people acquire bacterial infections in the hospital each year, more than 70 percent of which are resistant to at least one antimicrobial commonly used to treat them. Hospital-acquired infections claim approximately 90,000 lives each year. Drug-resistant infections typically require more costly drugs and are difficult to treat, estimated to impose an economic burden of at least $5 billion annually. While the number of resistant organisms has burgeoned, the number of newly approved antibacterial agents has declined steadily over the past 20 years, dropping from 16 between 1983 and 1987 to 7 between 1998 and 2002, and to just 3 in 2003–04. In its 2003 report on *Microbial Threats*, the IOM pointed out that every antibacterial drug then in clinical development belonged to an already existing class of drugs, i.e., that not one new class of drugs was then in late-stage development.

As drug resistance spreads and vaccine-preventable threats loom, the declines in vaccine manufacturers and in new antimicrobials represent a dangerous, combined trend. Vulnerability to the reduced number of vaccine production facilities was revealed in last year's shortage of flu vaccine. Vulnerability to drug-resistant microorganisms plays out every day in U.S. hospitals and in clinics treating infectious diseases around the globe.

Strategies to Cope With Microbial Threats

Many of the same capacities, approaches, and tools to contend with naturally occurring infections apply equally to deliberately deployed infectious agents. Scientific research to create more effective anti-viral agents applies to influenza as it does to smallpox, and inter-disciplinary collaboration can reveal novel approaches to potential drug targets on any dangerous infectious agent. More vaccine manufacturers are needed to avert the kind of shortages seen in last year's flu season and to provide preventives against potential agents of bioterror. Incentives for investment in new vaccines and drugs can provide more effective preventives and care for a range of natural or intentional infections. Alert physicians, surveillance systems, epidemiologic investigation, and well-equipped laboratories will be necessary in identifying the cause of any new infection, from whatever source. A strategy of prevention and containment will be needed for infectious diseases, either natural or deliberate in origin, including vaccination programs; public education; appropriate use of isolation and quarantine; utilization of drugs, devices, and treatment facilities; clear and authoritative communication; professional collaboration among health care providers, public health officials, and veterinary experts; and coordination across departmental jurisdictions and among Federal, State, and local health authorities, as well as international agencies.

Of course, there are differences in preparing for the possibility of bioterror and of natural biological threats in terms of the specific agents of interest, the risks and scope of research, the means of deterrence, and the salience for special populations, such as the armed forces. An important step is being taken through the implementation of a National Science Advisory Board for Biosecurity to reduce the likelihood that legitimate research will inadvertently increase the risk of bioterrorism. A human adversary can take account of preparations and attempt to exploit a perceived, remaining weakness. This is what risk managers and military planners call the N+1 problem: prepare for N contingencies, and the enemy will try to exploit one you have not yet considered. By contrast, Nature, to paraphrase Einstein, may be

subtle, but is not devious. The microbial world, however, is huge, diverse, and resilient, and a microbe's rapid generation time and multiple means of adaptation may render its lack of intent a distinction without much of a difference when it comes to the risk to human health. Microbes, in their natural course of survival and replication, may produce consequences as terrible and terrifying as any bioterrorist. Most of what needs to be done to prepare against either will serve against both.

The Public Health Infrastructure

Public health departments in communities and States across the Nation are highly variable in their capacity to respond to natural or intentional outbreaks of infection. The majority of personnel working in health departments in the United States today are not trained in relevant public health disciplines. Information technology and health information systems are often seriously deficient. Many public health laboratories are antiquated, and only about 60 percent of local health departments have any laboratory capacity whatsoever. Almost all departments lack a real-time surveillance system, and many lack a basic capacity for epidemiologic investigation. Communication networks are often ineffective and fragmented, and emergency response capabilities are severely limited. While national guidelines for reform of public health law have been proposed, many State public health statutes remain outdated and internally inconsistent. These and other shortcomings, and a comprehensive set of recommendations to overcome them, are enumerated in the IOM report on *The Future of the Public's Health* (2003). Systematic improvement in the Nation's public health infrastructure would go a long way toward strengthening the Nation's ability to respond to natural or intentional infection and provide many other benefits to protect the public's health.

Low-Likelihood, High-Consequence Events

An especially challenging dilemma for decision makers is how to respond to events that are relatively unlikely, but carry severe consequences if they materialize. Such low-likelihood, high-consequence risks include infectious diseases that may be natural (such as a new SARS, or the appearance of pandemic influenza in any given year) or intentional (such as smallpox or anthrax). In such cases, preparedness and selected measures may be prudent and wise, yet cynics and armchair critics will most often be correct if they claim the preparations were for naught. That is the nature of a low-likelihood event. If the low-likelihood, high-consequence event does eventuate, the preparations will nearly always be seen in retrospect to have been less than was optimal. The prospective dilemma intensifies when preparations are expensive, intrusive, complex, and laden with risk. These conditions make policymakers politically vulnerable, even when they are making the right decision. Acknowledging this dilemma does not excuse flawed decision making; indeed, the only hope for improvement is to learn the strategic lessons from past errors of over-reaction and under-reaction. Recognizing the dilemma, however, does place a premium on establishing clear lines of authority and the necessary resources in advance. Without such authority and means, there can be no legitimate accountability.

If there are ways that I or my colleagues at the Institute of Medicine or the National Academies can be helpful as you proceed with your deliberations, please do not hesitate to call upon us.

SELECTED REPORTS FROM THE INSTITUTE OF MEDICINE AND THE NATIONAL RESEARCH COUNCIL

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I. Infectious Diseases

The Threat of Pandemic Influenza: Are We Ready? Workshop Summary (2005). Stacey Knobler, Alison Mack, Adel Mahmoud, and Stanley Lemon, editors.

Public health officials and organizations around the world remain on high alert because of increasing concerns about the prospect of an influenza pandemic, which many experts believe to be inevitable. Moreover, recent problems with the availability and strain-specificity of vaccine for annual flu epidemics in some countries and the rise of pandemic strains of avian flu in disparate geographic

regions have alarmed experts about the world's ability to prevent or contain a human pandemic. This workshop summary on *The Threat of Pandemic Influenza: Are We Ready*? addresses these urgent concerns. The report describes what steps the United States and other countries have taken thus far to prepare for the next outbreak of "killer flu." It also looks at gaps in readiness, including hospitals' inability to absorb a surge of patients and many nations' incapacity to monitor and detect flu outbreaks. The report points to the need for international agreements to share flu vaccine and antiviral stockpiles to ensure that the 88 percent of nations that cannot manufacture or stockpile these products have access to them. It chronicles the toll of the H5N1 strain of avian flu currently circulating among poultry in many parts of Asia, which now accounts for the culling of millions of birds and the death of at least 50 persons. It also compares the costs of preparations with the costs of illness and death that could arise during an outbreak.

Learning from SARS: Preparing for the Next Disease Outbreak—Workshop Summary (2004). Stacey Knobler, Adel Mahmoud, Stanley Lemon, Alison Mack, Laura Sivitz, and Katherine Oberholtzer, editors.

The emergence of severe acute respiratory syndrome (SARS) in late 2002 and 2003 challenged the global public health community to confront a novel epidemic that spread rapidly from its origins in southern China until it had reached more than 25 other countries within a matter of months. In addition to the number of patients infected with the SARS virus, the disease had profound economic and political repercussions in many of the affected regions. Recent reports of isolated new SARS cases and a fear that the disease could reemerge and spread have put public health officials on high alert for any indications of possible new outbreaks. This report examines the response to SARS by public health systems in individual countries, the biology of the SARS coronavirus and related coronaviruses in animals, the economic and political fallout of the SARS epidemic, quarantine law and other public health measures that apply to combating infectious diseases, and the role of international organizations and scientific cooperation in halting the spread of SARS. The report provides an illuminating survey of findings from the epidemic, along with an assessment of what might be needed in order to contain any future outbreaks of SARS or other emerging infections.

Microbial Threats to Health: Emergence, Detection, and Response (2003). Mark Smolinski, Margaret Hamburg, and Joshua Lederberg, editors.

Infectious diseases are a global hazard that puts every nation and every person at risk. The recent SARS outbreak is a prime example. Knowing neither geographic nor political borders, often arriving silently and lethally, microbial pathogens constitute a grave threat to the health of humans. Indeed, a majority of countries recently identified the spread of infectious disease as the greatest global problem they confront. Throughout history, humans have struggled to control both the causes and consequences of infectious diseases and we will continue to do so into the foreseeable future. Following up on a high-profile 1992 report from the Institute of Medicine, Microbial Threats to Health examines the current state of knowledge and policy pertaining to emerging and re-emerging infectious diseases from around the globe. It examines the spectrum of microbial threats, factors in disease emergence, and the ultimate capacity of the United States to meet the challenges posed by microbial threats to human health. From the impact of war or technology on disease emergence to the development of enhanced disease surveillance and vaccine strategies, Microbial Threats to Health contains valuable information for researchers, students, health care providers, policymakers, public health officials. and the interested public.

The Resistance Phenomenon in Microbes and Infectious Disease Vectors: Implications for Human Health and Strategies for Containment—Workshop Summary (2003). Stacey Knobler, Stanley Lemon, Marian Najafi, and Tom Burroughs, editors.

The emergence of new diseases such as SARS and the looming threat of bioterrorist attacks remind us of how vulnerable we can be to infectious agents. With advances in medical technologies, we have tamed many former microbial foes, yet with few new antimicrobial agents and vaccines in the pipeline and drug resistance increasing rapidly among infectious microbes, we teeter on the brink of losing the upper hand in our ongoing struggle against these foes, old and new. *The Resistance Phenomenon in Microbes and Infectious Disease Vectors* examines our understanding of the relationships among microbes, disease

vectors, and human hosts, and explores possible new strategies for meeting the challenge of resistance.

The Emergence of Zoonotic Diseases: Understanding the Impact on Animal and Human Health—Workshop Summary (2002). Tom Burroughs, Stacey Knobler, and Joshua Lederberg, editors.

Zoonotic diseases represent one of the leading causes of illness and death from infectious disease. As defined by the World Health Organization, zoonoses are those diseases and infections that are naturally transmitted between vertebrate animals and man with or without an arthropod intermediate. Worldwide, zoonotic diseases have a negative impact on commerce, travel, and economies. In most developing countries, zoonotic diseases are among those diseases that contribute significantly to an already overly burdened public health system. In industrialized nations, zoonotic diseases are of particular concern for at-risk groups such as the elderly, children, childbearing women, and immunocompromised individuals. *The Emergence of Zoonotic Diseases: Understanding the Impact on Animal and Human Health* covers a range of topics, which include: an evaluation of the relative importance of zoonotic diseases against the overall backdrop of emerging infections; research findings related to the current state of our understanding of zoonotic diseases; surveillance and response strategies to detect, prevent, and mitigate the impact of zoonotic diseases on human health; and information about ongoing programs and actions being taken to identify the most important needs in this vital area.

Considerations for Viral Disease Eradication: Lessons Learned and Future Strategies—Workshop Summary (2002). Stacey Knobler, Joshua Lederberg, and Leslie Pray, editors.

Since smallpox eradication, the science of eradication has changed and with it, our definitions of what diseases it is possible to eradicate. However, eradication must not beget complacency. As has been learned from past control or eradication attempts with a variety of viral diseases from yellow fever to influenza, accidental or intentional reintroduction is a real threat—one that could strike anywhere and for which we need to be fully prepared. The criteria for assessing eradicability of polio, measles, and other viral infections have been debated extensively. With the elimination and eradication of several viral diseases on the horizon, issues surrounding the cessation of immunization activities become exceedingly important. In an effort to better understand the dynamics of disease eradication and post-immunization policies, the Institute of Medicine's Forum on Emerging Infections hosted a 2-day workshop on "The Consequences of Viral Disease Eradication." This summary of the workshop explores the principles underlying the biological challenges, medical interventions, the continuing research agenda, and operational considerations for post-immunization strategies for vaccine-preventable viral diseases, and highlights important efforts that may facilitate wise decisionmaking.

Emerging Infectious Diseases from the Global to the Local Perspective—Workshop Summary (2001). Jonathan Davis and Joshua Lederberg, editors.

In October 1999, the Institute of Medicine's Forum on Emerging Infections convened a 2-day workshop entitled "International Aspects of Emerging Infections." Key representatives from the international community explored the forces that drive emerging infectious diseases to prominence. *Emerging Infectious Diseases from the Global to the Local Perspective* includes summaries of the presentations from this workshop and suggests an agenda for future action. The topics addressed cover a wide range of issues, including trends in the incidence of infectious diseases around the world, descriptions of the wide variety of factors that contribute to the emergence and reemergence of these diseases, efforts to coordinate surveillance activities and responses within and across borders, and the resource, research, and international needs that remain to be addressed.

Perspectives on the Department of Defense Global Emerging Infections Surveillance and Response System: A Program Review (2001). Philip S. Brachman, Heather C. O'Maonaigh, and Richard N. Miller, editors.

This report describes the capacity, quality, and effectiveness of the international and domestic facilities and programs that are a part of the Defense Department's system to monitor and address emerging infectious diseases globally. The committee concludes that the goals of the system are in U.S. military, U.S. civilian, and global public health interests and that substantial progress has been made toward achieving system goals.

Orphans and Incentives: Developing Technology to Address Emerging Infections—Workshop Summary (1997). Polly Harrison and Joshua Lederberg, editors.

Infectious diseases remain a leading cause of prolonged illness, premature mortality, and soaring health costs. In the United States in 1995, infectious diseases were the third leading cause of death, right behind heart disease and cancer. Mortality is mounting over time, owing to HIV/AIDS, pneumonia, and septicemia, with drug resistance playing an ever-increasing role in each of these disease categories. This summary from a Forum on Emerging Infections workshop focuses on product areas where returns from the market might be perceived as being too small or too complicated by other factors to compete in industrial portfolios with other demands for investment. Vaccines are quintessential examples of such products. The lessons learned fall into four areas, including what makes intersectoral collaboration a reality, the notion of a product life cycle, the implications of divergent sectoral mandates and concepts of risk, and the roles of advocacy and public education. The summary contains an examination of the Children's Vaccine Initiative and other models, an industry perspective on the emerging infections agenda, and legal and regulatory issues.

Infectious Diseases in an Age of Change: The Impact of Human Ecology and Behavior on Disease Transmission (1995). Bernard Roizman, editor.

Twenty-first century progress against infectious diseases is threatened by urbanization, population growth, war refugees, changing sexual standards, and a host of other factors that open doors to the transmission of deadly pathogens. *Infectious Diseases in an Age of Change* reports on major infectious diseases that are on the rise today because of changing conditions and identifies urgently needed public health measures. This volume looks at the range of factors that shape the epidemiology of infectious diseases—from government policies to economic trends to family practices. Describing clinical characteristics, transmission, and other aspects, the book addresses major infectious threats—sexually transmitted diseases, Lyme disease, human cytomegalovirus, diarrheal diseases, dengue fever, hepatitis viruses, HIV, and malaria. The authors also look at the rising threat of drug-resistant strains of tuberculosis, rapid exhaustion of the weapons to fight bacterial infections, and prospects for vaccinations and eradication of pathogens.

II. THE PUBLIC HEALTH SYSTEM

Human Resources at U.S. Ports of Entry to Protect the Public's Health—Interim Letter Report (2005). Committee on Measures to Enhance the Effectiveness of CDC Quarantine Station Expansion Plan for U.S. Ports of Entry, Institute of Medicine.

