CURRENT CHALLENGES IN COMBATING THE WEST NILE VIRUS

HEARING

BEFORE THE

SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS

OF THE

COMMITTEE ON GOVERNMENT REFORM

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CURRENT CHALLENGES IN COMBATING THE WEST NILE VIRUS

WEDNESDAY, OCTOBER 6, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Doug Ose (chairman of the subcommittee) presiding.

Present: Representatives Ose, Miller, Tierney, and Kucinich.

Staff present: Barbara F. Kahlow, staff director; Danielle Hallcom Quist, counsel; Lauren Jacobs, clerk; Megan Taormino, press secretary; Krista Boyd, minority counsel; and Cecelia Morton, minority office manager.

Mr. OSE. Good morning. Welcome to today's hearing of the Government Reform Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs. Today's hearing is titled "Current Challenges in Combating the West Nile Virus." I want to recognize a quorum as being present.

We are joined today by two very distinguished panels to discuss the West Nile virus issue. Our first panel will be composed of Dr. Anthony Fauci—is that right?

Dr. FAUCI. "Fauchi."

Mr. OSE. "Fauchi." OK—Dr. Stephen Ostroff and Mr. Benjamin Grumbles, respectively, from the NIH, the CDC and the EPA.

Our second panel is composed of Mr. John Pape, Dr. Jonathan Weisbuch, Mr. Joe Conlon, Mr. David Brown, Ms. Wendy Station, and Dr. Marm Kilpatrick, respectively, from the Colorado Department of Public Health and Environment, from Maricopa County, AZ, Department of Public Health, from the American Mosquito Control Association, from the Mosquito and Vector Control Association of California, from Encephalitis Global, and from the Consortium for Conservation Medicine and Wildlife Trust.

It has been 5 years since public health officials diagnosed the first case of West Nile virus in the United States. Since then the virus has crisscrossed this Nation, leaving thousands sick from a debilitating form of meningitis, encephalitis and about 620 people dead. This year, while many parts of the country have a respite, people in the Southwest are fiercely combating the West Nile virus as the epidemic rages in California and Arizona.

Over the last several years, the Centers for Disease Control and Prevention and the EPA have coordinated with local vector control

districts and public health officials to control and eliminate mosquitoes from spreading the virus. Meanwhile the National Institutes of Health, the States and private companies have been conducting research to develop better treatments for those who suffer from encephalitis and to develop a vaccine for West Nile virus. Together with State and local officials, Federal agencies have also organized a national public education effort to encourage individual bite prevention and source reduction.

Today our vector control districts are working around the clock to locate and diagnose infected dead birds and kill virus infected mosquitos before they infect people. While local health and abatement officials work tirelessly to reduce the threat posed by mosquitos, a minority of our population is using our Federal court system to insert regulatory obstacles that tend to obstruct efforts to end this epidemic.

Since the Ninth Circuit decided in March 2001 that pesticide applicators required Clean Water Act National Pollutant Discharge Elimination System permits to apply aquatic pesticides to waters of the United States, California and Washington have required mosquito control professionals to obtain NPDES permits. With similar challenges pending in the Second Circuit Court, local officials await court decisions that would determine whether such permits are needed in those jurisdictions as well.

In July 2003, EPA issued an interim statement and guidance memorandum to its regional offices in an effort to clarify whether pesticide applications required NPDES permits. The guidance stated EPA's position that under certain circumstances, Federal, Insecticide, Fungicide, Rodenticide Act compliant pesticide applications do not require NPDES permits for purposes of mosquito abatement. Agency guidance, however, is not binding on non-Federal entities; therefore, a few States continue to require NPDES permits because of the 9th Circuit legal precedent.

Unfortunately, EPA's guidance has not protected vector control districts from citizen lawsuits under the Clean Water Act. The vector control district in Gem County, Idaho was sued under the Clean Water Act for application of pesticides to waters of the United States even after EPA decided in August 2003 that Gem County did not need an NPDES permit to conduct its mosquito abatement activities. The result of the Gem County case and other lawsuits still pending is to add legal permit application and water quality monitoring costs and uncertainties to vector control districts already strapped for funds to control mosquitoes. Moreover, in controlling mosquito born illnesses, time is of the essence, as the testimony will clarify today, and the addition of regulatory obstacles hampers the efforts of our public health officials.

We must support the efforts of local officials in combating the West Nile virus, not add additional uncertainty. I strongly urge EPA to promulgate a regulation to replace its nonbinding guidance and to provide unchallengeable clarity for this issue. We need a safe harbor. We can protect people from the West Nile virus while still maintaining the health of our aquatic ecosystems.

Today we will discuss these challenges and other challenges facing us in the eradication of the West Nile virus. We will hear testimony from Federal, State and local experts in an effort to gain a

better understanding of why the virus continues to be a public health threat and how close we are to eliminating it and other mosquito born illnesses.

I have previously introduced our two panels today. I would be pleased to recognize my friend from Massachusetts for the purpose of an opening statement.

[The prepared statement of Hon. Doug Ose follows:]

Opening Statement of Chairman Doug Ose
Current Challenges in Combating the West Nile Virus
October 6, 2004

It has been 6 years since public health officials diagnosed the first case of West Nile Virus in the United States. Since then, the virus has crisscrossed this nation leaving thousands sick from a debilitating form of meningitis and encephalitis, and about 622 people dead. This year, while many parts of the country have a respite, people in the Southwest are fiercely combating the West Nile Virus as the epidemic rages in California and Arizona.

Over the last several years, the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA) have coordinated with local vector control districts and public health officials to control and eliminate mosquitoes from spreading the virus. Meanwhile, the National Institutes of Health (NIH), States, and private companies have been conducting research to develop better treatments for those who suffer from encephalitis and to develop a vaccine. Together, with State and local officials, Federal agencies have also organized a national public education effort to encourage individual bite prevention and source reduction. Today, our vector control districts are working around the clock to locate and diagnose infected dead birds and kill virus infected mosquitoes before they infect people.

While local health and abatement officials work tirelessly to reduce the threat posed by mosquitoes, a vocal minority is using our Federal court system to insert regulatory obstacles to obstruct efforts to end this epidemic. Since the 9th Circuit decided in March 2001, that pesticide applicators required Clean Water Act (CWA) National Permit Discharge Elimination System (NPDES) permits to apply aquatic pesticides to waters of the United States, California and Washington have required mosquito control professionals to obtain NPDES permits. With similar challenges pending in the 2nd Circuit, local officials await court decisions that would determine whether NPDES permits are needed in those jurisdictions as well.

In July 2003, EPA issued an "Interim Statement and Guidance" memorandum to its regional offices in an effort to clarify whether pesticide applications required NPDES permits. The guidance stated EPA's position that, under certain circumstances, Federal, Insecticide, Fungicide, Rodenticide Act (FIFRA) compliant pesticide applications do not require NPDES permits for purposes of mosquito abatement. Agency guidance, however, is not binding on non-Federal entities; therefore, a few States continue to require NPDES permits because of the 9th Circuit legal precedent.

Unfortunately, EPA's guidance has not protected vector control districts from citizen lawsuits under the CWA. Indeed, the vector control district in Gem County, Idaho, was sued under the CWA for application of pesticides to waters of the United States, even after EPA decided in August 2003, that Gem County did not need a NPDES permit to conduct its mosquito abatement activities. The result of the Gem County case, and other lawsuits still pending, is to add legal, permit application, and water quality monitoring

costs to vector control districts already strapped for funds to control mosquitoes. Moreover, in controlling mosquito born illnesses, time is of the essence and the addition of regulatory obstacles hampers the efforts of our public health officials.

We must support the efforts of local officials in combating the West Nile Virus, not add additional uncertainty. I strongly urge EPA to promulgate a regulation to replace its non-binding guidance and to provide unchallengeable clarity for this issue. We can protect people from the West Nile Virus while still maintaining the health of our aquatic ecosystems.

Today, we will discuss those challenges and other challenges facing the eradication of the West Nile Virus. We will hear testimony from Federal, State and local experts in order to gain a better understanding of why the West Nile Virus continues to be a public health threat and how close are we to eliminating it and other mosquito-borne illnesses.

Today's witnesses include: Dr. Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases, NIH, Department of Health and Human Services (HHS); Dr. Stephen M. Ostroff, Deputy Director, National Center for Infectious Diseases, CDC, HHS; Benjamin J. Grumbles, Acting Assistant Administrator, Office of Water, EPA; John Pape, Chief Epidemiologist; Colorado Department of Public Health & Environment; Dr. Jonathan Weisbuch, Director of Public Health Maricopa County, Arizona; Joe Conlon, Technical Advisor, American Mosquito Control Association; David Brown, Chair of Integrated Pest Management, Mosquito and Vector Control Association of California; Wendy Station, Founder, Encephalitis Global; and, Dr. A. Marm Kilpatrick, Senior Research Scientist, Consortium for Conservation Medicine at Wildlife Trust.

September 29, 2004

MEMORANDUM FOR MEMBERS OF THE GOVERNMENT REFORM SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS

FROM: Doug Ose

SUBJECT: Briefing Memorandum for October 6, 2004 Hearing, "Current Challenges in Combating the West Nile Virus"

On Wednesday, October 6, 2004 at 10:00 a.m., in Room 2247 of the Rayburn House Office Building, the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs will hold a hearing on the West Nile Virus (WNV). The hearing will explore recent activities and challenges to Federal, State and local efforts to control or eliminate the WNV epidemic.

Since 1999, when the WNV was first diagnosed in New York City, about 622 people have died in the United States from the WNV. Thousands more have suffered the debilitating consequences of meningitis and encephalitis that are caused by the WNV. Although many States have at least temporarily controlled the epidemic, the West and South are still facing epidemic conditions. The recent onslaught of devastating hurricanes in the Southern and Eastern regions of our country will add to the epidemic, as local officials struggle to address regressing flood waters and breeding mosquito populations. The WNV remains a serious public health threat that has destroyed the lives and families of people throughout this nation.

The WNV is a mosquito borne disease that infects humans, birds, horses and other animals. About 176 species of mosquitoes are recognized in the United States, each with its preferred aquatic breeding habitat. These habitats vary widely and mosquitoes frequently adapt to changing weather and water surface conditions. Any collection of standing water can serve as a potential breeding site, from a bottle cap, tire depression, storm water retention pond, or salt water marsh. Mosquitoes proceed through their first three life stages in water and, under high temperature conditions, can emerge as flying adults in as little as a few days.

Since the epidemic began in 1999, many States have successfully reduced instances of the disease. For example, last year, Colorado suffered 63 deaths and 621 cases of severe neuro-

invasive sickness. This summer, dryer and cooler weather helped to lower the infected mosquito population that can be easily managed by aggressive public health and mosquito abatement officials. Many experts also give credit to the changes in individual behavior and public awareness as factors lowering instances of WNV in many parts of the country. Federal, State and local officials administered a nationwide campaign to "Fight the Bite" by educating citizens on source reduction and bite prevention. While personal responsibility is very important, many caution that public education is a limited disease prevention strategy. Recently, a study by the Harvard School of Public Health confirmed that citizen education has its limits and complacency is rampant.

As a public health and regulatory concern, all levels of government have coordinated to fight the challenges posed by the WNV. At the Federal level, the Centers for Disease Control (CDC) and the National Institutes of Health (NIH), both of which are in the Department of Health and Human Services (HHS), and Environmental Protection Agency (EPA) have coordinated to control and prevent the human WNV epidemic. CDC serves as the lead Federal agency coordinating the Federal response to the WNV. Meanwhile, CDC assists State and local health departments in monitoring potential sources and outbreaks, and providing consultation on mosquito surveillance, source reduction and control. CDC provides grant assistance to State health departments to enhance laboratory and epidemiological capacity. Meanwhile, NIH serves as the primary research center for treatments and vaccines that may some day relegate WNV to the list of easily treatable diseases.

As the sole regulatory authority over the regulation, sale and use of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA plays a pivotal role in the availability of pesticides to eliminate mosquitoes (7 U.S.C. §136 and 40 CFR §§150-189). Mosquitoes are designated by EPA as a pest of "significant public health importance" under the Food Quality Protection Act (7 U.S.C. §136w-3). EPA also oversees State-administered Clean Water Act (CWA) National Permit Discharge Elimination System (NPDES) storm water program best management practices (BMPs) that have contributed to the epidemic by collecting and holding rainwater and pollutants (33 U.S.C. §1342 and 40 CFR §§122-125.24). More recently, some States have required an NPDES permit for use of chemical mosquito control in aquatic environments.[1]

States generally license and monitor mosquito abatement operations and water quality through their respective departments of health, agriculture, and pesticides/toxics. California's additional pesticide regulations require its Department of Pesticide Regulation to cooperate with EPA to ensure that pesticides are specifically formulated for use within the State. In addition, since the WNV outbreak began, States have modernized laboratories, coordinated State public health, environment and agriculture regulatory entities, and coordinated surveillance and tracking activities.

The frontlines of mosquito abatement are handled locally by public health officials and specially organized mosquito abatement districts. Many State statutes permit the establishment

[1] California and Washington currently require mosquito abatement districts to obtain NPDES permits when appropriate. Oregon does not mandate NPDES permits, but suggestes that pesticide applicators obtain state-issued permits to protect against lawsuits.

of vector/mosquito control districts that may levy taxes, assessments or fees for purposes of vector control activities.[2] County health and vector control officials conduct surveillance and trapping activities, and take actions to prevent, abate and control mosquito populations.

