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RESPONDING TO WEST NILE VIRUS: PUBLIC HEALTH IMPLICATIONS AND FEDERAL RESPONSE

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

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RESPONDING TO WEST NILE VIRUS: PUBLIC HEALTH IMPLICATIONS AND FEDERAL RESPONSE

THURSDAY, OCTOBER 3, 2002

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:25 p.m., in room 2167, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Cummings and Schakowsky.

Staff present: Christopher Donesa, staff director and chief counsel; Roland Foster, professional staff member; Nicole Garrett, clerk; Tony Haywood, minority counsel; and Earley Green, minority assistant clerk.

Mr. SOUDER. The subcommittee will come to order, and I would like to recognize myself for an opening statement.

Good afternoon, and thank you all for being here today. Today's hearing will examine the public health implications of the West Nile virus and the Federal response to the growing epidemic. We will hear from both Federal agencies and local officials who are responding in different ways to protect the public from the West Nile virus.

While West Nile virus has been recognized as a health threat for over 60 years in other parts of the world, the disease only appeared in the United States in 1999. For the past 3 years, the virus has spread quickly across most of the United States and is now believed to be permanently established in the western hemisphere. My State of Indiana, and particularly Allen County, is one of the most heavily impacted areas in the Nation.

Much is known about West Nile virus, but mysteries and questions still remain. In fact, only recently was it learned that the virus could be contracted from organ and possibly blood donations. Likewise the West Nile virus is also being blamed for a previously unseen polio-like paralysis in some of those infected. Just this past week scientists announced that genetic material from the virus has been detected in breast milk, raising the possibility that the microbe could be transmitted through nursing.

The virus is primarily spread by the bite of an infected mosquito and can infect people, horses, birds and other animals. And while West Nile virus is believed to make about 20 percent of those in-

fected sick, most of whom experience very mild flu-like symptoms such as headache and fever which last only a few days, the virus can cause a severe inflammation of the brain. Only recently have scientists linked West Nile virus to a polio-like partial paralysis. And West Nile virus infection can result in severe and sometimes fatal illnesses. This year alone the deaths of over 110 Americans have been attributed to the West Nile virus. Those most at risk for the severe effects of the disease are the elderly and those with weakened immune systems, although young are people are affected, too.

And I personally want to add I have not seen an issue that has so rattled so many people in an area as it has in my hometown of Fort Wayne. It has changed band practices, football games. You get sprayed when you go into a football game. It is a constant conversation every night at my house at the dinner table as to whether my son should go out and rollerblade, whether he should go out at all. I just had one of our major executives in Fort Wayne say his kids aren't allowed out in the evenings right now. It has caused disturbances in school board fights all over my district. There are few things that have caused as much controversy.

I've had many people ask to include things to be inserted into the record, and over the next few days I'll be doing that, but in particular we could not accommodate my friend Indiana State senator and former county councilman, leader in Allen County, Tom Wyss to be one of the witnesses today, but he asked that I include his full statement. I wanted to put a couple of statements in here, because he's been very outspoken in our area.

[The information referred to follows:]

State of Indiana — Senate

Senator Thomas J. Wyss
12133 Harvest Bay Drive
Fort Wayne, Indiana 46845-8982

OCT - 6 2002

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Corrections, Criminal & Civil Procedures
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Taxation Subcommittee
Legislative Apportionment & Elections

October 3, 2002

The Honorable Mark Souder
US House of Representatives
1227 Longworth HOB
Washington, DC 20515

Dear Congressman Souder,

Thank you for the opportunity to write to you concerning your Congressional hearing on the West Nile Virus epidemic in our communities. Not only does this epidemic transcend city, county and state borders, but also presents we elected officials, with major concerns on reacting and preventing more cases in the future. An interesting side note is that a colleague in the Indiana House of Representatives, Ron Herrell of Kokomo, has been diagnosed as a West Nile Virus patient.

Allen County in Indiana has been identified with 1/3 of the cases in our state. Our health departments, both county and state, have responded commendably. The cooperation with our Federal agencies has also been commendable. We must however ensure that we are prepared to address any outbreaks which may occur next year. This will require a concerted effort to continue this cooperation between all entities. In addition to funding concerns, it is imperative that the public is aware of the use of precautions against the virus-carrying mosquitoes and all public officials achieve an understanding of the preventative measures necessary to protect the public health.

I wish you and your congressional colleagues success and look forward to the results of your committee hearings.

With ~~kind~~ personal regards,

THOMAS J. WYSS
State Senator

TJW:mg

cc: Commissioner, Allen County Board of Health
Commissioner, Indiana State Department of Health

Mr. SOUDER. There comes a time when public officials need to depend upon the advice of experts when you have a situation like the spread of West Nile virus. When the Indiana/Allen County boards of health agreed that spraying was needed to help reduce risk of the West Nile virus spreading, it should have not been delayed by some public officials. We need to work together, local, State, and Federal, to fight the public enemy of West Nile virus like we are working together to fight terrorism.

As I say, this has been a very difficult issue, multiple deaths, still more notices pouring in on the infection. Part of the problem has been that there has been no clear test, and people can't get the results for 3 weeks. Some of them are now down to 10 days. No specific medication exists to treat it, and no vaccine is available to prevent it, which means it's as scary a phenomenon as you can have as a parent and family member.

Food and Drug Administration has predicted the test may be available by next summer, and the National Institutes of Health forecasts a vaccine will not be ready for at least 3 to 5 years. Doctor Jesse L. Goodman of the FDA is here today to provide us with an update on the progress that is being made in developing these necessities. Until tests, treatments, and vaccines are available, prevention remains the only defense we have against West Nile virus.

Earlier this week the House of Representatives passed a bill authorizing $100 million in grants for communities to develop mosquito control programs. Dr. James Hughes, the Director of the National Center for Infectious Diseases at the Center for Disease Control and Prevention will tell us today what actions his agency is taking to protect the public's health as well as what individuals can do to protect themselves.

We will also hear testimony from several State and local officials who are on the front lines of our Nation's effort to control the West Nile virus. We will hear from my own Allen County health commissioner, Dr. Deborah McMahan. In Allen County, by the way, we have one-third of the cases in the entire State of Indiana.

We're also going to hear from Dr. John Lumpkin, Director of the Illinois Department of Public Health, which has more cases than anywhere in the United States; Dr. Mohammad Akhter, Executive Director of the American Public Health Association; and Mr. George Wichterman of the Lee County, Florida, mosquito control district.

It is my hope that from this hearing we in Congress can get a better understanding of what we can do to assist the efforts of the Federal and local health authorities in controlling West Nile virus. Likewise, I hope that the representatives of the Federal agency will listen to the testimony of our other witnesses so they can gain a greater appreciation of those needs and the viewpoints of those in the front lines in our efforts to control West Nile virus.

We had originally hoped that the administration panel could go second to respond to those issues by State and local, but they have requested they testify first, and that is the long-standing protocol of our committee, and we can do followup questions if we need.

I thank you again for—all of you for being here, and I look forward to hearing your testimony and insights. And I'd now like to yield to the distinguished ranking member, Mr. Cummings, of Maryland.

[The prepared statement of Hon. Mark E. Souder follows:]

Opening Statement
Chairman Mark Souder

"West Nile Virus: Public Health Implications
and Federal Response"

Subcommittee on Criminal Justice, Drug Policy,
and Human Resources
Committee on Government Reform

October 3, 2002

Good afternoon and thank you all for being here today. Today's hearing will examine the public health implications of the West Nile virus and the federal response to the growing epidemic. We will hear from both federal agencies and local officials who are responding in different ways to protect the public from West Nile virus.

While West Nile virus has been recognized as a health threat for over 60 years in other parts of the world, the disease only appeared in the United States in 1999. Over the past three years, the virus has spread quickly across most of the United States and is now believed to be permanently established in the Western Hemisphere. My state of Indiana, and particularly Allen County, is one of the most heavily impacted areas in the Nation.

Much is known about West Nile virus, but mysteries and questions still remain. In fact, only recently was it learned that the virus could be contracted from organ and blood donations. Likewise, West Nile virus is also being blamed for a previously unseen polio-like paralysis in some of those infected. Just this past week, scientists announced that genetic material from the virus has also been detected in breast milk, raising the possibility that the microbe could be transmitted through nursing.

The virus is primarily spread by the bite of an infected mosquito, and can infect people, horses, birds, and other animals. And while West Nile virus is believed to make about 20 percent of those infected sick, most of

whom experience very mild flu-like symptoms such as headache and fever which last for only a few days, the virus can cause a severe inflammation of the brain. Only recently have scientists linked West Nile virus to a polio-like, partial paralysis. And West Nile virus infection can result in severe and sometimes fatal illnesses. This year alone, the deaths of over 110 American have been attributed to West Nile virus. Those most at risk for the severe effects of the disease are the elderly and those with weakened immune systems, although younger people are affected too.

There is no test for West Nile virus infection, no specific medication exists to treat it, and no vaccine is available to prevent it. The Food and Drug Administration has predicted a test may be available by next summer and the National Institutes of Health forecasts a vaccine will not be ready for at least three to five years. Dr. Jesse L. Goodman of the FDA is here today to provide us with an update on the progress that is being made in developing these necessities.

Until tests, treatments and vaccines are available, prevention remains the only defense we have against West Nile virus. Earlier this week, the House of Representatives passed a bill authorizing $100 million in grants for communities to develop mosquito-control programs.

Dr. James Hughes, the Director of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention will tell us today what actions his agency is taking to protect the public's health as well as what individuals can do to protect themselves.

We will also hear testimony from several state and local officials who are on the front lines of our nation's effort to control the West Nile Virus. We will hear from Allen County Health Commissioner Dr. Deborah McMahan, as well as Dr. John Lumpkin, Director of the Illinois Department of Public Health, Dr. Mohammed Akhter, Executive Director of the American Public Health Association, and Mr. George Wichterman of the Lee County, Florida, Mosquito Control District.

It is my hope that from this hearing we in Congress can get a better understanding of what we can do to assist the efforts of federal and local health authorities in controlling West Nile virus. Likewise, I hope that the

representatives of the federal agencies will listen to the testimony of our other witnesses so they can gain a greater appreciation of the needs and viewpoints of those on the frontlines in our efforts to control West Nile virus. We had originally hoped that the Administration panel could go second to respond to the issues raised by state and local officials, but they have requested to testify first and we will honor that longstanding protocol.

Thank you all again for being here. I look forward to hearing your testimony and insights.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. Let me, first of all, thank all of our witnesses for appearing before us today to discuss their efforts, the challenges they face and the lessons they are learning as front-line combatants against the West Nile virus epidemic.

West Nile virus is new to the United States, but it is not a new disease. First diagnosed in Uganda in 1937, West Nile virus has since spread to other areas in Africa, the Middle East and parts of Europe. Three years ago it arrived in the United States, and it's rapid spread from New York City where the initial outbreak occurred to other parts of the country confirms that the virus is now firmly established in the Western Hemisphere.

Today's hearing, Mr. Chairman, is especially timely. Just this morning the tragic impact of the West Nile virus hit home for my constituents as Maryland public health officials reported that a kidney transplant patient at Johns Hopkins Medical Center, which is located in my district, died after testing positive for the West Nile virus. Although there had been six previously reported cases of West Nile virus infection in Maryland, none had resulted in the life-threatening illness, and this is the State's first West Nile fatality.

As is the case in a number of the 116 West Nile deaths that have occurred across the country, the source of the infection in the Maryland death is unclear for the time being. According to the Maryland Department of Health and Mental Hygiene, initial tests for the virus on the organ donor were negative. And the department, the American Red Cross and the Centers for Disease Control and Prevention are investigating the possibility of transmission through blood transfusions or from outside exposure.

The West Nile virus epidemic is frightening to Americans because we have limited testing capability, no vaccine, as the chairman said, and no specific therapies for treating the West Nile encephalitis and meningitis that develop in a small percentage of persons infected with the virus. It is the rare individual who does not receive a mosquito bite during the course of a summer season.

The rapid spread of the virus suggests that within a short period of time, virtually all Americans could be at risk of West Nile virus infection if they are not already. There's still much we do not know. Indeed the possibilities of contracting the virus from organ transplantation and blood transfusions was confirmed only within the last month or so. Fifteen people this year have been diagnosed with the West Nile virus within a month after receiving blood transfusions. Another recent case raised questions about the safety of nursing by mothers who may be infected with the virus. Just over 2 hours ago the Centers for Disease Control and Prevention confirmed that the infant in that case did, in fact, get the virus from breast milk. The suspected source of the mother's infection is a blood transfusion, and blood from the same donor is also believed to be the source of another West Nile infection.

Numerous investigations into individual cases as well as efforts to map the spread of the virus nationwide are ongoing. To date, 42 States have reported cases of West Nile infection in humans, mosquitoes, birds or other animals. Thirty-two States have reported cases of human infection. Inexplicably, for the first—for the time

being Illinois has been the hardest hit with 32 human deaths having occurred this year alone and massive impact on bird populations. As you know, Mr. Chairman, three members of this panel are from Illinois, so I'm glad that Dr. John Lumpkin, the Director of the Illinois Public Health Department, is able to appear today at the minority's request. We can only hope that the terrible experience Illinois is having will yield knowledge that will be instructive to other States across the country.

By all accounts, the Centers for Disease Control and Prevention, the Food and Drug Administration and other Federal agencies that make up our Federal public health infrastructure ought to be commended for their efforts to respond to this epidemic. Even as we recognize the aggressive efforts of our public health agencies to respond to this new threat, it is the duty of this oversight subcommittee to ascertain what gaps may exist in our public health system and what more might be done by our government to ensure the health and safety of the American public from West Nile virus and similar future threats. This hearing is a constructive step in that process. And I commend you, Mr. Chairman for calling this hearing and giving us the opportunity to hear from all of our invited witnesses. I yield back.

Mr. SOUDER. Thank you.

Before proceeding I would like to take care of a couple of procedural matters. First I'd ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record. And any questions, and any answers to written questions provided will also be included in the record. Without objection, it is so ordered.

Second, I ask unanimous consent that all exhibits, documents and other materials referred to by Members and the witnesses may be included in the hearing record, and that all Members be permitted to revise and extend their remarks. Without objection, it is so ordered.

Would the witnesses on the first panel please rise. Raise your right hands. I'll administer the oath. As an oversight committee it is our long-standing tradition to swear in all witnesses.

[Witnesses sworn]

Mr. SOUDER. Let the record show that the witnesses have each answered in the affirmative.

I think we're going to go ahead with the testimony on the first panel. I know Congresswoman Schakowsky from Illinois wants to give a statement, and we'll get at least your statements in the record. I just ran into her in the hall a few minutes ago. She's trying to cover two things simultaneously, so she'll be over. But we'll start with Dr. Hughes.

STATEMENTS OF DR. JAMES HUGHES, DIRECTOR, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND DR. JESSE L. GOODMAN, M.D., M.P.H., DEPUTY DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION

Dr. HUGHES. Thank you very much, Mr. Chairman, Mr. Cummings. It is a pleasure to be here with my good friend and col-

league Dr. Goodman from FDA. Thank you for your invitation to testify on West Nile virus-related illnesses and CDC's public health response.

Although Americans have not regarded mosquito-borne diseases as a major health risk for some time, the introduction and rapid spread of West Nile virus in the country has changed this. In 1998, CDC issued Preventing Emerging Infectious Diseases: A Strategy for the 21st Century, which described CDC's plan for combatting today's emerging diseases and preventing those of tomorrow. The plan emphasizes the need to be prepared for the unexpected. The West Nile virus is a dramatic example of an unexpected emerging infection.

West Nile virus was first recognized in the West Nile district of Uganda in 1937, as we've heard. Since then it has been seen in Europe, the Middle East, Africa and as far east as India. The West Nile virus was first recognized in Northeastern United States in 1999, and as you can see on the map, it has subsequently spread across much of the country. The virus has been found in 42 States and Washington, DC.

This year, through yesterday, there have been 2,530 reported human cases of West Nile virus infection; 125 of these patients have died tragically. While most people who become infected with West Nile virus develop a mild illness or do not become sick at all, a small fraction, less than 1 percent, develop neurological disease. Approximately 10 percent of these severely ill patients die. Some patients with West Nile virus infection experience a polio-like paralysis. It is not known how long the paralysis will last, and we are planning long-term followup of these patients.

CDC, FDA, HRSA and State and local partners are investigating some cases of West Nile virus infection with onset of illness following blood transfusion and organ transplantation. To better assess these risks, we are actively engaged in identifying and following up on additional possible cases. Dr. Goodman will address the transfusion issue in more detail in his statement.

In addition, breast milk from a woman with West Nile encephalitis has been found to contain West Nile virus RNA. The infant, who remains well, has IGM antibody to West Nile virus.

CDC is the lead Federal agency for response to the West Nile virus outbreak in humans. Building on lessons learned from last fall's anthrax attacks, we have activated our emergency operation center to coordinate our response, deploying field epidemiologists, vector-borne disease experts and communications specialists to assist State and local health departments in the affected States in conducting surveillance, investigating cases and implementing prevention and control efforts.

With the U.S. Geological Survey, the Department of Agriculture and other partners, we are monitoring the spread of West Nile virus in humans, birds, and animals. Maps such as these aid in developing and implementing prevention and control strategies regionally and locally. You can see perhaps in that graphic the reported human cases on top, this year the geographic distribution in the middle, the avian cases, and on the bottom the veterinary cases, which are predominantly in horses.

We have provided education to health care workers, disseminated information to clinicians and public health officials, and held frequent press telebriefings, all critical activities both for this disease outbreak and for strengthening our future capabilities.

Since fiscal year 2000, the Department of Health and Human Services and CDC have provided more than $58 million to State and local health departments to develop or enhance epidemiologic and laboratory capacity for control of West Nile virus and other mosquito-borne diseases.

In conclusion, addressing the threat of emerging infectious diseases such as West Nile virus depends on a revitalized public health system and sustained and coordinated efforts by many agencies and organizations. We have made substantial progress to date in enhancing the Nation's capability to detect and respond to this infectious disease outbreak. However, the emergence of West Nile virus in the United States has reminded us yet again that we must not become complacent. As our new Director Dr. Julie Gerberding says, "complacency is the enemy of preparedness."

Priorities include strengthened public health laboratory capacity, increased surveillance and outbreak investigation capacity, education and training for clinical and public health professionals at the Federal, State, and local levels, and communication of health information and prevention strategies to the public. A strong and flexible public health system is the best defense against any disease outbreak.

Thank you again for the opportunity to testify. I will be happy to answer any questions you may have.

Mr. SOUDER. Thank you.

[The prepared statement of Dr. Hughes follows:]

Testimony
Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
United States House of Representatives

CDC's Public Health Response to West Nile Virus

Statement of
James M. Hughes, M.D.
Director,
National Center for Infectious Diseases
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00pm
on Thursday, October 3, 2002

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Dr. James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am pleased to be here to update you on CDC's public health response to the West Nile virus (WNV)-related illnesses in the United States. I will also discuss the status of our WNV prevention programs.

Mosquito-borne illnesses in the United States were largely eliminated as a health risk in the middle of the last century, although mosquitoes that can transmit malaria, dengue, and yellow fever remain. Although Americans have not regarded mosquito-borne diseases as a major domestic threat for some time, the introduction and rapid spread of WNV has changed this. CDC has played an important leadership role in rebuilding the nation's capacity to monitor and diagnose mosquito-borne viral diseases through state and local public health partners around the country, but this year's events show that more work remains to be done. The more we strengthen our nation's front-line workers, whether in the field or in the laboratory, the better prepared we are to respond to new and emerging infections, such as WNV.