Nearly 40 newly emerging or reemerging infectious diseases have appeared and spread to multiple continents since 1970—from HIV/AIDS and SARS to West Nile virus and poliovirus. A significant vehicle for the spread of disease today is the speed and volume of international and transcontinental travel, commerce, and human migration. These trends and the risk of bioterrorism have prompted the U.S. Government to expand efforts to prevent communicable diseases of public health significance from being imported into the United States. As part of this endeavor, Congress and the Bush Administration have given CDC's Division of Global Migration and Quarantine (DGMQ) a mandate to more than triple the size of its system of quarantine stations at U.S. ports of entry and to play an active, anticipatory role in nationwide biosurveillance. DGMQ has asked the IOM to examine the proposed quarantine station expansion plans and recommend how the system should evolve to meet public health needs of the 21st century. This interim letter report, *Human Resources at U.S. Ports of Entry to Protect the Public's Health*, is the first of two reports responding to DGMQ's request. In this report, the IOM's Committee on Measures to Enhance the Effectiveness of CDC Quarantine Station Expansion Plan for U.S. Ports of Entry offers preliminary suggestions for the priority functions of a modern quarantine station, the competencies necessary to carry out those functions, and the types of health professionals who have the requisite competencies. The committee's final report, to be released in early summer 2005, will comprehensively assess the current role of quarantine stations and articulate a vision of their future role as a public health intervention.

Vaccine Safety Research, Data Access, and Public Trust (2005). Committee on the Review of the National Immunization Program's Research Procedures and Data Sharing Program, Institute of Medicine.

The Vaccine Safety Datalink (VSD) is a large, linked database of patient information that was developed jointly by CDC and several private managed care organizations in 1991. It includes data on vaccination histories, health outcomes, and characteristics of more than 7 million patients of eight participating health organizations. Researchers from CDC and these managed care groups have used VSD information to study whether health problems are associated with vaccinations. A subsequent VSD data sharing program was launched in 2002 to allow independent, external researchers access to information in the database. In this report, the committee that was asked to review aspects of this program recommends two new oversight groups to ensure that the policies and procedures of the VSD and its data sharing program are implemented as fairly and openly as possible. The Centers for Disease Control and Prevention, which oversees the VSD and the data sharing program, should create a new, independent committee to review researchers' proposals to use VSD data, monitor adherence to protocols, and advise the agency and its partners on when and how to release preliminary findings based on the data, the report says. In addition, CDC should create a new subcommittee of the National Vaccine Advisory Committee (NVAC), or tap an existing one, to enable stakeholders to review and provide input on the VSD research plan every year. The committee makes additional recommendations on specific aspects of the VSD data sharing program and on conditions governing whether, when, and how preliminary findings should be shared with others.

The Smallpox Vaccination Program: Public Health in an Age of Terrorism (2005). Alina Baciu, Andrea Pernack Anason, Kathleen Stratton, and Brian Strom, editors.

This report constitutes an archival compendium of the committee's smallpox reports to the Centers for Disease Control and Prevention, summarizing milestones in the smallpox vaccination program and the committee's assessment of what has been accomplished in the course of the program. The report discusses lessons learned from the vaccination program, concluding that there is a need to balance scientific communication with national security imperatives in the context of bioterrorism and similar programs in a way that preserves the authoritative voice of the CDC (or other appropriate agency, depending on the type of emergency). The report also recommends that smallpox preparedness should be defined, preparedness goals should be set based on the best available scientific and public health reasoning, preparedness should be comprehensively assessed, and the status of preparedness efforts should be communicated to the public.

"Discovery of Antivirals Against Smallpox" (2004). Stephen Harrison, et al., Proceedings of the National Academy of Sciences vol. 101, no. 31, pp. 11178–11192.

This *PNAS* article summarizes the findings and recommendations from a workshop hosted by the National Academies on scientific priorities in smallpox research and policies that are needed for promoting the development of effective countermeasures against any possible reintroduction of smallpox into the public community.

The Future of the Public's Health in the 21st Century (2003). Committee on Assuring the Health of the Public in the 21st Century, Institute of Medicine.

The anthrax incidents following the 9/11 terrorist attacks put the spotlight on the Nation's public health agencies, placing them under an unprecedented scrutiny that added new dimensions to the complex issues considered in this report. *The Future of the Public's Health in the 21st Century* reaffirms the vision of Healthy People 2010 and outlines a systems approach to assuring the Nation's health in practice, research, and policy. This approach focuses on joining the unique resources and perspectives of different sectors and challenges these groups to work in a concerted, strategic way to promote and protect the public's health. Focusing on diverse partnerships as the framework for public health, the book discusses (i.) the need for a shift from an individual to a population-based approach in practice, research, policy, and community engagement; (ii.) the status of the governmental public health infrastructure and what needs to be improved, including its interface with the health care delivery system; and (iii.) the roles that non-government actors, such as academia, business, local communities and the media, can play in creating a healthy nation.

Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century (2003). Kristine Gebbie, Linda Rosenstock, and Lyla M. Hernandez, editors.

Bioterrorism, drug-resistant disease, transmission of disease by global travel—there is no shortage of challenges facing America's public health officials. Men and women preparing to enter this field require state-of-the-art training to meet these increasing threats to the public health. But are the programs they rely on providing the high caliber professional training they require? *Who Will Keep the Public Healthy*? provides an overview of the past, present, and future of public health education, assessing its readiness to provide the training and education needed to prepare men and women to face 21st-century challenges. Advocating an ecological approach to public health, the Institute of Medicine examines the role of public health schools and degree-granting programs, medical schools, nursing schools, and government agencies, as well as other institutions that foster public health education and leadership. Specific recommendations address the content of public health education, qualifications for faculty, availability of supervised practice, opportunities for cross-disciplinary research and education, cooperation with government agencies, and government funding for education. Eight areas of critical importance to public health education in the 21st century are examined in depth: informatics, genomics, communication, cultural competence, community-based participatory research, global health, policy and law, and public health ethics. The report also includes a discussion of the policy implications of its ecological framework.

Financing Vaccines in the 21st Century: Assuring Access and Availability (2003). Committee on the Evaluation of Vaccine Purchase Financing in the United States, Institute of Medicine.

The national immunization system has achieved high levels of immunization, particularly for children. However, this system faces difficult challenges for the future. Significant disparities remain in assuring access to recommended vaccines across geographic and demographic populations. These disparities result in part from fragmented public-private financing in which a large number of children and adults face limited access to immunization services. Access for adults lags well behind that of children, and rates of immunizations for those who are especially vulnerable because of chronic health conditions, such as diabetes or heart and lung disease, remain low. *Financing Vaccines in the 21st Century: Assuring Access and Availability* addresses these challenges by proposing new strategies for assuring access to vaccines and sustaining the supply of current and future vaccines. The report recommends changes to the Advisory Committee on Immunization Practices (ACIP)—the entity that currently recommends vaccines—and calls for a series of public meetings, a post-implementation evaluation study, and development of a research agenda to facilitate implementation of the plan.

Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military (2002). Stanley Lemon, Susan Thaul, Salem Fisseha, and Heather O'Maonaigh, editors.

Infectious diseases continue to pose a substantial threat to the operational capacity of military forces. Protecting Our Forces reviews the process by which the U.S. military acquires vaccines to protect its warfighters from natural infectious disease threats. The committee found that poorly aligned acquisition processes and an inadequate commitment of financial resources within the Department of Defense vaccine acquisition process rather than uncleared scientific or technological hurdles contribute to the unavailability of some vaccines that could protect military personnel and, implicitly, the welfare and security of the Nation. *Protecting Our Forces* outlines ways in which DOD might strengthen its acquisition process and improve vaccine availability. Recommendations, which include combining all DOD vaccine acquisition responsibilities under a single DOD authority, cover four broad aspects of the acquisition process: (i.) organization, authority, and responsibility; (ii.) program and budget; (iii.) manufacturing; and (iv.) the regulatory status of special-use vaccines.

The Anthrax Vaccine: Is It Safe? Does It Work? (2002). Lois M. Joellenbeck, Lee L. Zwanziger, Jane S. Durch, and Brian L. Strom, editors.

The vaccine used to protect humans against the anthrax disease, called Anthrax Vaccine Adsorbed (AVA), was licensed in 1970. It was initially used to protect people who might be exposed to anthrax where they worked, such as veterinarians and textile plant workers who process animal hair. When the U.S. military began to administer the vaccine, then extended a plan for the mandatory vaccination of all U.S. service members, some raised concerns about the safety and efficacy of AVA and the manufacture of the vaccine. In response to these and other concerns, Congress directed the Department of Defense to support an

independent examination of AVA. *The Anthrax Vaccine: Is It Safe? Does It Work?* reports the study's conclusion that the vaccine is acceptably safe and effective in protecting humans against anthrax. The report also includes a description of advances needed in main areas: improving the way the vaccine is now used, expanding surveillance efforts to detect side effects from its use, and developing a better vaccine.

An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program (2002). Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Research Program, Institute of Medicine.

In 1998, the Department of Defense (DOD) began a program of mandatory immunization against anthrax for all military personnel. As the program proceeded, however, some military personnel and their families raised concerns about the safety and efficacy of the anthrax vaccine. Acknowledging both the need to protect military personnel and the concerns about the anthrax vaccine, Congress directed the Centers for Disease Control and Prevention (CDC) to carry out a research program on its safety and efficacy. To assist in the development of this program, CDC requested the Institute of Medicine to convene a committee to review the completeness and appropriateness of the research program. In *An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program*, the committee makes an overall assessment of the CDC research plan and reviews the specific studies proposed by CDC in the three areas of efficacy, safety and acceptability. The committee also notes additional research needs that became evident following the bioterrorist events of 2001 and makes recommendations about the leadership of the research program.

Vaccines for the 21st Century: A Tool for Decisionmaking (2000). Kathleen R. Stratton, Jane S. Durch, and Robert S. Lawrence, editors.

Vaccines have made it possible to eradicate the scourge of smallpox, promise to do the same for polio, and have profoundly reduced the threat posed by other diseases such as whooping cough, measles, and meningitis. What is next? There are many pathogens, autoimmune diseases, and cancers that may be promising targets for vaccine research and development. This volume provides an analytic framework and quantitative model for evaluating disease conditions that can be applied by those setting priorities for vaccine development over the coming decades. The committee describes an approach for comparing potential new vaccines based on their impact on morbidity and mortality and on the costs of both health care and vaccine development. The report examines: (i.) lessons to be learned from the polio experience; (ii.) scientific advances that set the stage for new vaccines; (iii.) factors that affect how vaccines are used in the population; and (iv.) value judgments and ethical questions raised by comparison of health needs and benefits. The committee provides a way to compare different forms of illness and set vaccine priorities without assigning a monetary value to lives, and its recommendations will be important to anyone involved in science policy and public health planning: policymakers, regulators, health care providers, vaccine manufacturers, and researchers.

Managed Care Systems and Emerging Infections: Challenges and Opportunities for Strengthening Surveillance, Research, and Prevention—Workshop Summary (2000). Jonathan Davis, editor.

This workshop summary examines how the managed care revolution has created both problems and opportunities in the fight against infectious diseases. It highlights ways in which managed care systems can aid research, develop clinical guidelines, manage the use of antibiotics, support public education efforts, and monitor the spread of emerging infections and microbial resistance.

Public Health Systems and Emerging Infections: Assessing the Capabilities of the Public and Private Sectors—Workshop Summary (2000). Jonathan Davis and Joshua Lederberg, editors.

With a focus on our knowledge and understanding of the role of private and public health sectors in emerging infectious disease surveillance and response, this workshop summary explores the effects of the privatization of public health laboratories and the modernization of public health care. The issues discussed included epidemiological investigation, surveillance, communication, coordination, resource allocations, and economic support.

Assessment of Future Scientific Needs for Live Variola Virus (1999). Committee on the Assessment of Future Scientific Needs for Variola Virus, Institute of Medicine.

In 1980, the World Health Organization (WHO) officially declared that smallpox had been eradicated. In 1986, WHO's international Ad Hoc Committee on Orthopox Virus Infections unanimously recommended destruction of the two remaining official stocks of variola virus, one at the Centers for Disease Control and Prevention and the other at the VECTOR laboratory in Siberia. In June 1999, WHO decided to delay the destruction of these stocks. Informing that decision was Assessment of Future Scientific Needs for Variola Virus, which examines (i.) whether the sequenced variola genome, vaccinia, and monkey pox virus are adequate for future research or whether the live variola virus itself is needed to assist in the development of antiviral therapies; (ii.) what further benefits, if any, would likely be gained through the use of variola in research and development efforts related to agent detection, diagnosis, prevention, and treatment; and (iii.) what unique potential benefits, if any, the study of variola would have in increasing our fundamental understanding of the biology, host-agent interactions, pathogenesis, and immune mechanisms of viral diseases.

America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests (1997). Board on International Health, Institute of Medicine.

This report focuses on the interest of the United States in global health developments, arguing that this country has a vital and direct stake in the health of people around the globe and that this interest derives from both America's long and enduring tradition of humanitarian concern and compelling reasons of enlightened self-interest. For the United States to engage successfully in global health, coordination among the multiple U.S. agencies with statutory responsibilities in the area is needed, as well as the formation of partnerships with the U.S. industrial and academic sectors and nongovernmental organizations, other nations, and international organizations. This report stresses those areas of U.S. global health engagement that are most likely to benefit the health of the U.S. population and recommends changes in policy and implementation that can enhance the health of Americans and other peoples of the world, provide economic benefit, and advance U.S. global leadership.

III. BIOTERRORISM AND SECURITY

Biotechnology Research in an Age of Terrorism (2004). Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, Development, Security, and Cooperation, National Research Council.

In recent years much has happened to justify an examination of biological research in light of national security concerns. The destructive application of biotechnology research includes activities such as spreading common pathogens or transforming them into even more lethal forms. This new book by the National Research Council recommends that the government expand existing regulations and rely on self-governance by scientists rather than adopt intrusive new policies. One key recommendation of the report is that the government should not attempt to regulate scientific publishing but should trust scientists and journals to screen their papers for security risks, a task some journals have already taken up. With biological information and tools widely distributed, regulating only U.S. researchers would have little effect. A new International Forum on Biosecurity should encourage the adoption of similar measures around the world. Seven types of risky studies would require approval by the Institutional Biosafety Committees that already oversee recombinant DNA research at some 400 U.S. institutions. These experiments of concern include making an infectious agent more lethal and rendering vaccines powerless.

Seeking Security: Pathogens, Open Access, and Genome Databases (2004). Committee on Genomics Databases for Bioterrorism Threat Agents, National Research Council.

Within the last 30 years, the genomes of thousands of organisms, from viruses, to bacteria, to humans, have been sequenced or partially sequenced and deposited in databases freely accessible to scientists around the world. This information is accelerating scientists' ability to fight disease and make other medical advances, but policymakers must consider the possibility that the information could also be used for destructive purposes in acts of bioterrorism or war. Based in part on views from working biological scientists, the report concludes that current policies that allow scientists and the public unrestricted access to genome data on microbial pathogens should not be changed. Because access improves our ability to fight both bioterror-

ism and naturally occurring infectious diseases, security against bioterrorism is better served by policies that facilitate, not limit, the free flow of this information.

Giving Full Measure to Countermeasures: Addressing Problems in the DOD Program to Develop Medical Countermeasures Against Biological Warfare Agents (2004). Lois M. Joellenbeck, Jane S. Durch, and Leslie Z. Benet, editors.

In recent years, substantial efforts have been initiated to develop new drugs, vaccines, and other medical interventions against biological agents that could be used in bioterrorist attacks against civilian populations. According to this Congressionally mandated report from the National Academies, to successfully develop these drugs, vaccines, and other medical interventions against biowarfare agents, Congress should authorize the creation of a new agency within the Office of the Secretary of the U.S. Department of Defense. The report recommends that Congress should improve liability protections for those who develop and manufacture these products in order to stimulate willingness to invest in new research and development for biowarfare protection. *Giving Full Measure to Countermeasures* also identifies other challenges such as the need for appropriate animal models and laboratories equipped with high-level biosafety protections that will require attention if DOD efforts to develop new medical countermeasures are to be successful.