The challenge to mosquito abatement officials is to formulate Integrated Mosquito Management (IMM) practices using a combination of physical source reduction, biological, and chemical controls to minimize the economic, health and environmental risks caused by mosquitoes. Professionals must carefully conduct surveillance activities in order to monitor and predict the location of mosquito populations.

To reduce the mosquito population, officials use physical source reduction methods, which may include digging ditches to move water, removing excess vegetation and debris, and biological control through natural mosquito predators. The public has been strongly encouraged to contribute to this effort by removing standing water around residences. Although the use of non-chemical strategies will often reduce mosquito breeding habitat, they are usually not sufficiently effective control agents.

To control the WNV epidemic, public officials typically use both non-chemical controls and chemical control methods. The application of extremely low-risk, environmentally sensitive, host-specific materials are used to control mosquitoes. Two types of materials are generally used: (1) larvicides, which target the aquatic immature or larval/pupal stages of these insects, and (2) adulticides, aimed at killing flying mosquito adults. IMMs seek to prevent emergence of adult mosquitoes and, therefore, apply larvicides directly to water that act to suffocate, prevent growth, or interfere with molting of the larvae. When larvicides fail, operators will use ground or aerial foggers to dispense very fine aerosol droplets that stay airborne and kill adult biting mosquitoes on contact. Before spraying occurs, public officials notify the public.

The WNV has been a persistent epidemic for the last five years; nonetheless, the use of pesticides has created some controversy over mosquito control methods that have been in practice for decades. In some locations, local citizens have objected to the use of chemical pesticides, particularly adulticides, as a method of mosquito control. Recent 9th Circuit Federal Court decisions have resulted in the requirement for pesticide applicators to obtain NPDES permits before application to navigable waters.[3] Meanwhile, citizen suits under the CWA filed in the 9th and 2nd Federal Court Circuits[4] have left many mosquito abatement professionals in fear that additional regulation and lawsuits are likely in the near future.

In July 2003, EPA responded to these concerns by issuing for public comment an "Interim Statement and Guidance" memorandum to its regional offices, stating its position that, under certain circumstances, FIFRA compliant pesticide applications do not require NPDES

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[2] For example, California authorizes vector control districts under section 2002 of the California Health and Safety Code.

[3] Headwaters, Inc. v. Talent Irrigation Dist., 243 F. 3d 526 (9th Cir. 2001) and League of Wilderness v. Forsgren, 309 F.3d 1181 (9th Cir. 2002).

[4] Altman v. Town of Amherst, N.Y. 2002 App. LEXIS 20498; No Spray Coalition, Inc. v. City of N.Y., 351 F.3d 602 (2nd Cir. 2003); and the St. John's Organic Farm v. Gem County Mosquito Abatement District.

permits for purposes of mosquito abatement (68 FR 48385). While the nonregulatory interim guidance somewhat clarifies EPA's position and may convince courts to defer to EPA's legal interpretation, as it stands, the interim guidance does not bind non-Federal entities. To date, EPA has not initiated formal rulemaking, leaving vector control districts still vulnerable to citizen lawsuits under the CWA for failure to obtain NPDES permits.

Combating the WNV has taxed the stamina of local scientists and mosquito control specialists. Scientists at all levels of government strive to understand how the WNV is spread, how it adapts to local hosts and aquatic environments, and how to treat and prevent the most serious neuro-invasive diseases that effect thousand of citizens.

This hearing will explore State and local strategies and challenges for combating the WNV, particularly as it rages in the West. It will also address challenges faced by health and mosquito abatement officials from regulatory and nonregulatory guidance uncertainties and suggestions for additional regulatory action to facilitate effective public health mosquito control. Finally, this hearing will look to the future to how citizens and government can use the lessons learned from this epidemic to respond to threats from other mosquito borne diseases that are only an ocean away.

Invited witnesses include: Dr. Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases, NIH, HHS; Dr. Stephen M. Ostroff, Deputy Director, National Center for Infectious Diseases, CDC, HHS; Benjamin J. Grumbles, Acting Assistant Administrator, Office of Water, EPA; John Pape, Chief Epidemiologist; Colorado Department of Public Health & Environment; Dr. Jonathan Weisbuch, Director of Public Health Maricopa County, Arizona; Joe Conlon, Technical Advisor, American Mosquito Control Association; David Brown, Chair, Integrated Pest Management, Mosquito and Vector Control Association of California; and, Wendy Station, Founder, Encephalitis Global.

Mr. TIERNEY. Thank you, Mr. Chairman, and I want to thank you for holding this hearing on the West Nile virus. Obviously, we are all concerned because there is no available vaccine. There are no specific treatments yet known and there is not yet enough information to effectively predict what areas might be hit the hardest. Public health workers are on the front line when it comes to defending and responding, and so it is essential that those communities have the tools and the support and the resources that they need in order to be effective.

Public education we are told is probably the best and most effective means of dealing with this. So I would like obviously today to hear more from our witnesses on how those educational efforts can be improved as well as other responses that might be available.

And as the chairman mentioned, I know that one of the issues we are dealing with here today is how local mosquito abatement efforts, as varied as they are, will include spraying pesticides against larva and against adult populations and whether or not there can't be some reconciliation between protecting the clean waters of this country and making sure that we respond effectively to this concern of West Nile virus.

I have read a lot of the materials here, and I know that there are positions on both sides. I am curious to know whether or not the initial EPA tests do in fact take into consideration the NPDES consideration with regard to clean waters and, if not, why they can't and why both of these issues aren't reconcilable. I should think that they would be. I should think that we would be able to both keep our waters clean and have the Clean Water Act lived up to and adhered to while at the same time making sure our local communities have the ability to respond in the way that they should effectively.

So, Mr. Chairman, again I thank you for this hearing. I look forward to our witnesses and want to proceed as quickly as we can. Thank you.

Mr. OSE. I thank the gentleman. Gentlelady from Michigan.

Mrs. MILLER. Thank you, Mr. Chairman. I want to thank you for holding this hearing today. You know, with so many threats that are facing our Nation today certainly the threat of disease is one that we cannot overlook. The spread of the West Nile virus is a problem that's troubled our Nation for the past 5 years. But the purveyor of this threat is a thing that's been annoying us for our entire lives, the lowly mosquito. It is hard to believe that the mosquito is the cause of all these things.

Since the first case was reported in 1999 there have been 622 reported human deaths related to this virus. It is a virus that has a dire potential because it affects livestock, other animals. In my home State of Michigan we know very well, unfortunately, firsthand the dire consequences of this damaging disease. But this is an issue that's not only affected humans. As I say, livestock, other animals as well.

The first case that was detected in Michigan was found in birds actually in 2001. I know I will never look at a crow the same way, either live or dead. By 2002 the virus activity had expanded to horses and then to humans, and in that year Michigan actually had 644 recorded cases of the West Nile infection, which was the

second highest number of any of the States. 51 of these cases unfortunately resulted in death.

In the last 2 years, the disease seems to have sort of moved to the West and to the South as well. Thus far in 2004 there have been a total of six human cases of the West Nile virus in my home State of Michigan. And even though the number of West Nile infections in the East and the Midwest has declined, fortunately, the threat certainly has not.

In Michigan our officials have actually developed a comprehensive campaign to inform the public and to expand efforts to stop the spread of this virus. The State actually introduced a Web site in 2003, which is a fantastic Web site, with a focus on educating our State's citizens. This Web site also contains a diseased wildlife observation report that can be filled out by the citizen to notify the appropriate authorities of any sick or diseased birds, where they are located and what citizens actually are observing in these cases. In 2003 alone—I thought this was interesting—we had actually over 5,000, I think 5,500 cases that were reported through the Web site, which was significant. And with this new system certainly the State of Michigan is trying to take a very proactive response to this problem.

We have also put together a West Nile virus working group as well to monitor the disease within our State, and after 51 deaths in only 1 year I think every resident, certainly of Michigan and now our entire Nation, are very perceptive as to the West Nile impact.

So I want to thank each of the witnesses for appearing today. I am certainly looking forward to your testimony. As you see, it is something that has a very high degree of perception in my State of Michigan, and I am looking forward to what we can do to work together to avail ourselves of getting rid of this threat.

Thank you, Mr. Chairman.

Mr. OSE. I thank the gentlelady. Now I'd just advise the witnesses as a matter of course in our subcommittee we swear everybody in. It is not judgmental. It is just standard practice here. So if you would all rise, please, and if you have folks that are going to provide oral testimony they need to rise and be sworn in too. I just need to make sure I have who's standing where.

[Witnesses sworn.]

Mr. OSE. Let the record show that the witnesses all answered in the affirmative. Now we have received your written testimony, and we have reviewed it. What we do here is we are going to recognize each of you in turn for 5 minutes to summarize your testimony. I would urge you in the course of your remarks to focus on a couple of things in particular. First, the precursor conditions that lead to an outbreak of West Nile virus, heat, water, etc., the cross-species communicability of the disease, and the treatment and prevention protocols that we need to consider. Dr. Fauci, you're recognized for 5 minutes.

STATEMENTS OF DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. STEPHEN M. OSTROFF, DEPUTY DIRECTOR, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND BENJAMIN J. GRUMBLES, ACTING ASSISTANT ADMINISTRATOR, OFFICE OF WATER, ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY ADAM SHARP, ASSOCIATE ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES, AND TOXICS

Dr. FAUCI. Thank you, Mr. Chairman. I appreciate the opportunity to testify before you and the other members of the committee. I am going to focus my remarks on the NIH research efforts involved in one of the components that you mentioned; namely, the development of treatments and prevention in the form of vaccine.

This first poster that I have here up on the board puts into the general context of what West Nile virus is. It is one of a rapidly growing group of diseases that we refer to as emerging and reemerging infections. An emerging is a new infection that we've never experienced before, like HIV/AIDS, SARS or nipa virus, whereas a reemerging infection is one that has been around perhaps for a very long time, but reappears in a different location and in a different form. That is the case with West Nile virus.

Now the NIH has had a headstart on research endeavors with West Nile virus even before we knew it was a problem in this country, because West Nile virus falls under the category of a Flavivirus group, which includes yellow fever, dengue, Japanese encephalitis and others, for which we have had research programs for decades. So when West Nile came along, as you could see on the next slide, we markedly escalated our research resources to approach this problem with an almost tenfold increase from 1998 through 2005, and that allowed us to hit the ground running in looking for ways to intervene, particularly in the form of treatment and vaccines.

With regard to our research agenda, it is multi-faceted. As I mentioned, we now have over $40 million in funding specifically for this particular endeavor of West Nile. We are doing a number of research projects, including the development of animal models. Of course, all that we do is based on fundamental basic research with application where we can do as rapidly as possible. We do some research on vector biology and control, and all are aimed at the application for the development of countermeasure in the form of vaccines, therapies and diagnostics.

Let me just take a moment to point out one of the vaccine programs that's particularly exciting to us. We call it a Chimeric vaccine, named after the Greek mythological figure Chimera, which is an animal that had the body of a goat, the head of a lion and the tail of a serpent; in other words, multiple animals mythologically put together. In a vaccine approach to West Nile we did just that. Since we already had vaccines for yellow fever, which is the same general class as West Nile, we were able to take that vaccine and use molecular approaches to insert the genes of West Nile into the

yellow fever or the dengue virus, which will ultimately cutoff at least several years in the vaccine development process because of this running start that we had.

Next, with regard to therapies we had basic research and targeting our therapeutic approach to vulnerable components of the virus, but also a major screening program where we screened over 1,000 known drugs and compounds in our libraries to see if there's activity. Particularly interesting is a program that's ongoing now where we are passively transfusing into West Nile virus patients in the United States sera, anti-sera antibodies that we have collected from people in Israel because the baseline level of antibodies, because Israel has had a problem with West Nile before we did, that we perhaps would be able to get some degree of protection from those passively transferred antibodies.

And finally, we have a vector control program that's modest in size but it is taking novel approaches to being able to figure out ways to control the principal vector, as Congressman Miller mentioned, the mosquito, which is really a very important issue with regard to West Nile as well as other diseases. We are trying to understand the role of vectors in introducing and maintaining this virus in nature as well as its transmission not only to humans but to other hosts such as horses.

So finally, on this last poster, which shows the headline from last August from the Baltimore Sun, in which it talks about West Nile, both flaring and fizzling, and there's a lesson to that because, as you'll hear from Dr. Ostroff in a moment, that the epidemiology and the pattern of this disease is such that you can have a bad year 1 year and then the next year might be a modest or easy year followed by a bad year. So whatever the flares and the fizzles are, the message that we leave from the research standpoint is that we need to continue and to escalate our research endeavors to ultimately get the appropriate countermeasures, particularly in the form of safe and effective vaccines and therapies that can be safely administered to patients who suffer from West Nile.

Thank you for this opportunity. I'd be happy to answer any questions later.

[The prepared statement of Dr. Fauci follows:]

Testimony
Before the Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs
United States House of Representatives

NIH's Biomedical Research Response to West Nile Virus

Statement of

Anthony S. Fauci, M.D.

Director,
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National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00AM
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Mr. Chairman and members of the Committee, thank you for the opportunity to appear before you today to discuss research conducted by the National Institute of Allergy and Infectious Diseases (NIAID) on West Nile virus. Today I will briefly outline what we know about the basic biology of West Nile virus and summarize our research programs for the development of new vaccines, which will help to limit the number of West Nile cases, and new treatments, which will reduce the human cost the virus exacts from infected people and their loved ones.