Emerging Infectious Disease Threats

The past decade has seen a significant number of emerging infectious disease problems in the United States. Some, such as *E. coli* O157:H7 and *Cyclospora*, are foodborne. Others, like hantavirus pulmonary syndrome, are transmitted from animals to people. Still others, like Lyme disease and ehrlichiosis, are vector-borne, while others, like vancomycin-resistant enterococci, result from the development of antimicrobial resistance in response to the misuse of antibiotics. Some emerging infectious diseases appear to be caused by new pathogens; others, in retrospect,

have been here all along but were just not recognized. Some are clearly domestic in origin and others just as clearly have been introduced from abroad, illustrating the futility of thinking of infectious diseases in purely domestic or international terms. Infectious diseases know no borders. We must learn from the experiences of other countries in dealing with diseases such as bovine spongiform encephalopathy (BSE), variant Creutzfeldt-Jakob disease (vCJD), and foot and mouth epidemics in Europe, Ebola hemorrhagic fever in Africa, and avian influenza in Hong Kong.

CDC launched a major effort in 1994 to rebuild the component of the U.S. public health infrastructure that protects U.S. citizens against infectious diseases. In 1998, CDC issued *Preventing Emerging Infectious Diseases: A Strategy for the 21st Century*, which describes CDC's plan for combating today's emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to the detection of and response to WNV: 1) disease surveillance and outbreak response; 2) applied research to develop diagnostic tests, drugs, vaccines, and surveillance and prevention tools; 3) public health infrastructure and training; and 4) disease prevention and control. The plan emphasizes the need to be prepared for the unexpected – whether it be the next naturally occurring influenza pandemic or the deliberate release of anthrax organisms by a terrorist. This CDC plan is available on CDC's website at www.cdc.gov/ncidod/emergplan/index.htm, and copies have been provided previously to the Committee.

Despite the diversity of emerging infectious diseases, public health workers, in partnership with health care providers in the United States, must detect them and respond. This is particularly true at the state and local levels of the system. CDC and other Department of

Health and Human Services agencies have worked to strengthen the infectious disease public health infrastructure through cooperative agreements with states to build epidemiologic and laboratory capacity and through the development of emerging infections programs which are now in place in nine locations around the country. In many instances, these programs have significantly improved our ability to respond to infectious disease emergencies. Resources for bioterrorism preparedness and response have also bolstered capacity at the state and local level. But as highlighted by the Public Health Security and Bioterrorism Preparedness and Response Act, which originated in the Health, Education, Labor, and Pensions Committee and as illustrated by the challenges posed by the emergence of WNV, we still have gaps and needs to be addressed.

West Nile Virus

WNV is a mosquito-borne virus first recognized in the West Nile district of Uganda in 1937. Since then, it has been seen in Europe, the Middle East, Africa, and as far east as India. The virus lives in a natural cycle involving birds and mosquitoes, and only incidentally is transmitted to humans and other mammals, often in outbreak situations. A closely related virus, St. Louis encephalitis (SLE) virus, acts similarly in North America. Most humans who become infected with WNV through the bite of an infected mosquito will develop a mild illness or will not become sick at all. However, in a small fraction (<1%), encephalitis (inflammation of the brain) or meningitis (infection of the membranes surrounding the brain and spinal cord) will develop; approximately 10% of these patients will die. The elderly are recognized to be at higher risk than the rest of the population for the development of severe illness following WNV infection. It is likely that persons with compromised immune systems are also at higher risk.

The human and animal epidemic of WNV encephalitis which began in the northeastern United States in the summer and fall of 1999 underscored the ease with which emerging infectious pathogens can be introduced into new areas. The persistence of virus activity through 2002 indicates that WNV has become established in North America. This dramatic introduction and spread across the United States of a disease not previously seen in the Western Hemisphere reinforces the need to rebuild the public health system to prevent and respond to potential future introductions of other emerging infections.

WNV was recognized in the United States in late August 1999 when an alert infectious disease clinician at the Flushing Medical Center in Queens, New York, reported to the New York City Department of Health an unusual syndrome of fever and severe muscle weakness in several elderly patients. Eventually, 62 cases of human illness with WNV were recognized in the New York City area in 1999.

Laboratory studies of the virus demonstrated it was essentially identical to a WNV strain which had been isolated from geese in Israel in 1998, and all viruses identified in New York were indistinguishable by molecular typing techniques, indicating the outbreak resulted from a single introduction. When and how that introduction occurred is uncertain, but based on the wide circulation of the virus in the New York City area by August 1999, the virus likely was introduced several months earlier with subsequent unnoticed amplification in nature. Testing of a limited number of banked specimens from birds and humans have found no evidence of WNV in New York prior to 1999. Among the possibilities for how it was introduced are through an infected bird, through infected mosquitoes, or through an infected human.

In 2000, WNV was detected in 12 northeast and mid-Atlantic states. A total of 21

persons were found to be infected, 19 with severe illness and 2 with milder symptoms.

Randomly conducted household surveys where residents were asked to provide blood specimens were conducted in Richmond County (Staten Island) and Suffolk County, New York, and in Fairfield County, Connecticut – all areas with intense epizootic activity. Infection rates in the three locations were 0.46%, 0.11%, and 0%, respectively – far lower than the 2.6% seen the year before in northern Queens. In 2001, 359 counties in 27 states and Washington, DC, reported WNV activity, including 66 human illnesses, to ArboNET, a web-based, surveillance data network maintained by 54 state and local public health agencies and CDC. This activity represented a marked increase from 2000 in both geographic range and number of cases.

Current West Nile Virus Spread

This year, as you know, WNV infection has continued to expand geographically, reaching epidemic proportion in some states. As of September 27, 2002, surveillance in humans, birds, mosquitoes, and horses has detected WNV activity in 42 states and Washington, DC. Among humans, 2,339 cases with laboratory evidence of recent WNV infection have been reported from 32 states and Washington, DC. Among the 1,996 patients for whom data are available, the median age was 56 years, with age ranging from 1 month to 99 years; 1053 patients were male; and the dates of illness onset ranged from June 10 to September 23. A total of 116 human deaths have been reported.

Building on lessons learned from the anthrax attack, we have activated our emergency operations center to coordinate our response, deploying field epidemiologists, vector-borne disease experts, and communications specialists to assist state and local health departments in the

affected states in conducting surveillance, investigating cases, and implementing prevention and control efforts. As part of this effort, we have utilized the National Pharmaceutical Stockpile contract aircraft to rapidly transport specimens to CDC laboratories for diagnostic testing. In addition, we have provided education to health care workers, utilized the Health Alert Network (HAN) and the *Epidemic Information Exchange(Epi-X)* systems to disseminate information to clinicians and public health officials, and held press telebriefings – all critical activities both for this disease outbreak and for strengthening our future response capabilities.

CDC, FDA, and HRSA, in collaboration with blood collection agencies and state and local health departments, are investigating a series of cases of WNV infections in recipients of organ transplantation and blood transfusion. An initial investigation in Georgia and Florida has demonstrated transmission of WNV in four recipients of solid organs from a single donor. The source of the organ donor's infection remains unknown and an investigation of the numerous transfusions of blood products that the organ donor received is ongoing.

Since the report of these cases, CDC has been informed of other patients with WNV infection diagnosed after receiving blood products or organ transplants within a month of illness onset. All of these patients resided in areas with high levels of WNV activity; investigations are underway to determine whether transfusion or transplantation was the source of WNV transmission. In each instance, precautionary measures, including withdrawal of unused blood products from donors whose blood was given to these patients, has been initiated.

These investigations have provided evidence that WNV can be transmitted through blood transfusion. For example, two patients tested positive for WNV infection after receiving different blood products derived from a single blood donation subsequently found to have

evidence of WNV. In another instance, WNV was isolated from a unit of frozen plasma that had been withdrawn as a result of the investigation. This finding indicates that the virus can survive in some blood components and probably can be transmitted by transfusion. In contrast, another investigation has found that a patient who received a unit of blood potentially-contaminated with WNV did not develop serologic evidence of subsequent WNV infection.

To better assess the risk of WNV transmission through blood transfusion or organ transplantation, CDC is actively engaged with FDA, HRSA, blood collection agencies, hospitals, and health departments to identify and follow-up additional possible cases. CDC has requested public health authorities to determine if persons reported with WNV infection donated or received blood transfusions or organs preceding their illness. Prompt reporting of these persons can facilitate withdrawal of potentially infected blood components. Additionally, the Public Health Service will work with industry to identify potential strategies to further increase the safety of the blood supply, including the development and application of assays that could be used to screen blood and plasma donations for WNV.

CDC studies have indicated that some patients with WNV infection have a syndrome similar to that caused by the polio virus. This finding is particularly important since many of these patients were being treated for Guillain-Barré syndrome—treatment which would have no benefit for a poliomyelitis-like syndrome and could lead to severe side effects. It is not known how long the paralysis will last; CDC is planning long-term follow-up studies of these patients.

In addition, CDC recently reported evidence of WNV nucleic acid and antibody in a sample of breast milk from a woman who had likely acquired WNV by transfusion. Further studies of the breast milk and of her new-born infant (who remains healthy) are underway to

assess the potential significance of these findings.

Public Health Response

After the outbreak of WNV in 1999, a West Nile Virus Interagency Working Group was formed to facilitate information sharing and coordination of activities among federal agencies with a role in monitoring and control. CDC leads the working group which includes representatives from the Departments of Agriculture, Commerce, Defense, and Interior, the Environmental Protection Agency, and the National Institutes of Health (NIH) who continue to monitor for WNV activity and seek ways to prevent future outbreaks, including research by NIH into the development of an effective vaccine and effective treatment. The working group routinely assembles for telephone conference calls and has provided several briefings to keep Congress informed of ongoing activities. CDC has also conducted weekly conference calls with our state partners to assure coordination of national surveillance.

As with many emerging infectious disease problems, addressing the WNV outbreak also requires a strong partnership between public health and veterinary agencies and the public. Effective systems need to be in place to ensure: 1) effective monitoring for WNV and other mosquito-borne diseases and 2) further development of prevention and control measures, including integrated pest management, public education, optimal mosquito control measures, vaccines and antiviral therapy. Further research on the basic biology of the virus and its natural ecology is also needed.

CDC has been the lead federal agency to respond to the WNV outbreak in humans. Since fiscal year 2000, DHHS and CDC have provided more than $58 million to state or local health

departments to develop or enhance epidemiologic and laboratory capacity for WNV and other mosquito-borne diseases. In fiscal year 2002, approximately $35 million was awarded to those public health agencies to address the continued spread of the virus.

CDC has also provided extramural funding to other federal agencies for related WNV surveillance and diagnostic activities in support of the states. A university-based research cooperative agreement was initiated in fiscal year 2001 to support studies on WNV distribution, pathogenesis, and variability and to provide training to future entomologists, biologists, and other vector-borne specialists. And, in fiscal year 2002, CDC awarded funding to three educational institutions to initiate a program to train scientists in vector-borne infectious diseases. Finally, CDC has undertaken an aggressive intramural research program in several scientific areas to address the long-term needs related to epidemic WNV.

Surveillance, combined with professional and public health education, is the best strategy to confront the WNV problem. Among the recommended prevention measures to reduce the risk of exposure to WNV are 1) eliminating any areas of standing water around the house, i.e., draining standing pools, cleaning gutters, and emptying bird baths; 2) minimizing outdoor activities at dawn, dusk, and in the early evening; 3) wearing long-sleeved shirts and pants when outdoors; and 4) applying insect repellent according to package directions to exposed skin and clothing.

In addition to current activities, the following are some specific measures that CDC has implemented since the first WNV outbreak three years ago:

- Developing the tests for use at state laboratories to diagnose WNV in humans, making

and supplying the reagents used for these tests, and training every state laboratory in how to run them and how to diagnose infection;

- Implementing Arbo-NET, an electronic surveillance system to track and monitor WNV and other mosquito-borne illnesses;

- Convening a national meeting each year to provide public health workers, laboratorians, and local officials an opportunity to exchange the latest information about this disease;

- Producing, in collaboration with partners, consensus guidelines for the surveillance, prevention, and control of WNV;

- Developing educational materials for health care providers on the clinical aspects and diagnosis of WNV infection as well as public education materials; and

- Assisting local officials with guidance on mosquito control.

Conclusion

In conclusion, addressing the threat of emerging infectious diseases such as WNV depends on a revitalized public health system and sustained and coordinated efforts of many individuals and organizations. As CDC carries out its plans to strengthen the nation's public health infrastructure, we will collaborate with state and local health departments, academic

centers and other federal agencies, health care providers and health care networks, international organizations, and other partners. We have made substantial progress to date in enhancing the nation's capability to detect and respond to an infectious disease outbreak; however, the emergence of WNV in the United States has reminded us yet again that we must not become complacent. We must continue to strengthen the public health systems and improve linkages with health care providers and colleagues in veterinary medicine and public health. Priorities include strengthened public health laboratory capacity; increased surveillance and outbreak investigation capacity; education and training for clinical and public health professionals at the federal, state, and local levels; and communication of health information and prevention strategies to the public. A strong and flexible public health infrastructure is the best defense against any disease outbreak.

Thank you very much for your attention. I will be happy to answer any questions you may have.

Mr. SOUDER. Dr. Goodman.

Dr. GOODMAN. Good afternoon, Mr. Chairman, Mr. Cummings. I'm Dr. Jesse Goodman. I'm an infectious disease physician and scientist and Deputy Director of the Center for Biologics Evaluation and Research at FDA. I would like to thank you for providing FDA with the opportunity to talk with you about West Nile virus today.

There are and always will be newly emerging infectious diseases which pose a threat to human health. Unfortunately, some of these will likely also threaten the safety of the blood supply, and West Nile virus is the newest such challenge.

In this testimony I'd like to try to do three things. First I'll provide a chronology of recent events from the perspective of the safety of the blood supply; second I'll tell you about what our response has been to date; and finally, I'll tell you about plans to further address the problem. I think you'll see we've come a very long way in just 4 short weeks.

I'd also like to take this opportunity to mention what I feel has been extraordinary cooperation between CDC and FDA and an impressive pace with which the case investigations of concern here have been and are being conducted. I also want to thank the involved States and the blood organizations whose response has been exemplary under very difficult and challenging circumstances.

Until a month ago the potential threat of West Nile virus to the blood supply was thought to be very low. Because of the dramatic increase in the spread of West Nile this year, on August 17, FDA, in consultation with CDC and NIH, issued an alert. This alert to blood banks emphasized the importance of careful attention to screening procedures for blood donors, especially the exclusion of donors with even mild flu-like symptoms which could be early signs of West Nile infection. And I should say we did this with no—in a setting of no previous reported cases of transmission of West Nile in this manner.

Then about 4 weeks ago, as you know, the initial results of the investigation of a cluster of cases of West Nile among organ transplant recipients from a single donor led to the strong suspicion that the virus could be transmitted by organ transplantation, and we now believe it's almost certain that the organs from a single donor carried the infection to four recipients. The source of that donor's infection, as you have heard mentioned, may have been from a mosquito or from transfusions.

During our current state of heightened alert, additional cases in which West Nile virus disease developed in the days to weeks following transfusion both in and out of the setting of transplantation have been reported to date and are under investigation; for example, the case—the unfortunate case mentioned by Mr. Cummings. In each case studied so far, the patients were from areas of known mosquito transmission. However, special studies of blood donated to a single patient in Mississippi who later developed West Nile disease suggested that three blood donors may have unknowingly and coincidentally had the West Nile virus in their blood at the time of their donations. So far one of these donor's infections has been confirmed, including detection of live virus in frozen plasma from the same patient.

In addition, just last week, we learned that two different individuals who developed West Nile virus infection had both previously received transfusions; in one case platelets, and in the other red cells from a single donor whose retained blood samples from that donation have tested positive for West Nile virus.

Based on these ongoing investigations and particularly the cases I mentioned, we have identified a risk to blood safety. We do not yet know how big or small that risk might be. Critical studies are being implemented in different donor populations to better assess the risk to blood and organ recipients. Meanwhile, we have taken several important steps.

First, we're continuing to encourage reporting of cases of West Nile that follow recent transfusion or transplantation, and if a case is reported in a recent donor, any blood products which might still be available are being withdrawn to protect others, even before any infection in the donor has been documented.

Second, FDA is working with blood banks and will soon provide guidance to improve the reporting of postdonation illnesses and the appropriate actions to be taken. I should mention in one of these cases an individual who had been well at the time of donation shortly thereafterwards developed symptoms of infection. And these steps again include withdrawal of products where needed to help protect others.

Third, because of the potential—and this is what we're quite concerned about—for West Nile virus transmission from donors who never develop any symptoms of infection, FDA believes it is important to be ready and able to move rapidly toward testing donor blood. No validated test is currently available for screening of donor blood, and such screening of large numbers of samples cannot be implemented overnight.

To jump start that process of getting a reliable and practical blood screening test, we recently took the step of proactively meeting with the American Association of Blood Banks, AdvaMed, which is a medical device manufacturer association, and other partners in the blood banking and diagnostic testing laboratories, along with Federal and State laboratories whose tests could be readily adapted to this need. We have signaled our view of the high importance of making testing available and our willingness to provide maximum flexibility in moving this forward. CBER will also continue and, where necessary, seek to expand its related work relevant to the development and review of potential West Nile virus diagnostic tests, vaccines and treatments.

I'm pleased to be able to continue to report that the medical diagnostic and blood banking communities are highly engaged and motivated by the public health importance of this problem. While the success of these efforts depends largely on their overcoming some scientific and technical obstacles that may be significant, our hope and intent is that a West Nile virus screening test for blood could be made widely available at least for study use under an investigational new drawing exemption for the next transmission season and perhaps sooner, if possible in more limited settings.

In addition, based on our evolving knowledge, my expectation is that if the epidemic continues, FDA will recommend the use of blood donor screening tests for the presence of West Nile virus once

approved. At the same time, we're continuing to explore a relatively new strategy for treating blood to kill microbes called pathogen inactivation, and we are working with the developers of these technologies to help carefully assess their safety and to determine whether they will work for West Nile virus.

In conclusion, we do believe there is sufficient evidence to say that there is a risk to the blood supply from West Nile virus, and we are taking this risk extremely seriously, and we are acting upon it. At the same time, we want to communicate this risk in perspective. There are approximately 4½ million people in the United States who receive blood products each year. Both blood transfusion and organ transplantation are often life-saving or life-enhancing. While it is currently believed that the risk from West Nile virus is likely to be low overall, our knowledge is very recent and is limited and changing rapidly, and, in fact, as Jim mentioned, through frequent telebriefings, public meetings, etc., we are trying to continuously communicate new knowledge as it becomes available, including to you Members of Congress.

Patients should be aware that this risk exists and can discuss their concerns and their medical treatment and possible options with their physicians. FDA, CDA, HRSA, all our partners are continuously monitoring this situation. We can expect continued reports of West Nile virus both naturally occurring and potentially transfusion-related to occur even as the peak period of West Nile virus transmission passes for this year. We will continue to work together to better understand and deal with this risk as quickly and effectively as possible.

Meanwhile, I'd also like to take the opportunity to remind everyone that voluntary blood donation is a key to maintaining an adequate blood supply, and regardless of the findings here, blood donation remains safe. Blood has been in short supply very recently, and we encourage and we thank all of America's blood donors for making a commitment to donate blood periodically. We've come a long way in a few short weeks. I'm optimistic that we can and will respond to this new challenge quickly and effectively. Ultimately, though, success and controlling the mosquito-borne epidemic itself will be critical in determining the risk of infection to the blood supply and the need for routine blood donor screening.

Again, I thank you very much for the opportunity to be here today and would be very happy to answer your questions.

[The prepared statement of Dr. Goodman follows:]

Testimony
Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
United States House of Representatives

FDA's Response to the Emerging Threat of West Nile Virus

Statement of
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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Jesse Goodman, an Infectious Diseases physician and scientist and Deputy Director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to appear today to discuss FDA's response to the emerging threat of transmission of West Nile virus (WNV) through blood and tissue. One of FDA's primary responsibilities is to help ensure the safety of the nation's blood supply. Within FDA, CBER is responsible for regulating blood and blood-related products. Our goal is to help ensure the safety of the nation's blood supply by minimizing the risk of infectious disease transmission and other hazards, while maintaining an adequate supply.