Biological Threats and Terrorism: Assessing the Science and Response Capabilities—Workshop Summary (2002). Stacey Knobler, Adel Mahmoud, and Leslie Pray, editors.

In the wake of the September 11th and anthrax events, our Nation's bioterrorism response capability has become an imminent priority for policymakers, researchers, public health officials, academia, and the private sector. In a 3-day workshop, convened by the Institute of Medicine's Forum on Emerging Infections, experts from each of these communities came together to identify, clarify, and prioritize the next steps that need to be taken in order to prepare and strengthen bioterrorism response capabilities. From the discussions, it became clear that of utmost urgency is the need to cast the issue of a response in an appropriate framework in order to attract the attention of Congress and the public in order to garner sufficient and sustainable support for such initiatives. No matter how the issue is cast, numerous workshop participants agreed that there are many gaps in the public health infrastructure and countermeasure capabilities that must be prioritized and addressed in order to assure a rapid and effective response to another bioterrorist attack.

Countering Agricultural Bioterrorism (2002). Committee on Biological Threats to Agricultural Plants and Animals, National Research Council.

Public confidence in the security of the U.S. food and fiber system has been sustained by the quality, variety, abundance, and affordability of agricultural products in the United States. Although the system in place to defend against unintentional threats to agriculture has weaknesses and needs, the demonstrated ability of the system to resolve, accommodate, or manage critical food safety problems, temporary shortages of some commodities, plant and animal infestations and diseases, and natural disasters indicates that, in general, such confidence has been warranted. However, over the last several years, there has been recognition of the possibility and consequences of intentional threats directed at U.S. agriculture. Such attacks could come from foreign or domestic terrorists and use biological, chemical, or radiological agents. They could be directed at the pre-harvest (live plant and live animal) or post-harvest (processing and distribution) stages of food and fiber production. *Countering Agricultural Bioterrorism* assesses the vulnerability of U.S. agriculture to intentional threats and provides recommendations needed to strengthen and adapt the U.S. system for defense against biological threats to agriculture.

Making the Nation Safer: The Role of Science and Technology in Countering Terrorism (2002). Committee on Science and Technology for Countering Terrorism, National Research Council.

Vulnerabilities abound in U.S. society. The openness and efficiency of our key infrastructures transportation, information and telecommunications systems, health systems, the electric power grid, emergency response units, food and water supplies, and others make them susceptible to terrorist attacks. *Making the Nation Safer* discusses technical approaches to mitigating these vulnerabilities. A broad range of topics are covered in this report, including: (i.) nuclear and radiological threats, such as improvised nuclear devices and dirty bombs; (ii.) bioterrorism, medical research, agricultural systems and public

health; (iii.) toxic chemicals and explosive materials; (iv.) information technology, such as communications systems, data management, cyber attacks, and identification and authentication systems; (v.) energy systems, such as the electrical power grid and oil and natural gas systems; (vi.) transportation systems; (vii.) cities and fixed infrastructures, such as buildings, emergency operations centers, and tunnels; (viii.) the response of people to terrorism, such as how quality of life and morale of the population can be a target of terrorists and how people respond to terrorist attacks; and (ix.) linked infrastructures, i.e., the vulnerabilities that result from the interdependencies of key systems. In each of these areas, there are recommendations on how to immediately apply existing knowledge and technology to make the Nation safer and on starting research and development programs that could produce innovations that will strengthen key systems and protect us against future threats. The report also discusses issues affecting the government's ability to carry out the necessary science and engineering programs and the important role of industry, universities, and States, counties, and cities in homeland security efforts. A long-term commitment to homeland security is necessary to make the Nation safer, and this book lays out a roadmap of how science and engineering can assist in countering terrorism.

Countering Bioterrorism: The Role of Science and Technology (2002). Committee on Science and Technology for Countering Terrorism, National Research Council.

This publication reprints material from the above report, *Making the Nation Safer: The Role of Science and Technology in Countering Terrorism* (2002), that dealt specifically with issues relating to bioterrorism.

Preparing for Terrorism: Tools for Evaluating the Metropolitan Medical Response System Program (2002). Frederick J. Manning and Lewis Goldfrank, editors.

The Metropolitan Medical Response System (MMRS) program of the U.S. Department of Health and Human Services (DHHS) provides funds to major U.S. cities to help them develop plans for coping with the health and medical consequences of a terrorist attack with chemical, biological, or radiological (CBR) agents. DHHS asked the Institute of Medicine to assist in assessing the effectiveness of the MMRS program by developing appropriate evaluation methods, tools, and processes to assess both its own management of the program and local preparedness in the cities that have participated in the program. This report provides the managers of the MMRS program and others concerned about local capabilities to cope with CBR terrorism with three evaluation tools and a three-part assessment method.

Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response (1999). Committee on R&D Needs for Improving Civilian Medical Response to Chemical and Biological Terrorism Incidents, Institute of Medicine.

What do we need to know to help emergency and medical personnel prepare for terrorist attacks? *Chemical and Biological Terrorism* identifies the R&D efforts needed to implement recommendations in key areas: pre-incident intelligence, detection and identification of chemical and biological agents, protective clothing and equipment, early recognition that a population has been covertly exposed to a pathogen, mass casualty decontamination and triage, use of vaccines and pharmaceuticals, and the psychological effects of terror. Specific objectives for computer software development are also identified. The report addresses the differences between a biological and chemical attack, the distinct challenges to the military and civilian medical communities, and other broader issues.

Controlling Dangerous Pathogens: A Blueprint for U.S.-Russian Cooperation, A Report to the Cooperative Threat Reduction Program of the U.S. Department of Defense (1997). U.S.-Russian Collaborative Program for Research and Monitoring of Pathogens of Global Importance Committee, National Research Council.

After extensive consultations with key Russian officials and scientific leaders, and drawing on the experience gained through the initiation of six pilot projects at two Russian facilities to investigate the practical aspects of cooperation, the National Academy of Sciences Committee on U.S.-Russian Cooperation on Dangerous Pathogens has recommended a 5-year Pathogens Initiative, followed by a second phase of sustained joint U.S.-Russian research and related efforts. The program would support collaboration on the epidemiology, prevention, diagnosis,

and therapy of diseases associated with dangerous pathogens that pose serious public health threats, as well as related fundamental research. The Pathogens Initiative would engage a substantial number of highly qualified specialists from the former Soviet biological weapons complex and would serve important U.S. national security and public health goals.

Senator BURR. And as a successful way of transitioning, I would like to turn to an area of the world that has many of the same challenges. We talked earlier about the borderless nature of infectious disease, and I would like to welcome Dr. Guenael Rodier and apologize to the Doctor for butchering his name to begin with at the start of this hearing. He is the Director of the Department of Communicable Disease Surveillance and Response at the World Health Organization, truly an organization that is a partner of ours as we address the threat that is presented with biologics in the future.

Dr. Rodier, welcome.

Dr. RODIER. Thank you very much, Mr. Chairman, and you will have to suffer my English, actually. I hope it will go fine.

Good afternoon. I just want to thank the committee for this opportunity to speak today on a topic which is central to the work of the World Health Organization.

I have been working to control outbreaks of infectious diseases my entire career, including 4 years with a U.S. Navy research laboratory. Most of my career was spent in the field with a focus on the control of hemorrhagic fevers in Africa and in the Middle East. With this field experience, I was brought into the WHO headquarters in 1995 to help develop WHO's new response program on epidemics and emerging infections. As Director of the Department of Communicable Disease Surveillance and Response, I played a central role in the coordination of WHO's global response to the SARS outbreak in 2003 and today against the continuing threat from highly pathogenic avian influenza.

I am speaking to you today from WHO's Strategic Health Operations Center. We coordinate all our outbreak and emergency responses through this room. It is a state-of-the-art communications and command center which provides direct and secure links to all WHO 148 country and regional offices and to Ministries of Health and essential laboratories worldwide, including the Department of Health and Human Services and the U.S. Centers for Disease Prevention and Control.

This global interconnectedness is not a luxury. It is essential. By their very nature, infectious diseases have the potential to spread internationally, and WHO needs to be connected to the front lines of outbreaks, to assess the risks, to provide expert advice, and, if needed, to launch international assistance to affected countries rapidly.

Each morning in this room, about two dozen WHO outbreak disease control specialists gather, and this morning, for example, we were tracing 18 outbreaks using this list. These included the tracking of the polio virus which has spread from Nigeria across Africa, into the Middle East, and is now trying to establish itself in Indonesia. We also received updates from our teams on the effort to control the largest Marburg fever outbreak in Angola, the largest meningitis outbreak in India in a decade, and the continuing re-

ports of avian influenza from North Korea to Vietnam and Cambodia.

In the last 5 years, the outbreak response group has detected, verified, and often helped control more than 960 events in 147 countries.

These outbreaks threaten every country. We live in a world more interconnected than ever. As this daily outbreak list shows, the world now finds itself in a situation where epidemics have the potential for spreading around the globe unchecked at unprecedented speed. And mankind is increasingly vulnerable to infectious diseases as the human population is increasingly larger, older, urban, mobile, and, for most, has limited access to safe drinking water and food and modern health care.

New or newly recognized infectious agents that cause human disease are being reported at the rate of approximately one per year.

Microbes can incubate in apparently healthy travelers, hide in food, animals, or cargo, or be carried by insects stowed away in the cabin and luggage holds of jets or in the pots of exotic plants.

As an international health agency with over 50 years of experience in infectious disease control, the World Health Organization is uniquely positioned to gather global disease intelligence, assess public health risk, trigger and coordinate the rapid, multifaceted response needed to contain outbreaks quickly, and prevent their international spread.

The WHO staff, consultants, and expert advisers have privileged access to all countries from Afghanistan to Zimbabwe.

WHO has unique and permanently positioned geographical resources. These include six regional offices and an additional 141 country offices, located within or in close proximity to ministries of health.

WHO's disease control activities are supported by a network of over 250 laboratories and institutions formally designated as WHO Collaborating Centers. These centers provide the expertise and facilities needed to conduct field investigations, handle dangerous pathogens, test samples, identify unknown agents, and confirm diagnosis.

Very, very few countries have all the experts needed to fight all the dangerous and emerging diseases. But these experts exist, working in universities and hospitals and for departments of health. What has been needed is an effective way to organize them so that they can be called on short notice to join an outbreak response team. So WHO created a model similar to the American volunteer fire department.

This "volunteer fire department" model works. This year, thousands of deaths were prevented following the tsunami thanks to this coordinated effort. Last year, meningitis outbreaks which swept across northern Africa were controlled with massive vaccination campaigns. And right now teams from North and South America, from Europe, and from Africa are fighting to keep the Marburg outbreak contained in Angola.

The U.S. Government is a precious partner for WHO in building up global alert and response capabilities for combating the threat posed by infectious diseases. Various U.S. Government agencies have contributed to this effort in line with the multifaceted nature

of the threat. Most extensive is WHO's long tradition of reliance on the practical experience, technical expertise, and staff resources of the CDC to conduct a range of fundamental activities needed to contain the international spread of epidemics. This collaboration has become even closer and more vital as the number of outbreaks requiring an international response continues to escalate.

In addition to targeting known risks such as influenza and responding to the unexpected like the emergence of SARS, a third strategic direction focuses on improving preparedness by strengthening national surveillance and response systems. WHO conducts a number of activities aimed at helping countries expand their laboratories and epidemiological capacity and take advantage of new tools such as Web-based communications, mapping software, and remote sensing data from NASA and other satellites.

In a world that is now closely interrelated in matters of health as well as in economics and trade, defense against the threats posed by infectious diseases requires a collaborative, multifaceted, global response. WHO wishes to express its gratitude for the support provided on so many fronts by the United States and its agencies as part of this global response.

Outbreaks can be most effectively controlled at their origin, preemptively, when they are small and contained. If they break out, we will be fighting them in the hospitals of London, Paris, and Wichita.

We need to significantly strengthen countries' early warning and response systems—to build labs, train epidemiologists, improve communications. We need to continue to effectively assist countries and further develop global and regional operational platforms. This step will benefit the global public health, as well as enhance security and provide business with stability rather than the chaos which often accompanies an outbreak and leads to large economic losses. It was estimated that SARS took (U.S.) $30 billion out of the global economy.

What will future investments in global health security buy? Even a profound shift in resources will not stop the emergence of new diseases. But we can guarantee, with confidence, that if we have the tools to identify outbreaks early and the resources to respond quickly, we can limit the impact of these epidemics. That means fewer lives lost and less harm to economies. This is the spirit of the proposal for the revised International Health Regulations which should provide the global community with collectively agreed ground rules to prevent and respond to public health emergencies of international concern.

I am happy to take your questions. Thank you very much.

Senator BURR. Dr. Rodier, thank you very much, and I realize that it is probably after 9:00 p.m. at night where you are. I can't thank you enough for your willingness to participate in this, and if you can stay with us for the next 20 to 30 minutes as we finish the rest of the testimony, I hope you will make yourself available for some questions from members of the Senate.

[The prepared statement of Dr. Rodier follows:]

PREPARED STATEMENT OF GUENAEL R. RODIER, M.D.

Introduction

Good afternoon, I want to thank the members of the committee for this opportunity to speak today on a topic which is central to the work of the World Health Organization.

I have been working to control outbreaks of infectious diseases my entire career, including 4 years with a U.S. Navy research laboratory. Most of my career was spent in the field with a focus on the control of hemorrhagic fevers in Africa and the Middle East. With this field experience, I was brought into WHO headquarters in 1995 to help develop WHO's new response programme on epidemics and emerging infections. As Director of the Department of Communicable Disease Surveillance and Response, I played a central role in the coordination of WHO's global response to the SARS outbreak in 2003 and today against the continuing threat from highly pathogenic avian influenza.

Strategic Health Operation Center

I am speaking to you today from WHO's Strategic Health Operations Center. We coordinate all our outbreak and emergency responses through this room. It is a state-of-the-art communications and command center which provides direct and secure links to all WHO 148 country and regional offices, and to Ministries of Health and essential laboratories worldwide, including the Department of Health and Human Services, and the U.S. Centers for Disease Prevention and Control.

This global interconnectedness is not a luxury. It is essential. By their very nature, infectious diseases have the potential to spread internationally and WHO needs to be connected to the front lines of outbreaks, to assess the risks, to provide expert advice and, if needed, to launch international assistance to affected countries rapidly.

Trends in emerging and re-emerging infectious disease raise the spectre of highly virulent and communicable pathogens, some of them resistant to existing medical countermeasures, arriving anywhere in the world in 24 hours. The risk of deliberate introduction of infectious diseases such as the anthrax attacks in the United States in 2001—or as has happened recently, the accidental wide laboratory distribution of a potentially dangerous flu strain—adds a new dimension to the challenge of naturally occurring outbreaks and demonstrates the potential for very serious global health implications of natural, accidental and deliberate events.

Each morning in this room, about two dozen WHO outbreak disease control specialists gather for a daily update on global health threats. This morning, for example, we were tracing 18 outbreaks. These included the tracking of the polio virus [SLIDE 1 spread of polio virus] which has spread from Nigeria, across Africa, into the Middle East, and is now trying to establish itself in Indonesia. We also received updates from our teams on the effort to control the Marburg hemorrhagic fever outbreak in Angola; the largest meningitis outbreak in India in a decade, and the continuing reports of avian influenza from North Korea to Viet Nam and Cambodia.

In the last 5 years, the outbreak response group has detected, verified, and often helped control more than 960 events, in 147 countries.