West Nile virus is a relatively new threat in this country. As such, it joins the ranks of the many other emerging and re-emerging infectious disease threats we currently face. These include HIV, multi-drug resistant tuberculosis, influenza, and SARS, just to name a few. To these naturally emerging infections, we must now add threats from "deliberately emerging" diseases such as anthrax, smallpox, and plague—diseases that would not pose significant hazards to our society were it not for the possibility that they might be used in a deliberate biological attack. Unpredictable new threats from infectious diseases, whether emerging, re-emerging, or deliberately-emerging, will be with us indefinitely.

The NIAID research portfolio for West Nile virus, therefore, is best understood in the broader context of our comprehensive emerging infectious diseases program. The effort to cope with new and emerging infectious diseases is one of the most important missions of NIAID, and encompasses a significant portion of the

research carried out by NIAID. It involves comprehensive and closely coordinated efforts to identify new threats as they emerge, and to develop the vaccines, treatments, and diagnostic tools that are necessary to confront these new threats.

Basic Research

West Nile virus is a member of the flavivirus family of viruses, which also includes the viruses that cause yellow fever, dengue, and St. Louis encephalitis. It can infect many species of mammals and birds, and even reptiles (e.g., alligators). The virus is transmitted to humans by mosquitoes that have first fed on an infected animal, typically a bird; more than 40 species of mosquitoes are capable of transmitting the virus. About 80 percent of infected people clear the virus before experiencing any symptoms at all. For those who do become ill, mild symptoms begin three days to two weeks after infection, and include fever, malaise, headache, and muscle aches, sometimes accompanied by swollen glands and a mild rash. If the virus enters the central nervous system, it can cause serious illness or death. People with compromised immune systems and people over the age of 50 are at highest risk for such severe outcomes. Recovery from severe illness can be very slow, and cognitive and functional disabilities can linger for months or years after the acute phase; some of the neurological effects—such as paralysis—may be permanent.

When West Nile virus appeared on the East Coast of the United States in 1999, NIAID immediately initiated a program to develop specific countermeasures. Fortunately, we already had in place an active basic research program on flaviviruses that served as a solid foundation for the West Nile virus research effort, and that allowed us to move forward far more rapidly than we could have otherwise. Research funding on West Nile virus has increased approximately ten fold since the virus first appeared in North America. With this infusion of resources, scientific progress over the past five years has been swift.

The development of specific countermeasures to any disease depends on painstaking and detailed basic scientific investigation. To this end, NIAD grantees and intramural investigators are in the process of determining the mechanisms by which West Nile virus causes disease, and are working to understand precisely how viral proteins interact with the human host. They are also studying the genetic and ecological factors that allowed the virus to establish itself in North America, and unraveling the complex interactions between the mosquito vector that spreads the virus and the animal reservoirs that maintain it.

Two recent published studies by NIAID-supported investigators help to illustrate current progress in basic research. In one study, published last year in *Science*, researchers used advanced electron microscopy and image reconstruction techniques to determine the physical structure of the West Nile virus strain that

has spread throughout the United States; this structural information will be of great value in the development of antiviral drugs and vaccines. Another group of researchers carried out a detailed study of the spread of West Nile virus in California since it first appeared there last year; this study has shed light on the mechanisms by which the virus propagates and is maintained in a new environment.

Vaccines

The goal of any vaccine is to prime the immune system to respond quickly and effectively should the vaccinated person ever be exposed to the pathogen against which the vaccine is designed to defend. NIAID scientists are pursuing several strategies to develop a West Nile virus vaccine, one of which already is being tested in humans.

One very promising approach is to create a so-called "chimeric vaccine," based on research that NIAID pioneered more than a decade ago. Just as the chimera of Greek myth was a blend of different animals, a chimeric vaccine is a combination of more than one virus. In the early 1990s, NIAID scientists were the first to show that chimeras can be made from closely related flaviviruses. They then went on to replace genes for the surface proteins of one flavivirus with genes for the surface proteins from another flavivirus, and showed that the resulting engineered chimera could be used as a vaccine. In 2000, NIAID

entered into a fast-track development agreement with the vaccine manufacturer Acambis to develop a chimeric West Nile virus vaccine based on this approach, using a licensed live, attenuated Yellow Fever virus as the starting platform. Testing of the chimeric West Nile virus vaccine candidate in mice, hamsters, horses, and non-human primates indicated that it could protect these animals against West Nile virus infection. Phase I safety and immunogenicity testing in humans is currently under way, with promising preliminary results. If this work proceeds as expected and no adverse side effects are uncovered, this West Nile virus chimeric vaccine could be on the market within the next two to three years. NIAID intramural researchers have also created another chimeric West Nile virus vaccine based on a dengue virus platform, which has been tested successfully in animal models; initial safety and immunogenicity testing in healthy volunteers is awaiting FDA approval.

Another promising vaccine strategy for West Nile virus, called a DNA vaccine, is currently being developed under a Cooperative Research and Development Agreement between the NIAID Vaccine Research Center and Vical, Inc. A DNA vaccine is unique in that it contains no protein or whole virus, but only certain genes from the virus encoded in short sequences of DNA. When these DNA sequences are injected, cells in the host take up the genes, translate them into proteins, and display them on their outer surfaces; circulating immune cells bind to the displayed foreign proteins, and sensitize the host immune system so that it

can mount a fast protective response should the host ever encounter the live virus. Research data suggest that a DNA vaccine containing two West Nile virus genes protects mice against West Nile virus infection. Initial human studies are planned for early 2005, pending FDA approval.

Treatment

Currently, doctors can only offer supportive care for West Nile virus infection; no specific therapy is available. NIAID is pursuing several lines of research to increase the treatment options for the most severe cases of West Nile disease.

One treatment strategy is called passive immunization, in which human antibodies that can bind to West Nile virus particles are injected directly into a patient's bloodstream. A randomized, double-blind clinical trial currently is under way to evaluate whether a mixture of purified human antibodies manufactured by an Israeli pharmaceutical company can reverse or prevent life-threatening cases of West Nile infection. Because this preparation is derived from blood plasma donated by people living in a region where West Nile virus has been endemic for many decades, it contains a significant amount of antibodies specific for West Nile virus. In this study, patients who already have been diagnosed with West Nile neurologic illness, or who are infected and at high risk for developing neurologic illness, are given either the Israeli preparation, a different immunoglobulin preparation that does not contain West Nile antibodies, or a

placebo. Patients in the trial also are being studied in great detail to better understand and delineate the medical course of severe West Nile disease. This ongoing trial began in 2003 at 35 sites, and recently was expanded to more than 60 sites in the United States and Canada with an enrollment goal of 100 patients.

Antiviral drugs are another treatment opportunity, and NIAID is conducting a vigorous program to find promising drug candidates. The program is referred to as the NIAID Preclinical Antiviral Screening Program and is carried out by our Collaborative Antiviral Testing Group. This program screens large numbers of compounds, including drugs already licensed for other uses, for their ability to prevent viral growth in cell culture. Promising candidates are then subjected to further testing in animal models and, if appropriate, human volunteers. To date this program has screened more than 1000 compounds, and has identified 12 candidates that showed significant activity against West Nile virus; these are now being evaluated further in animal models. In addition, several interferons, which are small, antiviral proteins produced by cells when they come under viral attack, and interferon inducers have been identified as possible drug candidates. Although animal testing so far has shown that in order to be effective these interferons must be given before exposure to the virus, further work on these compounds is continuing.

Conclusion

NIAID will continue to pursue its research agenda to combat West Nile virus, and we are hopeful that both an effective vaccine and specific treatments for use in severe cases will be available in the not-too-distant future. It is unquestionably true that the research program on West Nile and other flaviviruses that we had pursued before the virus appeared in the United States was of major benefit; had we been obliged to start the program *de novo*, we would not be nearly as close to our goals as we are today. It is also important to bear in mind that West Nile virus is only one of many emerging, re-emerging, and deliberately emerging infectious disease threats to confront us, and it certainly will not be the last. NIAID's past successes and current strengths make us ready to meet new infectious disease threats that we will inevitably face in the future.

Thank you for the opportunity to appear before you today. I would be pleased to answer any questions that you may have.

Mr. OSE. Thank you, Dr. Fauci.

Our next witness comes to us from the CDC, where he is the Deputy Director for the National Center for Infectious Diseases. Dr. Ostroff, welcome to our subcommittee. You're recognized for 5 minutes.

Dr. OSTROFF. Thank you, Mr. Chairman, and let me thank you as well for holding this hearing to discuss our current efforts to monitor and control West Nile virus. We've submitted a longer written statement for the record.

As mentioned, West Nile was first detected in the United States in 1999 and therefore holds the dubious distinction of being the last of the major emerging infections detected in this country in the 20th century. Through last year there have been more than 14,000 cases reported to the CDC and so far another 1,800 have been reported this year. These are really pretty amazing statistics. For those of us who have followed the saga from the beginning, these numbers are to us much more than statistics. Each represents a name and a face, including people who have experienced very severe illness, some lying in coma for weeks, some paralyzed for months to years. And as was mentioned, for more than 600 of these persons this infection was tragically fatal.

Our hearts and prayers go out to all of these individuals who developed this disease and to the families of those who didn't survive. This commits us to working each and every day to try to prevent additional cases from occurring.

West Nile's natural host is birds. Migratory birds carry it from place to place and mosquitos transmit it from bird to bird. Sometimes instead of biting another bird the mosquitos bite a horse or a human, transmitting the virus to them instead. It is unlikely that we will ever know how the virus was actually introduced into the United States in 1999.

In the first poster you'll see since its introduction West Nile's march across the country has been very steady and relentless. It has swept across the entire continent, leaving wave after wave of illness in its wake during the summer mosquito season.

Next poster. In its first 3 years its impact was fairly modest, but in 2002 as it moved into the Midwest case counts exploded. In the following year the case numbers doubled as the virus moved into the high plains and the Rocky Mountain States.

Next poster. 2004 brings both bad and good news. The bad news is that the virus has continued its western movement principally impacting the Southwest and far West, with Arizona and California being most affected. The good news in the next poster is that the overall disease burden is down significantly from last year, with the number of cases and deaths about half of what we saw at the same time last year.

In addition, in the next poster, illness seems to have peaked quite early in Arizona and has been on the decline ever since. Trends in California are less clear, but appear to be following a similar trend.

CDC has been at the forefront of the efforts to respond to the challenge of West Nile virus in concert with our partners at the State and local level. Our efforts have been multi-faceted. First, using funds allocated by Congress, we have supported all States to

conduct West Nile monitoring, not only for human illness but also for the presence of the virus in birds, mosquitos and other animals. Only by knowing when and where the virus is present can steps be taken to control it.

This effort also revealed unknown routes of transmission, including blood transfusion, leading to rapid steps to protect the blood supply. Starting only last year, we now screen more than 12 million units annually and we estimate that this effort has prevented more than 1,000 West Nile infected units from being transfused.

Second, we have developed diagnostic tests for West Nile and provided them to public health labs throughout the country to speed accurate diagnosis.

Third, we have supported academically based research to address how West Nile survives and spreads, to evaluate the impact of control measures and to optimize these measures. We have also supported academic programs to train experts in mosquito control.

Fourth, we have provided extramural funds to develop model guidelines for sustainable State and local mosquito control programs. In this poster you'll see we've also developed guidelines on all aspects of West Nile prevention and control and update them annually with public health and academic partners.

These guidelines emphasize the fundamentals of mosquito transmitted disease prevention and control in this country: Namely, one, integrated pest management to reduce habitat where mosquitos breed, treat habitats to keep mosquitos from hatching into adults, and control adult mosquitos if they do hatch through EPA approved products; second, educate providers to appropriately diagnose and treat West Nile; and, third, as seen in the next poster, educate the public about what they can do to avoid exposure to West Nile.

Shown here are some examples of posters produced by our partners at the State and local level. They emphasize several important messages: One, reduce breeding sites around the home; two, properly screen windows and doors; three, use DEET containing insect repellent when outdoors; four, reduce skin exposure by wearing long sleeves and pants; and, five, for those at the highest risk of severe disease, such as the elderly, avoid outdoor activities during peak dawn and dusk biting periods.

West Nile has taught us many lessons. It has shown us that we won't be complacent about mosquito control in this country. We don't know what the future holds for this infection, but we do know that everywhere that West Nile has shown up it continues to produce disease season after season. As new vaccines and therapeutics become available for West Nile, we will still need to control and avoid mosquitos. Everyone needs to do their part not only today but also in the future.

Thank you, and I'll be happy to take any questions.

[The prepared statement of Dr. Ostroff follows:]

Testimony
Before the Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs
United States House of Representatives

CDC's Public Health Response to West Nile Virus

Statement of
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U.S. Department of Health and Human Services

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For Release on Delivery
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Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. Stephen Ostroff, Deputy Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention. I am pleased to be here to update you on West Nile virus (WNV) activity in 2004, CDC's public health response to WNV-related illnesses in the United States, and how we work directly with state and local public health officials to address this and other emerging infectious threats. I will also discuss the status of our WNV prevention programs. We thank the Congress for your continued support and recognition of the critical need for a strong and flexible public health system to deal with West Nile virus, and other emerging threats, including bioterrorism.