Since the beginning of this West Nile virus outbreak, we have taken many steps to meet this goal by collaborating closely with the Centers for Disease Control and Prevention (CDC) and other Department of Health and Human Services (DHHS or the Department) agencies, while working with our partners in the blood and diagnostics industry to ensure rapid and effective responses to the evolving problem based on the best available information and technologies. I will summarize for you the background, current state of our knowledge and actions, and our process for promptly responding as new information becomes available to enhance blood safety for those who need transfusions

THE DEPARTMENT OF HEALTH AND HUMAN SERVICE'S COORDINATION

In 1995, DHHS created the Blood Safety Committee to ensure coordinated activities across the Department. Chaired by the Assistant Secretary for Health, the Committee includes

the Commissioner of FDA, the Director of CDC, and the Director of the National Institutes of Health (NIH). There have been periodic meetings to discuss important safety and availability issues concerning the blood supply. On September 13, and October 2, 2002 the issue of West Nile virus was discussed with the Chair of the Blood Safety Committee.

DHHS also established the Advisory Committee on Blood Safety and Availability (Advisory Committee) to look at broad issues including global public health, legal, ethical, and economic matters related to the blood system. On September 5, 2002, the issue of West Nile virus was discussed at this Advisory Committee meeting so the public and blood industry would be informed of the latest CDC and FDA efforts.

In late September, Secretary Thompson announced the creation of an intergovernmental working group on West Nile virus. CDC and FDA will participate in this working group, and the first meeting is scheduled for October 4, 2002.

In addition to these activities at the Department, the current status of the West Nile virus epidemic was presented as an information item at FDA's Blood Products Advisory Committee (BPAC) on September 12, 2002. The BPAC considers scientific technical issues related to regulation of blood and tissue. FDA will continue to work with the other DHHS agencies in a collaborative effort to address the public health issues posed by WNV.

FDA'S ROLE

In recent years, tremendous steps have been taken that have greatly enhanced the safety of our blood supply. While we now face a new challenge, the American public can be assured that FDA is vigilant in its efforts to keep blood as safe as possible. In July 1997, CBER initiated a

Blood Action Plan to increase the effectiveness of our scientific and regulatory actions and to ensure greater coordination with other parts of the Public Health Service (PHS). We recognized then, and recognize now, that potential threats to the blood supply will continue to emerge. We believe that helping to ensure blood safety requires timely action and a coordinated approach. Consequently, FDA works closely with CDC and NIH, and seeks input from consumers and the blood, diagnostic, and biomedical industries, to develop strategies that lead to appropriate studies, risk assessment, communication, and any other prevention strategies or regulatory controls needed to protect the blood supply.

Over a period of years, we progressively strengthened overlapping safeguards that protect patients from unsuitable blood and blood products. FDA's blood-safety system includes the following five measures; all of which are relevant as we address the threat of West Nile virus:

- **Donor screening:** Donors are provided educational materials and asked specific questions by trained personnel about their health and medical history. Potential donors whose blood may pose a health hazard are asked to exclude themselves. Donors also undergo medical screening to ensure that they are in good health at the time of donation.
- **Blood testing:** After donation, each unit of donated blood undergoes a series of tests for blood-borne agents such as HIV-1, HIV-2, HBV (hepatitis B virus), HCV (hepatitis C virus), HTLV-1 and HTLV-II (Human T-Cell Lymphotropic Viruses), and the agent of syphilis.
- **Donor lists:** Blood establishments must keep current a list of individuals who have been deferred as blood or plasma donors and check all potential donors against that list to

prevent use of units from deferred donors.

- **Quarantine:** Donated blood must be quarantined until it is thoroughly tested and the donation records have been verified.
- **Problems and deficiencies:** Blood establishments must investigate any failures of these safeguards, and correct system deficiencies that are found by the firms or through FDA inspection. Firms must report to FDA any manufacturing problems, e.g., biological product deviations that may affect the safety, purity, or potency of products that were distributed.

If any one of these safeguards fails, affected blood products are considered unsuitable for transfusion and subject to recall.

WEST NILE VIRUS

Background

WNV is the most recent emerging infectious disease threat to public health and, potentially, to the safety of our blood supply. WNV primarily infects birds but can be transmitted to humans and other animals by mosquitoes. While the majority of humans who become infected by the mosquito borne route never develop symptoms, approximately one in 150 develop serious and life-threatening nervous system infection. At this time we do not know whether this proportion would be similar for transmission via transfusion. It is likely that not all patients exposed to WNV by transfusion would develop clinical evidence of infection. However, patients receiving transfusions by definition are already ill and may be at higher risk of developing serious disease, if exposed.

Our information about the risk of transmission of WNV by transfusion has changed dramatically in the last few weeks. Only four weeks ago, the possibility that WNV might be transmitted by blood transfusions was theoretical, as no cases of such transmission had ever been documented here or elsewhere in the world. Even so, we knew that such transmission was plausible because the virus is believed to be present in the blood for a period of a couple of days to weeks early in infection, including the blood of people who never develop symptoms of infection. Thus a donor could feel well but after mosquito exposure, could have the virus present in the blood for a short time and, while unaware of this, could donate blood. However, the risk of such an infected donor transmitting infection was believed to be very low because, unlike classic transfusion-transmitted viruses such as HIV and hepatitis B and C, where individuals may be infected for life, in West Nile infection there is no known chronic carrier state. Persons infected with WNV develop a rapid immune response, which clears the virus from the blood stream. Thus, to pose a risk to recipients, a donor would need to donate blood on one of the relatively few days in which the virus is present in the blood. In addition, levels of virus in the blood, when present, are low compared, for instance, with HIV or hepatitis. Finally, as mentioned, despite three previous years of reported WNV cases in the United States and many years of epidemic infections in other nations, no cases of transfusion transmission had been reported.

Even though the risk was considered theoretical at that time, the growing distribution and increased numbers of WNV cases prompted FDA, working with CDC and NIH, to issue an alert to the blood banking community on August 17, 2002, about the possibility of transfusion-transmitted WNV, and to emphasize the need for careful attention to screening procedures for

blood donors, especially the exclusion of donors with even mild symptoms that could represent early or mild WNV infection.

RISK TO THE BLOOD SUPPLY

FDA has been working closely with CDC, state health departments, and blood organizations as part of the ongoing investigations of the recent WNV cases where patients had received organ transplants or blood transfusions. Based on the preliminary results of these investigations, we believe that it has been shown that organ transplantation can transmit WNV and that it is highly likely that blood transfusion also has done so. Thus, there is a newly recognized threat to blood safety.

It is important to recognize that the true dimension of the risks of either blood transfusion or transplantation spreading West Nile virus is not defined at this time and more information is critically needed. The risk could be higher or lower than the case reports suggest. Our investigations continue and new information, which shapes our understanding of the risk, comes to light almost daily. We are working closely with CDC, NIH, the Health Resources and Services Administration (HRSA), and with colleagues in the blood transfusion community, to address this evolving situation and to share new knowledge. We are communicating with Congress, the public, the media, the blood industry, and health professionals. As we have much to learn, we strive to present a clear picture of our evolving understanding of this potential risk.

To better define the risk and to determine what interventions are needed will require more knowledge. We are investigating case reports as they are received. We are also working with CDC, the blood community, and NIH to design and help implement studies that will give us a

better idea of what proportion of donors may be infected in areas of differing intensity of disease transmission. We are hopeful that additional studies can provide information as to the degree to which infection of donors then translates into risk for blood recipients. FDA also believes that studies are needed to confirm that long-lived blood stream infection (viremia) does not occur in persons who are potential blood donors. In addition, we are encouraging further studies of the effects of the virus on various conditions of blood product storage and manufacturing. We also are working with our partners to study the incidence of infection in frequently transfused individuals or those receiving plasma derivatives, such as patients with thallassemia, hemophilia, and immune deficiencies, even though existing information indicates that steps normally taken in the manufacturing of plasma derivatives are expected to kill this virus, thus protecting recipients. All of this knowledge, as it becomes available, will help us not only to better understand the nature and the degree of any risk, but also to shape effective policy and better protect the public.

Two reports currently being studied support transmission of WNV by transfusion, and other suspicious cases are being investigated. In one report, two patients who developed WNV infection shortly after receiving blood products likely containing WNV from a donor whose reserve samples were later tested and found to be positive for WNV, confirming that the donor had a WNV infection at the time of donation from Mississippi. In the case of another patient under study who developed WNV following transfusions of products from multiple donors. Three different blood donors to this patient, among the 15 tested, may have carried the WNV at the time of donation. This would obviously suggest far greater prevalence than the predicted prevalence of approximately 1 or 2 in 10,000.

The estimate of 1 or 2 in 10,000 is from a CDC modeling study based on the density of

infection during the 1999 epidemic in Queens, New York. Unanswered questions include: Is the West Nile virus persisting longer than expected in the bloodstream of some patients? Is there something unusual about the donors to this recipient? Is mosquito borne transmission to certain populations far more intense this year than previously believed? These possibilities are under investigation. Regardless of the answers, we now have a very heightened level of suspicion and concern about all such reports, even if some may represent coincidental occurrence of transfusion and infection. Such coincidences can be expected to occur because the same individuals who need transfusions--the elderly, the chronically ill, and the immunosuppressed--are also most likely at higher risk to develop severe West Nile infection.

FDA RESPONSE

Based on the growing distribution and increased number of cases of WNV in this year's epidemic, FDA, working with CDC and NIH, decided it would be prudent to issue an alert on August 17, 2002, to the blood banking community about the possibility of transfusion-transmitted WNV, and to emphasize the need for careful attention to screening procedures for blood donors, especially the exclusion of donors with even mild symptoms that could represent early or mild WNV infection. In addition, where there have been reports suggesting that recipients of blood transfusions may have been infected by donated blood, we have worked with the blood banks and state health departments involved to take a precautionary approach. In these cases, the blood banks, at FDA's request, have withdrawn any untransfused blood components from these donors to protect other potential recipients while we investigate whether the donor(s) may actually have been infected.

More recently, we learned that the Mississippi blood donor, who likely transmitted WNV to a transfusion patient, became ill four days after donating blood. FDA policies encourage reporting by patients and the evaluation by blood banks of such so-called "post-donation" events. We have alerted blood banks to this finding and plan to issue guidance shortly to emphasize the importance of soliciting and investigating post-donation reports of illness. In cases of serious illness, quarantine of blood products and investigation of the donor illness should provide an additional safeguard to reduce the risk to possible blood recipients. With regard to donors who never develop symptoms, we need to continue to investigate and collect information so that we can develop appropriate policies to further reduce the risk of transfusion-transmitted infection.

Some have raised the question whether not allowing anyone who reports mosquito bites to donate blood would be appropriate. This would likely be both inefficient and ineffective. Most people living in areas where WNV is spread will have had recent mosquito bites and we would exclude a large number of safe donors for every one donor with actual WNV infection. In addition, some individuals with WNV infection will not recall mosquito contact. These factors suggest that such measures could create serious blood shortages which present a serious potential to hurt far more people than might be helped.

If areas of intense WNV transmission can be identified, another measure that could be considered is excluding donors from those areas. This approach could potentially reduce risk, but the ever-expanding map of transmission makes it likely that this approach could likewise cause blood shortages, while still failing to exclude a significant number of infected donors. Nonetheless, if an unexpectedly high risk is identified in a specific area, such measures could be considered, particularly if no other effective interventions might be immediately available. It is

also reasonable that a greater use of autologous blood collections could be encouraged in areas of intense infection.

The most effective potential means of reducing the risk of WNV transmission by blood transfusion would be to test donor blood samples for the presence of the virus. Such testing could be performed generally (e.g., on all blood donors nationally). Alternatively, if transmission is more restricted, testing could be performed during seasons where transmission is occurring, or, in donors from selected regions. If specific populations (e.g., transplant or other immunosuppressed individuals) were to be identified as being at special risk for severe disease from receiving WNV infected blood products (and other populations not), donor screening could be performed to target blood intended for such individuals. It is unlikely, however, that an approach focused on specific recipients would be either desirable or practical, except perhaps as an interim measure were one needed until testing methods for broader use were made available. All individuals exposed to WNV are at risk for infection, and the elderly, who appear most at risk for severe disease, also need transfusions more frequently than other populations.

What are the prospects for availability of a good blood screening test for this disease? In short, the prospects are encouraging although it cannot happen overnight. Significant challenges are being addressed. Classic tests for infectious agents involve looking for the human's immune response to the agent, in the form of antibodies. However, in the case of this virus, the WNV is present in the blood during the time period before antibodies develop. Therefore, direct methods to detect the virus itself will be needed. These methods are more complex, more expensive, and more difficult to implement on a broad scale than antibody tests. On the positive side, in response to the emergence of WNV, state and academic labs, some diagnostic companies, and

the CDC, have developed sensitive tests that can amplify and detect the genetic material of this virus. Thus, we are continuing to make advances in the development of blood screening tests for WNV.

Tests based on similar technologies, called NAT (for nucleic acid amplification test), are now universally used in the U.S. to test all donated blood for the presence of early HIV and hepatitis C infection. These tests have helped make our blood supply very safe from these infections, with risks of transmission of these agents in the 1 in 1,000,000 range for hepatitis C and in the 1 in 2,000,000 range for HIV. The medical diagnostics industry, the blood industry, and FDA have significant expertise in the development, implementation, and evaluation of NAT testing. Such experience will be useful in rapidly adapting WNV test methodologies currently in use in diagnostic laboratories to more widespread and automated use for blood screening. There are many challenges, including the need to achieve high levels of reliability when used in populations with very low frequencies of infection, the lower levels of virus compared to those currently tested, the difficulties involved in scale-up, and time needed for test development and wide implementation. For testing organ donors, special challenges would be added, including timing, logistics, and determination of whether screening blood samples can rule out infection in tissues and organs. While we do not yet know if screening of blood will be needed, we believe it is likely to be needed, and that it is therefore most prudent to move forward to facilitate the development and availability of effective tests as soon as possible.

To this end, we are working with our partners in the blood and diagnostics industries, including the American Association of Blood Banks and AdvaMed. Recently, they hosted an important meeting with FDA, CDC, and state health departments with potential WNV

diagnostics methodologies. The purpose of the meeting was to discuss the development of assays of potential utility, stimulate interest in testing, identify barriers and approaches to resolve them, and foster technology transfer and sample sharing. These efforts are designed to get all partners the information and materials needed to be as prepared as possible to meet the potential need for testing. This meeting was quite successful and we are continuing to interact with these partners in the near future. We are also holding a follow-up public workshop at FDA co-sponsored by CDC, NIH, and HRSA in the near future. Further development and implementation of effective screening tests for WNV will depend in large part on the efforts and innovation of our public health and blood and diagnostic industry partners. It is important to note, however, that FDA can use its regulatory authority to make such tests available for investigational use under an investigational new drug (IND) application even before approval. We have made it clear to industry that we will show maximum flexibility and assist them in any ways that are feasible. Based on our most recent interactions with scientists from industry, we are hopeful that, if needed, a WNV blood screening test could be made widely available under IND by next summer, and that it may be possible to make some testing available even sooner.

One final approach that could be used in helping to address the WNV threat, as well as other future and potential infectious risks to the blood supply, is called "pathogen inactivation." In pathogen inactivation, a chemical and/or physical treatment of blood products is used that is capable of killing many infectious agents. FDA recently held a workshop on this promising and innovative strategy. Several approaches are currently under study and may be effective at inactivating viruses such as WNV. Although promising, it is important to realize that preventive treatment of blood products affects the products given to all recipients. In other words, if only 1

in 5,000-blood units had an infectious agent present, for every patient protected from the disease 4,999 would receive a product that may be altered in some ways that could affect its other characteristics and, perhaps, its safety.

For these reasons, these approaches must be, and are being, carefully evaluated for their immediate and long-term safety. However, should WNV risk prove to be significant in degree, or should blood screening be difficult to implement in a timely manner, pathogen inactivation may prove valuable as an approach to reducing risk in blood products from high risk areas and/or potentially in blood products for recipients at the highest risk of developing severe disease. Such approaches could also be initiated and evaluated in pre-licensure pilot studies under an IND application. FDA is also currently planning to specifically address the inactivation of WNV by such methods in conjunction with its upcoming workshop on WNV donor blood testing.

TREATMENTS FOR WNV AND VACCINE DEVELOPMENT

Most people who become infected with WNV will have either no symptoms or only mild ones. More severe disease occurs in approximately 1 in 150 of those infected and is manifested as encephalitis, meningitis, or meningoencephalitis. Encephalitis refers to an inflammation of the brain; meningitis is an inflammation of the membrane around the brain and the spinal cord, and meningoencephalitis refers to the combination of both. There are currently no drugs on the market to treat this virus. There are currently six IND applications involving two products in effect at FDA for the treatment of WNV. The National Institute of Allergy and Infectious Diseases (NIAID) has also supported promising research to identify and develop potential treatments for this disease.

While there is currently no licensed vaccine available to prevent WNV infection, FDA is aware of several promising approaches to vaccine development and believes that this is a potentially viable strategy to address this increasing public health threat. Because of the increased presence of WNV in the U.S., NIAID has supported research in this area. NIAID announced that in 1999 it funded a fast-track project to develop a candidate WNV vaccine with Acambis PLC. Scientists at CBER are also engaged in studies, which may hold promise for developing a vaccine effective against WNV.

Given the important and increasing public health impact of WNV infection, including the potential threat to blood safety, and the lack of available vaccines and therapeutic measures, FDA places a high priority on facilitating the development and review of such products.

CONCLUSION

As we continue to act on our current and evolving knowledge of the risk of WNV to the blood supply, and share information with the public as it becomes available, it is also important that we keep the risk, even a risk that is not yet fully defined, in perspective. There has been a remarkable decrease in the transmission of viral diseases through blood in recent years. We believe that our experience in dramatically reducing the risk from HIV and hepatitis will serve us well in addressing whatever needs to be done with respect to the challenges we now face with the WNV. Thousands of individuals' lives are saved or transformed every year by organ transplants. Millions of lives are enhanced by transfusion of blood and related products. It is essential that we keep these medical procedures and related products as safe as possible.

We will continue to work closely with our partners in CDC, NIH, HRSA and the states,

and to engage the blood and diagnostics industries to harness their capabilities to help make a sensitive blood test a reality as soon as possible. It is important to keep in mind that success in controlling the mosquito-borne epidemic itself will be critical in determining the risk of infection in the blood supply and the need for routine blood donor screening. We will continue to share information with and seek input from the public and from experts outside of government, as we recently did with both FDA's Blood Products Advisory Committee and the DHHS Advisory Committee on Blood Safety and Availability. We will continue to engage the highest levels of attention with the Department, including discussion of major blood safety policy issues with the Assistant Secretary's Blood Safety Committee and discussion of agency activities at the upcoming Friday meeting of the DHHS intergovernmental working group on West Nile Virus.

As a final note, FDA would like to encourage the public to continue donating blood because supplies are low and the need is great. Blood remains in short supply, in part, because of the extensive safety measures already in place. Some people are concerned that they might get an infection by donating blood. We want to assure you and the public that donating blood is a safe procedure. We also want to take this opportunity to thank blood donors and to emphasize that the cornerstone of our blood safety system is the volunteer blood donor.

Thank you very much for the opportunity to testify today. I welcome your ideas and your questions.

Mr. SOUDER. I want to thank you both for your testimony.

Before we move to questions, Congresswoman Schakowsky is recognized for an opening statement.

Ms. SCHAKOWSKY. I want to thank you, Mr. Chairman and Congressman Cummings, for convening today's hearing to explore the public health implications of West Nile virus and the Federal response. This is a particularly important hearing for my State of Illinois and for my district. Although the statistics are changing daily, the most recent numbers that Illinois—show is that Illinois has suffered the highest numbers of human cases of West Nile virus in the country: 614 cases. Is that right, Dr. Lumpkin? Something like that. Thirty-five people have died as a result, including 15 in suburban Cook County. In my own district there have been 42 confirmed cases of West Nile virus in the village of Skokie, almost 50 in Evanston, and 10 in Morton Grove and Lincolnwood. The mayor of Morton Grove is now recovering from a bout with West Nile.