As you can see, the microbial world is complex, dynamic, and constantly evolving. Microbes proliferate rapidly, mutate frequently, and adapt with relative ease to new environments and hosts. They will also eventually develop resistance to the drugs used to treat them. Numerous factors, including those linked to human activities, can accelerate and amplify these natural phenomena, as has happened in recent years. Complacency towards public health practices has proven to only hasten opportunities for microbes to spread, adapt, and resist. This was well highlighted by the 1992 and 2003 reports on emerging infections and microbial threats to health of the Institute of Medicine.

The combination of natural, accidental or deliberate occurrence of infectious diseases demands the establishment or strengthening of national and local capacities to contain these incidents.

Vulnerability

These outbreaks threaten every country. We live in a world more interconnected than ever. As this daily outbreak list shows, the world now finds itself in a situation where epidemics have the potential for spreading around the globe unchecked at unprecedented speed. And mankind is increasingly vulnerable to infectious diseases as the human population is increasingly larger, older, urban, mobile and, for billions, particularly in developing countries, has limited access to safe drinking water and food, sanitation, and modern health care.

New or newly recognized infectious agents that cause human disease are being reported at the rate of approximately one per year. AIDS emerged as an important infectious disease in the early 1980s and is now entrenched on a scale that threatens global security. Other emerging diseases, such as Marburg virus and Severe Adult Respiratory (SARs) disease, illustrate the severe damage caused by lethal new agents that cannot currently be curbed by vaccines or drugs. The continued occurrence of human cases of avian influenza in Asia highlights the potential for the emergence of a new pandemic of a highly virulent virus that could meet or exceed the estimated 20 million deaths during the deadly Spanish Flu of 1918. Altogether, over 30 new infectious diseases have emerged over the past 25 years.

Microbes can incubate in apparently healthy travellers, hide in food, animals, or cargo, or be carried by insects stowed away in the cabin and luggage holds of jets or in the pots of exotic plants. In the UK alone, 1,128 cases of malaria were imported into the country by travellers in 2000. Cases of "airport malaria," in persons who live or work near international airports yet have not travelled, are detected regularly in cities such as London, Paris, Brussels, Geneva, and Oslo as well as in the United States and Canada. In just the past 2 years, unexpected outbreaks of relatively new or previously rare diseases have taken populations on every continent by surprise. Legionellosis and leptospirosis in Australia, Lassa fever, yellow fever, hantavirus, listeriosis, and new variant CJD (human cases of "mad cow" disease") in Europe, and yellow fever, West Nile fever, monkeypox, cryptococcosis, and *E. coli* O157 in the United States are just some examples. In the face of such highly mobile, microscopic, and easily disguised threats, national borders are porous. An outbreak anywhere in the world must now be considered a threat everywhere else.

Global Health Security

As an international health agency with over 50 years of experience in infectious disease control, the World Health Organization is uniquely positioned to gather global disease intelligence, assess public health risk, trigger and coordinate the rapid, multifaceted response needed to contain outbreaks quickly, and prevent their international spread.

During the course of 2004, the WHO's system for verification of public health emergencies of international concern identified 385 events with potential importance for international public health concern. Of the 385 events, 293 were verified, 24 were unverifiable, 42 were defined as "no outbreak verified" and 26 were tracked by WHO for information only.

WHO staff, consultants, and expert advisers have privileged access to all 192 of its member States, which include countries from Afghanistan to Zimbabwe. WHO's technical expertise and long standing relationship with countries allows the Organization, in the interest of safeguarding international health, to transcend the prevailing political sensitivities in which access to critical expertise might be denied because of one country's political relationship with others. On many occasions, the Organization's ability to secure laissez-passer visas has proved decisive in getting the best experts quickly and smoothly into countries. This ability to obtain privileged status is extended to all of the many security-cleared partners who may be needed to mount an effective international response.

WHO has unique and permanently positioned geographical resources. These include six regional offices and an additional 141 country offices, located within or in close proximity to ministries of health. All WHO offices are staffed with medical experts and often with epidemiologists, and all have the essential logistic equipment, including vehicles and local communications, needed for the prompt on-the-scene initial investigation of a suspected outbreak.

WHO's disease control activities are supported by a network of over 250 laboratories and institutions formally designated as WHO Collaborating Centres. These centers provide the expertise and facilities needed to conduct field investigations, handle dangerous pathogens, test samples, identify unknown agents, and confirm diagnosis.

WHO coordinates a large number of electronic surveillance systems and databases for keeping experts alert to changes in the volatile infectious disease situation. These networks, most of which now operate in real time, keep watch over disease-related events ranging from new strains of influenza virus, through outbreaks of salmonellosis and dengue, to the emergence of drug-resistant pathogens. Most of these networks also include quality assurance and training components to ensure that data submitted from all parts of the world are comparable and conform to established standards. The oldest of these, FluNet, was established over 50 years ago and has served as the prototype for the design and implementation of subsequent systems.

WHO has decades of experience in coordinating the field operations needed to control infectious diseases. Current campaigns build on the epidemiological approaches and logistic infrastructure that contributed to the successful global eradication of smallpox. These mechanisms, which have been refined over time, have proven to be robust and effective even under difficult conditions. The successful containment of the largest recorded outbreak of Ebola, which began in Uganda in October 2000, was coordinated by WHO and involved over 500 local staff and volunteers, supported by some 120 international staff from 22 institutions and agencies, including CDC. WHO coordinated the considerable efforts and logistics needed for the identification and confirmation of 425 cases and the surveillance of approximately 5,600 contacts in an area in which 70 percent of the population was internally displaced because of civil disturbances.

Very, very few countries have all the experts needed to fight all the dangerous and emerging diseases. But these experts exist all over the world, working in universities and hospitals and for Departments of Health. What has been needed is an effective way to organize them, so that they can be called on short notice to join an outbreak response team. So WHO created a model similar to the American volunteer fire department. This model is known as GOARN, the Global Outbreak Alert and Response Network [SLIDE 2: GOARN institutions]. GOARN coordinates outbreak assistance found in 120 international technical institutions, NGOs and networks for global alert and response operations. Within 24 hours, GOARN teams can be assembled and launched to any outbreak site in the world.

The annual budget for operating this WHO-run global volunteer fire department is only $8 million. This is about half the money spent on the fire departments of Wake County, North Carolina.

This "volunteer fire department" model works. This year, thousands of deaths were prevented following the tsunami thanks to this coordinated effort. Last year, meningitis outbreaks which swept across northern Africa were controlled with massive vaccination campaigns. And right now, [SLIDE 3: Marburg outbreak in Angola] teams from North and South America, from Europe and from Africa are fighting to keep the Marburg hemorrhagic fever outbreak contained in Angola.

WHO country offices, Regional Offices and headquarters have been directly involved in responding to outbreaks. International epidemic control and field operations have been coordinated with GOARN. During 2004, WHO and technical partners in GOARN responded to outbreaks in Bangladesh, Burkina Faso, Cambodia, Chad, Central African Republic (CAR), People's Republic of China, Democratic Republic of Congo (DRC), Indonesia, Laos, Liberia, Sudan, Sierra Leone, Thailand, and Viet Nam. This represents the major communicable disease outbreak responses but does not reflect all of the response operations of WHO country offices to many other events and emergencies.

The work of coordinating large-scale international assistance, which can involve many agencies from many nations, is facilitated by operational protocols, developed by WHO, which set out standardized procedures for the alert and verification process, communications, coordination of the response, emergency evacuation, research, evaluation, monitoring, and relations with the media. WHO has also issued guidelines for the behavior of foreign nationals during and after field operations in the host country. By setting out a chain of command, and imposing order on the containment response, such protocols help protect against the very real risk that samples of a lethal pathogen might be collected for later provision to a terrorist group.

SARS has disappeared thanks to this coordinated volunteer firefighting approach combined with increasing capacity for real-time telecommunications. I might point out that one of the most unusual accomplishments of that outbreak included the building of a virtual lab in response to the health emergency—a lab which was composed of a dozen labs knitted together from around the world. Working around the clock, and sharing information without restriction, this lab group was able to identify the cause of SARS within 5 weeks. It took 3 years to identify the virus which caused AIDS.

U.S. Involvement

The U.S. Government is a precious partner for WHO in building up global alert and response capabilities for combating the threat posed by infectious diseases. Various U.S. government agencies have contributed to this effort, in line with the multifaceted nature of the threat. Most extensive is WHO's long tradition of reliance on the practical experience, technical expertise, and staff resources of the CDC to conduct a range of fundamental activities needed to contain the international spread of epidemics. This collaboration has become even closer and more vital as the number of outbreaks requiring an international response continues to escalate. At times, such as during the simultaneous outbreaks of Ebola and Rift Valley fever in 2000,

the resources of both agencies have been stretched to the limit. As with the strengthening of national capacities and infrastructure elsewhere, any U.S. decision to strengthen CDC benefits WHO as well as a large number of countries where populations and governments have been weakened by repeated outbreaks and epidemics. Any decision to strengthen CDC would likewise count as a sure, sustainable, and cost-effective measure for defending world security against the mounting threat of infectious diseases. The United States has been a critical partner in controlling outbreaks around the world. Representations from the U.S. Centers for Disease Prevention and Control have worked with WHO on all continents fighting a long list of diseases. In addition to the CDC, WHO has drawn on the expertise of the National Institutes of health and the DOD Global Emerging Infection Surveillance and Response System (GEIS). These experts have worked shoulder to shoulder with experts from Japan, Australia, the EU, South Africa, China and elsewhere. U.S. support made possible the creation of the Strategic Health Operations Center at WHO headquarters.

Strategy

In addition to addressing known risks such as influenza and responding to the unexpected like the emergence of SARS through the volunteer fire department approach, a third strategic focus for WHO is improving preparedness by strengthening national surveillance and response systems. Global health security depends on strengthening capacities everywhere for early local alert and response, but especially in resource-poor settings where current capacities are poor or non-existent. Such poverty often is associated with increased risk for disease outbreaks and, conversely, improving local capabilities in such places contributes to making the whole world safer. WHO conducts a number of activities aimed at helping countries expand their laboratory and epidemiological capacity and take advantage of new tools such as Web-based communications, mapping software and remote sensing data from NASA and other satellites. In collaboration with CDC, WHO formed the Training Programmes in Epidemiology and Public Health Interventions network (TEPHINET), another global network utilized by the Global Outbreak Alert and Response Network, which seeks, through shared resources and expertise, to enhance the effectiveness of national training programs. In 2001, WHO opened a new office in Lyon, France, to provide specific assistance to countries in developing national plans for strengthening their alert and response systems and improving biosafety and biosecurity, including training of senior managers and implementing quality assurance programs.

Within the context of its outbreak alert and response activities, WHO has developed protocols for containing outbreaks of diseases, such as anthrax and viral haemorrhagic fevers, which could result from the intentional use of biological agents. As part of its official mandate for dealing with smallpox-related issues in the post-eradication era, WHO is also responsible for ensuring the security of the remaining stocks of smallpox virus and overseeing their final fate.

What is Needed?

The resurgence of infectious diseases, and the emergence and spread of antimicrobial resistance, have unleashed threats whose magnitude is almost certain to grow. Epidemics are again sweeping across continents. The tools needed to control emerging diseases are, in many cases, non-existent. The control of re-emerging and epidemic-prone diseases likewise suffers from the spread of resistance to inexpensive first-choice drugs. Nonetheless, today's information society is better equipped to protect itself, through effective networking, early detection and proactive preventive measures, than in the past, when isolation and quarantine comprised the sole measures for control. Aided by powerful electronic communication tools and rapid access to modern biotechnology, key defense strategies now include early alert, through sensitive global networks for real-time outbreak detection and verification, and rapid national and international responses once outbreaks are confirmed. The strengthening of infrastructure in epidemic-prone countries is vital to the successful and cost-effective implementation of both strategies.

In a world that is now closely interrelated in matters of health as well as in economics and trade, defense against the threats posed by infectious diseases requires a collaborative, multifaceted, global response. WHO wishes to express its gratitude for the support provided on so many fronts by the United States and its agencies as part of this global response. WHO also wishes to express its strong desire to stay in close dialogue with the United States as we continue to track the evolving infectious disease situation, sound the alarm when needed, share expertise, and mount the kind of tailored responses needed to protect us all from the health consequences of epidemics, whatever and wherever their origin might be.

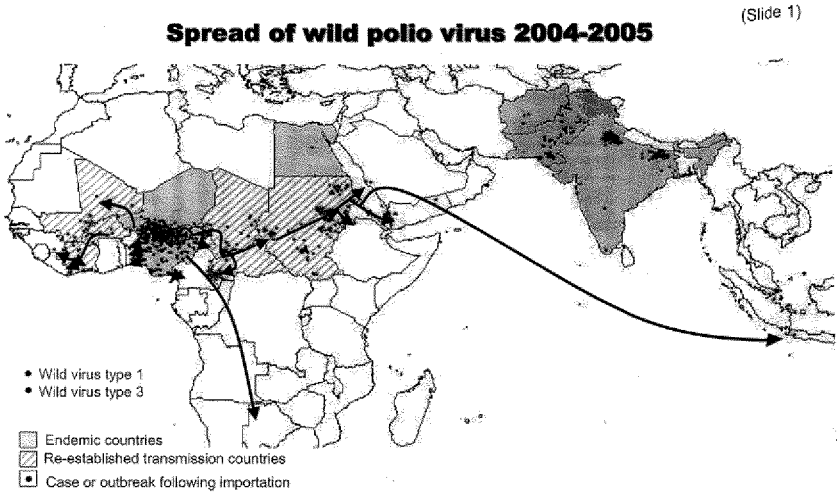
Outbreaks can be most effectively controlled at their origin, preemptively, when they are small and contained [SLIDE 4: Verified outbreaks, 2003–04]. While not all outbreaks can be anticipated and prevented, our goal in WHO is to keep outbreaks from turning into epidemics, and to keep epidemics from becoming pandemics, through preparedness, rapid alert and coordinated global response. If outbreaks can be contained locally, we will not have to fight them in the hospitals of London, Boston and Raleigh.

We need to significantly strengthen countries' early warning and response systems—to build labs, train epidemiologists, improve communications. We need to continue to effectively assist countries and further develop global and regional operational platforms. This step will benefit the health of citizens of all countries, as well as enhance timely public health response to security threats. More economic security and stability for business is also a benefit of avoiding the chaos which often accompanies an epidemic and can lead to large economic losses. It was estimated that SARS took (U.S.) $30 billion out of the global economy.

What will future investments in global health security buy? Even a profound shift in resources will not stop the emergence of new diseases. But we can guarantee, with confidence—that if we have the tools to identify outbreaks early and the resources to respond quickly—that we can limit the impact of these epidemics. That means fewer lives lost and less harm to economies. This is the spirit of the proposal for the revised International Health Regulations which should provide the global community with collectively agreed ground rules to prevent and respond to public health emergencies of international concern.

Thank you. I am happy to take your questions.