As a result of major public health efforts, the overall impact of mosquito-borne illnesses in the United States was significantly reduced in the middle of the last century, although mosquitoes that can transmit malaria, dengue, and yellow fever remain. Since then, Americans have not regarded mosquito-borne diseases as a major domestic threat. But the introduction and rapid spread of WNV has changed this. CDC has played an important leadership role in responding to this new threat, principally by rebuilding the nation's capacity to monitor and diagnose mosquito-borne viral diseases through state and local public health partners around the country. 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. Just last year, we were reminded once again that infectious diseases know no borders. In February, CDC began assisting with the global outbreak of Severe Acute Respiratory Syndrome (SARS); then in May, CDC responded to an outbreak of monkeypox imported into the U.S. via African rodents.

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 is 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. The timing of this report is noteworthy, since WNV was recognized in New York City only one year later, highlighting many of the issues it addresses.

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 10 locations around the country. These programs have significantly improved our ability to respond to infectious disease emergencies. Resources for bioterrorism preparedness and response have also substantially bolstered capacity at the state and local level.

West Nile Virus

WNV is a mosquito-borne flavivirus 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. Individuals aged 50 or older 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 dramatic introduction and spread across the United States of a disease not previously seen in the Western Hemisphere reinforces the importance of rebuilding the public health system to prevent and respond to potential future introductions of other emerging infections.

WNV was first recognized in the United States in late August 1999 in New York City.

Eventually, 62 cases of human WNV- illness were identified that year. A randomly conducted household survey where residents were asked to provide blood specimens was conducted in the fall of 1999 in the New York City borough of Queens. The human infection rate was 2.6% - indicating that as many as 8,000 New York City residents had been infected with WNV. Subsequently, WNV-infected mosquitoes were trapped in New York City during the winter of 2000. This result suggested that WNV had established itself in the United States and was likely to expand its geographic range.

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 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. Continued genomic analysis of WN viral isolates since 1999 indicates that even though the virus has expanded throughout the United States, it has remained genetically stable. This information is important when designing vaccines, assays for diagnosis and possible therapeutic interventions.

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. In 2001, WNV transmission expanded into the south with an epicenter of activity in Florida and Georgia. In total, 359 counties in 27 states and Washington, DC, reported WNV activity, including 66 human illnesses, to ArboNET -- a web-based, real-time surveillance data network maintained by 57 state and local public health agencies and CDC.

The geographic range of WNV expanded greatly in 2002 and 2003, ending up at the front range of the Rocky Mountains. In 2002, 4,156 human WNV-infections were reported, and in 2003, 9,858 human WNV-infections were reported. The rapid spread and increased human activity of WNV in 2002 and 2003 were likely the result of permissive conditions for virus transmission and the fact that WNV reached the areas of the country that are historically at high risk for large outbreaks caused by other epidemic flaviviruses, such as St. Louis encephalitis.

In concert with the increased case counts, new routes of WNV-transmission were identified in 2002. These included WNV transmission through transfusion of contaminated blood products, breast feeding, and possible intrauterine infection of babies during pregnancy. The discovery of transfusion-associated transmission of WNV resulted in the initiation of nationwide screening of the blood supply since July

2003. Development and implementation of the blood screening processes resulted from a very successful collaboration between federal public health agencies, state public health officials, blood collection agencies, and private industry that implemented rapid assays for detection of WNV-contamination in blood specimens. More than 12 million blood donations are now screened for WNV each year. Since screening began, 1000 presumptively viremic donors have been reported to CDC. CDC continues to work with partner agencies and organizations to identify the best approaches to use in the future to ensure the safety of the blood supply. It is believed that at least 800 transfusion-associated human WNV-infections were averted in 2003 because of the blood screening protocols currently in place.

Current West Nile Virus Spread

This year, WNV infection has continued to expand geographically; it now covers all of the continental United States, with the greatest activity in highly populated areas of Arizona and southern California. As of October 1 2004, surveillance in humans, birds, mosquitoes, and horses has detected WNV activity in 47 states and Puerto Rico. Among the 1821 human patients for whom data are available, the median age was 51 years (range 1 month to 99 years); 58% were male. A total of 59 human deaths have been reported. Building on lessons learned from previous years, CDC activated our emergency operations center to assist the states in improving their outreach and communication campaigns. 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.

Public Health Response

As WNV continues to spread geographically, the federal and state public health response continues to evolve. CDC has been the lead federal agency to respond to the WNV outbreak in humans. Much progress has been made in monitoring and managing the epidemic over the last few years. Since fiscal year 2000, DHHS and CDC have provided more than $100 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 2004, approximately $23.6 million was awarded to those public health agencies to address the continued spread of the virus.

CDC has provided extramural funding to other federal agencies for related WNV surveillance and diagnostic activities in support of the states. In addition, CDC funds university-based research grants to support studies on WNV distribution, pathogenesis, clinical outcome, and variability. CDC continues to fund cooperative agreements with four universities to provide trained entomologists, biologists, and other vector-borne specialists for the WNV public health response. Finally, CDC has undertaken an aggressive intramural research program in several scientific areas to address the long-term needs related to epidemic WNV.

In collaboration with our partners, CDC has developed public and professional health education strategies to confront the WNV problem. The "Fight the Bite!" campaign recommends prevention measures for individuals to reduce their risk of exposure to WNV by: 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.

This year CDC provided specific support for California and Arizona, the two states hardest hit with WNV epidemics. Over one million dollars in supplemental funds were distributed to Arizona and California. These funds support mosquito control activities in Arizona. In California these funds will help enhance WNV surveillance activities, supplement human and dead bird testing, and will support a WNV public health education campaign.

In preparation for the expansion of WNV activity to the western United States, 2 years ago CDC initiated activities that continue to support WNV prevention and control activities in California. CDC funds the California State Health Laboratory as a regional WNV testing center for the Western United States. This funding ensures that California develops and sustains state of the art testing technology and increases their

capacity for large scale WNV testing. CDC WNV funding also supports the Border Infectious Disease Surveillance Project, which strengthens laboratory infrastructure and capacity to perform WNV diagnostic testing in Mexico border laboratories. To complement this surveillance project, CDC funds a collaborative project between Imperial County and Baja California health authorities to develop mosquito-borne disease prevention strategies and educational tools appropriate for residents in the US-Mexico border regions.

In addition to the specific WNV prevention and control activities outlined above, the following are some additional national measures that CDC has implemented since the first WNV outbreak five years ago:

- developing and commercializing diagnostic tests for use at state laboratories to identify WNV in humans, 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 and revising consensus guidelines for the surveillance, prevention, and control of WNV;

- working with the Association of State and Territorial Health Officials to collaborate with state and local health departments in the development and distribution of consensus recommendations for sustainable mosquito control programs;
- performing registry studies of birth outcomes among women with WNV infections during pregnancy;
- evaluation of pesticide resistance in mosquito populations;
- developing educational materials for health care providers on the clinical aspects and diagnosis of WNV infection as well as public education materials;
- providing routine technical assistance during WNV season through bi-weekly conference calls for all state and local health departments to discuss the current status of WNV in each respective jurisdiction;
- collaborating with 4 states to evaluate health impacts and monitor pesticide levels in residents to determine whether mosquito-control spraying during the West Nile epidemic increases the amount of pesticides to which people are exposed;
- conducting a feasibility study to determine the impact of mosquito control in two cities in 2003; and
- collaborated with FDA to develop guidance on "Recommendations for the assessment of donor suitability and blood and blood product safety in cases of known or suspected West Nile virus infection".

Conclusion

In conclusion, addressing the threat of emerging infectious diseases such as WNV depends on a flexible and responsive 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.

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

Reported Human West Nile Virus Infections
United States 1999-2003

Year	No. cases	No. states	No. counties
1999	62	1	6
2000	21	3	10
2001	66	10	39
2002	4,156	39*	740
2003	9,858	45*	1,081

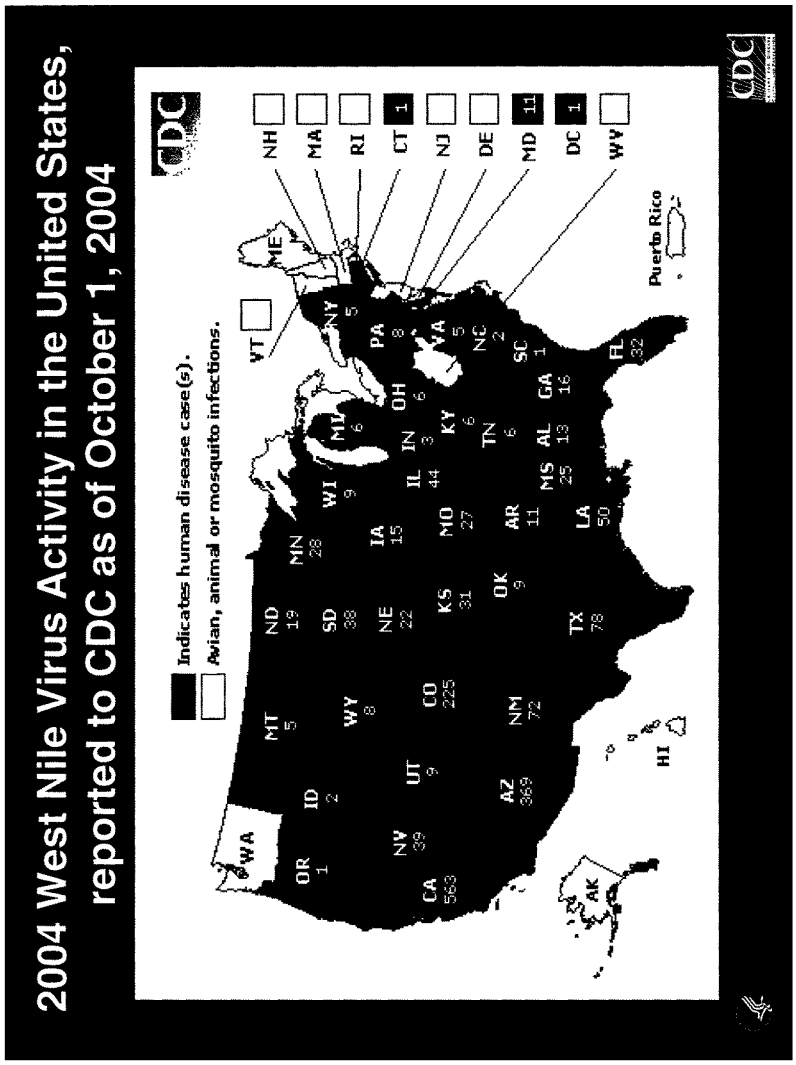
*Plus D.C.

West Nile Virus National Data Overview

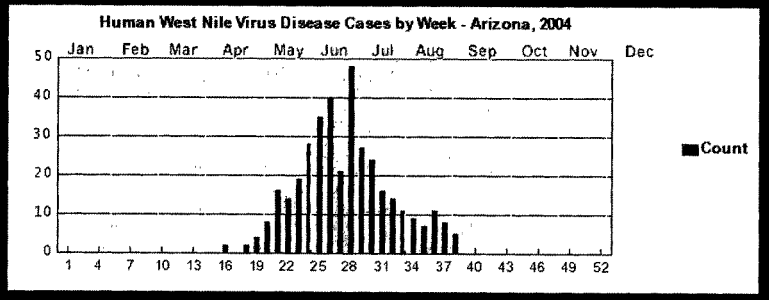
(Cases reported as of Oct 1, 2004, and Oct 1, 2003)

Cases reported	2004	2003
Total	1821*	5861
Deaths	59	115

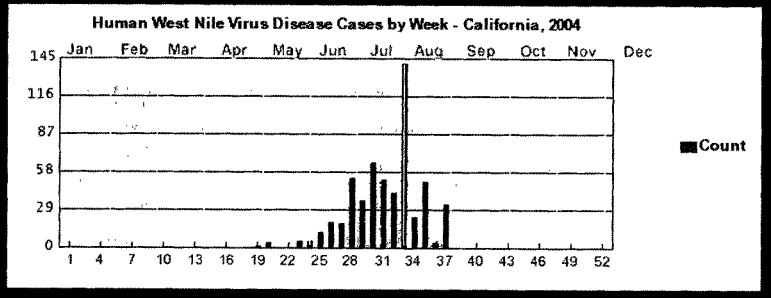
* Arizona (369), California (563), Colorado (225)


2004 West Nile Virus Activity in the United States, reported to CDC as of October 1, 2004
CDC
Indicates human disease case(s).
Avian, animal or mosquito infections.
WA
OR 1
CA 563
NV 39
ID 2
MT 5
WY 8
UT 9
AZ 369
CO 225
NM 72
ND 19
SD 38
NE 22
KS 31
OK 9
TX 78
MN 28
IA 15
MO 27
AR 11
LA 50
WI 9
IL 44
MS 25
MI 6
IN 3
KY 6
TN 6
AL 13
OH 6
GA 16
FL 32
SC 1
NC 2
VA 5
PA 8
NY 5
VT
ME
NH
MA
RI
CT 1
NJ
DE
MD 11
DC 1
WV
Puerto Rico
AK
HI
CDC