These numbers reflect the uncommonly high outbreak ratio in the Chicago metropolitan area, which accounts for 86 percent of all cases throughout the State. I'm pleased to say that the contact the municipalities in my district have had with Federal authorities, specifically the CDC, have been quite useful in providing critical expertise and assistance.

On behalf of my constituents and their local elected officials, I want to thank our CDC witness for the work the centers have done; however, I am concerned that Illinois, one of the most affected States in the Nation, has not received its fair share of Federal resources in combatting this epidemic. While Illinois received $300,000 at the beginning of the year and additional emergency funding in August and on September 30, the funding received by Illinois and the city of Chicago lags far behind those of other States. In fact, the totals for Illinois and the city of Chicago come out to $1.6 million for the fiscal year out of a total of roughly $35 million handed out to State and local health departments. That is 4.5 percent.

I commend Senator Durbin in his fight to bring more funding to our State, funding that is needed to allow us to win the battle against this horrible virus. I'm not arguing that other States should not receive the funds that they need to respond to West Nile. I'm not arguing that the Federal officials have not been as responsive as they can. I'm arguing that we need to provide all the funding necessary so that Illinois can receive the resources necessary to protect against the West Nile outbreak and other public health threats. We must invest necessary resources in providing States, and in turn localities and individuals, with information, funds and training.

As a Chicagoan I never thought I would find myself praying for an early and a cold winter, but I am. Winter will give us some relief, but it should not lull us into inaction. We need to use the coming months to aggressively plan for when the warm weather and mosquito season return next spring and summer. We must be not only prepared to respond for the next season of West Nile, but need to take preventative measures to try and avert an even worse out-

break next year. Part of that means adequate funding for States and local abatement authorities.

As Dr. Lumpkin, our Illinois health department director, will suggest, we may need to expedite training and certification protocols so that more hands will be available to participate in the prevention process and so that other key personnel will not be diverted from ongoing public health care needs. We need to do much more to educate the public. We need to do more multilingual outreach. We need to do more to alert the elderly to this problem who are particularly vulnerable and the steps that they can take to protect themselves. We need to reach special populations through a multimedia campaign and by direct outreach. We need a major new investment in our public health care system to prepare not just for the future West Nile outbreaks, but all possible health threats, the expected as well as the unexpected. I'm particularly interested in the recommendations of Dr. Akhter of the American Public Health Association in this regard.

I want to welcome our witnesses. I want to extend a special welcome to our public health director from Illinois, Dr. John Lumpkin. I appreciate each of you taking time to be with us, and I look forward to your testimony and to working closely with you on protecting and improving our Nation's public health.

Thank you, Mr. Chairman.

Mr. SOUDER. Thank you.

One of the things that's apparent is that we have a particularly huge shift into the midwest, with Illinois, with 600 cases Michigan I believe is second. I represent the northeast corner of Indiana. If you extrapolated our one county to the State of Illinois, you'd have 1,250 cases in Illinois. That suggests that we have a corridor, if they're concentrated in Chicago, rather than downstate and southern Michigan and northern Indiana.

Something has happened, and I wanted to kind of—we were looking at the April 2001 CDC Set of Revised Guidelines for Surveillance, Prevention, and Control of West Nile, and it recommended enhanced surveillance for many States, including active bird and mosquito surveillance as well as enhanced surveillance of animals and humans. And the guidelines note an appropriate timely response to surveillance is the key to preventing human and animal disease associated with West Nile and other arboviruses. The guidelines recommended this type of approach for the northeast in spring and fall, and also active ecological surveillance and enhanced pest surveillance in the southern United States; but it is not recommended for the midwest and Western States, only that there would be efforts to increase awareness in the medical community, dead bird surveillance and enhanced passive human surveillance during the spring.

That last graphic was described elsewhere in the report as a backup system that I'm interested in the process of. Obviously you have difficult tradeoffs. Obviously there are funding questions. How do you—how did you determine that the midwest in particular, which has been hard hit in this season, would not have a more active? When did you start to do more active in the midwest? You alluded to now going in and providing local assistance, and could you

explain the process a little bit so we can understand that here in Congress?

Dr. HUGHES. Yes. Thank you, Mr. Chairman.

Let me try to respond to that. As all of us have acknowledged this is an emerging infectious disease. An excellent example, the disease first appeared in New York City in 1999 and, as the other map showed, has moved to the South initially over the last couple of years, and to the West, and then this year back up into the midwest. The cases occurred earlier this year than in previous years, and they occurred initially in Louisiana, Mississippi and Texas. That outbreak has appeared now to have waned. As the summer went on, as we all know, the disease has emerged in a major way in the upper midwest.

We anticipated that this virus would move through the country. It's the reason that over the recent years we've provided support to all of the 48 continental State health departments to enhance their capacity to deal with this problem. We have developed diagnostic laboratory tests that are now in place in all the State public health laboratories, and we've trained people to use them properly. This is an excellent example of why people should care very much about the capacity of their State public health laboratory as well as their State public health—or the State public health department in general and also the capacity of their local health departments.

Each of the previous 3 years following the transmission season we have held meetings with State and local partners initially to develop the initial set of those guidelines that you allude to, and then during the past 2 years to update and refine those. The pattern of movement up until this year had been to the south and then westward in the southerly States. So we're not surprised that it has appeared in the upper midwest, but it points out the need to have surveillance in place so that this virus can be tracked.

Mr. SOUDER. Since there was some occurrence moving toward 2001, what's—already—what's in the midwest, part of the question would be why—how do you determine when to do as a predictive agency as opposed to a rec—in other words, did you have no evidence, either from FDA or bird death research or suggestions of mosquito patterns, that when you had the first signs that this could all of a sudden became a major wave—because this isn't like a—the signs were coming, and all of a sudden it's overwhelming, I mean, the numbers.

Dr. HUGHES. Right. Well, Dr. Lumpkin and I have talked about this, and as I'm sure he will tell you in his testimony, the disease in the Illinois area is behaving very much like St. Louis encephalitis, caused by a virus that's a cousin of West Nile, behaved back in 1975 when it caused a very large epidemic there. So in that sense, I mean, there's ample evidence historically that this is, for reasons that we don't fully understand, an area that is prone to mosquito-borne diseases. So, as I said, we had made investments in strengthening the public health capacity in those areas, and happily so.

In terms of prediction versus reaction, I've learned over the years that these microbes are pesky critters, and they're extremely difficult to predict exactly what they're going to do, particularly when they are either newly recognized or emerging in a new area. At

CDC we feel that the public health action starts with active aggressive surveillance that requires the clinical community and the public health community be tied closely together. This is true whether we're dealing with antibiotic-resistant and vector-borne disease or the threat of bioterrorism. It's very important, and we put a lot of resources into that. It doesn't stop there because all of these emerging diseases raise a lot of research questions, and they stretch our capacity to deal with them.

In terms of research issues, one of them relates to prediction and modeling, and that work is very, very important, but as always, it is a tradeoff with limited resources in terms of how to most effectively utilize them.

Mr. SOUDER. Does the prediction usually lose out in the budget debate?

Dr. HUGHES. Well, I can't comment on that. I think we go with the things that we think are most critical, and right now—because, you know, predictive modeling would not have told us that hanta virus was going to emerge in the Southwest in 1993, nor would it have told us that a terrorist was going to use the U.S. postal system to disseminate anthrax. So we have to be, both on the clinical side and on the public health side, on high alert.

Having said that, we need to think about diseases in other parts of the world to which we are vulnerable, and there are a number of examples. If we were talking 5 years ago, we might have had West Nile encephalitis on our list. I can tell you we should have another related virus, Japanese encephalitis virus, which causes very severe disease in much of Asia. That should be on our list. That would be, could be introduced. Recent experience in Virginia reminds us that malaria can appear in this country. We have vectors that are capable of transmitting malaria here.

So there's a long list. There's the recent experience with nepa virus encephalitis, Malaysia and Singapore, a devastating biodisease that affects pigs and spreads from pigs to people, that would be a major problem if that were to be introduced into the United States. So we have to pay attention to problems in other parts of the world. We have to make determinations about diseases that could be introduced in ways in which we might be vulnerable to them. So it's a very important part of a great big puzzle.

Mr. SOUDER. Dr. Goodman, do you have any comments?

Dr. GOODMAN. No. I really am very supportive of everything that Jim said. The way we try to interact with this is by taking the kind of surveillance data and predictions that our colleagues at CDC are so helpful with,and working with CDC and NIH periodically—and here I'm talking with respect to blood safety—periodically looking at the potential agents that are out there, getting a feeling for what the risk may be from them, again in the best way we can with respect to prediction and the disease incidence that's going on, and to try to be as prepared as possible.

Again, do we need to learn new lessons from what has currently occurred? Well, we certainly should try to learn as much as we can from that. Can we effectively use additional resources to move these—to increase preparedness at all times? That's something we want to look at very carefully, too.

Mr. SOUDER. Thank you.

Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Gentlemen, what—I mean, this is not a new disease, and I was just wondering, why is it, do you think, that we have not been able to—our counterparts in foreign lands have not been able to develop a vaccine for this?

Dr. HUGHES. I think in large part it has not been viewed as a priority in other parts of the world where this disease occurs, recognizing, as I am sure you do, that in Africa where the disease first appeared, of course, the continent's devastated by HIV infection, by TB and by malaria. So you could see how on their radar screen, you know—West Nile virus would be pretty far down the list. With the introductions in Eastern Europe and in France and in the Middle East, it's been introduced. I don't think it's had, I mean, like the dramatic impact that it has here, and it's been a problem that has kind of died down after a year or 2, and so it hasn't gotten in those countries high on the priority list either.

Mr. CUMMINGS. Do we have a—do we—do you anticipate we'll have a vaccine for this any time soon?

Dr. HUGHES. Well, Dr. Fauci and his colleagues at NIH are supporting a lot of research around vaccine development, and the results of some of the candidate—of the work with some of the candidate vaccines are quite promising. But it does take time to bring these vaccines through appropriate testing to production and marketing. It's—I know it is a very high priority for them, and we see it, as I'm sure Dr. Goodman does as well, as a high priority.

Mr. CUMMINGS. I've noticed that when we had problems in Baltimore, the—with the mosquitoes, they did the spraying. And I guess that's what they usually do. They spray?

Dr. HUGHES. Well, there are a number—what we try to promote is what we call integrated pest management, and that has a lot of components to it. It has—it starts with control and reduction of sources, and that's where people, individual members of the public, have an important role to play in terms of taking steps in their living environments to reduce settings in which these mosquitoes can breed.

Surveillance of mosquito populations is very important. Larval control is important. That can begin much earlier in the year. Spraying is somewhat of a last resort which is done when the mosquito populations proliferate where there is transmission to humans, and it comes at kind of the end of the intervention spectrum, if you will.

Mr. CUMMINGS. And is that—have you found that the spraying is effective as far as preventing cases; in other words, in places where they spray?

Dr. HUGHES. Well, you're widely raising the need to rigorously evaluate interventions that are done.

Mr. CUMMINGS. And I understand you want to do stuff before you get to spraying. I understand that. It's just that, I mean, I just see all the effort that goes into it, and I think that's basically what the public sees. I mean, you get—you know, you hear on the radio, on the radio and television, don't let water sit still and all that kind of stuff. I know that. But I'm just trying to figure out—you know, I'm always interested in measuring what we do so that we can de-

termine whether or not we're being effective. And so when I see in the city, for example, these trucks going through all-night spraying all over the place, I'm just wondering, as a result of that, are we seeing a—I mean, do we—are we—can we tell whether we are preventing or not?

Dr. HUGHES. Well, again, it is an excellent question, and I wish I could answer that concisely, but what we have seen now down in Louisiana and Mississippi is the epidemic has peaked, and it has fallen off. They have taken very aggressive control measures there, but those include public education campaigns in Louisiana. They have the Fight the Bite program that they think has been very effective. But at the same time it is a multifactorial set of interventions, so it is a bit difficult to tease out in terms of whether the reduction of transmission is more because of public education and the public response vis-a-vis, you know, use of insect repellent versus staying indoors at dawn and dusk versus a continued larviciding versus introduction of adulticiding.

Mr. CUMMINGS. Let me just ask you this: In the death of the kidney transplant patient I mentioned a little bit earlier in Baltimore, it was reported that the organ donor tested negative for the West Nile, but it appeared that the blood the patient received may not have been tested. What, if any, recommendations is the FDA making to blood collection centers and hospitals regarding the testing of donated blood?

Mr. GOODMAN. OK. Well, you have asked an important question, which is how with can we deal effectively with the potential threat through the blood supply. I would say that in the investigation of that case, donor samples that exist are being retrieved to be studied to see if any of those donors may have been infected and may have been involved in spreading this to this individual who developed West Nile disease. So that is being investigated. But as a more general question, what we have been doing is taking the steps that we now have available to us to reduce that risk, and those steps, such as they are, we are taking aggressively, but they are not perfect and complete at this time.

I mention that, for instance, to try to remove from the pool of potential blood donors those who might even have a mild illness that could be West Nile virus, we think that is helpful, and that was something we worked on a couple of months ago with the blood community and our alert, providing guidance about those groups of individuals who soon after blood donation may become sick so that they can be tested and their product withdrawn.

But as I had mentioned, and as I think you are focusing on, that does not deal with the issue of those individuals who may have no symptoms at all, but unbeknownst to them have—after mosquito bites for what we believe a short period of time have virus presence in the blood and potentially could transmit this to somebody, causing serious disease. And for that, what we really need to do is to be able to screen donor blood in real-time, ahead of time, to reduce the risk of transmission to others, and since this problem became apparent, we have been working very hard and closely to bring that quickly toward reality.

The positives on doing that are that over the last years, as this has become West Nile virus, in general a public health problem in

this country, there has been investment and work in diagnostic technology, some of which is very relevant and promising for blood screening.

The other—you know, what I should mention here is this isn't like the simple—what we would need to do isn't like the simple blood test that one would go to one's doctor and get, which might measure your body's response to a virus. OK, that is what you have, that is your diagnosis. That is the diagnostic test that Jim mentioned that the State health departments perform. That's relatively straightforward. To detect it in the blood, we need to detect it before the body has even responded to it, so we need to detect the presence of the virus itself, and that involves much more sophisticated, demanding tests to detect tiny amounts of the genes of the virus, amplify them to a level that we can detect them.

As I said, the good news is that those technologies exist. They have been developed to a certain point. And another very good piece is that FDA and the blood industry and the medical diagnostics industry have taken exactly that approach over the last several years, and now all blood in the United States is tested with those kinds—same kinds of tests for HIV and hepatitis C, which has reduced the risk from those diseases in transfusion down to 1 in a million to 1 in 2 million.

Mr. CUMMINGS. I've got to ask you this, and then this is my last question.

Dr. GOODMAN. Sure.

Mr. CUMMINGS. And try to put this in lay terms, if you can. You know, like some people, if they eat certain types of food, shellfish or whatever, it is like they get allergic to it while everybody else is eating it, and there is no problem. Or MSG. I have seen people just, I mean, swell up. Is this something like—you know, when I think about all the people who get mosquito bites and are not affected, is there something—you may have already answered this. Is there something special in these people that you have noticed that is common? Are you following what I'm saying? And is that——

Dr. HUGHES. Yeah. Yes. Let us both respond to that. Again, another excellent question. You are doing very well in defining a research agenda for addressing these infections.

We don't know why the elderly are the ones at greatest risk for development of severe manifestations of the disease. We don't—it is not surprising that immunosuppressed people such as organ transplant recipients would be at risk for development of severe disease. We see that with a broad range of agents. But not every elderly person who gets infected with the virus develops severe disease.

So, as you say, why do some and not others? There are clearly other factors that play, whether it is behavioral factors or genetic factors or other drugs that a person might be taking or—you know, it is very important that we try and determine that, but we most definitely don't have all the answers.

Mr. CUMMINGS. Thank you.

Mr. SOUDER. Congresswoman, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

In the 1980's, the CDC provided Iraq with a number of biological samples, including West Nile virus. I have two questions. One is, has the CDC—does it commonly get requests from countries around the world? And is there any possibility of any connection between that virus that was provided to Iraq earlier and what's the epidemic in the United States right now?

Dr. HUGHES. Thank you actually for asking that, and let me respond. I will take your second question first, if you don't mind, and that is, given that West Nile virus strain was supplied to Iraq back in the 1980's, does that have anything to do with the current outbreak? And the answer is no. The strain that was provided is not closely related to the strain that is causing the current outbreak, which is one that was recognized in the Middle East back in 1998, and it is the one that is uniformly present, so far as we know, with the studies that have been done to characterize the genetic structure of the virus; that all the virus in the country currently, as far as we know, is related to that strain that appears to have had an origin in Israel using molecular techniques.

Now, the other part of your question is excellent.

Ms. SCHAKOWSKY. Yeah. But did you just say that it does seem to be—we are finding it in Israel, the strain related to that which was provided to Iraq in the 1980's?

Dr. HUGHES. No. The strain in the United States is virtually identical to a strain that was first recognized in Israel in 1998.

Ms. SCHAKOWSKY. I see.

Dr. HUGHES. It is not closely—neither of those is closely related to the strain that was sent to Iraq.

Ms. SCHAKOWSKY. Thank you.

Dr. HUGHES. So that is a very, very important point.

Now, the question about is this important to work with colleagues in other countries, it absolutely is, and the West Nile experience illustrates that. Fortunately, CDC colleagues were involved in investigating a West Nile outbreak that occurred in Romania back in 1996, and from that we learned some lessons that have been helpful in responding to the introduction here.

Another story that might be of interest to you is with hanta virus pulmonary syndrome, again that disease that was recognized in the Navajo reservation in 1993. We were able to recognize that only because we had the benefit of reagents developed by DOD, Department of Defense, supported researchers who focused on the problem of another severe hanta virus infection that occurred in Korea and infected a number of U.S. soldiers during the Korean War. Because of that work, which is research in another part of the world, we actually have reagents that could be used that cross-reacted with the virus that occurred here, and it was through that happy coincidence that we were involved in the cross-reaction that unusual outbreak was recognized and the agent identified within 7 or 8 days of notification of the first cases.

We at CDC are involved in a global network that is sponsored by the World Health Organization that consists of collaborating centers that are focused on a broad range of diseases, starting with influenza. And data from that network, which we support through provision of reagents and in training of scientists around the world, generates the data that we use every year and in collaboration

with our colleagues at FDA to formulate the recommendations for the composition of the annual influenza vaccine.

So this idea of collaborating and working with scientists in other parts of the world is very, very important. Having said that, we all recognize in the current world in which we live, this has to be done with great care and in compliance with the existing regulation. So we take this very seriously.

Ms. SCHAKOWSKY. Well, I would hope that there would be a renewed look. I am reading from a news report that says that invoices from the 1980's included in the documents read like shopping lists for biological weapons programs. And I guess some of the material was delivered directly to—the companies sent the bacteria to the University of Baghdad, which U.N. inspectors concluded had been used as a front to acquire samples for Iraq's biological weapons programs. The CDC, meanwhile, sent shipments of germs to the Iraqi Atomic Energy Commission and other agencies involved in Iraq's weapons of mass destruction programs.

So I am assuming that we are reviewing wherever we are sending anything right now?

Dr. HUGHES. Well, we absolutely are, and we are making sure that we are in compliance with the current regulations. And we work closely with the Department of Commerce, which issues export permits, and there is a list of countries to which we don't send anything. But things are different today than they were in the mid to late 1980's.

Ms. SCHAKOWSKY. I understand. But we don't want it to quite literally come back and bite us.

Dr. HUGHES. We agree.

Ms. SCHAKOWSKY. Mr. Chairman, can I ask one other question? Are we going to do another round? OK.

Regarding Illinois, you know, though we are pleased that there, on September 30th, was more money freed up, if we look at other places where they have less of a problem with West Nile, I just—maybe you said this already and I missed it—a formula for how you would distribute funds particularly for this. And I understand that the September 30th had to do with reserve revenues, and now that money was distributed on the 30th, are there more—are we out of reserve revenues to do that?

Dr. HUGHES. We have a little more money left that can be used through the rest of this transmission season. It is not a lot. We are trying to be responsive to specific requests from States who continue to have a problem, and, in fact, Dr. Lumpkin and I were talking about that before the session began.