(Slide 1)



(Slide 2)

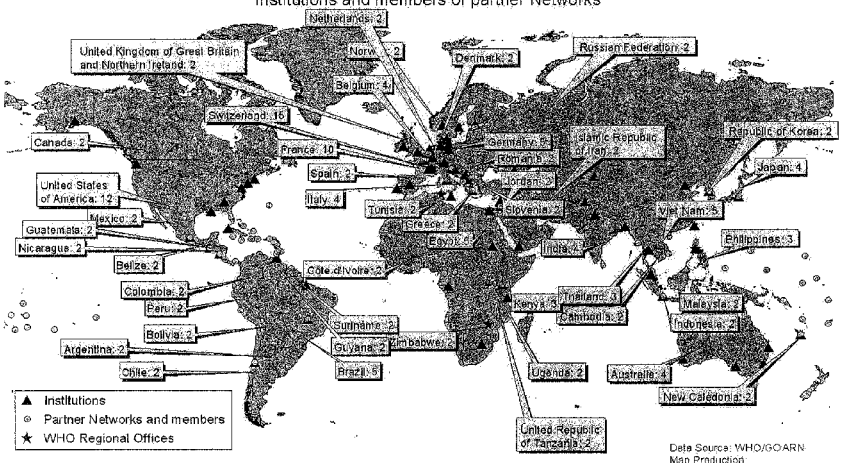
Marburg Haemorrhagic fever, Angola May 2005

Key figures

- 322 cases incl. 284 deaths (CFR 88%)
- cases identified in 5 provinces, including the capital city Luanda
- 17 institutions in the field including CDC Altanta (mobile laboratory)

Global Outbreak Alert and Response Network (GOARN)
Institutions and members of partner Networks

(Slide 3)



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.
Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: WHO/GOARN
Map Production:
Public Health Mapping & GIS
Communicable Diseases (CDS)
World Health Organization
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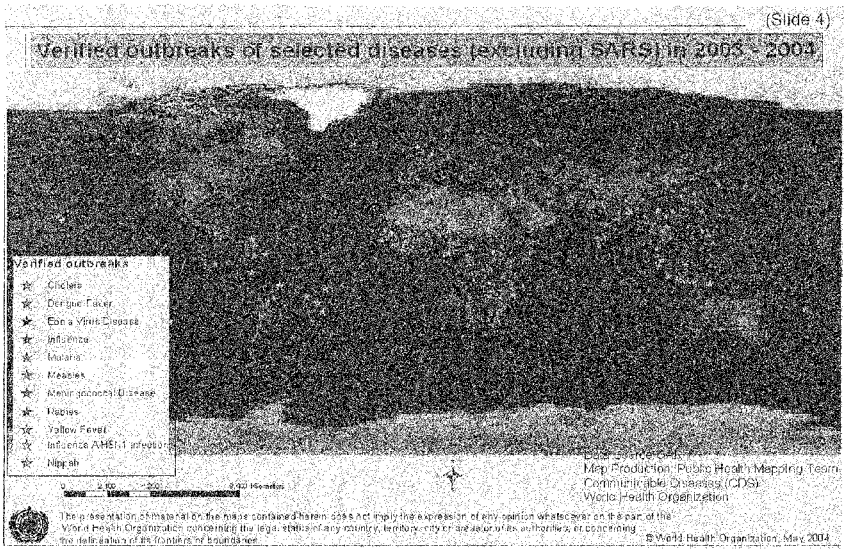

Senator BURR. At this time, let me recognize Dr. Craig Venter. Craig, welcome, and please take the floor.

Mr. VENTER. Thank you, Mr. Chairman, Senator Hatch. I appreciate very much the opportunity to be here today to testify before your subcommittee. This is a very key area that affects all of us going forward.

I am here as a scientist, a basic research scientist that works in the field of genomics. My teams over the last decade have decoded many of the key pathogen genomes, starting with smallpox 10 years ago during the first genome for a free-living organism. I have been going on to do tuberculosis, malaria, anthrax, and many other organisms that are commonly discussed in this field. This cumulated with the human genome in the year 2000.

It is clear from the previous testimony that the threat of emerging infections and the threat of deliberately introduced agents is real, and like the previous speakers, I do not make a distinction between them because we need the same countermeasures for either one.

We have two major areas of problem. One is detection. Right now, we use the human population as our canaries. That is how we know there is a new infection, a new outbreak somewhere. We are not using the modern tools of science where we can now, instead of taking a decade to sequence a genome, we can do it in two hours. So instead of tracking emerging viruses in the field, which we are trying to train groups in Southeast Asia to do at the current time, where we could try and predict things in advance, we are waiting until they occur. That needs to change and we need new support for the science to drive that area. If we are trying to predict what the outbreaks are going to be, it is virtually impossible.

We have seen from some of the materials included with this hearing, the interview with Mr. Popov, that as early as 1976 in the former Soviet Union, they tried to use synthetic genes as a means

of producing new biological warfare agents. The field of synthetic biology and synthetic genomics is now rapidly maturing and this has been viewed as the new latest risk in this area. The technology now exists in multiple laboratories, including several commercial companies, to synthesize genes in virtually any existing viral genome.

But the threat does not exist to design new organisms from scratch. We understand so few of the basic principles of biology. We don't know, for example, why the 1918 pandemic influenza virus is so lethal. We can't tell that from looking at the sequence. So we do not have the knowledge in this field yet, nor is it a threat for somebody to go make a new hypothetical organism that we don't know the consequences of. That will be possible in coming decades.

The only solution is for the counter-events having vaccines, having broad-spectrum antibiotics and broad-spectrum antivirals that work against a whole set of organisms. That looks like it is possible. It looks like it is possible in cancer. It looks like it is possible in antivirals, in antibacterials. The pharmaceutical and biotech industries aren't currently incented to work in this area. Major pharmaceutical companies are shutting down their programs and not increasing their research in this area. I think this committee, this Congress, can have a major role in providing the proper incentives for moving forward.

With that, I would be happy to take further questions. Thank you.

Senator BURR. Thank you, Dr. Venter.

[The prepared statement of Mr. Venter follows:]

PREPARED STATEMENT OF J. CRAIG VENTER, PH.D.

Mr. Chairman and subcommittee members, I welcome the opportunity to testify today before you. I would like to present my observations about the nature of the threat of bioterrorism over the coming decades and to present my views and recommendations regarding the state of the science in biotechnology, particularly genomics, which could be "dual use." As with many new technologies, these areas of science can be useful in preventing or alleviating the threat of bioterrorism or can contribute to increasing the risk. I will also address the need for improvements in the system of detection and treatment of emerging infectious disease, which in my opinion is a much greater threat than is a bioterrorist attack. It is my firm belief that investment in basic science research is one of the most effective ways to ensure that our country is adequately protected against the potential threat of either an emerging infectious disease or a bioterrorism agent.

My name is J. Craig Venter, and I am the Founder and President of the Venter Institute and Founder and Chairman of The Institute for Genomic Research (TIGR), both affiliated nonprofit basic research institutes located in Rockville, Maryland, that are devoted to pursuing and supporting genomic research and its impact on society. They are described in the Appendix to my testimony. The genomics research underway at both of these Institutes is helping us better understand the potential of biothreats that we face today, and more importantly, improve tomorrow's biodefenses. In fact, our DNA sequencing center is a designated Federal emergency response center to aid in dealing with a bioterrorism event.

Our Nation needs to prepare for two kinds of bioterrorism threats: those that we know are within the technological capabilities of bioterrorists today and the new but largely unknown threats that will be added a decade or two in the future. Add to this the greater threat from emerging infectious diseases and you can see the importance of ensuring that our current defense needs do not distract us from adequately preparing for what may become an even greater challenge in the future.

It is virtually impossible for anyone to accurately predict the nature, or precise disease agents, of an infectious outbreak next year or decades away. Thus, I am among those who firmly believe that the best way to protect ourselves from both

the manmade and natural disease agents is to advance cutting edge fields of basic biological research.

The Landscape of the Science of Genomics

In the last decade, since my team sequenced and published the first complete genome of a living organism, the field of genomics has changed dramatically. The basic science advances in genomics have begun to shape and change the overall landscape of science and medicine. To date about 260 organisms' genomes, including most major human pathogens and the human genome[1] have been sequenced. Innovations in the enabling technologies of genomics—high-throughput DNA sequencing, high-performance computing, DNA microarray technology, and bioinformatics—are allowing this science to grow exponentially. Our ability to sequence and analyze all the genetic components of an organism helps us to better understand how an organism functions at its most basic level. This provides a platform from which to launch solutions to a plethora of problems such as better healthcare, improved treatments for disease, improved agricultural yields, cleaner and more efficient energy production, and environmental monitoring and remediation.

The output of genomics has been vast stores of biological data. Most pharmaceutical and biotechnology companies are utilizing these data to design new therapeutics to treat many of our most feared diseases such as infectious disease and cancer, as well as developing more advanced and sensitive diagnostics.

The National Institute for Allergy and Infectious Disease (NIAID), an institute of the National Institutes of Health (NIH), is a world leader in the use of genomics approaches to understand and treat infectious disease. The Department of Energy, Office of Science, has long valued genomics for its potential for bioremediation and energy production. Both have been embracing this area of science and are driving more research both in academia and in the commercial sector through funding of important grants and contracts.

Yet, we have much to learn. We are just beginning to be able to interpret the genetic code. We do not have a clear understanding at the genetic level of what makes most pathogens dangerous and why. Though technology exists for duplicating some existing pathogens, the ability to "design" a wholly new pathogen is likely decades away.

We clearly need to learn how to harness the potential of basic science of genomics to help ensure that our Nation and the world is protected against new infectious agent threats.

Venter Institute and TIGR

In 1992, the year I founded TIGR, the Secretary of Health asked us to sequence the smallpox genome, in collaboration with the CDC, as part of a bilateral treaty agreement with the Soviet Union. This was supposed to be done as a prelude to destruction of all stocks of the virus.[2] In 1995 my team at TIGR decoded the first genome of a living organism, the bacterium pathogen, *Haemophilus influenzae*.[3] The novel technique that we developed to sequence this genome, called "whole genome shotgun sequencing," opened the door to rapid, accurate, and cost-effective genome sequencing and is now the technique used by all major centers to sequence genomes. TIGR has now sequenced more than 40 genomes including many of the major human pathogens that are of concern as potential use as agents of terror. These include smallpox, anthrax, tuberculosis, cholera, listeria, two strains of malaria, syphilis, and various respiratory infectious agents.

NIAID has been a key supporter of genomics research at TIGR for more than a decade. NIAID, working with the FBI and other agencies, has funded TIGR to sequence multiple strains of the anthrax bacterium, with the goal being the development of a microbial forensics database that will hopefully provide new insights into the source of the anthrax mailings that occurred in the fall 2001. NIAID has also funded, through monies appropriated by Congress as part of NIAID's Biodefense Re-

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[1] Venter JC, Adams MD, Myers EW, Li PW, Mural RJ, Sutton GG, Smith HO et al., 2001. The Sequence of the Human Genome. *Science 291*: 1304–1351.

[2] Massung RF, Liu LI, Qi J, Knight JC, Yuran TE, Kerlavage AR, Parsons JM, Venter JC, Esposito JJ. 1994. Analysis of the Complete Genome of Smallpox Variola Major Virus Strain Bangladesh-1975. Virology 201: 215–240.

[3] Fleischmann RD, Adams MD, White O, Clayton RA, Kirkness EF, Kerlavage AR, Bult CJ, Tomb J-F, Dougherty BA, Merrick JM, McKenney K, Sutton G, FitzHugh W, Fields C, Gocyne JD, Scott J, Shirley R, Liu L-I, Glodek A, Kelley JM, Weidman JF, Phillips CA, Spriggs T, Hedblom E, Cotton MD, Utterback TR, Hanna MC, Nguyen DT, Saudek DM, Brandon RC, Fine LD, Fritchman JL, Fuhrmann JL, Geoghagen NSM, Gnehm CL, McDonald LA, Small KV, Fraser CM, Smith HO, Venter JC. 1995. Whole-Genome Random Sequencing and Assembly of Haemophilus Influenzae Rd. *Science 269*: 496–498; 507–512.

search Agenda, a multi-million dollar Pathogen Functional Genomics Resource Center at TIGR that is providing genomic reagents, laboratory services, and training to the Nation's infectious disease researchers. As part of this grant, TIGR has developed a database called Pathema that will house functional genome data pertaining to pathogenicity of organisms that are listed on the NIAID category A-C system. This is the kind of important research that the government, through its agencies like NIAID, has been wise to fund and needs to continue to allocate monies to do more.

At the Venter Institute, I lead a team of about 185 scientists and staff who are undertaking research into several aspects of genomics—synthetic genomics, biological energy, environmental genomics, and human genomic medicine. As well, we operate one of the world's largest DNA sequencing centers. We also have a policy group that is focused on exploring the ethical and social implications of the research that we, and others in this dynamic field, are conducting. I will discuss further those aspects of our work that have direct implications for potential use in the detection and prevention of a bioterrorist event.

Synthetic Genomics

Synthetic genomics comprises a constellation of emerging technologies that allow for the construction, from chemical precursors, of any specified sequence of DNA. It offers the potential of spectacular benefits (vaccines, drugs, efficient manufacture of biobased compounds); at the same time one must also be aware of the possibility of a bioterrorist using this technology to synthesize a pathogen. The number of pathogens that can be synthesized today is small and limited to those with sequenced genomes. And for many of these the DNA is not infective on its own and poses little actual threat. Our concern is what the technology might enable decades from now. I will talk about how we are addressing this concern later in my testimony.

Synthetic genomics is part of a larger set of approaches commonly referred to as "synthetic biology," itself a part of the overarching field of biotechnology. Synthetic biology encompasses the design and construction of both systems that already exist in nature, and those that do not. While a new field, it is rapidly growing and already a large meeting of its practitioners has been held.[4] Several universities have synthetic biology departments and/or major efforts in synthetic genomics in other divisions. The Massachusetts Institute of Technology offers a course for undergraduates in which students use standard synthetic biology techniques to fabricate a variety of engineered biological systems.

Coupled with this increasing interest in the ideas and techniques of synthetic biology, a number of academic laboratories and companies have been working on improving specific aspects of synthetic biology approaches, including synthetic genomics. Dr. George Church's group at Harvard is perfecting a chip-based approach that could rapidly speed DNA synthesis and lower the cost of gene synthesis to about a penny per base pair of DNA.[5] Further developments are coming rapidly from companies. Kosan Biosciences in Hayward, California, recently reported the full-length, accurate synthesis of a multi-gene cluster about 32,000 base pairs in length.[6] Blue Heron Technologies of Bothell, Washington, for example can quickly provide its clients with DNA of thousands of base-pairs in length for around $2 per base-pair.

Our synthetic genomics group was founded based on work conducted at TIGR several years ago called "the minimal genome project." We sequenced the organism Mycoplasma genitalium, which at the time was the smallest living organism to be sequenced. Our data showed that Mycoplasma's essential gene set was between 265–350 genes.[7] Because of these characteristics *M. genitalium* is often used as a model of a minimal cell. Through this work we began to imagine that we could uncover much information about the basic functions of life, and that we could contemplate construction of a synthetic genome based on first principles of biology. To

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[4] Synthetic Biology 1.0: The First International Meeting on Synthetic Biology. June 10-12 2004, Massachusetts Institute of Technology. http://web.mit.edu/synbio/release/conference/.

[5] Tian J, Gong H, Sheng N, Zhou X, Gulari E, Gao X, Church G. 2004. Accurate Multiplex Gene Synthesis From Programmable DNA Microchips. *Nature 432*: 1050–1054.

[6] Kodumal SJ, Patel KG, Reid R, Menzella HG, Welch M, Santi DV. 2004. Total Synthesis of Long DNA Sequences: Synthesis of a Contiguous 32-kb Polyketide Synthase Gene Cluster. *Proc Natl Acad Sci USA 101*: 15573–15578.

[7] Hutchison CA, Peterson SN, Gill SR, Cline RT, White O, Fraser CM, Smith HO, Venter JC. 1999. Global Transposon Mutagenesis and a Minimal Mycoplasma Genome. *Science 286*: 2165–2169.

demonstrate that one fully understands the properties of a chemical or biochemical entity, one must be able to synthesize it.

Synthetic genomics work in my institute began in 2003 under the direct guidance of Hamilton Smith, M.D., a Nobel laureate who has unique expertise in DNA research. Our team set out to synthesize a bacteriophage (a virus that attacks bacteria) called PhiX 174. With funding from the Department of Energy, Office of Science, and using newly devised methods, the group improved the speed and accuracy of genomic synthesis by assembling the 5,386 base pair PhiX 174. DOE was interested in this research because if we could construct an entire genome synthetically, we could contemplate valuable applications of such work including more efficient and cleaner energy sources like biologically produced hydrogen and ethanol, and better ways to produce textiles, chemicals and pharmaceuticals.