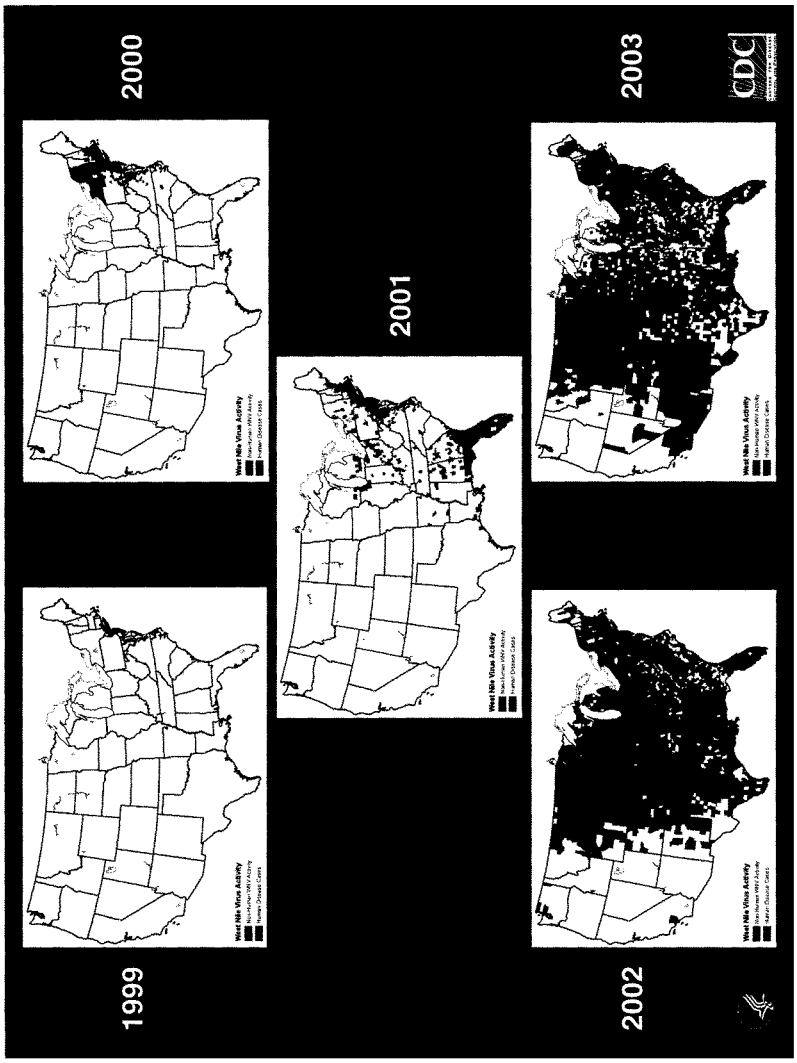
2004 Human Cases of WNV, by Week of Onset, reported to CDC as of Oct 1, 2004



Arizona



California


1999
2000
2001
2002
2003
CDC

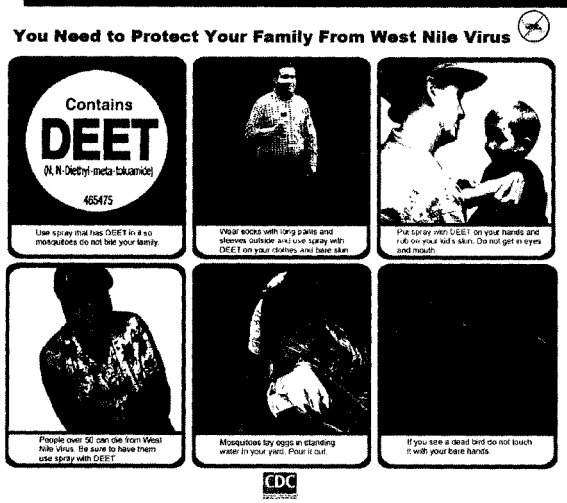
Centers for Disease Control and Prevention

Epidemic/Epizootic West Nile Virus in the United States: Guidelines for Surveillance, Prevention, and Control

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention
National Center for Infectious Diseases
Division of Vector-Borne Infectious Diseases
Fort Collins, Colorado
3rd Revision

2003

http://www.cdc.gov/ncidod/dvbid/westnile/index.htm



CDC


FIGHT THE BITE!
PROTECT YOURSELF AGAINST WEST NILE VIRUS
Defend yourself against mosquitoes.
DRAIN standing water around the house weekly since it's where mosquitoes lay eggs, including: tires, cans, flowerpots, clogged rain gutters, rain barrels, toys and puddles.
DUSK & DAWN are when mosquitoes that carry the virus are most active, so limit outdoor activities or take precautions to prevent mosquito bites.
DEET is an effective ingredient to look for in insect repellents. Always follow label instructions carefully.
DRESS in long sleeves and pants during dawn and dusk or in areas where mosquitoes are active.
WEST NILE VIRUS disease is rare, but if you have symptoms including high fever, severe headache and stiff neck, contact your health care provider immediately.
Toll-Free California Helpline
1-877-968-2473
San Joaquin County
West Nile Virus Task Force
www.sjgov.org/oes or (209) 468-8200
Used with Permission, Copyright 2004. Courtesy of www.FightTheBiteColorado.com.
Prevent West Nile Virus
Eliminate common backyard mosquito breeding sources.
Neglected swimming pool
Open boat
Clogged gutters
Broken screens
Poorly maintained pond (Stock with mosquito larvae-eating fish)
Items that hold water for more than a few days
Leaky watering equipment
Birdbath (Change water twice a week)
Protect yourself from mosquito bites:
• Avoid outdoor activity during peak mosquito times – dusk to dawn
• Wear long, loose, light-colored clothing
• Use insect repellent when outdoors after sunset
For more information, visit the Arizona Department of Health Services web site: www.hs.state.az.us
YOU CAN...
Fight the Bite!
West Nile Virus
Remember the "Five D's" to defend yourself against West Nile virus.
DRAIN standing water in your backyard and neighborhood. Old tires, flower pots and clogged rain gutters are mosquito breeding sites.
DEET is a safe ingredient to look for in your insect repellent. Follow label instructions, and always wear repellent when outdoors.
ORANGE COUNTY HEALTH CARE AGENCY
ochealthinfo.com
Fewer than 1 percent of those bitten by infected mosquitoes become severely ill. If you have symptoms that include stiff neck, high fever or severe headache, contact your health-care provider immediately.
CDC

Mr. OSE. Thank you, Dr. Ostroff.

Our third witness on the first panel is Mr. Benjamin Grumbles. He's the Acting Assistant Administrator for Water at the U.S. Environmental Protection Agency. Sir, welcome.

Mr. GRUMBLES. Thank you.

Mr. OSE. Welcome back. Nice too see you. You're recognized for 5 minutes.

Mr. GRUMBLES. Thank you, Mr. Chairman and Congresswoman Miller. It is an honor and a pleasure to be here to represent EPA. I am the Acting Assistant Administrator for the Office of Water, and I am joined by Adam Sharp, who is the Associate Administrator for the Office of Prevention, Pesticides and Toxics.

Mr. OSE. If I recall, he was one of those who rose to be sworn in.

Mr. GRUMBLES. Yes, that's correct.

Mr. OSE. Thank you.

Mr. GRUMBLES. And Adam also has formerly served as the Acting Counselor on Agricultural Issues for the Administrator, so he brings a wealth of knowledge to the table.

Mr. Chairman, I would like to talk briefly about the role of the EPA in ensuring the protection of public health and the environment, particularly in the context of mosquito control and pesticide and clean water programs. I'd like to ask that the prepared testimony be entered as part of the record.

Mr. OSE. Without objection.

[The prepared statement of Mr. Grumbles follows:]

TESTIMONY OF
BENJAMIN H. GRUMBLES
ACTING ASSISTANT ADMINISTRATOR FOR WATER
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES AND REGULATORY AFFAIRS
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

October 6, 2004

Introduction

Good morning, Mr. Chairman and members of the Subcommittee. I am Ben Grumbles, Acting Assistant Administrator for Water at the U.S. Environmental Protection Agency (EPA).

I am pleased to have the opportunity to discuss EPA's role in public health mosquito control. I would like to explain our role in informing and educating the public on ways to control mosquitoes and I would also like to discuss the current guidance on the National Pollutant Discharge Elimination System under the Clean Water Act (CWA). I am accompanied today by Adam Sharp, Associate Assistant Administrator of the Office of Prevention, Pesticides, and Toxic Substances, who will assist on pesticide-specific issues. EPA is pleased to appear today with Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH) – our federal partners in public health issues.

Federal Pesticide Regulatory Program

The Environmental Protection Agency is responsible for protecting human health and the environment from potential pesticide risks and ensuring that pesticides meet today's more stringent safety standards and offer benefits to society. Under the statutory framework of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), EPA regulates the sale, distribution, and use of pesticides in the United States. Before registering (licensing) a new pesticide or new use for a registered pesticide, EPA ensures that the pesticide, when used according to label directions, can be employed without posing unreasonable risks to human health and the environment. All pesticides must undergo a rigorous registration procedure where EPA assesses a variety of potential human health and environmental effects associated with use of the product. The producer of the pesticide must provide data from tests done according to EPA guidelines. The Agency is also continuing to review older pesticides – those initially registered prior to November 1984 – to ensure that they meet current scientific and regulatory standards under a process called reregistration. Reregistration considers the human health and ecological effects of pesticides and results in actions to reduce risks that are of concern. EPA also is reassessing tolerances – pesticide residue limits in food – to ensure that they met the safety standard established by the Food Quality Protection Act of 1996 (FQPA).

Limiting Mosquito-borne Diseases

Mosquito-borne diseases such as malaria, dengue fever, and West Nile virus, affect millions of people worldwide each year. Since it first appeared in the United States in 1999, West Nile virus has spread to nearly every State. The spread of West Nile virus has brought increased attention to public health mosquito control activities. In 2003, there were more than 9,800 reported human cases of West Nile virus in the United States reported to CDC. As of September 24, 2004, more than 1,600 cases have been reported to CDC.

The Environmental Protection Agency's role in public health mosquito control is to ensure that State and local public health departments and vector control agencies – the mosquito control professionals front lines – have access to effective mosquito control tools that they can use without posing unreasonable risk to human health and the environment. EPA also encourages nonchemical mosquito prevention efforts, such as eliminating standing water around the home that provides breeding sites. Through its outreach efforts, the Agency also empowers the public by promoting an understanding of mosquitoes, the benefits of control measures and the public's role in preventing mosquito-borne diseases. EPA also believes it is important that the public be notified and informed when vector control professionals are applying pesticides so individuals can take appropriate precautions to reduce their exposure. We encourage consumers to read the label directions and precautions for the proper use of insect repellents and insecticides.

EPA provides much of its outreach and technical support through its Web pages with information about mosquito control and pesticides that may be used in control

programs. EPA's fact sheet on controlling mosquitoes around the home registered more than 37,700 hits from April through August of this year. EPA's regional field activities have established a network with State and local health officials to maximize communication and cooperation. Other EPA regional activities have included monitoring product composition, environmental monitoring of ambient water bodies, and surveillance of ground and aerial applications of pesticides.

EPA promotes integrated pest management (IPM) techniques. IPM is an effective and environmentally sensitive approach to pest management that relies on a combination of commonsense practices. IPM programs use current and comprehensive information on the life cycles of pests and their interactions with the environment. This information is used in combination with available pest control methods, by the most economical means, and with the least possible hazard to people, property, and the environment. IPM programs take advantage of all pest management options possibly including, but not limited to, the judicious use of pesticides.

Mosquito control officials seek to reduce the source by eliminating the habitat or modifying the aquatic habitat to prevent mosquitoes from breeding. This includes sanitation measures where artificial containers, such as discarded automobile tires or anything else that can collect water and become mosquito habitats, are collected and properly disposed. Habitat modification may also involve management of impounded water or open marshes to reduce production and survival of the flood water mosquitoes. Mosquito control officials often apply biological or chemical *larvicides* to the aquatic habitats. To have the maximum impact on the mosquito population, larvicides are applied during those periods when immature stages are concentrated in the breeding

sites and before the adult forms emerge and disperse. Modifying or eliminating the habitat, combined with proper use of larvicides, can reduce or eliminate the need for *adulticide* applications. Adulticides are applied by truck-mounted or aircraft-mounted sprayers that dispense very fine "ultra-low volume" aerosol droplets that kill mosquitoes on contact. Adulticides are short-term solutions for when source reduction and larviciding have been inadequate or not feasible. With resources for information and an availability of effective tools, the public health officials can make the right choices that will protect human health and the natural environment.

Storm Water Ponds

Storm water retention ponds have received attention regarding their potential as breeding grounds for mosquitoes. Storm water retention ponds (both wet and dry) represent one important class of controls that are used to address storm water runoff. These ponds are beneficial in that they provide a high level of flood control and storm water treatment, have relatively low maintenance requirements, and are practical for areas with high water tables or poorly percolating soils. Properly designed, operated, and maintained ponds do not contribute to significant increases in mosquito populations. Guidance for wet pond design often suggests a minimum pool depth and establishment of predacious native species in the area such as dragonflies and mosquito fish to help control insect populations. Pesticide application is typically viewed as a last resort to control insects on these basins.

Regulatory Update

EPA's pesticide regulatory programs evaluate the safety of all pesticides to ensure that they meet stringent health and environmental standards required today for pesticides. For all mosquito control products, as well as any other pesticide, registration is the process through which EPA examines: the ingredients of a pesticide; the intended application site and directions for use; and, supporting scientific studies for human health and the environmental effects and exposures. The Agency is also required by law to reassess the potential human health and ecological effects of pesticides registered prior to November 1984, and take regulatory action to eliminate unreasonable risks. EPA is currently re-evaluating pesticides employed in public health mosquito control programs to determine if any changes in pesticide use are necessary. In reassessing these products, the Agency applies the most current scientific standards, and gives special consideration on potential exposure risks to children who may be more vulnerable to risks from pesticides.