Ms. SCHAKOWSKY. Great. Thank you very much.

Mr. SOUDER. Do you have some additional time that we can do a second round with you?

I have a couple of different type of questions. One is do you agree that the rate of spread—when you looked at the cases of this around the world, that the rate of the spread in the United States is occurring faster that in previous cases in other countries?

Dr. HUGHES. Well, I can't see the original map, but you may recall from the colors that the impacted geographic area each year has more than doubled. There—thank you. There you can see it. Again, blue were the four States in 1999. And you can see what

happened in 2000 in green, 2001 in red, and 2002 in yellow. The virus in Romania, as far as we know, the outbreak that I mentioned in the mid-1990's, did not spread beyond the country of Romania. So, obviously, this is a much more dramatic spread.

See, the virus, though, had been present in Central Europe from time to time in the past. It is brand-new to the Western Hemisphere. So, not only do people not have any immunity to it, our bird populations don't have any immunity to it. They may be developing it along the eastern seaboard now after several years of experience. But certainly, the bird populations in Indiana would have had absolutely no experience with this virus and would have no immunity at all. So I think in part that contributes to the spread as well as the bird migration patterns.

Mr. SOUDER. Could the strain that we sold or gave or whatever to Iraq have been genetically altered?

Ms. HUGHES. It would be very difficult for me to imagine how that strain could have been converted into this particular strain.

Mr. SOUDER. We may have some followup questions. It is a very potent question being asked in a lot of places, given the spread and the rapidity of the spread.

Let me ask another line of questions, and once again, looking at the international cases and even our United States, basically, it seems to be within the last few weeks we are really looking at the blood supply in the organ donors. Did that not happen anywhere else in the world? Did it not happen in other years? Why is this all of a sudden an intense focus?

Dr. GOODMAN. Well, it is an excellent question that we have talked a lot about at all hours of the day and night. We do not—there were no previous case reports from any country or from the United States that showed transmission of West Nile virus by either organ transplantation or transfusion. So that is part of the background and kind of the background that led to, although this was on our radar screen, it seemed to be a low risk. So that is a good question.

In terms of what is different, I think there are potentially a number of factors. I think that, as Jim just alluded to, this virus is spreading rapidly in populations with no previous immunity, human, bird, and others, and the sort of crescendo and just sheer number of cases and burden of disease is quite high at this time.

So, certainly increased numbers of people are at risk of being infected, and even though those—the number of people with disease and symptoms is small—or not small. I mean, it is remarkably larger this year than previous years. But we do know there is a much higher ratio of people who never have any symptoms and get infected.

So I think part of this is the sheer burden of disease, but another part of it may reflect things about our population and medical progress, the degree to which we use health care and attendant blood transfusions, the degree to which organ transplantation has become a common and lifesaving event in this country, and the fact that, at least in those cases under investigation now, the majority of them are individuals—not all, but the majority who would be expected to have immune systems that are not functioning well.

But it could be that in other countries some transmission in this route occurred, but may not have attracted attention because it wasn't being looked for in the same way, or may not have caused a severe disease, because if it were in healthy people, it may be that even when you get it by the blood, a healthy person many times will not develop symptoms.

But these are good questions, and we are working with CDC and the blood community to rapidly mobilize studies to help answer these questions.

Mr. SOUDER. And I want to make sure I reinforce on the record that even with the epidemic outbreaks in certain parts of the country, more people die from—and potentially die from not having blood transfusions than the risk at this point. And this could be—we don't want to have a panic about people giving blood or taking blood, because that is a daily dependency in our hospital and medical system in the United States, but we want to try to make sure that it doesn't explode and get out of control.

I have two other brief things I want to address, sir, that are important to us in Indiana that can be extrapolated. The season is generally considered mosquito season, late summer, but we have some sign that we could see the first cases in the early spring season. Do you see that in other parts of the midwest, other parts of the country? And what do you—when you earlier referred to season, how do you define that? And are there preventative things you can do before the early spring season so we don't see—right now in my area it is concentrated in one county, but so that it doesn't explode to the rest of the counties around it?

Dr. HUGHES. Yes. The early case this year occurred in the southern part of the country, which I guess wouldn't be surprising given the temperatures.

I think, in terms of thinking about next year, you know, we definitely all—you know, this—dealing with this, as I think has been apparent from the discussion, requires a real partnership between people in clinical medicine and in public health; and within public health, among many partners at the Federal level, the State level, and the local level.

We are going to continue to learn. We have to look at areas that have been particular hot spots this year, as in the case in two parts of Cook County and in the area that you referred to in Indiana, and anticipate that next year they may again be at high risk for transmission.

And so mosquito control efforts that ought to begin early in the season—again, it is this integrated pest management early in the year, source reduction, use of larvicides when appropriate to try to keep mosquito populations down is very appropriate and should be particularly intense, I would submit, in these areas where transmission have been highest this year. So we will need to be sure that resources are provided in advance so that work can begin early in the year.

Mr. SOUDER. One last, and I will yield to the other Members for additional questions.

I have been trying not to be offended by the senior designation, because when you turn 50, you get the AARP thing; and I am wondering whether that is the definition of senior you are working off

of, because I believe several of our deaths in Allen County were in the 1950's, not in the 1960's; 1953 I think was—'56; and that I also know some who are very sick who are between 25 and 35. They weren't either very young or very old, and they were in very good physical shape.

That I understand, the potentially weaker immune systems of the elderly or the very young. Clearly there has been a lot of focus on teens. But this—going back to Congressman Cummings' question—seems on the surface to be a little more generic. Could it be, well, blood sugar? Are you looking at other things in the system? Because it doesn't seem to quite have this pattern in my area.

Dr. HUGHES. Yes. Thank you.

Let me give you just a little bit of data and say that in public health we often think of populations. So if you look at the median age of people who have died this year, it is actually 79 years of age. Now, what the median is, it is just right in the middle. That means that 50 percent of the people are older and 50 percent of the people are younger. The youngest person that we know of that has died of West Nile this year is 27 years of age. I can't tell you offhand where that tragic death occurred. But, you know, on average we can say that it is the elderly people that are at greatest risk for severe disease and death, but that risk is not limited to people above a certain age.

Mr. SOUDER. Thank you.

Mr. Cummings.

Mr. CUMMINGS. Is this easy to diagnose?

Dr. HUGHES. It is easier to diagnose today than it was 4 years ago. Four years ago, it was extremely difficult to diagnose. And you may, in fact, recall that when the initial cases were recognized by an alert clinician in Queens, reported to the New York City Health Department, investigation was done, specimens were collected and analyzed, the initial results suggested that this was St. Louis encephalitis virus in a new part of the country, in New York City. We were misled initially by the cross-reactivity because of the genetic relatedness of these two viruses. So we had to go back and develop tests specifically for the diagnosis of West Nile infection, and develop those tests, develop the reagents that are required to run them, get them to the State public health laboratories, and get people trained in how to do the tests, and at the same time maintain confirmatory laboratory capacity at our CDC laboratory in Fort Collins.

So, it is easier today. The public health laboratories have the capacity. There are companies working on developing tests. We need licensed tests that are more widely available that could be used in clinical laboratory settings. So we are not totally there.

Mr. CUMMINGS. Is there any such thing that if I got to a doctor early, does that make a different at all?

Dr. HUGHES. There is no effective specific treatment today for West Nile encephalitis, so it would make a difference to that proportion of people who were going to go on to develop severe illness, because obviously the earlier someone is recognized to have a severe illness, the sooner proper supportive care can be provided. So in some people it—certainly, the earlier you are diagnosed, the better off you are.

Mr. CUMMINGS. The money that the CDC funds, what—I notice in fiscal year 2000, $10 million, to fiscal year 2001, $25 million. And then it says 2002—2002, $46 million. What is that money used for?

Dr. HUGHES. Well, of the $46 million, $35 million has gone to the State and local public health jurisdictions, and there it is used for a number of things. It is used to strengthen surveillance programs, it is used to support the delivery of these diagnostic laboratory tests that we have been talking about, it is used for prevention and control programs and outreach to the public. In some cases—although we don't encourage this, in some cases some of that money has been used by local jurisdictions for spraying.

Mr. CUMMINGS. How do you all prioritize, I mean, particularly with the spread? And is there something comparable—has something comparable happened in the world to what's happening now in the United States, in other words, this extent, and seems to be growing quite rapidly?

Dr. HUGHES. OK. In terms of the budgeting, you know, there is no precise formula that's used to determine the allocation of funds, and as has been pointed out, the funding to the State and local jurisdictions this year occurred initially, and then there have been three supplements following the initial allocation. Those supplements have really been targeted toward the—or been determined really by the behavior of the epidemic and the movement of the virus. So, in fact, I am actually glad we did it that way, because if we had used all available resources back early in the year and put it into the South where the problem had been last year, we would have had precious little left over to deal with the progression of the virus.

We listen very carefully to what the States tell us about what their priority needs are, and we try to be as responsive to those as we can be.

In terms of your question about the geographic movement over large areas, I think we are going to have to stay tuned for that. The virus has spread to Canada. It has been identified in the Cayman Islands. The Caribbean is certainly at risk. Mexico is certainly at risk. This virus may be with us in the Western Hemisphere, but time will tell. It is another reason why working with colleagues in other countries is important to do, and we have tried to do some of that to strengthen diagnostic capacity in the hemisphere, working with the Pan American Health Organization and others.

Mr. CUMMINGS. Has that been very helpful?

Dr. HUGHES. I think we have made progress in terms of increasing capacity, at least in some countries, to diagnose this. More work needs to be done, clearly.

Mr. CUMMINGS. Just the last thing. When you have folks in, say, small towns, and people come in with West Nile, how do you—what are they—I assume that folks come and seek information from the CDC, doctors, whoever, and trying to figure out, well, what do we do? The panic that the chairman—the concerns that the chairman mentioned about sending your kids out to the baseball game and stuff like that. I mean, what is the CDC saying to folks like that?

Dr. HUGHES. Well, again, thank you for bringing that up. This is this communication issue that is so critically important. You

know, we certainly have this emphasized to us in the response to the anthrax attacks last year. It did not go well. Because clinicians are so important in the initial recognition of these new syndromes, as we have talked about—and in fact, Dr. Gerberding, our Director, likes to talk about the golden triangle of close relationships between people in clinical medicine, people in the health care delivery system, and people in public health. Those cultures are somewhat different, and we must bridge the gulf between those different groups, and it is something that both she and I are very passionate about. And hopefully you are seeing some evidence of us becoming much more proactive on the professional educational side.

Then equally important is the public educational needs. People really need to understand. I mean, we have their attention now, so we need to take advantage of that to deliver to them practical advice that can help demystify some of this a little bit, and also give them constructive guidance about measures that they can take to reduce their risk. And we are trying to do that in a number of different ways.

Mr. CUMMINGS. Thank you.

Mr. SOUDER. Congresswoman Schakowsky.

Ms. SCHAKOWSKY. I just have one quick question. Is there any reason you think that Illinois would have more cases than other States?

Dr. HUGHES. I would ask that you ask Dr. Lumpkin for his thoughts on that when he comes, but I think, for whatever reason, as I had mentioned earlier, some of the areas of highest incidence this year in Illinois are the same areas where the incidence of St. Louis encephalitis was quite high in 1975. And so to me it must have something to do with the nature of the environment there and its interaction with the bird and the mosquito populations.

Mr. SOUDER. I want to thank each of you. I would encourage you to, and let us know, what we need to do on the budget side, because the initial funding request is flat level whereas we had a big supplemental this year, and yet potentially this is explosive. If 80 percent of the cases in Illinois are in Cook County, it suggests that while Cook County is a big county, that is only a small percentage of the State. In my congressional district, Allen County is the biggest county, but it is less than 40 percent of the district, and it is only a small percentage of the State; yet, nearly 50 percent of the cases are in one county, which suggests that it is not just going to stay localized as we work with this. So we'd appreciate working with you in addressing the midwest.

Thank you for your work. We will probably have a few written questions. And, with that, thanks for coming.

Would the second panel then come forth. Dr. Lumpkin, Dr. McMahan, Mr. Wichterman, and Dr. Akhter. If the second panel could remain standing, we will do the oath at this time. If you can remain standing, we will do the oath.

For those of you who were not here earlier, it is a standard practice as an oversight committee that all our witnesses are sworn. If you could raise your right hand.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that the witnesses have each answered in the affirmative.

We will first start with Dr. Lumpkin, the director of the Illinois Department of Public Health.

STATEMENTS OF DR. JOHN R. LUMPKIN, M.D., M.P.H., DIRECTOR, ILLINOIS DEPARTMENT OF PUBLIC HEALTH; DEBORAH McMAHAN, COMMISSIONER, ALLEN COUNTY HEALTH DEPARTMENT, FORT WAYNE, IN; GEORGE WICHTERMAN, CHAIRMAN, LEGISLATIVE AND REGULATORY COMMITTEE, AMERICAN MOSQUITO CONTROL ASSOCIATION; AND MOHAMMAD AKHTER, EXECUTIVE DIRECTOR, AMERICAN PUBLIC HEALTH ASSOCIATION

Dr. LUMPKIN. Thank you, Mr. Chairman, and members of the committee. Thank you for the opportunity to present before you. This year the Illinois Department of Public Health is celebrating its 125th anniversary as a State agency. Interestingly enough, our agency got its start in 1877, in response to an outbreak of yellow fever, which is a mosquito-borne illness, and as such, just as we started, now at our 125th anniversary we are facing a major outbreak.

Today we have the results of our testing. We now have 623 cases in Illinois and 35 deaths. West Nile virus has been found in every single county in the State of Illinois, all 102 counties, in birds, mosquitoes, and, in most of those counties, also in people. We are past the peak. Our numbers of cases and the date of onset have peaked somewhere in the beginning of September, yet we are continuing to see cases, and we expect we will be seeing cases because of the delay in diagnosis and reporting for some weeks to come.

And what we have seen is very much what we saw in 1975, when there was a major national outbreak of St. Louis encephalitis. And during the outbreak, the majority of the cases—a large number of those cases occurred in Illinois, more than any other State, where we had almost 600 cases.

As we began to look at this in perspective, something that was said by Joshua Lederberg, who is a Nobel laureate, that "nature is not benign; the survival of the human species is a not preordained evolutionary program;" and that our public health system has to be strong and be able to respond. And the challenges of West Nile, in fact, demonstrate why we need to be prepared.

In 2001, West Nile had a national total of somewhere in the neighborhood of 157 cases and 15 deaths. There have been as many cases in Representative Schakowsky's district as there were in the entire United States prior to this year, and that includes 1999, 2000, and 2001. So obviously, what we are facing this year is dramatically, dramatically different.

We as a State began to get prepared based upon—with resources provided us by Center for Disease Control, and last year we prepared our first West Nile plan prior to having any cases in birds or in mosquitoes, and that plan was distributed throughout local health departments. We began funding them to develop their own West Nile plans and began to respond.

We developed a task force of State agencies that began meeting last fall after we had our first positive bird and began to put in plans. Recognizing the experience in 1975, we built upon a strong foundation of surveillance that have been in place since 1976 where

over 5,000 birds a year were trapped and sampled, looking for St. Louis encephalitis, western equine encephalitis, eastern equine encephalitis, and this year for West Nile virus. That system began to indicate that in July we were having quite a significant problem.

Thirty-five of the most involved counties and local jurisdictions have spent over $5 million this year on mosquito abatement. An additional $3.5 million was made available by Governor George Ryan to be able to address this issue. Once again, it has been a system that has indicated that our public health system has been able to respond and responds quite well.

But what we have done is we have borrowed from Peter to pay Paul. These funds that were made available—because there are no emergency public health funds in our State, and generally not in the Nation—were taken from an account that is used to fund local health departments to do food inspections and do infectious disease outbreaks, and what we did is we took the money from the fourth quarter. So come April we are going to be in very short supply of funds to support our public health programs at the local level.

We have to look at the lessons from this year as we begin to look toward next year. Obviously, we need to look at ways that we can support our public health infrastructure. Through the support of Congress and the administration, a significant amount of funds were made available to the States. Unfortunately, it was really too late to be able to shore up our public health system. In our laboratory—for instance, the reports on West Nile began coming in later and later. We started to check into it. It was because the person who was running it, Rosie, in the laboratory was doing it on a hand calculator, our inability to implement that. Now, with the funding that has been made available, we are going to start automating that, but it takes time, and it takes persistence, and it takes consistency. Trying to buildup for decades of neglecting our public health system cannot occur overnight and cannot be done with one single shot.

We need to look at how to support that public health system. We also have to recognize that public education is the key. In Representative Schakowsky's district, when we went there with the Centers for Disease Control to look at where the mosquitoes were coming from, the first two homes we went to had mosquito larva growing in containers that were in the yards of individuals. No mosquito abatement district can address those particular problems. It has to be a partnership between government and individual citizens, and that means we need to expend the resources to do the kind of research—I mean, the kind of outreach and public information that will help people realize how important they are in preventing the spread of this disease.

Research is also key. Public health, I believe, has once again responded, but will need assistance to respond again, and I think having hearings such as these are very important to highlight the problems and begin to address the needs for next year. Thank you.

Mr. SOUDER. Thank you for your testimony.

[The prepared statement of Dr. Lumpkin follows:]

Testimony of
John R. Lumpkin, M.D.,
Director of the Illinois Department of Public Health

Hearing on West Nile Virus
October 3, 2002
Before the House Government Reform Subcommittee
on
Criminal Justice, Drug Policy, and Human Resources

First of all, let me thank the Committee for the opportunity to provide testimony on West Nile Virus and it's very real and devastating effect in Illinois. As one of the States hardest hit, Illinois has been working hard, using every available resource, to make an impact on stopping the spread of West Nile. I am hopeful that my testimony can shed some light on our activities and the needs of our State, and probably other states that are impacted by this disease.

I know that there are specific questions of interest to committee members but, I would like to begin with some background on our experience in Illinois. As you probably know, Illinois, Louisiana, Ohio, Michigan, and Mississippi have reported the most cases of WNV during 2002.

- In Illinois cases have been reported in 43 of the 102 counties (Over 1/3 of the State). Through 10-1-02 Illinois had reported 614 cases including 35 deaths (this is a moving target) Although we have no hard data, numerous survivors have not been discharged to their homes, but to long-term care facilities or rehab facilities. We understand a major (at least short term) sequella is inability to ambulate

- The majority of cases have been in the Chicago metropolitan area. In the Chicago metropolitan area, the far northern and southwestern portion of the city as well as areas centered around the suburbs of Oak Lawn/Evergreen Park and Skokie/Evanston have been over-represented in the case count.

- IDPH has actually planned for WNV since summer 2001. Included in the Department's FY02 budget was an initiative related to West Nile. IDPH provided funding to allow a number of local health departments to develop their own plans to ensure coordination of efforts with municipalities, mosquito abatement districts, street departments or other entities that would be involved in such an endeavor.

- Infections in Illinois were unlikely prior to 2002. The virus was first documented to be present in Illinois in September 2001 when there was evidence in dead crows. Not much time remained in the mosquito feeding season after discovery

of WNV in Illinois in 2001 but the evidence of it's presence started our preparations in earnest.

- Realizing the potential impact, Governor George H. Ryan created a Cabinet level work group, headed by IDPH, to coordinate the state's response among the various agencies involved which included the Department of Agriculture, Natural Resources, Environmental Protection and Public Health.

- The Work Group has been meeting consistently since the early Fall of 2001, and more recently, talking on a daily basis to coordinate our efforts and information.

- In more general terms, a plan for surveillance of human mosquito borne infections was established in 1976 and has been implemented annually since that time.

Current Efforts to Control the Spread of West Nile Virus in Illinois

- After WNV was first detected in wild birds in Illinois in May 2002, IDPH put out press releases concerning personal protection and the removal of standing water and produced 30,000 color posters and fliers, over half of which have been distributed to local health departments and others that request them. Bulletins were issued to all local health departments and municipalities recommending that at minimum, larvicide be applied to street catch basins twice during the summer to prevent an outbreak of WNV.