The PhiX synthesis was done from short, single strands of synthetically produced, commercially available DNA (known as oligonucleotides or "oligos") using an adaptation of polymerase chain reaction (PCR), known as polymerase cycle assembly (PCA), to build the PhiX 174 genome. Our team produced the synthetic PhiX in just 14 days and published these results in the *Proceedings of the National Academy of Sciences* (PNAS).[8] We are continuing to make advances on this work in the following areas: faster and more efficient means of synthesizing DNA, joining together longer pieces of DNA, and correcting errors in the synthetic DNA pieces to enable larger molecules to be synthesized.

Building on this work, we envision a day when we could build "cassettes" of desired genetic components with their associated function that could then be programmed to execute the particular industrial processes needed. A specific rationale for building and using a minimal genome versus genetic modification of existing species is to control the cells from continued self-evolution and to prevent cell survival outside of the laboratory or industrial setting. One application for synthetic genomics that we are pursuing is in the area of renewable energy. For example, some organisms produce hydrogen as part of photosynthesis. If these biochemical pathways could be harnessed and these hydrogen-producing functions optimized, I can envision bioreactors that could generate clean hydrogen fuel from sunlight and water.

Environmental Genomics

Another area of research at my institute pertains to using genomics for understanding the environment. The high-quality mathematical algorithms that my teams have developed to assemble genomes makes it possible to ascertain what organisms are represented by the random sequence samples taken from various environments. Using our algorithms and high-performance computing, we are able to classify organisms by their unique DNA and gene structures.[9] We are characterizing ocean and soil environments as part of our Sorcerer II Ocean Research Expedition, which is funded through the DOE, Office of Science; Gordon and Betty Moore Foundation; and the Venter Foundation. We are just beginning to characterize air samples in a newly announced project we are conducting with funding from the Alfred P. Sloan Foundation. Since we know so little about these environments at the microscopic level, this research is allowing us to take a baseline measurement of the organisms in each environment and then going forward to monitor the changes occurring and what that means for the ecological balance of life. With the air genome project we are sampling air inside and outside a building in midtown Manhattan in New York City. We have modified the protocols we developed to filter seawater as part of the Sorcerer II Expedition to capture the bacteria, viruses, and fungi suspended in air. We then ship our samples back to our high-throughput DNA sequencing center and sequence the DNA from the organisms we have captured. The sophistication of our bioinformatics programs and the expertise of our scientists who analyze these data allow us to organize the seemingly random DNA into various classes of organisms. This work has broad implications for science, and for helping to design monitors to detect the release of any deadly organisms. It is very difficult to figure out how to find a needle in a haystack if you do not know of what the haystack is made.

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[8] Smith HO, Hutchison CA, Pfannkoch C, Venter JC. 2003. Generating a Synthetic Genome by Whole Genome Assembly: phiX174 Bacteriophage from Synthetic Oligonucleotides. *Proc Natl Acad Sci USA 100*: 15440–15445.

[9] Venter JC, Remington K, Heidelberg JF, Halpern AL, Rusch D, Eisen JA, Wu D, Paulsen I, Nelson KE, Nelson W, Fouts DE, Levy S, Knap AH, Lomas MW, Nealson K, White O, Peterson J, Hoffman J, Parsons R, Baden-Tillson H, Pfannkoch C, Rogers Y-H, Smith HO. 2004. Environmental Genome Shotgun Sequencing of the Sargasso Sea. *Science 304*: 66–74.

Human Genomic Medicine

As I stated earlier, I believe that we face a greater threat from emerging infectious disease than from a bioterrorist attack. Genomics is a key part of the solution. We are talking with countries in Southeast Asia about sequencing strains of avian influenza (bird flu) isolated from poultry and wildlife. The concern is that these strains may spread from birds to animals and then to humans, possibly resulting in a pandemic. Genomics offers the ability to track how these strains are changing through time in nature, from the random genome recombination events that shuffle viral genomes to create new versions. Some of these new versions can be highly lethal to humans, such as the 1918 flu pandemic virus. The techniques of synthetic genomics may eventually help us rapidly construct new vaccines to counter such threats.

Moving Forward With Synthetic Genomics: Ethical Considerations

Synthetic genomics is an area of science that holds both great promise for advances and improvement of human life, as well as presenting areas for debate and potential concern. I have always firmly believed that as scientists we have an obligation not only to passionately pursue the research, but also to pursue and contemplate with equal zeal the ethical and societal implications of our work. This self-policing nature of scientific research has with few exceptions worked well in maintaining the highest ethical standards. It is for this reason that I insisted on an ethical review of our idea to synthesize a minimal genome prior to its inception in the laboratory. We commissioned a team of bioethicists from the University of Pennsylvania Center for Bioethics who then convened various religious and scientific leaders to review our proposed work. They published their review and recommendations about the work in the same issue of the scientific journal where we published background results on, and proposed the concept of synthesizing, a minimal genome. The committee recommended that our work proceed, but with caution and with an eye to societal implications, particularly the bioterrorism implications, along the road toward progress.[10]

We have continued to pay particular attention to the societal implications as our work has progressed. For example, we took great care in selecting which organisms we would use in our synthetic genomics work. Rather than selecting a human pathogen, as other scientists have done in work with poliovirus,[11] we chose to work with PhiX, a bacteriophage that is harmless to humans. In our synthetic genome efforts we are working to ensure that any synthetic organism cannot live outside the confines of the laboratory environment. This is relatively easy to ensure through genomics and has been employed in many cases, including with the basic workhorse of molecular biology, *E.coli*, for decades.

Prior to the publication of the synthesis of PhiX genome we contacted our funding agency, DOE, who in turn notified the highest levels of government about our achievements. The work was vetted by the Administration who gave the go ahead for scientific publication. About the same time our work was being published, the National Academy of Sciences (NAS) released a report titled, "Biotechnology Research in an Age of Terrorism."[12] This report, chaired by Gerald Fink of the Whitehead Institute at MIT, and known as the "Fink Report," outlined a series of recommendations for the scientific community to ensure the safe undertaking of any research having the potential for misuse. We were pleased to note that we had already adhered to the recommendations of this committee. Having adequate review of research that has the potential for misuse, setting up additional committees specifically designed to review such research both during the work phase as well as prior to publication, and coordinating efforts with the international community on such research are all important recommendations to come out of the Fink Report. We would encourage these kinds of careful and serious reviews by respected scientific organizations.

To this end a team at the Venter Institute and a group of collaborators from other institutions is planning a series of several workshops on the societal implications of synthetic genomics. With funding from the Alfred P. Sloan Foundation, a team of scientists and policy analysts from the Venter Institute, the Synthetic Biology Group at MIT and the Center for Strategic & International Studies (CSIS), this

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[10] Cho MK, Magnus D, Caplan AL, McGee D, and the Ethics of Genomics Group. 1999. Ethical Considerations in Synthesizing a Minimal Genome. *Science 286*: 2087–2090.

[11] Cello J, Paul AV, Wimmer E. 2002. Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template. *Science 297*: 1016–1018.

[12] Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, National Research Council of the National Academies (USA). 2004. *Biotechnology Research in an Age of Terrorism*. The National Academies Press (Washington, DC).

project will explore the risks and benefits of synthetic genomics. Our goal is to construct and evaluate potential guidelines and regulation for policy makers to consider that will address both the risk of the technology being used for purposeful, nefarious ends, and other risks such as laboratory accidents. We want to engage multiple viewpoints through this series of expert workshops to discuss technological and societal issues; by producing a series of research papers; and by organizing an invitational, inclusive meeting of policymakers, scientists, press, and other interested parties. We plan to widely disseminate the output from these workshops by the means of articles, books, Web sites, and through the lay press. It is our hope that this project will serve as a model for how individual scientists and society can address other areas of potentially sensitive biological research in this heightened era of bioterorrism.

Recommendations and Concluding Remarks

As a young man I decided to become a scientist rather than a physician because I felt that science had the potential to positively affect more lives at an earlier intervention point than medicine. I have derived no greater joy than through making basic scientific discoveries—finding a new gene, understanding how adrenalin works in the body, sequencing the first genome and the human genome. I have always believed that scientific pursuit is the ultimate pursuit of truth. It always seemed like such a simple and honorable endeavor to me.

However, the pursuit of science is not simple and it cannot be conducted in a vacuum. We have made incredible advances that have the potential to profoundly and positively change our lives. We read everyday about breakthroughs in stem cell research, genomics, and other areas of science and medicine. Against this backdrop of rapid and promising advancement, looms the ever present reminder that the world post September 11th is a very different and in many ways, very uncertain place. To help harness the power of this new science to help us deal with our new world, I would like to recommend to you the following:

1. Continued support of basic science research.

A key way to advance such cutting edge sciences as genomics and all its exciting applications is through continued support through competitive grants and contracts. Increased knowledge is our best weapon in biodefense. Understanding common mechanisms of action associated with viral infectivity is absolutely crucial for moving forward. We need to develop drugs effective against a wide range of viral pathogens, much as we have developed broad-spectrum antibiotics that work against a wide range of bacterial pathogens. Future treatments will not be single drugs for single organisms but new agents that attack common mechanisms of viral and bacterial infectivity.

2. Increased support for better and more rapid detection of and treatment of new emerging infectious disease.

Everyday the potential for new infectious agents to emerge looms before us. We have experienced this recently with the emergence of the SARS virus in 2003 and we are experiencing it today with the outbreaks and spread of avian and other flu virus strains that could potentially kill hundreds of millions and wreak havoc with our global health system. Genomic tools were rapidly employed with SARS and thus scientists were able to accurately identify and mobilize to prevent the spread of the virus. A global monitoring system and enhanced global collaboration on genomic tools as well as collective intellectual capital could help prevent such potential catastrophes.

3. Incentives for pharmaceutical and biotechnology companies to increase development of improved broad spectrum antibiotics and better vaccines.

Over the last several years there has been a troubling trend in the decreased dedication to research on, and production of, antibiotics and vaccines. In this age of emerging infectious diseases and with a continual threat of bioterrorism, we need an increasing—not decreasing—commitment to research and infrastructure for antibiotic and vaccine development. Government directed funding in a DARPA like approach could provide the needed capital and incentives for an eager biotech industry. Direct leadership in setting research and specific drug development goals, e.g., broad spectrum antivirals with subsequent production contracts could help drive industry in the right direction. Congress needs to find new incentives for industry to build up these important areas of research.

I have held a privileged seat at the scientific research table for more than 30 years. I know first hand the power of science and most especially the power of understanding that my area of expertise, genomics can wield. Scientific advance can sometimes outpace societal understanding and comfort. Research can sometimes un-

leash unintended and harmful consequences. These are the facts of life in our technologically, intellectually and scientifically advanced society. We are at a crossroads now of how best to deal with the tantalizing science available to the world, to ensure that it is used for the best purposes to enhance society rather than be the vehicle for our demise.

I thank you for the opportunity to testify before you and welcome any questions.

APPENDIX

The Venter Science Foundation's Affiliated Nonprofit Organizations

The Venter Foundation includes two affiliated nonprofit entities, which conduct basic, scientific research: The J. Craig Venter Institute (Venter Institute) and the Institute for Genomic Research (TIGR).

The Institute for Genomic Research was founded in 1992 with venture capital funding and an initial goal to identify as many human genes as possible using Expressed Sequence Tags (ESTs)—a controversial, but rapid, cost-effective method that I developed while doing research in the intramural program at NIH. I left NIH to create TIGR in part because, at the time, NIH was not in a position to conduct a large-scale human gene discovery study within the intramural program. In our first 2 years, we at TIGR used the EST strategy to identify more than half of the genes in the human genome. Then, using many of the laboratory and computational methods that we developed for the human gene discovery program, we pioneered the whole-genome shotgun sequencing of the first complete genome of a free-living organisms, *Haemophilus influenzae*, a bacterium that causes ear infections in children.

In its first decade, TIGR has become one of the leading genomics institutions in the world, developing research critical to the fields of medicine, energy and environmental science.

With financial support from the National Institute of Allergy and Infectious Diseases (NIAID), the Institute has determined the complete genome sequence for forty microbial species, including important human pathogens that cause tuberculosis, cholera, syphilis, stomach ulcers, anthrax, and malaria.

In addition, TIGR has also sequenced a wide range of important environmental microbes—some of which live in extreme environments but may be critically important to the health of the planet—and that carry out a variety of interesting metabolic reactions, including degradation of cellulose and other organic matter, precipitation of heavy metals such as uranium from solution, and production of methane and hydrogen as potential new sources of fuel. These are areas relevant to the field of bioremediation and are of great interest to DOE.

TIGR has also played a leading role in the sequencing and analysis of many important plant species, including *Arabidopsis thaliana*, a small weed that serves as a model for understanding approximately 250,000 other more complex plants—rice, soybean, potato, and tomato among them. Together, these efforts are helping in the search for genes that control the rate of plant growth, yield, and resistance to diseases and drought.

The J. Craig Venter Institute is a not-for-profit research institute dedicated to the advancement of the science of genomics; the understanding of its implications for society; and the communication of those results to the scientific community, the public, and policymakers. Founded by J. Craig Venter, Ph.D., the institute is home to approximately 185 staff and scientists with expertise in human and evolutionary biology, genetics, bioinformatics/informatics, high-throughput DNA sequencing, information technology, and genomic and environmental policy research.

The Institute's areas of scientific focus include: genomic medicine with an emphasis on cancer genomics and human genome resequencing and analysis; environmental genomic analysis with an emphasis on microbial biodiversity, ecology, and evolution; use of molecular and genomic methods to develop biological sources of clean energy; synthetic genome development; and policy research on the ethical, legal, and economic issues associated with genomic science and technology.

A key component of the Venter Institute is the Joint Technology Center, which provides rapid, accurate, and low-cost DNA sequencing for both the Venter Institute and TIGR. The JTC, which functions as both a resource and technology development center, will work collaboratively with a wide variety of technology leaders in the private sector, as well as with academic and Federal scientists, in our work to advance the efficiency and lower the cost of genomic sequencing.

The JTC uses the latest in automated DNA sequencing, supercomputing, networking, and high performance storage technologies to rapidly and accurately sequence and analyze genomes in a more cost-effective manner. The JTC currently has a sequencing capacity of 45 million "reads" per year and an ultimate capacity in excess of 100 million "reads" per year. A goal of the JTC is to substantially re-

duce the cost of genomic sequencing so that everyone can benefit from the great promise that genomics holds.

The J. Craig Venter Science Foundation provides administrative and legal support for, and coordinates policy and research activities between TIGR and the Venter Institute. In addition, the Foundation explores new ways to foster science education and scientific innovation.

Senator BURR. At this time, I would recognize Dr. Hearne for her statement. I would also say to her that I am not sure how I would have introduced her had North Carolina not passed her test, but I am delighted that that evaluation went on and I am delighted that North Carolina did well.

Ms. HEARNE. Trust me, I am delighted, too.

[Laughter.]

On behalf of Trust for America's Health, which is a national nonprofit health organization, I would like to thank Chairman Burr and Senator Hatch for holding these hearings. I know he is getting whispered to in his ear, but I would actually, on behalf of my board's President—I am sorry to interrupt, but I was actually going to say on behalf of my board's President, who is the Honorable Lowell Weicher, I knew I would be remiss if I didn't personally thank you for being part of this. He talks with great pride about his time of advancing with you many health initiatives when he was in the Senate and just wanted to say thank you for being part of this.

Senator HATCH. Please give him my love and affection, too, because he was a powerful member of this committee, let me tell you, and I sure enjoyed working with him, so I will look forward to working with you, as well.