We are also taking steps to improve the label language on pesticide products used in wide-area application for the control of adult mosquitoes. The new language will help public health and vector control officials optimize mosquito control techniques while ensuring that use of these products will not pose unreasonable risks to public health or the environment.

The EPA-sponsored National Pesticide Information Center (NPIC), staffed by scientists, continues to respond to West Nile virus inquiries. In 2003, NPIC received 1,817 calls related to West Nile and mosquito control. As of August 2004, NPIC has responded to more than 1,300 inquiries. Furthermore, NPIC's West Nile Virus

Resource Page registered 182,000 hits in 2003 and currently has had more than 104,000 hits in 2004.

Building Partnerships for New Tools

Recognizing the expanding need to develop new tools to respond to potential public health threats, EPA recently met with representatives from Department of Defense (DOD), Department of Agriculture (USDA), Agency for International Development (USAID), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) to facilitate cooperation and coordination among the federal agencies involved in public health pesticides. The new committee discussed ways to pool resources, share information, and encourage development of new techniques and products. Both DOD and NIH are devoting resources to research new methods of control, including finding public health uses for pesticides that are already registered for other purposes. Also participating were representatives from the USDA-sponsored Interregional Research Project No. 4 (IR-4) whose experience with reduced-risk pesticides and information on "minor uses" in agriculture could lend the group expertise in developing similar "minor-use" registrations of pesticides for public health purposes. The committee is scheduled to meet again in December to continue addressing the need for new public health pesticides as efficiently and effectively as possible.

Working with this committee is EPA Pesticide Program's Public Health Official who helps to ensure implementation of the public health and aggregate risk provisions of pesticide laws. The Public Health Official serves as liaison between the Pesticide

Program and other Federal agencies and actively participates in regulatory activities pertaining to public health pest control issues.

Pesticides and the National Pollutant Discharge Elimination System

EPA recognizes that in the recent past questions arose about the appropriate role of the Clean Water Act in addressing application of pesticides to water, including for mosquito control. CWA prohibits anyone from discharging pollutants through a "point source" into waters of the United States unless they have a National Pollutant Discharge Elimination System (NPDES) permit. The NPDES permit involves limits on what can be discharged, monitoring and reporting requirements, and other provisions to ensure that the discharge does not adversely affect water quality or people's health. The permit specifies general requirements of CWA provisions tailored to activities that discharge pollutants.

Applying pesticides is lawful under FIFRA so long as the application is done in a manner consistent with the pesticide's label instructions. Pesticide labels generally do not require that applicators obtain NPDES permits before using pesticides, including those pesticides that contain label directions allowing direct application to bodies of water. Recent citizen lawsuits have further focused attention on this matter. In addressing these concerns, the Agency, in 2003, issued an guidance on circumstances under which NPDES permits are not required for applying pesticides to water. The guidance states EPA's position that, for pesticides applied to waters of the United States in compliance with FIFRA, an NPDES permit is not required in two circumstances:

"(1) The application of pesticides directly to waters of the United States in order to control pests. Examples of such applications include applications to control mosquito larvae or aquatic weeds that are present in the waters of the United States.

(2) The application of pesticides to control pests that are present over waters of the United States that results in a portion of the pesticides being deposited to waters of the United States; for example, when insecticides are aerially applied to a forest canopy where waters of the United States may be present below the canopy or when insecticides are applied over water for control of adult mosquitoes."

At the time we issued this guidance, the Agency solicited public comment, and is currently in the process of reviewing those comments. The Agency is evaluating ways to ensure that FIFRA and CWA continue to achieve important environmental goals and to advance the protection of public health while reducing potential areas regulatory confusion.

In closing, Mr. Chairman, I would like to thank you and the Subcommittee for inviting EPA to participate in this hearing. We look forward to working with you and our partners from the CDC and NIH to continue this important work of environmental protection while increasing protection of public health. Adam and I would be happy to answer any questions that you may have.

* * *

Mr. GRUMBLES. I would like to note that when my staff prepared the talking points for that they had a parenthetical after that said "pause," and I looked at that and I thought it said "applause." And as a former committee staffer, I know that what really was an applause line was when the witness asked for their whole eloquent statement to be submitted for the record. So I appreciate that. I would just like to focus on a couple of points.

One is the role of the agency in the registration of pesticides and carrying out the responsibilities under FIFRA. But I want to focus on integrated pest management. Then I also want to mention the integration of the statutes, FIFRA and the Clean Water Act.

Congressman Tierney talked about the need to reconcile the two statutes and we feel that it is a positive effort to integrate the statutes to get both protection of public health and the environment and to do so in a responsible way.

Also, integrated pest management, certainly EPA feels very strongly that is an appropriate path, that is the right approach. This means effective and environmentally sensitive management of pesticides using common sense measures. It involves going through a process where we really focus in on the source for the potential spread of the disease, and that often means habitat alteration and looking at those issues of standing water and things of that type. It is also very important to focus in on the early stages, whether it is the egg or the pupa or the larva, as the prime opportunity to eradicate and prevent the spread of adult mosquitos and the disease.

We take very seriously our responsibilities under FIFRA and the importance and the safeguards that the registration and reregistration and labeling process provide for both effective use of pesticides to protect public health and the environment and also ensuring enforceable and appropriate environmental safeguards. On the integration issue that you raised in your statement regarding the Clean Water Act, the agency did in fact issue a guidance. It was effective immediately, July 11 of last year, and it is important to emphasize that the guidance says: and we believe it is clear—that in certain situations Clean Water Act permits—NPDES permits—are not required and that the basis for that and the whole intent there is to make sure that the statutes are integrated and not always dueling or requiring two Federal approvals.

We don't want to stand in the way of appropriate use of pesticides. So the guidance specifically says that for the direct application of pesticides, direct application to waters of the United States, in accordance with all the relevant requirements under FIFRA. In that situation you do not need a Clean Water Act permit.

Also, in application directly over waters such as to control for aerial spraying like over the canopy of a forest, or also aerial spraying for, you know, adulticide, to nip that problem in the bud. Again, if that's carried out in accordance with FIFRA—all relevant FIFRA requirements—our view, our interpretation of the Clean Water Act is that a NPDES permit is not required.

We also issued guidance in September last year, the general counsel of the agency, addressing other cases and situations about point sources and when is and isn't a pesticide a point source.

The last point I want to make, Mr. Chairman, is that we continue to focus on reviewing the various facts and circumstances, making sure that guidance and the comments we have received on that guidance are reviewed. We are committed to ensuring through partnerships with other Federal agencies and through our Clean Water Act and FIFRA program responsibilities that we have a system where we have both protection and public health in the environment and not dueling programs or statutes.

Thank you, Mr. Chairman. Adam and I'd be happy to respond to any questions you or your colleague may have.

Mr. OSE. Thank you. I appreciate your attendance and participation. I am going to go ahead and claim time. I want to go back to your July 11 guidance.

Now, it is my understanding that guidance document was issued in the context of *Altman* v. *Town of Amherst.* In that case, the court opined that EPA needed to articulate a clear interpretation of the law. Since the guidance was issued, we still have a little bit of a divergence between how some States are treating EPA's guidance, and how others, in particular the States of Washington and California, have maintained that under the Talent case the Ninth Circuit's decision still requires them to get an NPDES permit for application of the chemical.

The first question I have is do you agree with California and Washington's decision to mandate NPDES permits for use of pesticides to combat the West Nile virus?

Mr. GRUMBLES. Mr. Chairman, I respect their decision to mandate permits. I don't believe that they are legally required and our interpretation of the statute in the Talent case and the other cases, coupled with our guidance, we believe that it is their discretion to choose to issue permits for pesticide applications. But it is not our interpretation that they are legally required or mandated to do that.

Mr. OSE. And again, this is for the very narrow purpose of mosquito abatement?

Mr. GRUMBLES. Right. And specifically, for the—what I am referring to is the two situations that we squarely address in our interim guidance. That is the direct application to waters of the United States of pesticides, and also application directly over waters such as when you have adulticides that you're spraying or——

Mr. OSE. So there's two different tests there at least. There's the mosquito abatement purpose and then there's the waters of the United States or the aerosol treatment over waters of the United States or in a canopy.

Mr. GRUMBLES. I think rather than focusing just on the purpose, it is the actual use. I mean, we want to make sure that we look not just to what the purpose of the applicator is, but how the applicator ends up following through on that purpose. If they use their pesticide, apply it in accordance with all relevant FIFRA requirements and it is in the context of a direct application to waters, or an application of pesticides directly over waters of the United States, then we believe a NPDES clean water permit is not required.

Mr. OSE. All right. I guess one of the questions I have is, at least in California, native of California who lives in California. I noticed

on one of the maps up there the dot matrix or the tracking system from 1999 to 2003. Frankly, the map didn't show a large population in California as yet. I am trying to get to some degree of certainty that my State can have a reasonable chance of forestalling an outbreak of this disease.

Now, how do we reconcile EPA's determination, which arguably is very narrow in scope, with California's basis for requiring an NPDES permit? There's some sort of disconnect and I don't quite understand what it is. Is it based on the Ninth Circuit's determination? Or is it something beyond that, that's not legally driven but driven perhaps from the State level?

Mr. GRUMBLES. I think it may be a combination of things, Mr. Chairman. Our view is that the interim guidance does specifically address not just the Altman case in New York, but also the Talent case, that situation. Now, one of the most important components here to keep in mind is that the Clean Water Act, a bedrock principle of the statute, is that the States always have the flexibility to have additional requirements that are more protective than, are broader in scope than the Federal requirements. I think there is a conscious effort by the State to choose to interpret the guidance and also to use the permits, the general permits or a permitting program as a tool in their toolbox. So I think that there are a variety of factors that are in play there.

Our basic position, Mr. Chairman, is that when you look at those situations, direct application into waters of the United States of pesticide or application directly above to deal with like adulticide, adult mosquitos, if the applicator is following their requirements under FIFRA, we do not see the need for—we don't think that legally the Clean Water Act would require a permit because the pesticide is not a waste. It is a product that's being used in accordance with Federal requirements.

Mr. OSE. My time's expired. The gentlelady from Michigan.

Mrs. MILLER. Thank you, Mr. Chairman. You were talking about States in regards to permits and that. But I am wondering how each of your agencies interacts with the various States on West Nile. It is great for us to sit here in Washington and talk about the West Nile virus. But it is really for the individuals right out into the neighborhoods to identify what is happening out there, and I have to show off a little bit for my State, I think, in Michigan. I mentioned to you that, you know, a couple of years ago, several years ago no one had ever heard of West Nile before. And I'll tell you, in our State it is a household word now. Everybody is well aware of the dangers of it. In fact, there's sort of a subtle paranoia, I think, that has set in in the psyche of many mothers watching their children and making sure that they are—and Dr. Fauci was mentioning some of the various therapies and that. But I think sort of the old therapies of just wearing long sleeves and long pants and trying to protect yourself, putting on your pesticides, insecticides I should say, and all these kinds of things probably work well. I guess my question is how you're working with the different States.

I mentioned to you that we have this Web site, and if you've not had an opportunity to look at it you might want to do that. I don't know what the other States are doing. I can only speak for our own State. But of course we are all a society now that is so much more

using the electronic format to access information. And this is a fantastic Web site. You can go on here and it tells you how to report a dead bird, a sick bird or a mammal, and then it actually gives you a bird identification page and the kinds of birds that might have the West Nile virus, the different kinds that you might—you're looking at a starling and you think it is a crow and all of these kinds of things, and then goes right into a site where the individual citizen would fill out their date of observation, when they observed this, what kind of thing they think they saw there and whether it was dead or they think it is sick and etc. If they want to have a lab come out and take a look at these sites. I just think it is a fantastic way to get information out into the public, and again, I am just wondering from the Federal Government's standard, from the agencies here, how are we doing? Are we doing similar kinds of things? Are your agencies doing similar kinds of things on the Web? Are you working with the States?

Dr. FAUCI. The direct involvement with the State and local public health officials is fundamentally the basis of how the Centers for Disease Control and Prevention interacts with the community. The National Institutes of Health, being fundamentally a basic and clinical research organization, is much more national and nonsegregated into States. So what we do is generically applicable to each of the States, and we fund grants and contracts. Clearly that are individuals that might be in State funded institutions, but it isn't directly related to a State function; whereas the CDC, as I am sure Dr. Ostroff will delineate for you, is much more connected to the State and local public health officials.

Dr. OSTROFF. Thanks, Dr. Fauci, and thank you, Congresswoman, for that question. Indeed, as was pointed out, one of our primary partners, if not our primary partner, are the State and local health departments. West Nile was first recognized in 1999; the following year we received an appropriation from Congress specifically to address the problem of West Nile virus in the United States. That allocation has gone up each year since, but has now plateaued. More than 50 percent of those resources have gone directly to the various State health departments to support specifically the activities that you mentioned, particularly monitoring, not only in humans, but also for dead birds, etc., to produce educational materials, to develop the Web site and to support the State public health laboratory in being able to do the diagnostic tests that are necessary to test those birds, to test humans who may conceivably have the disease.

Our resources specifically to the State of Michigan, as the virus moved to the West from its original focus in New York, went up in concert. They reached a peak in 2002 and 2003 of about $800,000 per year, specifically to Michigan, to support the various activities that I just described.