- Prior to the first human case of WNV, Public Health awarded $264,059 to 20 local health departments to prepare for the expected WNV outbreak in Illinois. The grants allowed many LHDs to train their personnel, provide information about WNV to municipalities, and make contacts with mosquito control agencies.

- An additional 18 grants totaling $462,490 have been made to LHDs to create vector control programs and cleanup mosquito-producing tire sites.

- Within a week of learning of the first Illinois resident to contract WNV on 8/8/2002, the Governor instituted daily meetings of the four-state agency WNV Task Force, created in 2001, to make funds available to local agencies to combat the advance of WNV in Illinois. Within 3 weeks, the first emergency grants were executed.

- Since then, emergency WNV mosquito control grants have been offered to the 46 agencies eligible. Requests for funding were received from 35 different agencies. The Task Force approved funding for these agencies totaling $3.4M and the Department released funding to 31 of these agencies totaling $2.9M providing additional protection for about 8.1 million people.

- Due to the shortage of licensed mosquito control personnel in Illinois, the Department of Agriculture, in cooperation with Public Health, issued an emergency rule to allow health department and municipal officials to apply certain mosquito larvicides, without a license, after attending a one-hour seminar. Public Health staff have offered over 20 emergency-rule larviciding seminars to over 500 local officials.

- Public Health has provided extensive technical assistance and advice to local health departments on mosquito control and is working closely with CDC and DNR and the UI Vet School to determine the etiology of WNV, especially concerning the two clusters of cases that have occurred near Chicago, and possible reservoirs and hosts.

- Public Health has responded to thousands of phone calls, e-mails and news media contacts to answer questions from the media and the general public.

What more can federal and state governments do to prepare for next summer?

While a lot of work has been done that puts us in a good position in preparing for next year, there is still much that could be done. We have to prepare as if next year will be as bad as this year. We continue to believe that increased attention in the form of federal funds are needed at both the state and federal level for more full-time Public Health staff to:

- Administer a grant program to assist local health departments in assuring that arbovirus surveillance and control programs are provided where these services are not offered by mosquito abatement districts or other agencies.

- Work with mosquito abatement districts and other municipal mosquito control programs to assure the implementation of comprehensive and effective mosquito control programs next spring that emphasize source reduction and larviciding.

- Provide mosquito control training for local health departments and municipalities that leads to licensing by the Department of Agriculture; and training in mosquito and bird collection techniques to assist Public Health in arbovirus surveillance work.

- Provide resources to state public health, animal disease, and research laboratories to provide the analytical, entomological, and epidemiological tools needed to fight WNV, as well as funding for materials and personnel to rapidly perform confirmatory testing

- Additional surveillance staff are also needed that can be mobilized to facilitate rapid processing of human surveillance data, rapid analysis of data and rapid dissemination of data.

- Of primary importance - Begin early public information campaigns.

- We also believe that USEPA should consider the creation of a special Pesticide Applicator license for municipal officials. Current licensing focuses on agricultural pesticide applications. The license should only require enough training so that municipal officials could apply low-risk mosquito larvicides.

Have State resources to fight West Nile virus come at the expense of other programs?

- Local Health Protection Grants, intended to support local health department programs in water supply, sewage disposal, food sanitation and infectious diseases were used to support the emergency WNV mosquito control grants provided by the WNV Task Force to LHDs.

- Public Health staff that operate other programs dealing with general administration, lead, mold and moisture, environmental toxicology, and structural pest control have been diverted to WNV response.

- Federal money to support bioterrorism preparedness, epidemiology and laboratory capacity, has made us better prepared to deal with this outbreak. Specifically, we believe this has been demonstrated with enhanced rapid communication to LHDs, hospital ICPs, hospital laboratories and infectious disease physicians and the funding used in disseminating information about responsibility to report human infectious disease cases responsibilities and methods of reporting

Where have West Nile Virus infections been most prevalent in 2002, and why have infections become significantly more common this year, as compared to years past? Can we expect the number and severity of human cases to worsen in years to come?

- The virus has expanded its range across the Midwest into areas that include large population centers, such as Chicago, suburban Cook County and the nearby suburban counties. Although the virus first appeared in Illinois during August 2001, it was near the end of the mosquito transmission season. Apparently, in 2001 virus amplification in wild birds did not reach a level where humans were at significant risk.

- In contrast, WNV-positive dead birds appeared in May 2002, at the beginning of

the summer, which permitted summer-long virus amplification in the wild bird population. Furthermore, the hot summer of 2002 was conductive to breeding and flight activity of the house mosquito, the primary vector of WNV. As a result, there was a high level of virus amplification in birds and mosquitoes. Consequently, more people were exposed to the virus in 2002.

Is West Nile Virus similar to any other mosquito-borne illnesses found in the United States? If so, what lessons has the Department learned from responding to previous outbreaks?

- WNV has many similarities to St. Louis encephalitis, which caused an outbreak in Illinois during 1975. Since then, cases of SLE have been rare in Illinois, although they have been more common in southern states.

- However, WNV appears to be better adapted to the temperatures in northern states; it has even been detected in southern Canada.

- Because there have been few cases of mosquito-borne disease in recent years, many local mosquito abatement programs have been reduced or eliminated, which results in less effective emergency control programs. Similarly, there are few environmental staff with experience in mosquito surveillance and abatement at the state level to assist local officials during emergencies.

- State and local mosquito abatement resources need to be rebuilt.

- A lesson learned from the SLE outbreak of 1975 was to establish a system for surveillance of human illnesses before cases occur. In Illinois we have such a system in place.

- Another lesson learned was to establish an "early warning system" that became functional in 1976 to detect evidence of arbovirus infections in wild birds. IDPH also has this type of system in place. The Department has traditionally collected some 5000 live birds annually for testing. The bird blood is tested for SLE, EEE and now, WNV. Additionally, we test mosquito pools as a supplement to live bird testing.

- Provide scientifically sound information to organizations that provide mosquito control services on appropriate mosquito abatement practices.

Our ability to identify and track disease is key to being able to take appropriate measures. In addition to that very real part of the equation - both government and individuals can do a lot to curb the spread of the disease by specific activities. Comprehensive mosquito abatement programs are important to addressing the problem. But what remains the single most effective precautions are those that can

and should be taken by individuals:

- Stay indoors at times when mosquitoes are most active
- when outdoors - wear protective clothing
- use mosquito repellent containing 25-35% DEET
- Check residential screens to ensure insects are kept out of living areas
- and, eliminate stagnant water where mosquitoes might breed.

Mr. SOUDER. Dr. McMahan is next. I want to thank you for your aggressive leadership in Allen County on this issue. And basically anybody who doesn't understand right now in Fort Wayne, my hometown, that they need to empty out every container and sweep off if there is any puddle in their driveway, you have done an excellent job of working to get that information out, and I am looking forward to your testimony.

Dr. MCMAHAN. Thank you.

Good afternoon, Mr. Chairman and members of the committee. The national impact of West Nile virus has generated intense media interest this summer. The evolving numbers of human cases and deaths can be found on a regular basis on the front pages of local and national newspapers as well as crawlers on national news programs. However, the local impact of the West Nile virus is not often explored or attended to, and we thank Chairman Souder and this subcommittee for inviting representatives from the front lines on the war against the West Nile virus to testify as to the impact this infection has caused in our community.

In Fort Wayne, Indiana, a community of approximately 330,000, we have identified 51 human cases of West Nile virus as of September 30th. This gives our area an attack rate of 15.4 cases per 100,000 population. It is important to note that West Nile virus has not been a benign illness for most of the people infected in our community. One of our residents who has been severely affected with West Nile virus had this to say about the virus: If I could say one thing to someone about West Nile virus, it would be that people should not take this lightly. I just wish I knew how long it is going to last.

Over 40 percent of the people identified with West Nile virus were hospitalized, and two patients required further treatment in a rehab facility after discharge from the hospital.

There has also been a significant economic impact locally due to the lost productivity by the 65 percent of those identified with West Nile virus who were unable to work while they were ill. In addition, considerable medical costs were incurred by all of the patients identified with West Nile virus, in addition to the 40 percent who were hospitalized for supportive care. But most importantly, there is no way to measure the grief caused by the three probable deaths due to the West Nile virus in Allen County; 37 spouses, children, grandchildren, and great-grandchildren have been left behind to try to understand how a simple mosquito bite could have killed their loved one.

From a resource perspective, our local health department has spent over $285,000 fighting the West Nile virus this summer. We have had to divert human resources from ongoing public health functions to keep up with the bird and mosquito surveillance and treatment, and the human case investigations. Although expensive, we do believe it has been effective at limiting the number of additional human cases of West Nile virus in our community. However, it is important to note that childhood vaccinations, restaurant inspections, septic system failures, disaster preparedness, and other public health responsibilities continue during this outbreak.

Infectious disease outbreaks serve as an important opportunity to understand the strengths and weaknesses of a community's and

a nation's ability to provide an integrated response to identify and contain the offending agent. What we have learned thus far in our community is that while we are rich in talent and communication, we are significantly lacking in the human and economic resources locally to implement the necessary interventions.

Our department, too, began planning last year for the first occurrence of West Nile virus in our community. West Nile virus requires a collaborative response from both environmental and medical specialists. We worked at length to develop a science-based comprehensive plan for the surveillance and treatment of West Nile virus in our community. Our Vector Control Division has worked extensively to identify and treat environmental sources of mosquito breeding. They have also worked in collaboration with the laboratory of both our department and the Indiana State Department of Health to perform timely bird and mosquito surveillance to identify areas of increased risk of human transmission.

Our medical community, whom we began educating last year about the West Nile virus, has done an exemplary job of identifying patients infected with the West Nile virus. This in turn has allowed our public health nurses and environmental investigators to quickly identify and treat high-risk areas surrounding the human cases, thereby preventing even more of our residents from becoming infected with the virus. Our public information officer and speakers bureau has provided timely epidemiological information and educational materials to both the media and the public. And finally, our board and public officials have been prompt and responsive in allocating the funding necessary to contain this disease, despite the significant economic hardship it has placed on the county.

West Nile virus has served to highlight one of the most important aspects of any infectious disease outbreak, the unpredictability of bacteria and viruses. We have seen significant changes in the West Nile virus this year, including a striking increase in the number of people and animals infected, the potential for transmission through organ transplants and blood transfusions, and an increase in the number of young people seriously affected by the virus.

Because bacteria and viruses have the ability to mutate, the potential for large-scale outbreaks will always exist. Therefore, humans will always be vulnerable to the potential health consequences of infectious disease agents and the extraordinary efforts needed to manage and contain the outbreak. This vulnerability requires an infrastructure that is sufficient in terms of human and economic resources so as to provide the necessary flexibility to rapidly identify, treat, and contain the infectious agent at every level.

Previous studies have indicated that our public health work force is woefully inadequate to effectively manage routine public health issues, let alone large-scale outbreaks. This is particularly true in Indiana where our local and State public health staffing rates are significantly less than the national standard. Indiana has 46 public health workers per 100,000 population compared to the national average of 138 per 100,000. Because the need is so great throughout the entire public health system, Federal dollars are often not realized at the local level. And it is important to remember that all outbreaks begin locally. Federal and State funds are needed to de-

velop the public health work force such that we will not be in this position when another perhaps even more deadly outbreak occurs.

In conclusion, public health serves as the interface between environmental conditions in the field and the medical consequences for patients seen in hospitals and doctors' offices. The solvency of the public health infrastructure reflects the values of the Federal, State, and local public officials that allocate financial resources. Let us use the West Nile virus outbreak and all the devastation it has caused for the thousands of people infected throughout the country, including the 51 people and their families identified at Fort Wayne, Indiana, as an opportunity to establish mechanisms by which we can develop and support our local, State and Federal public health system.

Thank you again for the opportunity to present the local perspective.

Mr. SOUDER. Thank you very much for your testimony.

[The prepared statement of Dr. McMahan follows:]

WEST NILE VIRUS in ALLEN COUNTY, INDIANA

October 3, 2002

Written and presented by

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WEST NILE VIRUS IN ALLEN COUNTY, INDIANA

Presented by Deborah A. McMahan, MD

The national impact of West Nile virus has generated intense media interest this summer. The evolving numbers of human cases and deaths can be found on a regular basis on the front pages of daily and national newspapers as well as crawlers on national news programs. However, the local impact of the West Nile virus is not often explored or attended to, and we thank Congressman Souder and the Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources for inviting representatives from the "front-lines" on the war on West Nile virus to testify as to the impact this infection has caused in our community.

In Fort Wayne, Indiana a community of approximately 330,000, we have identified fifty-one (51) human cases of West Nile virus as of September 30th. This gives our area an attack rate of 15.4 cases per 100,000 population. It is important to note that West Nile virus has not been a benign illness for most of the people infected in our community. One of our residents who has been severely affected with West Nile virus had this to say about it: "If I could say one thing to someone about West Nile virus, it would be that people should not take this lightly. It knocks the crap out of you. I just wish I knew how long it is going to last." Over forty percent (40%) of the people identified with West Nile virus were hospitalized. Two patients required further rehabilitation in an extended care facility after discharge from the hospital.

There has also been a significant economic impact due to the lost productivity by the sixty-five percent (65%) of those identified with West Nile virus who were unable to work during the course of their illness. In addition, considerable medical costs were incurred by all of the patients identified with West Nile virus and the forty percent (40%) that were hospitalized for supportive care. But most importantly, there is no way to measure the grief caused by the three probable deaths due to the West Nile virus. Thirty-seven (37) spouses, children and grandchildren have been left behind to try and understand how a simple mosquito bite could kill their loved one.

From a resource perspective, our local health department has spent over $285,000 fighting the West Nile virus this summer and fall, and we have not yet

reached the end of the season. We have had to divert human resources internally, from ongoing public health functions, to keep up with the bird and mosquito surveillance and treatment, and human case investigation. Although expensive, we believe it has been very effective at limiting the potential number of human cases of West Nile virus. However, it is important to note that childhood vaccinations, restaurant inspections, septic system failures, disaster preparedness and other public health responsibilities continue during infectious disease outbreaks.

Infectious disease outbreaks serve as an important opportunity to understand the strengths and weaknesses of a community's (and a nation's) ability to provide an integrated response to identify and contain the offending agent. What we have learned thus far in our community is that while we are rich in talent and communication, we are lacking in the human and economic resources to implement the necessary interventions.

Our Department began planning last year for the first occurrence of West Nile virus in our community. West Nile virus is somewhat unique because it is an infectious disease that requires a collaborative response from both environmental and medical specialists. We worked at length to develop a comprehensive plan for surveillance and treatment of West Nile virus in our community. Our Vector Control Division has worked extensively to identify and treat environmental sources of mosquito breeding. They have also worked in collaboration with the laboratory of both our Department and the Indiana State Department of Health to perform timely bird and mosquito surveillance to identify areas of increased risk of human transmission.

Established lines of communication have facilitated effective sharing of medical information in both directions between our healthcare providers and our Department. Our medical community, whom we began educating last year about West Nile virus, has done an exemplary job of identifying patients infected with the West Nile virus. This, in turn, allowed our public health nurses and environmental investigators to quickly identify and treat high-risk areas surrounding the human cases, thereby preventing even more of our residents from becoming infected with the virus. Our public information officer has provided timely epidemiological information and educational materials to the media and the public. And finally our Board and public officials have been

prompt and responsive in allocating the funding necessary to contain this disease, despite the *significant economic hardship* it has placed on the county.

The stress resulting from an infectious disease outbreak clearly identifies the weakness of the infrastructure necessary to rapidly identify, treat and contain the infectious agent. West Nile virus has served to highlight one of the most important aspects of any infectious disease outbreak, the *unpredictability* of bacteria and viruses. We have seen important changes in the West Nile virus this year including a significant increase in the number of people and animals infected, the potential for transmission through organ donations and blood transfusions, and an increase in the number of young people seriously affected with the virus.

Because bacteria and viruses have the ability to mutate and, therefore, be unpredictable, humans will always be vulnerable to the potential human consequences and the extraordinary efforts needed to manage and contain the disease. This unpredictability requires an infrastructure that is sufficient in terms of human and economic resources so as to provide the necessary flexibility to control the situation.

Previous studies have indicated that our public health workforce is woefully inadequate to effectively manage routine public health issues, let alone large-scale outbreaks. This is particularly true in Indiana where our local and state public health staffing rates are significantly less than the national standard. Indiana has forty-six (46) public health workers per 100,000 population – compared to the national average of 138 public health workers per 100,000 population. Because the need is so great throughout the public health system, federal dollars are often not realized at the local level. And it is important to remember that all disasters are local. Federal and State funds are needed to develop the public health workforce such that we will not be in this position when another, perhaps even more deadly, outbreak occurs.

Many infectious disease outbreaks reflect gaps in social or environmental conditions left unattended. Often infectious disease epidemics reflect, in some manner, our attitudes and behaviors, either individually or as a community. In the AIDS epidemic, our attitudes toward casual sex contributed to the spread of the disease. In the West Nile virus outbreak, our nonchalant attitude toward our

individual and community responsibility to protecting and developing effective sanitation systems has contributed to the transmission of the disease. The mosquitoes that carry the West Nile virus prefer to breed in polluted waters. Our sanitation system is the most important reason that mosquito-borne diseases are not the primary cause of death for our citizens, as is true for most underdeveloped countries. However, we often resent, as individuals and a community, the need to spend dollars in developing and/or maintaining this vital function of public health.

In conclusion, public health serves as the interface between environmental conditions in the field and the medical consequences for patients seen in the emergency room and in our doctors' offices. The solvency of the public health infrastructure reflects the values of the public officials that allocate financial resources. Let's use the West Nile virus outbreak and all the devastation it has caused for the thousands of people infected throughout the country, and the fifty-one (51) people and their families identified in Fort Wayne, Indiana, as an opportunity to identify mechanisms by which we can develop and support our local, state and federal public health system.

Mr. SOUDER. Next we will here from Mr. George Wichterman, who is chairman of the legislative and regulatory committee of the American Mosquito Control Association and is from Lee County. This is also going to be very interesting for my district, because I, like many others, I go to Sanibel Island, but at Fort Myers area, Sanibel, Captiva, and the areas just north and just south basically have almost as many Indiana license plates as Florida license plates in the spring. So I am interested in hearing that from a local as well as your national perspective.

Mr. WICHTERMAN. Thank you, Mr. Chairman and members of the committee.

Mr. Chairman, I would like to ask you, if at all possible, would you please include my written statement into the record as well what I am about to present.

Mr. SOUDER. Yes. We will have all your written statements. And if you have other information you would like to submit after you hear the full hearing, we will submit that also.

Mr. WICHTERMAN. OK. Thank you, sir.

I am George Wichterman, chairman of the legislative and regulatory committee for the American Mosquito Control Association, and senior entomologist with the Lee County Mosquito Control District in Fort Myers, Florida.

I would like to thank Chairman Souder for his leadership in holding this important hearing regarding the Federal response to West Nile virus and the challenges in addressing its spread and impact on the Nation's public health. The American Mosquito Control Association is a nonprofit international association involved in supporting mosquito and other vector control. Our mission is to provide leadership, information, and education leading to the enhancement of health and quality of life through the suppression of mosquitoes and other vector-transmitted diseases.

The AMCA commends this subcommittee inquiry into the West Nile virus. This disease represents a clear and present danger to the public's health. Given the nationwide potential spread of this disease, it is incumbent upon the Federal Government to determine what must be done to prevent its spread and ultimately eradicate it from our country.

The AMCA would request that as Congress studies the West Nile virus situation, it consider several issues which potentially affect the ability of our members to address not only the virus, but other diseases as well. The first issue concerns the shrinking supply of effective control agents to address the pests which carry this disease.

As you may be aware, the vector control industry has a very limited number of pesticide products available to treat dangerous pests such as mosquitoes. Our use is not considered a major use by the pesticide industry. Consequently, there is not a lot of ongoing research development of new pesticides that we can use. This volume of product we use is not remotely similar to the amount of corn, wheat, cotton, soy bean acreage which may be used in treatment for herbicides—as with herbicides.