Ms. HEARNE. Good. Part of why I have been asked to be here is to—it is fully described in my written testimony and I will also ask that it be submitted into full testimony—our report that we conducted in December of 2004—we have conducted it in the past, too, on an annual basis—called "Ready or Not: Protecting the Public's Health in the Age of Bioterrorism." In the time that I have allotted here, I will go through some of those key details, but it is going to be emphasizing what we clearly here have heard amplified by many of the previous witnesses.

Unfortunately, we hear over and over again that public health can be our weakest link in an effective and rapid response in a bioterrorism event. We got alerted to this shortly after 9/11 when the anthrax attacks hit. This Congress made a very smart and strategic decision when it passed the Frist and Kennedy Public Health Security and Bioterrorism Preparedness Act of 2002. It has provided nearly $3 billion over the past 3 years to States and localities to fortify our Nation's defenses against these various health threats.

We have also heard that a series of independent analysis has looked at the Nation's public health readiness and has found that while significant progress has occurred in several key areas, we know that to better protect Americans, there are still several serious vulnerabilities that we must do a better job in addressing.

The bottom line here is we are not ready for a bioterrorism event. There are still many basic questions that remain about what even constitutes preparedness and what protections Americans should expect.

That small Cessna plane that caused Congress and the White House to evacuate today could have been a modified crop duster. It could have been carrying biological, chemical, or radiologic agents, and thank God, it didn't. But as Professor Deutch had pointed out, and he is right on target, that had it been a catastrophic event, a ready-to-go public health system could have quickly responded and saved thousands upon thousands of lives.

Unfortunately, just 2 months ago, we had a false alarm here in D.C. where there was a possible anthrax attack over at the Pentagon. That gave us a glimpse to the fact that many gaps still exist. Rather than demonstrating that we are combat ready for biological agents, it was a little bit more of a Keystone Cop type of scenario. State and local health officials were not notified in a timely fashion, nor were their labs used to test the biosensors, nor was it even clear who was in charge at that time. Had it been a real attack, it could have resulted in an unnecessary loss of lives and dollars.

So whether we are facing an anthrax attack, or as has been noted earlier, a global epidemic of a deadly strain of influenza, our best defense is a full-range, modern day, 21st century public health system. So where are we?

Well, to fill the void in what the assessments are out there and the baseline comparisons of what is happening from State to State is why we conducted that report, "Ready or Not." We had the input of key public health experts to develop 10 indicators to take a look at a snapshot picture of how each State is doing as it has been getting these critical investments of Federal dollars.

Let me give you the top findings here, what we found in this report. We found that over two-thirds of the States had achieved a score of six or less on a scale of a possible ten points. North Carolina did receive a nine, Florida also. It is actually believed that a lot of the everyday experiences or challenges from threat of a natural disaster is part why those States have taken public health so seriously.

We also found, though, that nearly a third of the States in the fiscal year 2003–04 cut their public health budgets, and two-thirds of the States the year before had done so. So just at a time when the Federal Government was making smart strategic investments, the money from the State was not being matched and it left public health in the challenge of having to do more with actually less resources.

We found that six States had achieved the green status to receive the Strategic National Stockpile. Those are the emergency medical materials that can be brought into any location within 12 hours. Only six States are fully ready to go should that stockpile arrive.

Only five public health labs believed that they could adequately respond to a full-blown chemical terrorism threat, and only a third of the States report that they have sufficient capabilities to respond to a major bioterrorism event.

In the critical areas of disease tracking, which has been mentioned several times here today, we actually found that two-thirds of the States, including North Carolina and Massachusetts, do not electronically track outbreak information using national standards. This causes serious delays in reporting and could render the rapid and early warning response to a public health threat very difficult.

I do also want to point out, though, and here we go again, North Carolina getting some applause, but they were just yesterday recognized for their best practices by the Rand Corporation and specifically looking at taking the everyday public health practitioner and making sure that the ability to find a surveillance disease outbreak at the local level could be done with teams of people on the ground.

What that does, though, is rely on key public health practitioners. Perhaps one of the biggest challenges public health is facing right now is a brain drain of its best and brightest. We do not have the next generation of public health experts ready to go. We also have an enormous number of them about to retire within the next 5 years. It offers a critical challenge that these front-line responders will not be there if an emergency should happen.

Given all of these concerns, the Trust for America's Health recommends that we have the increased and sustained commitment to modernizing this public health preparedness, which includes the continuation and extension of Federal, State, and local bioterrorism funds. We are going to recommend the following here, which is in much more detail in my written testimony, but just to give the overview.

One is to build a better bio game plan and get back to basics. We need to have basic measurable standards in every State. They require a demonstration of how the funds were used, if we are meeting the measures that we need, and are we ready to go. A lot of the programs that have been coming out in recent years, and important ones—Biosense, Bioshield, Bio Watch—are very important, but we are concerned that there is not an overarching bio game plan. This was mentioned before by Dr. Deutch, that the bigger picture of how all these pieces are out there and how they connect are missing.

It is important to practice, practice, practice. We have got to have the States working together in regional assessments, doing those drills to make sure that we get it right and do that over and over again.

We also urge that we take immediate action to build a strong and fast track U.S. pandemic flu plan out there so that we really are, should either this recent avian flu or other potential novel strains evolve, that we are ready in this country.

And last, let me point out that we need to restore the proposed $130 million cut that is being made to the State and local preparedness funds. The job is long from done here. There are many gaps, many vulnerabilities. What we need to do is again step back and take a look, as this subcommittee is doing, and look at what is that bio game plan that we need.

We would actually recommend convening a national summit, bringing in leaders from key arenas such as the security side, such as the hospitals, the insurance industry, the pharmaceutical, public health community. Get those leaders together to really put together an actionable game plan. A lot of this isn't rocket science. It is about taking the best and brightest from a number of fields, getting the community to be working together, and get the commitment that over the next 5 years, here is what we need to do. Here is how we can get the job done, and let us move on it today.

So thank you very much for this time. I appreciate the thoroughness and I know many hearings that you will be having on this and that public health is part of that discussion.

Senator BURR. Dr. Hearne, thank you so much. I think that clearly from the title of the subcommittee, you understand that Chairman Enzi gets it, that it is bioterrorism and public health, that the two are connected, and I think that many times we separate those two.

Thank you for your comments on North Carolina. I think that North Carolina, as you well know, generates out of academia the public health experts of the future in some fine institutions that we have.

[The prepared statement of Ms. Hearne follows:]

PREPARED STATEMENT OF SHELLEY HEARNE, DRPH

Mr. Chairman, and members of the subcommittee, my name is Dr. Shelley Hearne and I am the Executive Director of Trust for America's Health (TFAH), a national non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. I would like to thank Chairman Burr, Ranking Member Kennedy, and members of the subcommittee for holding this important hearing, and appreciate the opportunity to present our thoughts about protecting the Nation's public health from bioterrorism.

The attacks of September 11, 2001, and subsequent anthrax tragedies alerted the Nation to the dangers we face from terrorists armed with biological, chemical, or radiological weapons. The U.S. Congress acted wisely and quickly by passing the Public Health Security and Bioterrorism Preparedness Act of 2002, which provided nearly $3 billion over the past 3 years to States and localities to fortify our national defenses against health threats. A series of independent analyses examining the Nation's public health readiness to respond to emergencies post-September 11 have found that these funds have resulted in significant progress toward better protecting the American people. However, serious vulnerabilities remain that must be addressed. Unfortunately, 3 years after September 11, many basic questions still remain about what constitutes preparedness and what protections Americans should expect.

Preventing and combating threats to our Nation's health is the unique responsibility of the public health system. These threats range from a potential global epidemic of a deadly strain of influenza to preventing the spread of disease in the wake of natural disaster. Our best defense against all of these threats is a modern, strong public health system.

Trust for America's Health "Ready or Not" Report Findings

In 2003 and 2004, Trust for America's Health studied the Nation's preparedness to respond to bioterrorism and other health emergencies. The results were issued in reports entitled, *Ready or Not? Protecting the Public's Health in the Age of Bioterrorism*. The reports found that while incremental improvements have been achieved, States were only modestly better prepared to respond to health threats than they were before the 2001 tragedies. We concluded that States have been left to manage shifting and competing priorities for limited public health resources, without enough support to focus on fixing the fundamental, tried-and-true basics that are the backbone of a well functioning public health system.

With input from public health experts, we developed 10 key indicators to assess a snapshot review of each State's public health preparedness. Together, the indicators provide a composite view of preparedness capabilities and trends. Each State was assigned a score on a 0 to 10 point scale, depending on the number of indicators met.

Some key findings from our 2004 report include:

- Over two-thirds of States and the District of Columbia achieved a score of six or less. Florida and North Carolina scored the highest, achieving nine out of a possible 10 indicators, and Alaska and Massachusetts scored the lowest, at three out of 10. These scores demonstrate that preparedness efforts are lagging behind goals and expectations. With most States still in the middle range of the scale, and with no States meeting all of the indicators, there are still areas of vulnerability that leave Americans at risk.

• Many basic bioterrorism detection, diagnosis, and response capabilities still are not in place. Bioterrorism preparedness policy is ill-defined and inconsistent. Bioterrorism preparedness planning still lacks strategic direction, well-defined priorities, and appropriate levels of resources to match needs. There is no clear definition for what the public should expect as protection in the event of bioterrorist attack or public health emergency, and there are no real performance standards in place to assess how well the public would be protected in the event of such tragedies.

• Nearly one-third of States cut their public health budgets between fiscal year 2003–04 and Federal bioterrorism funding decreased by over $1 million per State in 2004; States still do not have adequate resources to address their preparedness gaps.

• Only six States have achieved "green" status for the Strategic National Stockpile, which means being recognized as adequately prepared to administer and distribute vaccines and antidotes in the event of an emergency.

• Only five public health labs report capabilities (facilities, technology, equipment, and/or staffing) to adequately respond to a chemical terrorism threat, and only one third of States report that they have sufficient bioterrorism lab response capabilities (facilities, technology, and/or equipment).

• Nearly 60 percent of States report that they do not have adequate numbers of laboratory scientists to manage tests for anthrax or the plague if there were to be a suspected outbreak.

• In the crucial area of disease tracking, two-thirds of the States, including North Carolina, do not electronically track outbreak information using the national standards. This causes serious delays in reporting and rendering rapid or early warning of disease threats difficult. At the same time, North Carolina was recently highlighted in a new report by the RAND Corporation for other disease tracking efforts. They were featured as a "best practice" example for using Federal bioterrorism preparedness funds to support North Carolina Public Health Regional Surveillance Teams. This effort includes seven teams of public health practitioners to assist local health departments with disease outbreak preparedness and response.

• Coordination among Federal, State, and local health agencies is still strained, often due to competition for limited resources.

• The public health workforce is on the brink of an urgent "brain drain" as baby boomers retire and next-generation recruitment efforts suffer. State and local health agencies face shortages of epidemiologists, laboratory scientists, medical professionals, and other trained experts.

• Concerns remain that States are unprepared to implement quarantine, although every State except Alaska has adequate statutory authority to quarantine in response to a hypothetical bioterrorism attack.

TFAH Recommendations: A Sustained Bio-Game Plan is Needed

While Federal funds for bioterrorism preparedness have resulted in rapid and substantial improvements, many critical gaps remain. To address these concerns, TFAH recommends for an increased, sustained, and ongoing commitment to modernizing public health preparedness, which include the continuation and extension of Federal, State, and local bioterrorism funds. We recommend the following:

• **Building a better bio-game plan**, with consistent, measurable standards for improvement that require demonstration of how funds were used to achieve progress. While such programs as Bio-Sense, BioShield and BioWatch have been established in recent years, TFAH remains concerned that there is no overarching Federal bio-game plan. Congress should identify a lead agency to develop and oversee a comprehensive plan. In anticipation of the reauthorization of the Public Health Security and Bioterrorism Response Act of 2002, a systematic review of preparedness gaps should be conducted;

• **Getting back-to-basics**, by building on fundamental components of a comprehensive public health system that is fully prepared to meet both emergency and ongoing challenges from threats of terrorism to the flu and cancer. This includes addressing workforce shortages, modernizing disease surveillance, expanding laboratory capabilities, and communications planning. For instance, the proposed Public Health Workforce Act (S. 506) would help alleviate the dangerous shortage of public health emergency responders;

• **Conducting practice drills to assess capabilities and vulnerabilities**, to help identify gaps and improve coordination of roles and responsibilities;

• **Limiting liability to encourage vaccine development and protect health care workers.** Liability protection and additional incentives are needed to encourage private industry to invest in crucial research and development of vaccines and to provide protection for both public and private health care workers who could be putting themselves in harm's way or exposing themselves to disease;

• **Taking immediate action must be taken to build a strong, cohesive, fast-tracked U.S. pandemic flu strategy.** Although planning for a flu pandemic (often viewed as requiring a similar response to a bioterrorism attack) has improved, TFAH has more recently found that only between 25–30 States have made their plans publicly available. All of the plans have yet to be evaluated for quality and feasibility; and

• **Convening a national summit on the future of public health to develop a robust, integrated approach to public health protection.** It is clear that the United States needs to revitalize our public health system. A national summit of experts from a range of sectors should be convened to address all aspects of public health preparedness and what it would take to achieve a system designed to effectively face this century's current and emerging health threats.

The bottom line is we've only made baby steps toward better bioterrorism preparedness, rather than the giant leaps required to adequately protect the American people.

In order to examine the States' use of the Federal bioterrorism preparedness funds in States, Senator Lieberman, Ranking Member on the Senate Homeland Security and Government Affairs (HSGAC) Committee and Senator Kennedy, Ranking Member on the Senate Health, Education, Labor, and Pensions (HELP) Committee, and this subcommittee, recently requested and received a report from the Government Accountability Office (GAO). The report found that the funds were being adequately obligated and expended. The February 2005 GAO report found that "jurisdictions have expended a substantial amount of Bioterrorism program funds." As of August 30th of last year, "over four-fifths of the fiscal year 2002 funds awarded through the HHS P accounts during the third budget period [had been expended]." Further, the report stated that "it is useful to consider that the responsible use of public funds requires careful and often time-consuming planning before funds are obligated and expended. In addition, it is important to recognize that some expenditure take place over a period of time, which also can affect the speed at which jurisdictions expend funds." Unfortunately, the President's fiscal year 2006 budget currently recommends a $130 million cut to CDC's State and local bioterrorism preparedness program.

The new GAO report demonstrates that States have been responsible in the allocating and spending of the bioterrorism funds, and our study and others show that additional funds are critical to help States and localities achieve adequate preparedness capabilities to protect Americans in the event of a bioterrorist attack or public health emergency.

The Congress should restore the President's proposed $130 million cut in State and local preparedness funds; otherwise further readiness progress is in peril of being derailed. In addition, further efforts to reprogram funds away from this vital program should be halted. While programs including the Cities Readiness Initiative and the Strategic National Stockpile are extremely important, the resources to support these efforts should not come at the expense of support to build basic State and local emergency preparedness capabilities.

Additionally, to protect Americans from the spread of disease, whether it is caused by Mother Nature or a bioterrorist, there is a need to bolster the CDC's Global Disease Detection Program. This initiative is aimed at identifying, verifying and responding to global infectious disease outbreaks more quickly and efficiently.

Finally, it is critical that you continue to enhance capabilities to respond to chemical and radiologic threats as well as biologic ones. Developing responses to these hazards were not prioritized as highly in the first awards of bioterrorism preparedness funds, and, resultingly, these efforts are lagging. For instance, increased support is needed to give public health laboratories the "biomonitoring" capabilities they need to screen for human exposure to toxics and chemicals. This is an essential capability needed to assist with diagnosis and treatment responses to either a chemical terrorism or accidental threat. For example, the CDC participated in an exposure investigation of New York City firefighters involved in rescue operations after the terrorist attacks on the World Trade Center. Bolstering this essential component of chemical terrorism preparedness is reliant on additional support to the CDC's National Center for Environmental Health, which includes providing extramural funds to enhance States public health laboratories.