In addition, we keep in very close contact with the States. All of the States report in to our surveillance system, not only findings in humans, but finding in birds, finding in mosquitos, finding in humans and findings in horses. We produce updates that are published every week in terms of what's going on in the country, and we also hold weekly conference calls with all of our State partners

where they share information with all of the other States to tell them what's going on within their jurisdictions.

So we do have a fairly extensive program to support their activities. And last, if there are any unusual things going on in the State of Michigan or if they need specific technical support we actually send teams to work with them.

Mrs. MILLER. If I could followup on that just a bit, Doctor, as well, you mentioned in your remarks that you had a number of academic partners. And again, just from my own personal experience in Michigan we've actually put together a West Nile working group. Michigan State University is a critical element in that and I know the University of Michigan and some of the other universities as well. Could you expand a little bit on—some of our best research obviously is being done out in the universities, the campuses across our Nation. Are we bringing all of them into—utilizing them and advantaging ourselves of all of them as much as we need to?

Dr. OSTROFF. Well, actually in late 2002, which you pointed out was the worst year for Michigan, at the end of that year I actually went to the University of Michigan and gave medical grand rounds specifically on West Nile virus. We have a very close working relationship with the faculty of the Infectious Disease Division in the Department of Medicine, University of Michigan. We also have a very close working relationship with Michigan State University on veterinary issues, and you are indeed correct. There is superb capability to address West Nile. I do not know if any of the specific academic grants that we have related to West Nile go to the State of Michigan, but we can certainly find out.

Dr. FAUCI. You made the point that a substantial proportion of the research is done at the universities. As a matter of fact, the vast, vast majority of the research. If you look at the NIH funding, we only have about 10 percent of our research resources goes to our intramural program, which is fundamentally here in Bethesda, Maryland, and 85-plus percent of the money goes out to the universities. And we do have networks in coordination among them, particularly when we have interconnecting centers.

Particularly with West Nile, for example, we have the World Reference Center for Research Resources to allow investigators from throughout the country and even the world to have access to resources to do the research. That's located at the University of Texas Medical Branch at Galveston. We also have collaborating emerging disease research centers, one in New York, one in Texas. So the local universities is really where we do our business with regard to research in this country.

Mrs. MILLER. Thank you. I think my time is up, Mr. Chairman.

Mr. OSE. We'll have another round. The gentleman from Massachusetts.

Mr. TIERNEY. Thank you, Mr. Chairman. Mr. Grumbles, I want to just focus in with you for a couple of seconds on the issue of the Clean Water Act if I could. I know back some time ago that the EPA filed an amicus brief in a case called *Headwaters Inc.* v. *Talent Irrigation District in the Ninth Circuit.* In that brief, the position of the EPA was that nothing in FIFRA or the Clean Water Act remotely suggests that compliance with FIFRA also means compli-

ance with the CWA. The agency's brief highlights the distinct purposes of the two statutes and recognizes FIFRA's inability to adequately address the environmental effects.

Here's specifically what the language in that brief said. "In approving the registration of the pesticide, EPA concluded that the overall economic benefits of allowing the use of the product outweigh adverse environmental effects. EPA did not analyze, was not required to analyze, and could not feasibly have analyzed, whether, or under what conditions, the product could be discharged from a point source into particular public water bodies in compliance with the CWA. In approving the registration of Magnicide H, EPA did not warrant that a users compliance with the pesticide label instructions would satisfy all other Federal environmental laws. Indeed, EPA approves pesticides under FIFRA with the knowledge that pesticides containing pollutants may be discharged from point sources into navigable waters only pursuant to a properly issued CWA permit."

What is the basis for EPA's change of position from that point?

Mr. GRUMBLES. Mr. Chairman—Congressman, you made a strong reference in your opening statement to the need to reconcile the statutes and EPA fully agrees with that. It is about integrating the two statutes. On the specific points and the question you're asking, I would say a couple of things. One of them is, the footnote 1 in the July 11 memorandum, the interim guidance, that specifically addresses the brief that was filed in the case, the Talent case, and the basic point that's embodied in the EPA position and in the footnote in the July 11 guidance is that amicus brief was not saying—it wasn't, as you describe that, that it is that clear that the Clean Water Act needs to be added on top of FIFRA and will add value.

Mr. TIERNEY. Excuse me. You don't think that language was clear?

Mr. GRUMBLES. No. What I am saying is that the language that is clear is that there are not—just because the position of the agency is that there may be additional value added to a Clean Water Act program doesn't mean that a Clean Water Act permit should always be required in these cases. Specifically, our footnote says that EPA stated in the brief that compliance with FIFRA does not necessarily mean compliance with the Clean Water Act. However, the government's Talent brief did not address the question of how pesticide application is regulated under the Clean Water Act or the circumstances in which pesticides are pollutants under the Clean Water Act. And I think the key point, the key point, Congressman, is that in defining that phrase, that term "pollutant," which is the trigger for Clean Water Act regulation, you need to look at the particular item involved. And with pesticides if they are fully meeting FIFRA, labeling and other relevant requirements under FIFRA, our view is that they're not a chemical waste or a biological material, the terms in the definition of pollutant in the Clean Water Act. Instead they're more of a useful product. So that's our current position.

Mr. TIERNEY. And I have to tell you that is an ingenious stretch of language, and I mean I just think that you've gone way beyond the pale. Congress I would think would be the one to decide wheth-

er or not their statutes ought to be integrated or not. And I think that the department taking upon itself to change the position that was pretty clear, and I think concisely stated in your own brief, and then just decide at some point later that you're now going to say, well, we don't think you have to apply both of the Federal statutes that Congress put in place; we are going to say you pick and choose and then integrate, or however you want to phrase it, to say that one doesn't apply and the other does is troublesome to me. And on that it is troublesome. It is a change from your previous position without any apparent rationale for it and it is troublesome that you would take Congress's role upon yourself as an agency to start interpreting and choosing which to apply or not. The definition is there that this is a pollutant and I don't see how you're ever going to get around that. I think the courts have been pretty definitive on that also. But if you as an agency want to recommend to Congress some action so that they could reconcile those, I think that's an appropriate role for an agency. If you think that there's something there. But I think that having admitted in your brief that when you're doing a NPDES permit that you're not necessarily considering those facts that are important for a Clean Water Act compliance, you know, it gives a good example of why there are two statutes out there and not one. And what I'd be interested in hearing, if we are going to have another round, is if you claim that FIFRA is all you need, then how do we protect those things that the Clean Water Act is supposed to protect?

Mr. GRUMBLES. Can I respond? Mr. Chairman, first of all, EPA's position is that both FIFRA and Clean Water Act have important roles to play. We embrace the notion that even in those situations where our legal analysis is that the pesticide that's being lawfully applied is not a waste and therefore is not a pollutant and a NPDES permit is not required, that doesn't mean that other Clean Water Act provisions and authorities aren't relevant. And we fully recognize that the States have the authority to use additional Clean Water Act provisions or State law to add to the situation if they choose to do so. Because I think the point is worth making that while the FIFRA label does have environmental safeguards, a State may choose to add additional provisions that are more site specific or tailored to that particular water body. But our legal analysis, Congressman, I don't view that it has changed. We have fleshed out with greater specificity the types of analyses and factors you use in parsing out the language. And the courts across the country certainly recognize—I mean, there is a role for the agency and there is most definitely a role for the Congress on adding further specificity or clarifying what these sometimes vague terms mean in the statute.

Mr. OSE. I just want to followup on something here. Dr. Fauci and Dr. Ostroff, I am going to get to you. Don't worry. I am not ignoring you. You'll get your turn.

Mr. Grumbles, if I understood you correctly, you answered "no" to the following question, and that was do public health mosquito larvacide and adulticide applications made in strict accordance with EPA registered labels constitute point source application of pollutants? And I believe you said no, is that correct?

Mr. GRUMBLES. More specifically, I was saying that they do not constitute a pollutant. You know better than anyone. There are actually more than two, three tests as to whether or not a Clean Water Act permit is going to be required. One is, is it a discharge of a pollutant; the second one, from a point source; third, into navigable waters or waters of the United States is how it is further defined. What we are saying through our guidance and in our interpretation is that in that situation, if it is being lawfully applied in accordance with FIFRA and it is a direct application of a pesticide into waters of the United States, it is not a pollutant and it doesn't require a permit. That doesn't address the issue of the mechanism in which it is being applied, whether it is sprayed or aerially applied. The general counsel for the agency did issue in September of last year, an interpretive guidance that does address the question of point source that you're getting at in your question, and that guidance was also a direct response to the Forsgren case, which involved aerial application of the pesticide to control moth infestation in forests. And in the guidance of our general counsel, what we stated was, is that we interpret our regulations on silvacultural operations to be very narrow in terms of the types of point sources that are called point sources for silvacultural activities, and that other types of activities such as fire control are nonpoint sources. And so we have spoken pretty clearly on that point that the application is covered by our current regulations that say that type of silvacultural operation is not a point source.

Mr. OSE. I think my question is whether it was a pollutant, and I think I hear you saying it is not.

Mr. GRUMBLES. It is not a pollutant if it is being directly applied or directly over, that's the case.

Mr. OSE. OK. One of the reasons this issue is of such interest to me, it is right at the intersection of public health, our environmental concerns, and science. You could see by the preponderance of witnesses on this panel exactly what our interest is. The questions that Mr. Tierney asked drove home the point from my perspective of the need for a rule as opposed to guidance because a rule will provide that safe harbor that the vector control districts and the like across the country can then utilize to define whether application of this particular pesticide or herbicide or whatever is a pollutant in this case. We have to figure out a way where when we are talking about public health issues of this nature that we understand the nature of the application of the chemical we are using, and I think it is reasonable to ask that at least within that very narrow scope, that we obtain a rule, properly crafted through the Administrative Procedures Act and what have you, that we obtain a rule that provides a safe harbor for folks out in the rest of the country.

So the question I have is, will you issue a rule to that effect?

Mr. GRUMBLES. The answer is perhaps. We are going through 480 comments on the interim guidance. We are taking those very serious. I mean, there are a lot of substantive important components to the guidance. They can shed light on our decision on whether to finalize the guidance and also when we finalize it, and most importantly from your perspective, whether or not to issue a rule.

I would like to say that those who believe that a rule, a rulemaking process resulting in a rule, will create a safe harbor, may have false expectations. I think one of the reasons the Clean Water Act has been both a success and also been controversial at times is that citizens suit provisions—whether we finalize our interim guidance, Mr. Chairman, or go through a lengthier process of an actual rule, our view is that citizen suits will still be brought. If Congress changed the statute then that becomes a more difficult question whether or not citizen suits will be brought.

What we are focused in on is making sure that the agency's guidance, the policy we have is finalized, and we are taking very seriously your recommendations that we go forward with a rulemaking, but we frankly haven't reached that point yet, Mr. Chairman.

Mr. OSE. If I understand the written testimony from the other witnesses in the aggregate, it is that you can generally project 6 to 8 months in advance whether or not you are going to have an outbreak of West Nile virus based on infestation, or whatever the word is, within a bird population or something, and the evidence indicates that next spring we are going to have a problem in California.

The comments you have received on the guidance you have been working on for a year, and it is my further understanding that the courts give far greater deference to a rule issued by a Federal agency or department, however narrowly constructed, than they do to guidance.

So I just want to come back to this, and that is that the vector control districts across the country in areas that are likely or projected to have outbreaks of this disease in the spring of 2005 could stand the assistance in a timely fashion from EPA with a narrowly constructed rule that provides a safe harbor for the application of these pesticides for public health purposes. And, I want to communicate that in no uncertain terms to you. I like clarity, and I am trying to be clear.

Mr. GRUMBLES. And we appreciate that and receive it—understand it very clearly.

I think it is also important to keep in mind that States can—even if we do go through with a rule, States can still use their discretion to require a permit.

Mr. OSE. All right. The gentlelady from Michigan.

Mrs. MILLER. Thank you, Mr. Chairman.

I think I just have one other question, but I want to go to why there has been such a dramatic decline in the incidence that we are experiencing with the West Nile virus.

I think it was Dr. Fauci who provided us—I thought this was sort of interesting—this article in the Sun: West Nile Both Flares and Fizzles. Just 5 years after its arrival, the West Nile virus has completed its east to west invasion of the United States and Canada; and, at the same time, the mosquito virus may be having a diminished impact on Maryland and other States where it has resided.

I am also aware of an article, just in September here, from the Healthy Day News; and they describe the lower occurrences of the West Nile virus infections in the East and the Midwest. They said

that this was due to higher levels of animal immunity, actually, to the disease. So perhaps you could talk a little bit about the adaptability of the disease, and, as like all viruses, I suppose, it begins to change its shape. Are we sort of in danger of seeing a different strain that is going to reappear here?

Dr. FAUCI. Well, I can begin to answer the question. I am sure that Dr. Ostroff also has some comments on that.

In general, we don't know precisely why we have this waxing and waning. But if you look at it mechanistically it certainly is related, at least in part, to the building up of immunity not only in the intermediate hosts but also in humans themselves.

When it first came to the United States in 1999, we would be considered what is called a naive population in the sense that there is virtually no immunity in the population. You get a country like Israel that has had this before us, that their level of ability to protect is considerably better because they have had experience.