For economic reasons, pesticide manufacturers tend to focus on these other markets in developing new products. As a result, maintaining the limited number of existing tools that we have to combat

vectors such as mosquitoes is of vital interest to our members. These products are going through the reregistration process before the U.S. Environmental Protection Agency. In conducting those reviews, often vector control use is immediately in jeopardy because it is such a minor use, and registrants would rather focus their energies on other larger, more economically valuable uses. Sometimes the registrant simply cannot afford to address EPA's data needs for a vector control product because the cost of the data outweigh the return on sales of the product. EPA has one such pesticide under reregistration that may be lost due to this economic consideration, resulting in its cancellation.

Technically there was a section included in the Food Quality Protection Act of 1996 which was intended to address this situation. The public health provisions of FQPA established the Public Health Pesticide Data Collection Program administered by the Department of Health and Human Services to develop data to support the continued registration of these critical vector control products. Unfortunately, while this potentially valuable program was authorized, no funds have ever been appropriated for this program. DHHS has never even requested funding for this program. Our repeated attempts to try and meet with the DHHS Secretary's office on this important issue have been rebuffed. It appears that the Secretary simply is not interested in trying to tackle this issue. We have heard that this is considered an unfunded mandate by the DHHS, and no one in these economic times wants to consider unfunded mandates.

AMCA submits that such an approach is wrong. The West Nile virus and other vector-borne diseases are a clear threat to our Nation's citizens. If we, the persons charged with dealing with these disease outbreaks within each State, do not have the requisite tools to do our jobs, the conclusion is self-evident: More people will become exposed to these diseases, and potentially more people will die from such exposure. We need the leadership and assistance now of the Secretary of the DHHS to work with Congress to secure the necessary funding for this program. We need our limited supplies of pest controls tools protected.

The second issue represents a legislative initiative which was passed this week in the U.S. House of Representatives entitled the Mosquito Abatement for Safety and Health Act, H.R. 4793, which would authorize grants through the Centers for Disease Control and Prevention for mosquito control programs to prevent mosquito-borne diseases. This bill would enable political subdivisions of States to establish and operate mosquito control programs where none currently exist.

As of today, mosquito and other vector control programs throughout our Nation represent only 28 percent of the Nation's counties. Many of these mosquito control programs are situated in coastal areas of the United States, thereby leaving a greater number of counties and municipalities unprepared for this more ubiquitous task of controlling West Nile virus epidemics. By providing appropriate funding to these entities, entomological surveys or assessments may be conducted to determine potential mosquito breeding areas, thereby providing for the development of a plan for carrying out such a mosquito control program. Technical assistance with re-

spect to planning, development, and operation of control programs would be made available by the Secretary of DHHS, acting through the Director of the CDC, for program coordination. The American Mosquito Control Association supports this landmark legislation, and strongly encourages your colleagues in the U.S. Senate to support its passage through Congress.

As an organization of over 2,000 public health professionals across the Nation, the American Mosquito Control Association is dedicated to preserving and protecting the Nation's public health. We respectfully urge DHHS and the Bush administration to collectively work together to implement the Public Health Pesticide Data Collection Program by providing the appropriate funding which is necessary to preserve these important public health products. And with your colleagues in the U.S. Senate supporting passage of H.R. 4793, public health professionals will be able to function in an effective manner in order that they may protect our people and Nation, especially the most vulnerable segments of our population, our children and senior citizens.

Again, AMCA appreciates the opportunity to provide their views. If the subcommittee has any additional questions, we would be pleased to address them. Thank you so much.

Mr. SOUDER. Thank you very much.

[The prepared statement of Mr. Wichterman follows:]

Hearing on "Responding to West Nile Virus: Public Health Implications and Federal Response" Before the Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources

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Statement of the American Mosquito Control Association

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Testimony Before the Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources

Statement of the American Mosquito Control Association

I am George Wichterman, Chairman of the Legislative and Regulatory Committee for the American Mosquito Control Association, and Senior Entomologist with the Lee County Mosquito Control District in Florida. I am also a member of the Committee to Advise on Reassessment and Transition (CARAT) representing local government which is co-chaired by the United States Environmental Protection Agency and the United States Department of Agriculture.

I would like to thank Chairman Souder for his leadership in holding this important hearing regarding the federal response to West Nile virus and the challenges in addressing its spread and impact on our nation's public health.

The American Mosquito Control Association (AMCA) is a non-profit international association involved in supporting mosquito and other vector control. Our mission is to provide leadership, information, and education leading to enhancement of health, and quality of life through the suppression of mosquitoes and vector transmitted diseases.

The AMCA commends this Subcommittee inquiry into the West Nile Virus. This disease represents a clear and present danger to the public's health. Given the nationwide potential spread of this disease, it is incumbent on the Federal government to determine what must be done to prevent its spread and ultimately eradicate it from our country.

The AMCA would request that as the Congress studies the West Nile Virus situation it consider several issues which potentially effect the ability of our members to address not only this virus but other diseases as well.

The first issue concerns the shrinking supply of effective control agents to address the pests which carry disease. As you may be aware, the vector control industry has a very limited number of pesticide products available to treat dangerous pests such as mosquitoes. Our use is not considered a

"major" use by the pesticide industry. The volume of product we use is not remotely similar to the amount of corn, wheat, cotton or soybean acreage which may need treatment with a herbicide. For economic reasons, pesticide manufacturers tend to focus on these other markets in developing new products. Consequently, there is not a lot of ongoing research into new pesticides that we can use. As a result, maintaining the limited number of existing tools that we have to combat vectors such as mosquitoes is of vital interest to our members. These products are going through the reregistration process before the U.S. Environmental Protection Agency (EPA). In conducting those reviews, often vector control use is immediately in jeopardy because it is such a minor use and registrants would rather focus their energies on other larger, more economically valuable uses. Sometimes the registrants simply cannot afford to address EPA's data needs for a vector control product because the costs of the data outweigh the return on sales of the product. EPA has one such pesticide under reregistration that may be lost due to this economic consideration, resulting in its cancellation.

Technically, there was a section included in the Food Quality Protection Act of 1996 (FQPA), which was intended to help address this situation. The Public Health provisions of FQPA established a Public Health Pesticide

Data Collection Program administrated by the Department of Health and Human Services (DHHS) to develop data to support the continued registration of these critical vector control products. These funds could be used at land grant universities and consulting laboratories to promote research on disease carrying vectors that are important to maintaining the nation's public health. Unfortunately, while this potentially valuable program was authorized, no funds have ever been appropriated for the program. DHHS has never even requested funding for this program. Our repeated attempts to try and meet with the DHHS Secretary's office on this important issue have been rebuffed. It appears that the Secretary simply is not interested in trying to tackle this issue. We have heard that this is considered an unfunded mandate by the DHHS, and no one in these economic times wants to consider unfunded mandates.

AMCA submits that such an approach is wrong. West Nile Virus and other vector borne diseases are a clear threat to our nation's citizens. If we, the persons charged with dealing with these disease outbreaks within each State, do not have the requisite tools to do our jobs, the conclusion is self- evident. More people will become exposed to these diseases and potentially more people will die from such exposure. We need the leadership and assistance

now of the Secretary of the DHHS to work with Congress to secure the necessary funding for this program. We need our limited supplies of pest control tools protected.

A second issue represents a legislative initiative which was passed this week in the United States House of Representatives entitled "The Mosquito Abatement for Safety and Health Act," HR4793, which would authorize grants through the Centers for Disease Control and Prevention (CDC) for mosquito control programs to prevent mosquito-borne diseases. This bill would enable political subdivisions of States to establish and operate mosquito control programs where none exist. As of today mosquito and other vector control programs throughout our nation represent only 28% of the nation's counties. Many of these mosquito control programs are situated in coastal areas of the United States; thereby, leaving a greater number of counties and municipalities unprepared for this more ubiquitous task controlling West Nile Virus epidemics. By providing appropriate funding to these entities, entomological surveys or assessments may be conducted to determine potential mosquito breeding areas; thereby providing for the development of a plan for carrying out such a mosquito control program. Technical assistance with respect to planning, development and operation of

control programs would be made available by the Secretary of DHHS acting through the Director of the Center for Disease Control (CDC) for program coordination.

Additionally this legislation would provide for the enactment of a research program to be conducted by the National Institute of Environmental Health Sciences. The purpose of such a program would be to conduct or support research to identify or develop significant adverse health consequences. The AMCA supports this landmark legislation and strongly encourages your colleagues in the U. S. Senate to support its passage through Congress.

The third issue is also an operational issue and it involves the Clean Water Act. Simply stated, the 9th Circuit in Headwaters, Inc. v. Talent Irrigation District, 243 F.3d 526 (9th Circuit, 2002) ruled that a National Pollutant Discharge Elimination System (NPDES) permit is required to address the application of pesticides to water. Historically, the application of a pesticide in accordance with its labeled instructions to water for its pesticidal effect was not considered to require an NPDES permit. Indeed, EPA has never initiated an enforcement action against any person involved in a pesticide application under such circumstances. This is principally because the EPA's

Office of Pesticide Programs considers the potential effect of the pesticide on water and the environment before issuing a registration. Therefore, review by the Clean Water office is superfluous. The Office of Pesticide Programs is equipped to address any environmental impacts through the appropriate labeling of the product. Further, AMCA also believes that the application of a pesticide to water in accordance with label directions, does not contribute the discharge of a "waste" under the Clean Water Act. The pesticide is not being added to water for disposal purposes, but rather for its beneficial effect of killing vectors.

The 9th Circuit has disagreed with our interpretation and has required the issuance of NPDES permits in order for pesticide applications to water to not violate the Clean Water Act[1]. Such applications are resource intensive and potentially very expensive. Monitoring post application is a common requirement to the NPDES permit process. In situations in which we may be treating hundreds or thousands of acres, some of which may contain bodies of water which may come within the purview of the Clean Water Act, the Mosquito Control Districts may be forced to divert scarce resources to

[1] Other courts, including the U.S. District Court for the Southern District of New York in No Spray Coalition, Inc. et al v. the City of New York, et al. No. 00CIV.5 395 (JSM) is considering the same issue in the context of spraying to prevent the spread of the West Nile Virus. See also, Altman v. Town of Amherst, 190 F. Supp. 2d 467 (W.D.N.Y. 2001), currently on appeal to the Second Circuit.

address NPDES requirements. These are simply resources which many Districts do not have and cannot generate. This may lead to the increased reliance on adulticide applications rather than targeted larviciding operations in which we can address the vectors in the larva stage, precluding their development into adult mosquitoes. Larviciding actually lessens the broad cost spraying use of pesticide products.

To further illustrate the aforesaid, I offer the following example: The Lee County Mosquito Control District located in Southwest Florida (Fort Myers, Florida) is responsible for the control of mosquitoes including an area over 1,020 square miles. For the past 43 years our program based upon sound scientific research combined with the utilization of the latest available techniques for the control of mosquitoes continues to meet its commitment to the citizens of Lee County, Florida. This program represents only one of 54 organized programs currently sanctioned by the Florida Department of Agriculture and Consumer Services. Additionally, throughout the United States there are approximately 900 other publicly sanctioned mosquito and arthropod control programs operating throughout their state and local governments as well.

Lee County is located on the Southwest Coast of Florida bordered by the Gulf of Mexico to our west and the Florida Everglades on the Eastern side. Included within these coastal areas are 55,000 acres of mangrove marshes – all potential breeding grounds not only for salt marsh mosquitoes but also mosquito vectors capable of transmitting diseases, e.g., Eastern Equine Encephalitis, St Louis Encephalitis, West Nile Virus, etc. The citizens of Lee County have demanded our services in order that they may enjoy comfortable outdoor living on a year around basis.

The Lee County Mosquito Control District has always directed its efforts toward mosquito control by larviciding the areas of standing water after first establishing that it is a mosquito breeding site. Larviciding accomplishes several goals towards this effort: one, it mitigates the expanded use of adulticides by treating the affected area at its source, two, it lessens the selection pressure for mosquito resistance by attacking the mosquito during another phase of its life cycle, third, we are able to rotate our relatively few pesticide products, thus, preserving what remains in our inventory, fourth, it is also easier and more effective to larvicide a finite area which may be breeding mosquitoes, than it would be to broadcast by aerial application over a larger area, lastly and perhaps most importantly, we are able to maintain an

integrated pest management program which AMCA has partnered and been endorsed by the EPA. To this end our district has identified 668 different sites which would be applicable under the current NPDES permitting scheme as administered under the Clean Water Act for the sole purpose of larviciding. Based upon the initial California model to implement the 9th Circuit Court's decision, those yearly

costs incurred by application of larvicidal treatment would approximate $367,000 for our district alone. This figure does not include the hiring of additional personnel and equipment to carry out this edict. Currently, California is focused on yet another proposal to address the general permitting and monitoring requirements. This latest scheme entails a sampling cost of $1,200/sample due to the increase in the number and types of samples requested by the permitting authority. If this was applied to Lee County, the yearly costs would escalate to over $801,000 for our district alone, again not including additional personnel and equipment. Over 50 percent of our average annual rainfall (54 inches per year) occurs between the months of May and October. Consequently taking these samples within hours after application for each of the sites would be a logistical nightmare due to the inaccessibility to reach these affected areas by land-based vehicles. (There are not roads or bridges to many of our barrier islands and

mangrove fringed areas). This would necessitate flying individuals into these prescribed areas for water sampling. Just consider amplifying this activity to the many coastal mosquito controls located on the East and West Coasts as well as the Gulf Coastal Areas. The district authority would be hard pressed to cover these additional expenses. Therefore, it would follow, the inappropriate decision would be to cease and desist all further larviciding activities, compelling mosquito control districts across our nation to rely on an exclusive program of adulticiding.

The integrated pest management programs fostered by EPA and mosquito control programs across our land would no longer exist. Resistance management issues would increase on the mosquito population because we would be unable not only to rotate our pesticide products, but also unable to control more than one phase of the mosquito's life cycle. We in public health vector control, do not have the luxury of awaiting new products to replace our existing ones. No one in industry is developing new molecules for our use in public health vector control. This approach will definitely lead to more resistance to the public health pesticides within a shorter time period because of the increase in selection pressure. This begs the question from us in public health vector control, "What is wrong with the current

relationship between FIFRA and the stakeholders?" It is not a question of being unregulated, because FIFRA already regulates the public health pesticide program, but a question on what real benefit does the public receive from the added regulation?

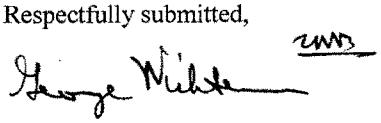
Congress could be extremely helpful if it would reaffirm to the EPA and the Courts that an NPDES permit is not required for vector control operations. As long as a pesticide label is being followed, the application of the pesticide to water is not the discharge of a waste for which an NPDES permit is required. This would help districts having to face the resource issues associated with these permits.

As an organization of over 2,000 public health professionals across the nation, the American Mosquito Control Association is dedicated to preserving and protecting the nation's public health. We respectfully urge DHHS and the Bush Administration to collectively work together to implement the Public Health Pesticide Data Collection Program by providing the appropriate funding which is necessary to preserve these important public health products. Together with your colleagues in the U. S. Senate supporting passage of HR 4793 and encouraging EPA and the Courts

that an NPDES permit is not required for vector control operations will enable public health professionals to function in an effective manner in order that they may protect our people and nation, especially the most vulnerable segments of our population – our children and senior citizens.

Again, AMCA appreciates the opportunity to provide their views. If the Subcommittee has any additional questions, we would be pleased to address them.

Respectfully submitted,



George J. Wichterman
Chairman of the Legislative and Regulatory Committee
American Mosquito Control Association

Mr. SOUDER. And for cleanup is Dr. Akhter from the American Public Health Association. We appreciate your coming today and look forward to your testimony.

Dr. AKHTER. Thank you, Mr. Chairman, members of the committee. My name is Mohammad Akhter. I am the Executive Director of the American Public Health Association. We are a membership organization of 55,000 professionals that work at the State, Federal, county level to provide services to the American people to make sure that their health is protected. I am delighted to have this opportunity to be able to speak to you.

You have heard all about West Nile virus, but now we are going to talk a little bit about West Nile virus, but more importantly talk about the future, the way we look at this emerging and reemerging infection, and what kind of actions we can all take to protect ourselves.

The world around us is changing. The ecosystem is changing, populations are shifting, globalization has taken over, and so the diseases have become global. Our last century's model of treating disease is no longer relevant. For this century we must substitute, we must add additional things to it to make it effective to protect the health of the American people, and our agencies are the very best. CDC, wonderful. FDA, excellent. NIH, no other country has such an agency. And they work very, very hard, they have done a superb job, and we are very grateful we have such agencies.

But despite all their efforts, their actions started after disease hit our shores, not before. We didn't do anything preemptive. We were just sitting and waiting for disease to come. And think about this: it is 3 years since the disease hit our shores. How many scientists, how many people does it take to really think proactively, that if HIV virus is transmitted through blood transfusion, if Hepatitis C gets transmitted through blood transfusion, is there a possibility that West Nile virus may be transmitted through blood transfusion, so we could start working and develop a test? Because we are not used to being proactive. We just want to sit and wait for the case to take place and then act.

And, Mr. Chairman and members of the committee, that is too late. That is now no longer acceptable. And despite our best efforts, we are unable to contain the outbreak. It has now gotten to the heartland of America. It is going to be with us for a long time to come and around our Nation. So we need to really look at it a little bit differently, and I suggest that we take four very distinct steps to deal with this situation for the future.

First, we need to have good medical intelligence around the world that we should collect ourselves. We can't rely on other countries. They don't have good infrastructures. They don't have good people to really do that. We need to know how disease is moving around, where it is coming, so that we are warned ahead of time so we could start taking actions. Developing vaccines takes 3, 4, 5 years. Developing tests take a long time. The sooner we are informed, the better we are in a position to help other countries as well as help ourselves.

Second, we should be looking at the diseases that are emerging and reemerging so that we should be doing research on them. We should be doing some work on them. Private industry is not going

to do this work, because there is no benefit in them. This is the work that needs to be done by the government, and that should go on all the time so that we could look at how the viruses are changing, what kind of conditions are changing, how the virus might spread, what might happen in the future.

But the first thing we need, Mr. Chairman and members of the committee, is a long-term, sustained thinking, not by the people who are doing the work. They are too involved. FDA, CDC, NIH, they are working too hard taking care of us all. We need people who are retired, people who have the expertise, people who come together to work on it as a think tank, who think, scan the horizon all around us to see what are the potential threats and what are the potential situations around the world, and then come up and give us the information, give you the information, Members of Congress, provide the administration with the potential threats, make different modelings so we are not caught by surprise that disease is spreading too fast, that it has gone South, then it has gone West, when we should know by modeling what kind of resources will be needed.

You shouldn't be asking professional people how much money, and they say, we don't know, we just will see what happens. Somebody should be calculating what kind of manpower will be necessary to deal with the disease if it spreads around, and that capacity we don't have in our country.

We are changing environments, Mr. Chairman. This is the most important and pressing need, that there be a think tank that looks for the future.

And finally, in concluding, we need to have, Mr. Chairman, continuous capacity-building at the State and local level. My good friends here have said and the Congress has provided the resources last year. We need to continue to maintain that capacity so that our people are able to take prompt action when disease outbreak does take place to make sure that our people are safe.

I greatly appreciate this opportunity, Mr. Chairman, to come before you and members of the committee, and look forward to answering any questions that you all might have for me and my colleagues. Thank you.

[The prepared statement of Dr. Akhter follows:]

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TESTIMONY OF THE AMERICAN PUBLIC HEALTH ASSOCIATION
Concerning Responding to West Nile Virus:
Public Health Implications and Federal Response

Mohammad N. Akhter, MD, MPH

Presented to the
House Government Reform Committee, Subcommittee on Criminal Justice, Drug Policy, and Human Resources

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Mr. Chairman and members of the subcommittee, my name is Mohammad Akhter. I am the executive director of the American Public Health Association. APHA is the oldest and largest public health association in the world, representing approximately 50,000 public health professionals in the United States and abroad. I am very grateful for the opportunity to discuss West Nile Virus and its implications.