Evaluating the country's vulnerabilities and gaps are necessary to ensure the public's safety and preparedness, and I appreciate the subcommittee's work to ensure we get the job done to meet the urgent need of protecting our Nation's public health from bioterrorism. An effective public health defense requires us to be prepared for the epidemics we already know and those we have yet to imagine. We are

counting on you to make prudent decisions that will save countless lives and protect our communities and Nation.

I respectfully submit for the record this testimony as well as a copy of our December 2004 report, entitled *Ready or Not?—Protecting the Public's Health in the Age of Bioterrorism*.

Senator BURR. At this time, I would like to recognize Senator Hatch for questions.

Senator HATCH. Thank you, Senator Burr. I want to commend you for holding this important hearing today.

As some of you know, Senator Lieberman and I recently introduced our biodefense bill known as Bioshield II, which does provide a comprehensive approach to engaging private enterprise in the area of biodefense prevention and countermeasures. Now, to accomplish this important goal, our bill includes tax incentives, intellectual property protections, contracting and liability protections, and improved technology transfer arrangements. It also expands covered research to include naturally occurring infectious diseases and pandemic threats.

So I would urge all of my committee colleagues to study this bill very carefully, because we need both your support and your constructive suggestions on how to improve it.

Senator Lieberman and I went to work with members of the HELP Committee on this important matter in the past and we want all the help we can get in the current system.

Again, I want to extend my appreciation to you, Chairman Burr, for taking the first step by holding today's hearing and raising the important issue of bioterrorism.

Dr. Rodier, if I could ask a question of you, we appreciate you waiting around and we know it is late over there, but you have stressed the international nature of the problem of disease outbreaks. Now, what do you consider to be each country's responsibilities in this area? What should be America's role? Should our goals differ from other nations? I think these are questions I think everybody would be interested in learning from you.

Dr. RODIER. Thank you very much Senator. A quick answer would be that we are all in the same boat, all being vulnerable. I think that between the rich and the poor, the G7, G8 countries, does not only have a key role to play in terms of solidarity, and also I think a right-made investment, which is good for solidarity, but also for national security purposes. Here we also touch on this dual-purpose strategy that was mentioned before by Dr. Fineberg. I think if the rich countries can really help the poor countries or less rich simply to have effective alert and response system, this we believe would be a good investment from a solidarity standpoint and also from the national security standpoint.

Senator HATCH. That is right. Dr. Rodier, let me just go a little bit further here. As a member of the Senate Select Committee on Intelligence, I followed with interest the recommendations that we strengthen the ties between the intelligence and medical communities to improve our Nation's biopreparedness. Now, do you have any concerns that closer connections between the CDC and intelligence community could cause problems with the World Health Organization's ability to work with other nations on disease outbreaks?

Dr. RODIER. I cannot comment really for the CDC, but I can certainly comment about this overlap between security and intelligence and public health. It is an area where we both have to be present—I would simply take the analogy of—you need a policeman and a physician. I think that both have to be very well defined and not confused, and I think the challenge for the public health sector is to work with these new partners, which is the security groups. We do not necessarily know them very well and we need to learn about different cultures and different [unintelligible] we will have to deal with [unintelligible], but from the public health standpoints will be [unintelligible]. If that was the case we may well lose some kind of privileged access that public health has today because we are only technical [unintelligible] and not [unintelligible] as playing with intelligence or sharing systematic information with intelligence community. So it is very important we work together, intelligence, security and public health, but we do not confuse the roles.

Senator HATCH. Well, we appreciate workers and scientists like you at WHO and the work that you do and we surely want to be helpful in every way we possibly can.

Dr. Venter, welcome back. It is good to see you again. You recommend that we use incentives for pharmaceutical and biotechnology companies to increase development of improved broad-spectrum antibiotics and better vaccines. Could you tell us why, or if you do, it appears to me, do you limit yourself with regard to antibiotics and vaccines, and might I add to that, what other new technologies—what about other new technologies, from devices to IT decision support to other forms of drugs? I would like you to cover that, if you could. And then should we not encourage as broad a field as possible so that the items are of use against biological threats?

Mr. VENTER. Thank you, Senator. That is clearly a compound question.

Senator HATCH. It sure was. I will be happy to repeat parts of it if you need it.

Mr. VENTER. Well, let me pick the parts that I might be able to answer.

Senator HATCH. OK.

Mr. VENTER. I think it is critical to provide new incentives because the research that is taking place in the pharmaceutical industry has really been falling off in this area. Some major companies have laid off their entire antimicrobial-antiviral groups because they don't see the same profit margins in those drugs as they do in some of their chronic treatments. So we can't leave it up to the pharmaceutical industry. I think we need a directed government-driven research in a DARPA-like fashion that will provide the key incentives for what I consider a very hungry biotech industry with a lot of talent to make broad-spectrum antibiotics, broad-spectrum antivirals that could work against a whole variety of threats.

The industry has been driven that way in terms of new treatments for cancer and it looks like there may be new mechanisms to interfere with, for example, Tyrosine kinase receptors that may work against a whole variety of cancers. Many in the community think that will be possible with viruses interfering with common mechanisms for their replication, for example.

So the incentives need to be there. I don't know enough about the industry, whether the incentives in your bill are the key ones, and I can't really speak to those.

We have to drive the basic research. It is not a matter of just making more drugs because we don't know the answers yet to most of these questions.

Senator HATCH. Thank you. Dr. Hearne, let me just ask one question of you. Would you be kind enough to get us, if you will, more details about your communications plan that you have recommended, or that you recommend.

Ms. HEARNE. Well, there are a number of pieces that we recommend.

Senator BURR. Your microphone.

Ms. HEARNE. Speaking of communications, it helps to turn on the microphone.

[Laughter.]

There are a number of pieces here that fit together, and I think it is important that as we talk about countermeasures that we do look carefully at the public health side, because as we make those smart investments into developing countermeasures, we need to make sure we also have the ability to deliver them in a time of need, which is the public health side.

There are several basic pieces that need to be fixed, and it is actually not, as I had mentioned before, rocket science. It is really about getting the State capacity along with the local health departments and the Federal oversight to be matching up, and that is basic things like communications, of making sure each of those entities, along with the hospitals, along with law enforcement, along with every first responder, can communicate when an event occurs. That has been some of the big progress that has happened with the first round of the bioterrorism grants, but we still have a long ways to go in being able to make sure that we are doing that early detection, that word is getting out to those who need to have the rapid response, and that we do have the right materials to get it out into the field.

So one of the examples in—we talk about the need to put a bio game plan together. It is critical that the evaluations that are going on for what are the right countermeasures, such as antidotes, vaccines, antibiotics that you would need, are also matching up to what you can go out there and deliver in an emergency response. And as we have been making investments in the Strategic National Stockpile in this country, there are concerns that some of those pieces aren't matching up.

For instance, there is a great concern about a global pandemic. We are now purchasing Tamiflu as part of the Strategic National Stockpile in vast enough numbers to protect the population. That then connects back to what would those different health agencies do in an emergency to take care and prioritize and communicate to all the different groups.

So I have put a lot into this answer for you, Senator Hatch, but part of it is, it is about getting our hands around, and think that is part of what this subcommittee will deal with, is making sure all those different dots are connecting.

Senator HATCH. Thank you very much.

Thanks, Mr. Chairman, for letting me have a little additional time.

Senator BURR. Senator Hatch, thank you so much for your contribution, not just today but your continual contribution to this effort. I said in my opening statement that we were benefited in the fact that you and Senator Lieberman had produced legislation, that Senator Gregg had legislation, and it was surely the intent of this subcommittee, and I have the assurance from the full committee chair, that we will include everybody in this process as we try to reach consensus on a piece of legislation.

Senator HATCH. Thank you so much. I appreciate it.

Senator BURR. Let me once again thank all of our panelists today.

I want to pick up on where Dr. Hearne left off, and you talked about the pandemic avian influenza. I am going to shift and go to Dr. Rodier, because Dr. Hearne said that around the world, individual countries have prepared by bringing in doses of Tamiflu in preparation for a potential outbreak.

Dr. Rodier, if there were an outbreak later this year, how would the World Health Organization approach containment, particularly if it extended outside of one country and into another country or several other countries, and do we have a possibility that one country might have the doses of Tamiflu and those that are also affected might not?

Dr. RODIER. Thank you very much. It is a tough question in a way because we know well that Tamiflu [unintelligible] that seems to work on this particular virus, will not be available in any case to the whole world. The only choice, looking at what could be done, and it is clear that shown by modeling, that there is something to do, including with Tamiflu early on before we start to really have a large-scale pandemic. But if we do detect early and before we reach [unintelligible] human cases of new [unintelligible] strains, there is an intervention which is using Tamiflu, pouring Tamiflu in this particular affected area that could really maybe not stop completely the pandemic, but help us to buy time to develop the main tool, which means the vaccine. Vaccine development takes about 6 months, 8 months to have that in large quantities, plus all the logistics on distributing the vaccine. So it is very important we detect early, respond early with Tamiflu and buy time for vaccine development.

Senator BURR. Thank you very much. We appreciate your comments concerning the United States' vital role in supporting the World Health Organization, its efforts around the world.

If you had to cite one area that the U.S. contribution has been the most crucial, what would that area be?

Dr. RODIER. I think our partnership with CDC has been through technical assistance and technical input to the work of the organization.

Senator BURR. Well, I certainly anticipated that that would be your answer and it is important that members here in Washington understand just how valuable the CDC is because it continually has the needs of the technological upgrades that the marketplace is providing and that will do nothing but get faster as time goes on.

Dr. Hearne, let me come back to you, if I may. You highlighted in your testimony that the public health workforce is on the brink of brain drain. In your opinion, how do we reverse this trend?

Ms. HEARNE. It is reversible by making public health a go-to place. I think there are many features that we could do today, but one piece is there is actually a Public Health Workforce Act that has been introduced to the Congress, that is about trying to replenish those dwindling numbers, about creating incentives so that students will want to go into public health. They will see this as the front line. They will have the incentives financially, academically, career-wise to know that this is a place where they want to go to and can go forward. So Congress is actually putting those pieces together. It would be wonderful to see that legislation go forward.

Senator BURR. Thank you for that.

You made a passing remark earlier that I want to stop and highlight on because I think it is probably one of the most important questions raised and one of the most important answers needed. You described a potential scenario and you said one of the problems is not knowing who is in charge. Can you expand on that?

I happen to believe that that is one of the questions that we have yet to answer in the big scope of—we understand here. We saw today who was in charge. There was somebody in charge. There was an evacuation. There was aircraft that was sent. All of the pieces of what was designed worked. My concern is when you take a locality somewhere in this country or you take a location somewhere in the world, who is in charge?

Ms. HEARNE. It is an excellent question and it is part where we have asked as part of our recommendations, really clarifying some of those roles, because let us continue with that example today. Had it been a more serious event, such as the example I had created of it the plane was carrying CBMs, the Congress has a very well practiced and structured response mechanism. But go a few blocks outside and you start to wander into, well, who really would be in charge in a biological event? How many times has that been practiced? And would the citizens have the same levels of rapid response and public health capabilities as, say, the Hill would?

Those are the kinds of questions that we do have to take some serious looks at and may, in fact, be a beautiful tabletop exercise that this committee could do to give a little open-ended insight into some of these challenges.

We do need much better and clearer leadership. You asked the tough question to Dr. Deutch about the Homeland Security, Department of Homeland Security. From the public health world, it may be a bit heresy, but I actually think that the role that the Department of Homeland Security has played in public health preparedness has been absolutely critical and healthy to getting us better along the road. And I say that because they have taken many of these natural, biologic, chemical, radiologic threats quite serious.

They understand that public health has been one of the weakest links in our security capabilities. And they also have started to really push the system and the concept of accountability, which is not what public health has done well in the past, and that is exactly what we need to be doing here, is asking those very tough

questions, going through and structuring, here is what we need to be doing, here are our expectations, and testing if we are making the mark on a routine basis.

Senator BURR. As you pointed out very well, the area of jurisdiction for the Congress extends several blocks outside of the Capitol. It is apparent when you see a decontamination tent two blocks from the Capitol. The reason it is not three or four or five is that we have no jurisdiction there. And the question is, when you go past that tent, who is in charge?

And I think that is one of the challenges that we are going to have, to begin to try to sort out what that answer is, to begin internationally to work with our colleagues at the World Health Organization to understand better how we bring that coordinated response capability, and clearly we have got some models that currently work. But public health is going to have to play an absolutely integral role in how we design it for the future.

Dr. Venter, of all the panelists here today, you are both a scientist and a CEO of a biotech company. From your perspective, what kinds of incentives would attract you and others like you to work on issues of biodefense, meaning both natural and deliberative biologic agent threats?

Mr. VENTER. Well, I am only currently head of a large research organization. I spent 3 years of my career as head of a biotech company to sequence the human genome. It was clear during that brief period of time and in-depth exposure to the biotech and pharmaceutical communities, they are ultimately businesses and driven by profit motives more than any other events. So they have to have products that they can see a market for. Beyond that, I don't think I am the right person to speak for that industry.

Senator BURR. Well, I think you will find Senator Hatch, myself, others taking every opportunity to get everybody's comment, because I think we are all stumped to some degree why the participation in this effort has not been more robust, and it is not limited to the United States, it is around the world. Clearly, we understand the profit needs of companies, but we are trying to understand as we begin to revise legislation, what can we do that achieves a different result in the level of participation from not just biotech, but big pharma, as well.

Your testimony today, and I read it, was both reassuring and unsettling. It was reassuring because you noted that the likelihood of a terrorist event or even a State biologic weapons program would be one or more decades away from synthesizing new pathogens, unsettling because it takes upwards of 10 or more years to create a new vaccine or a drug to counter an existing pathogen.

I am intrigued by the suggestion that government, I assume NIH, should take a DARPA-like approach. Can I ask you to expand on that DARPA-like approach?

Mr. VENTER. I don't think NIH is the right organization to do that. I think the infrastructure at NIH doesn't allow it to do things in a proactive fashion. It is a response to grant applications. DARPA has been an organization that has effectively, when the mission is known, with a large pool of money can go out and actually initiate new research and new construction efforts in industry and in academic organizations. So it is a small group of people, not

a large infrastructure, and they have been able to really push the envelope of what gets done in research. That won't happen probably through the existing organizations. The culture there does not exist to do that.

I was on Dr. Zerhouni's committee to award high-risk research awards to researchers at NIH. The committee and the infrastructure just did not have it within their bandwidth to do things in a high-risk fashion. Organizations like DARPA are designed to work in a much higher-risk environment where you are not guaranteed results, but you are trying to incent researchers and organizations to move in a new direction. I think DARPA has been very effective with that. We are trying to get new detection methods going.

Senator BURR. Dr. Venter, thank you. I was trying to get my facts straight. I think some suggested that you couldn't do the human genome mapping in the time frame that you did, and I am not exactly sure what they claimed it would take and you certainly shortened that by a lot, but thank you for the reminder that there are some things that we can't redo or some existing things that we just can't use and you have to go to people with proven track records that know how to do things in expeditious ways.

I want to thank all of you for your testimony. I hope even Dr. Rodier will make himself available to potentially written questions that might come from other members. As we go through this process, it is going to be absolutely vital that we get the input from many.

Dr. Rodier, I have noticed several staff members there with you tonight. Let me take this opportunity to thank them, as well, and to offer the collaboration of this committee in our joint efforts to move forward on this issue in a very positive way.

Again, I thank you for joining us long distance. I thank all of our panelists for their willingness to be here and the expertise that they have shared with us. We certainly look forward to this committee's work as we move forward.

This hearing is now adjourned.

[Whereupon, at 3:46 p.m., the subcommittee was adjourned.]

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