West Nile is an emerging infectious disease. It is not the first and it will not be the last. Changes in our ecosystem, population shifts and increasing international travel bring with them a globalization of disease. The problem of emerging infectious diseases is likely to become more acute, not less. Globalization has changed the world. We have more international travel today than in the last century. As a result, last century's model of protecting ourselves from disease is no longer sufficient. We need to look at new, more strategic models of doing business. The tragic events of September 11, 2001, were a wake-up call. We have learned that we need to expect the unexpected.

We need to be proactive in monitoring the global situation. West Nile is not new. It is simply new to the United States. West Nile was first isolated in Uganda in 1937. It was recognized in Egypt in the 1950s. There was an outbreak in Israel in 1957. In the 90s, outbreaks occurred in Algeria, Romania, the Czech Republic, the Democratic Republic of the Congo and Russia. It reached the United States in 1999. It is now spreading throughout North America, most recently isolated in Canada, and we suspect it is now in Mexico as well.

The Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration, state and local health departments—they are all doing yeomen's work. They are tracking the West Nile Virus; they are educating people about how to protect themselves. They are working on a vaccine. The expert response and impressive surveillance effort is testament to the fact that our public health system works and that investments in these important agencies and in our public health infrastructure pay off and must be sustained.

Still, it is important to point out that much of this great work started *after* the disease reached our shores. We are just now aggressively abating mosquitoes—more than 2 years after West Nile began its spread from New York. It is now in at least 32 states. Our processes are too long. Our public health system remains domestically focused and often still operates in reactive mode. Our disease detectives swoop in like the FBI to investigate a case once it has already occurred. We work on vaccines and cures for diseases that currently exist. But we are not aggressively addressing key questions: What is next? Where will our next outbreak be located? What can we do to prevent it?

It is not possible to answer these questions without addressing infectious diseases occurring outside our boarders. We need a heightened global awareness and the intellectual and physical capacity to develop a more proactive model of public health. Such a proactive, strategic approach has at least four components.

The CDC needs an increased presence outside of the United States.

Infectious diseases, as we learned from West Nile, do not adhere to political boundaries. Consider other examples. HIV/AIDS emerged in central Africa before spreading to Europe and the Americas. Approximately 46 percent of newly identified Tuberculosis (TB) cases in the United States originated in other countries. Malaria, which we thought was eliminated in the United States in the 1960s still yields more than a thousand U.S. cases each year, and most recently turned up in Virginia. Influenza, measles, polio -- these diseases still threaten people around the world.

We need to be gathering information from around the globe and tracking these old and emerging infections. Expanded disease surveillance networks around the world are an essential component of any proactive approach to protect our own citizens. Investments in providing technical assistance to our global partners, including building surveillance networks and improving laboratory capacity, are also investments we make to protect the health status of our own citizens. Strong public health systems around the world can help protect us from new outbreaks and help to contain infections from spreading.

Influenza is an excellent example of how the CDC proactively protects our population from influenza. Through the World Health Organization, CDC has provided support for influenza surveillance in China and other Asian countries. This long-term, year-round surveillance monitors for variant viruses that could circulate in the United States in the future. Early identification allows vaccine manufacturers to include new variant viruses in the annually reformulated flu vaccine *before* epidemics caused by these viruses occur in the United States.

We need to do a better job of studying these emerging diseases and new versions of old diseases.

Disease is unpredictable. The emergence of new organisms, shifting tactics of known infectious agents and the growing resistance of pathogens to existing antimicrobial drugs demands that we employ new science more effectively and more aggressively. HIV, West Nile, and Tuberculosis are spreading in new ways, taking on different forms, and have varying symptoms. These diseases are changing when they hit a new terrain. We need to do a better job of researching these diseases when they arrive in the U.S. We thought West Nile would focus on the elderly, we thought it meant encephalitis. Now we know it can be transmitted through blood, through organ transplants, and possibly though breast milk. It can also induce paralysis. People of a younger age are now being affected.

As information slowly trickles out, we need to ask ourselves what we do not yet know. NIH is conducting basic research to better understand West Nile. These much needed, long-term research efforts began after the disease was isolated in the United States and many of the findings will not be known for many years. Looking back, if we had taken a more global approach to disease, tracked its spread across the globe and conducted research before that mosquito or that bird got on a plane for New York, perhaps we would have been better prepared.

We need a war college for public health.

The NIH and the CDC are working together to study West Nile and other emerging diseases, but we also need a place where a more strategic review of the information and more tactical thinking and planning is fostered. We need an institution where long term, futuristic battle plans can take place. Where the best minds in public health science collaborate in a coordinated effort to attack difficult disease scenarios. The federal government needs to work together with the private sector in a "think tank" approach to address the broader agenda of what the public health threats are and where they are coming from next.

This effort should have a global focus. It should be sufficiently funded and coordinated with governments, foundations, scientific establishments and international organizations.

We need to ensure that our nation's public health system and the public health systems of other nations are prepared.

The public health system in the United States has been neglected for far too long. With the help of additional funding from Congress, we have begun to rebuild. But this is not like building a house. We can't just remodel every ten years. The job is never completed. The ground is consistently shifting and we need to ensure that our foundation remains solid. Our public health system must be consistently strengthened if we are to effectively respond to the next West Nile, the next bioterror attack, the next flu epidemic.

Last year Congress appropriated approximately $900 million to help prepare the nation's public health system for a bioterrorist attack. The utility of this investment is borne out in the coordinated, quick response to the spread of West Nile. Building the public health infrastructure will serve us well as we respond to other infectious and chronic diseases. I strongly urge you to maintain your commitment to the public health system. It is critical that we remain vigilant and prepared. Left unchecked, today's emerging diseases will be the common diseases of tomorrow.

Mr. SOUDER. Well, I thank you all. It has been very informative for each of us.

Let me ask a couple of kind of basic questions first.

Mr. Wichterman, I presume you have a mosquito control district in Lee County.

Mr. WICHTERMAN. Yes, that's correct.

Mr. SOUDER. Have you had any West Nile in Lee County?

Mr. WICHTERMAN. Yes. Mr. Chairman, I am from a mosquito-controll district, and we cover roughly 1,000 square miles in southwest Florida and Fort Myers, and we do have West Nile virus indicated in our surveillance program, both in the avian population as well as our sentinel flocks that we use for surveillence for determining whether we have encephalitis, whether it be St. Louis encephalitis or Eastern equine encephalitis. But to date we have not had any human cases in southwest Florida.

Mr. SOUDER. Why do you think you don't have any human cases?

Mr. WICHTERMAN. My best guess——

Mr. SOUDER. In other words, one of the things that somebody from Indiana would immediately look at is basically Florida is out of a swamp; you have huge migratory bird populations there, with Ding Darling and all sorts of wildlife refuges. You have more seniors. Why wouldn't you have any human cases?

Mr. WICHTERMAN. That is an excellent question. My best answer would be in the State of Florida there are currently 54 organized State-certified mosquito control programs out of the 67 counties in the State of Florida, and because each of these mosquito-controlled districts maintain a surveillance program like what you have been hearing earlier from Dr. Hughes, and surveillance is key to finding out whether you are going to have a problem or not, and surveillance helps to preclude any human cases that you may have on the horizon.

Currently in the State of Florida, as of this past day we have nine human cases of West Nile virus, but the cases are in southeast Florida around Miami, up in west central Florida, out in the western Panhandle of Florida, and up in north central Florida, where some of these mosquito control districts are not prevalent.

Mr. SOUDER. Let me move to Dr. McMahan next.

Could you for the record give a few pattern insights into what you have seen in Allen County? I'm going to ask the same question in Illinois. Do you see equally divided between the—Allen County is unusual because, for those people who aren't there, we have rural, suburban, and urban, an urban center of 200,000, and about 130,000 in the county, but we also have large Amish populations. So it is rural and urban. What percentage roughly is in the urban versus the rural? Have you been able to—could you give some kind of just rough breakdown—not precise—of when you have gone out to investigate, does it seem to be things that are in the immediate surroundings of the home or broader? Just a little bit of an insight into the mix of what you are finding at the grassroots level.

Dr. MCMAHAN. Well, what we have found in Allen County is that this is predominantly an urban problem. When a human case is identified, that triggers an environmental investigation, and halfway through our outbreak, we had evaluated 23 human cases. Sixty-five percent of those properties in those 1-mile target areas

surrounding the human case we were able to find multiple mosquito breeding sites, things like old tires, aquariums, containers, all sorts of containers that were breeding Culex mosquitoes.

So I think that really points to why it is so important for our medical community to do the surveillance, because it does assist us in identifying other areas for which other humans would be at risk surrounding those human cases that have been identified.

Mr. SOUDER. Have you seen similar patterns with the bird population?

Dr. MCMAHAN. The birds, I think, have been identified throughout Allen County. I think, unfortunately, we stopped our bird surveillance fairly early in the season once it was established that the West Nile virus was entrenched in Allen County, and our mosquito population surveillance was also turning positive. But we continue to hear from the farmers that they are just finding tremendous amounts of dead birds on their property.

It has also been a problem for our horses. We have had 45 horse deaths in Allen County due to the West Nile virus. Although, as you mentioned, a significant portion of our farmers are Amish, and unfortunately they didn't take advantage of the vaccine that was available. But there have been 350 horse deaths in the State of Indiana.

So it has been a significant problem. The virus is well established and entrenched in Indiana.

Mr. SOUDER. Well, is there—I discussed this earlier. But if you find a dead bird on your yard, it doesn't necessarily mean you are extra vulnerable? Or does it mean you are extra vulnerable? We talked earlier. If it is an owl or a red-tail hawk, that might be more unusual. Does that—do you see a direct correlation at all in the imminence of the immediate threat?

Dr. MCMAHAN. Well, I think the Cornell model that is used to identify risk predicts that if you find 1.5 birds with West Nile virus within a square mile, that area has a high risk for human transmission. And that was the model that we have used for our—one of the criteria that we have used for our adulticiding program.

But I think it is important to note that the reason that the larger birds are always selected by at least our State department of health for identification is that they have more brain tissue. But sparrows, chickens, all sorts of birds have been identified with West Nile virus. So I think if you find a dead bird on your property, I think it is important to make sure that you dispose of it properly and with care so as to minimize your own risk.

Mr. SOUDER. Are you suggesting it can be transferred by handling a dead bird?

Dr. MCMAHAN. I think we need to be very careful, and I think this year, with over 2,500 cases thus far, we are going to have—at the end of the year when we evaluate this epidemiological data, I think we are going to have such a much better understanding of this virus and all the potential rounds of transmission, more so than we had based on the 161 cases in the previous 3 years. So I would urge people to take all precautions that they can.

Mr. SOUDER. Not because there is any particular evidence, but just to be cautious.

Dr. Lumpkin, would you comment on some of the responses in Illinois, what some of the patterns you have seen, particularly in Cook County? We have huge cases, but I assume if you are in every county, you have got rural cases and urban cases.

Mr. LUMPKIN. We do. We are seeing cases in—human cases throughout the State. There are 35 counties; out of 102 that have had human cases. And we have seen deaths throughout the State. The largest concentration, though, of cases are in Cook County, and of those cases the largest concentration are in two areas, one in essentially Representative Schakowsky's district and the other in the southwest side of the suburbs in the area directly adjacent to the city. These are again two areas that we saw high concentrations of St. Louis encephalitis in 1975.

The pattern of human cases exactly follows the pattern of bird cases that we saw earlier on in the summer, where you can just see an explosive progression beginning in July, starting in the Chicago metropolitan area and then fanning out across the State, so it really has been quite an extensive experience.

But one of the key questions we are asking is why those two areas? And we have asked the CDC and we are looking to do studies over the winter to see if there are any things that place those communities particularly at risk. At first blush, there is no evidence. There is no evidence of increased amounts of vegetation. The two areas do have a higher rate of people who are over the age of 50, but why that would necessarily mean that there would be more transmission from mosquitoes we are not really certain at this time.

Mr. SOUDER. Do you know why there wouldn't have been a focus, given the correlation of St. Louis, if that would have been an immediate focus of the Federal Government to look at?

Mr. LUMPKIN. I am not sure how many people in the Federal Government are still in their positions who were around in 1975. We were obviously very aware of that in Illinois because of our continued ongoing commitment to do surveillance of mosquitoes and birds. So I think—that would be my only explanation.

Mr. SOUDER. Could—Mr. Cummings, let me finish up this line of questioning.

Did we have—I should know, but I don't. Did we have any St. Louis encephalitis in Allen County in any extraordinary amounts?

Dr. MCMAHAN. In 1975, probably at the same time that you had your outbreak, we had an extensive outbreak in Indiana. We had 27 cases of St. Louis encephalitis in Allen County at that time. That was actually when we started our vector control division, after that outbreak. That was when the vector control division actually was initiated.

Mr. SOUDER. Was that a complete shock?

Dr. MCMAHAN. Pardon me?

Mr. SOUDER. It is not a complete shock of the patterns of places, given the previous patterns. It is interesting—it would be interesting if the Federal Government's taken—have we had much Federal Government money come into Allen County? We have a huge supplemental boost nearly of 40 percent of the Federal expenditures. Did any of that get in as the problem became greater in Allen County?

Ms. MCMAHAN. We've received $1,000 directly from the State for mosquito control.

Mr. SOUDER. And what about in Illinois?

Dr. LUMPKIN. In Illinois I think the total funding, as someone mentioned before, was about $1.6 million. We made available, as I also said, about $3½ million that we pulled out of another fund to accelerate the payments.

Mr. SOUDER. As the problem developed later in summer, did you receive any boost-up in the supplemental?

Dr. LUMPKIN. We received for the entire State in August—we received a total of about $400,000—an additional 350,000 in September.

Mr. SOUDER. Thank you. Mr. Cummings.

Mr. CUMMINGS. Dr. Lumpkin, do you know what your request was?

Dr. LUMPKIN. The way the funding was allocated to us, we were told what we could apply for, so we basically applied for about 100,000 more than they said we could, and we were funded for all that we asked for.

Mr. CUMMINGS. And what did you use those funds for?

Dr. LUMPKIN. Well, those funds were restricted. We were particularly told that they were not for mosquito abatement. So we used those to enhance some of our activities in our laboratory. We also used them to develop a PSA that we then put out for the media, as well as other surveillance activities.

Mr. CUMMINGS. Dr. McMahan, the—I take it that this is—I guess this has kind of strained your Agency a bit, huh?

Ms. MCMAHAN. Oh, definitely. As I mentioned in my report, over $280,000 was necessary over and above the normal moneys that are spent on vector control. And that doesn't account for all of the time that myself, the administrator, we've had one public health nurse that's been devoted exclusively over—for the past 3 months investigating cases, the environmental investigators that need to go out and, you know, investigate the cases to identify sources. It's been a tremendous strain, yes.

Mr. CUMMINGS. So how do you make up for that. In other words, are you sort of deficit spending or what? I mean——

Ms. MCMAHAN. Well, we've been very fortunate. First of all, we've worked long hours. But we've been very fortunate that our county council has appropriated the moneys that we have needed. They have been very responsive to our need and have appropriated the funds when requested.

Mr. CUMMINGS. What would you like to see the Federal Government do to be of assistance? And are you satisfied—and this is to you to Dr. Lumpkin—with the CDC and what they've been doing and the other agencies?

Ms. MCMAHAN. Well I think there's been a lot of educational support from the Centers for Disease Control. Their Web site has been very helpful. They have sent updates with respect to issues like blood transfusions and organ transplant issues. I think what we need is more support at the local level. I think the need is so great at every level for funding that our State is in desperate need of funds; that when money is allocated at the State level, very little

can trickle down to the local level. Not because of greed but because of need.

And so it would be nice if there were a way that local departments of health would be able to apply for resources to actually provide treatment, the intervention, the adulticiding, the larvaciding, and all of those sorts of things. Those are expensive, and as it is right now, we've received $1,000 for surveillance this year. So our county has for—you know, over $280,000. So I would like to see more funds given at the local level.

Dr. LUMPKIN. I think that there are a number of things that we would—where we could appreciate assistance. First of all, I think that given the experience that we had last year, we need to look at addressing next year differently. West Nile is here. It's here with a vengeance. And we would be looking for assistance from the Centers for Disease Control in developing a public information campaign that I think needs to be national in scope reflecting West Nile.

People need to know that they place themselves, their families, and their neighborhoods at risk by having containers that hold water that will breed mosquitoes. People need to understand the importance of wearing long sleeves and long pants when they go out at dawn, dusk, and early evening. That message needs to be repeated and repeated frequently. And it needs to be done in a way that—where people are—can address it.

To tell you the truth, doing public service announcements that are put on at 4 o'clock at night, 4 o'clock in the morning, or, you know, odd hours, is not going to do much to help people learn what they need to do about West Nile. You need to spend money to get that message out.

There are some other concrete things that we need assistance in. Obviously we're going to run into trouble in April in our local health departments, and funds available for emergency funds for mosquito abatement I think is important. In addition, I think that there needs to be a national fund for public health emergencies. We've seen them come. We need to be able to respond, and respond quickly, without exhausting local and State resources.

Our State is facing anywhere from a $1 to $2 billion deficit in our budget coming up, as many States are. And our ability to respond to these kind of things are certainly restricted.

The USEPA needs to look at the issue of municipal pesticide application, particularly in dealing with mosquito abatement control. Using larvicides, there needs to be special licenses that are available so that we can actually get these treatments out without expending large sums of money or hiring private companies.

There are limited things that can be trained, particularly with larviciding. In Illinois, for instance, we established the 1-hour course and the special licensing for people who just do larviciding in the catch basins throughout the city of Chicago and other places.

Resources and research are crucial. We need to better understand as far as how it impacts, how it grows, what's involved with the bird population, to what extent are we going to see resistance in the bird population that would prevent the spread of the disease. So there a number of things that I think are on the agenda for Federal action.

Mr. CUMMINGS. I thank you.

Mr. SOUDER. I'd like to ask, Dr. Akhter, you noted in your testimony that the West Nile is spreading in different ways and taking on different forms. Should we be concerned that like other viruses this may mutate and become more harmful, and do you have any evidence of that?

Mr. AKHTER. Mr. Chairman, we don't have any evidence at the moment. But I think this is the kind of thing we need to look at other viruses of similar type: how have they behaved in the past and what they might do, and that's why the need for a think-tank. We just don't need to have the firm evidence here. We need to have accurate projections, some reasonable projection on the basis of which we would take evasive actions to make sure that it would not do the damages that it would do otherwise.

Mr. SOUDER. Well, I want to thank each of you for your testimony that Dr. Akhter was—it has been very challenging when we look at the international changes which are going to accelerate in the growing diversity of the communities all over the country and the trade and the items that we bring in that—how we address that between our universities and the research, and possibly tapping in, as you said, into retired experts and others; because it's clear we're weaker on the predictability, and even when there are patterns. But if you're doing hand-held calculators and trying to react out of low budgets, it's very difficult to do predictive behavior. If you're drowning in alligators, it's hard to predict where the next thing's coming.

I also appreciate, Mr. Wichterman, your specific comments on—it's interesting to look at where there are at least somewhat success stories and then say, well, we might not even be able to execute those if we are not paying attention. And how to make sure that you have product available to do what the mosquito control districts do, that's another whole challenge.

And it's been very informative at the local level, both statewide, and I know the Indiana Board of Health has been very active, too, and I'm sure in Cook County specifically.

But it's been a good mix of a panel, and if you think of additional thoughts or if you want to approach anybody else in your States or organizations to give additional testimony in this record, clearly my guess is that there will be, particularly in the midwest as we get into the fall season, it won't be as high on the agenda.

Congress is going to adjourn. This will probably restart up again the next session of Congress, and we need to look at it as we move through that budget process and in the authorizing. This is an oversight committee our goal is to identify where some of the holes were and try to see what might move into the legislative process. So I thank you for being part of our hearing. I encourage you to stay involved. Thank you for your work at the grassroots level. With that, the hearing stands adjourned.

[Whereupon, at 4:30 p.m., the subcommittee was adjourned.]

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