So one could project that over years, as we get more and more seasonal involvement, that the naivete will go down and there will be, in the population, people who have some degree of immunity. Obviously, as new children are born, they will come in and will also be naive, in a sense; and there may be the transient people that come back and forth.

So you will always have a group of naive patients, naive individuals, but as you go further and further into what we call an endemic area, where it is there and it has been there, then you would unlikely see major blasts like we saw on the slide that Dr. Ostroff showed where we went from 62 cases to 32 to 100 and then 4,000 and then 9,000. It is unlikely that once you reach a stable baseline that is going to happen.

We have similar experiences with other Flaviviruses. For example, St. Louis Encephalitis Virus, you don't hear much about that now, but it has the potential to do the same thing that West Nile did. So it really is related, at least in part, to the baseline immunity in the population of people as well as in the animal hosts.

Dr. OSTROFF. I would echo Dr. Fauci's comments.

There are a couple of points that I think are salient. One of them was that, after West Nile first appeared in New York, particularly in the areas most affected, such as Queens, we actually did surveys the following year where we went out and caught live birds and tested them to see whether they had immunity against West Nile. In New York alone that immunity ranged from more than one in two birds that we caught, so 50 to 60 percent of the birds were immune. In some other areas that were not heavily impacted, it was only 1 or 2 percent.

You need susceptible birds out there to amplify the virus in nature. If you don't have that susceptibility, the virus has a difficult time amplifying the following year.

We believe that, as this wave has moved across the country, similar patterns have followed. So if you go into the Rocky Mountains this year in places like Colorado, you would find high levels of immunity in the bird population. Their immunity traps the virus from being able to amplify to levels that increase chances for exposure to an infected mosquito.

However, the important thing is that birds don't live very long. So after a couple of years all of those immune birds, if the virus hasn't been widely circulated, go away, and you once again have a susceptible population of birds.

As far as humans are concerned, we have done a number of surveys in various locations after West Nile has swept through. There has been no population that we have seen with relatively high levels of immunity, despite the fact that for every severe case of illness that occurs with West Nile there is somewhere between 100 to 150 other people that were infected but never got sick.

So that if there were, let's say, 600 or so cases in Michigan in 2002, you can multiply that by a factor of 100 to 150 and see that there were probably 60,000, 80,0000, 100,000 individuals that were infected. That doesn't do enough to actually block subsequent transmission to humans.

Other reasons that we may be seeing this waxing and waning include West Nile's very complicated ecology in this country. We know that have there have been more than 50 different species of mosquitos that have been identified as carrying this virus. Not all of them are as competent in being vectors to humans.

In addition, there have been more than 250 different bird species that have been identified as being infected. So as you go from place to place around the country the predominant mosquitos that are responsible for transmission tend to be different, which causes the impact and the amount of disease from place to place would also be expected to also vary.

The third thing that I think might be playing some role is what we are doing to reduce the impact of the disease; and whether it is public education or whether it is what the local mosquito control districts are doing, I would like to think that some of our best programs such as the programs in California, are also having some impact.

Mrs. MILLER. Thank you.

Mr. OSE. The gentleman from Massachusetts.

Mr. TIERNEY. Thank you.

Mr. Grumbles, I just want to try to wrap up some things. I have really three things that are bothering me here, is your definition of pollutant, your attempt to reconcile two statutes that seem to me to be distinct in their purposes, and that—the so-called guidance itself, which I think you purport is not a rule and somehow didn't need notice and comment.

So take it maybe the first order first. Can you explain to me your legal rationale for determining that what you have done in putting out this so-called guidance somehow doesn't meet the definition of a rule as it is put out in the Administrative Procedure Act as has been interpreted by the courts? Because I think I look at it quite differently.

Mr. GRUMBLES. Our approach is that it is interpretative guidance, in essence, an interpretive rule. It is not a rulemaking. We didn't have to, Congressman, but we did seek notice and comment; and we have had——

Mr. TIERNEY. But after the fact. You put it into effect, and then you sought notice and comment, right?

Mr. GRUMBLES. We put it into effect immediately and——

Mr. TIERNEY. Well, let me just read to you what the Administrative Procedure Act says. Basically defines a rule as the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy.

The courts in fact have held that definition is broad enough to include nearly every statement an agency can make. I am having a hard time figuring out how you somehow manage to think just because you don't call it a rule that you avoid that interpretation of the law.

Mr. GRUMBLES. Well, our attorneys made it very clear that this was an appropriate, accepted practice through the Administrative Procedure Act to issue this interim guidance; and our plan, Congressman, is to take full analysis of the comments and then——

Mr. TIERNEY. Sorry to interrupt you. Because that is late. The whole purpose of the Administrative Procedure Act is that you have notice and comment before it goes into effect. And I don't care what kind of back-flips your attorneys are telling you are OK to take. I don't think there is any room for wiggle where it says, the whole or part of an agency's statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy. The Court is clear. Just about any statement the Department makes comes under that.

I would like you to take back to your lawyers and maybe go back to their first year of law school and go back to reading that. Because I think they are dead wrong on that. I think it is offensive to the whole act. I think that, you know, we all want to get the right answer on this, but we want to do it the right way.

If there are Federal laws that are trying to protect our health and safety, you know, it is Congress that should be listening, as we are here today having hearings. I thank the chairman for having these. If something needs to be reconciled, we should do it.

But that brings me to the second point.

The Federal Insecticide, Fungicide, Rodenticide Act [FIFRA], deals with establishing, through a labeling, the general acceptability of that product, am I correct?

Mr. GRUMBLES. Yes.

Mr. TIERNEY. Now, that is fine. But how is EPA then going to determine with regard to the specific application or injection of that product into a particular local body of water if it doesn't take the Clean Water Act and do a NPDES permit? Aren't you abrogating your responsibility under the CWA, the Clean Water Act, and the NPDES requirements to just give out that first level of FIFRA and then say, hey, we are going to try to make them reconcile by having it apply to those particular circumstances without taking a look?

Mr. GRUMBLES. Congressman, I don't think we are abrogating our responsibility. I think the intent is to integrate the statutes and to have them work together.

Mr. TIERNEY. Well, let me ask you that. If you are integrating them and you think you are going to serve that purpose, then at the time you are going giving out the FIFRA thing are you then purporting to look at every local body of water to see whether or not it is going to be a pollutant in that body of water, whether or

not it meets the clean water standard? Because I think that's the only way you can do just one of the two and serve the purposes of both.

So how do you do that? If you rely just on FIFRA, how do you do that, what is required by the CWA?

Mr. GRUMBLES. I think there are two aspects. One is, we don't just rely on FIFRA. There are Clean Water Act relevant factors and programs that play into this, just not the NPDES permitting program.

Mr. TIERNEY. Why not?

Mr. GRUMBLES. Because our best legal reading of the statute is that in two situations when an applicator is following all of the relevant requirements of FIFRA, which are extensive——

Mr. TIERNEY. They are not. You have already said yourself they may be extensive, but they are general. And they do not handle the specifics of a particular body of water. Right?

Mr. GRUMBLES. Well, there is nothing in the Clean Water Act or in EPA policy that would prohibit or discourage other laws being used or States using clean water provisions or laws to address those site-specific factors. It doesn't always——

Mr. TIERNEY. But EPA has the responsibility, does it not, under the CWA to make these kinds of determinations to issue or not issue a NPDES, unless Congress tells you otherwise?

Mr. GRUMBLES. We have a responsibility under the CWA which we take very seriously, and that is to implement it as it is written and to make good judgment as to where there are grey areas as to which licensing or permitting program applies.

Mr. TIERNEY. You have two different statutes. Congress has told you two different things. On FIFRA, they are giving you directions on what to do, and on the NPDES, within the CWA, they have told you what to do. Tell me where it is that your agency then decides when it will apply one and not the other, because we are just going to make some theory up that they somehow can be reconciled, when you have already admitted to me that one does a very general overview on that and the other deals with specific bodies of waters and injections into them.

Mr. GRUMBLES. The Clean Water Act is going to be 34 years old in a few weeks; and at this point in time, there are areas where courts, State, local, Federal agencies, citizens have questions about the jurisdictional scope.

Mr. TIERNEY. When they have a question, then Congress will answer it, I suspect, not the agency and a reinterpretation, even from its own previous statements and legal briefs, where they made clear that FIFRA deals with one thing and that the NPDES deals with the other and that when they approve a pesticide under FIFRA they do it with the knowledge that pesticides containing pollutants may be discharged from point sources into navigable waters only pursuant to a properly issued CWA permit.

That is your department's language. When you think that something has become unclear to you, even though it was clear as a bell apparently at one point here that you put in a legal brief, I would think that you would come back to Congress with a recommendation that all of a sudden things have gotten fuzzy for you. Maybe it is the new lawyers on your staff. Maybe we ought to have them

in, Mr. Chairman, for a little conversation. Because I think it is somewhat unfair to put Mr.—you are not a lawyer, Mr. Grumbles?

Mr. GRUMBLES. I am.

Mr. TIERNEY. You are. Well, maybe it is fair to have you here then, and maybe we can go over your legal background.

Mr. OSE. Let the record show that the witness answered in the negative, that it is fair.

Mr. TIERNEY. Let me just say how is it that you are so crystal clear in one brief and then all of a sudden you decide that for Congress—you are going to take the role of Congress and decide now that we are just going to do one of those and that is going to cover everything.

Mr. GRUMBLES. Congressman, in all fairness, I don't think things are crystal clear in this area. What I think is clear is the legal basis we have for articulating our view, the view that when a pesticide is being lawfully applied under FIFRA, which does include environmental and water quality related safeguards——

Mr. TIERNEY. In general.

Mr. GRUMBLES [continuing]. In general, that it is not a waste. The best reading of the statute—and there is lawsuit after lawsuit, as you know, over how to interpret those words in the definition of pollutant.

Mr. TIERNEY. But so far they have been interpreted to apply to both FIFRA and NPDES.

Mr. GRUMBLES. Well, my understanding is no. The history of the agency is not to require a NPDES permit under the Clean Water Act for those situations.

Mr. TIERNEY. But the interpretation of the courts is what you are talking about, and they have so far instructed that both are applicable?

Mr. GRUMBLES. I would say just as many courts have not and have taken a very different view, the view that if it is being lawfully applied it is not a waste, it is a product. And if it is a product, then it is not a pollutant.

We embraced the notion that Clean Water Act programs and factors should be taken into account precisely for that reason. When the agency issued the July 11 interim guidance, we also established a work group between the FIFRA folks and the clean water permitting folks specifically with the task of doing several case studies on pesticides, one of which would be a mosquitocide, to analyze the risk minimization and risk management structures under the two statutes and to see how they differ.

But from a legal analysis, Congressman, our view, until Congress gives us clearer direction, is that the best reading of the statute, the one that we have had over the years, is that the pesticide is not a waste or a biological material, it is not a pollutant under the act when it is being applied fully in accordance with all relevant FIFRA requirements in those two situations of direct application above waters of the United States and also direct application to waters in the United States.

Mr. TIERNEY. Thank you.

Mr. OSE. Dr. Ostroff, you had that map—1999, 2000, 2001, 2002, and 2003. Can we get that back up on the easel, please? I have

asked for this map to be put back up because it very graphically depicts the concerns that all three of us up here have expressed.

If you look in the upper left-hand corner, you see 1999; upper right-hand corner 2000, 2001, 2002, and 2003. If you look closely, you will notice that every State represented up here on the map is affected by this issue; and what I hear us saying in no uncertain terms is that the development and issuance of a rule, however crafted or scoped, will provide a great deal of certainty to this process.

Mr. Tierney I think makes a very good point, that the lack of enforceability, if you will, under guidance leaves a lot of doors open. I have made that point not nearly as eloquently. I think Ms. Miller did, too, more eloquently than I did. But my point is that, absent the certainty of a rule that has gone through due process and what have you, we are going to be stuck in this circle.

Now every one of us up here recognizes that the guidance came out for a very real purpose. That was there was a threat to public health, and we needed to provide some guidance, and that served its purpose. But we are now to the next step, and we need that rulemaking, at least as it relates to the public health issue that we are all confronted with as represented by that map.

Now, Dr. Fauci, Dr. Ostroff, educate us a little bit. When we talk about these mosquitos, the period of time during which the larvae can be laid and mature to traveling mosquitos, that is a highly technical term, mosquitos that can fly, what period of time are we dealing with? Is it 48 hours, 72 hours? Do either of you know?

Dr. OSTROFF. It probably varies by the mosquito, but it is a relatively brief period of time. And, obviously, it also depends on the weather conditions. So it is not a straightforward answer, but you are not talking months, you are certainly talking about days for the mosquitos to go through their lifecycles.

Mr. OSE. So, under optimal conditions, it might be as little as how many days?

Dr. OSTROFF. I believe as little as 1 or 2 days.

Mr. OSE. From the time the larvae are laid to the time where they are in the air? I have people shaking their heads.

Dr. OSTROFF. They are the experts from the Mosquito Control Association.

Dr. WEISBUCH. Our experience in Arizona is that——

Mr. OSE. Would you identify yourself?

Dr. WEISBUCH. I am Dr. Jonathan Weisbuch from the State of Arizona, Maricopa County.

Our experience is that there are multiple—I will be presenting a little more of this at the next panel. Our experience has been that there are multiple different mosquito types that are potential vectors for this disease. The most common mosquito that we see, and I think it is true across the country, are the Aedes vexans and other flood water mosquitos. They are usually not carriers of the disease, and they are very short-lived. Their larvae cycle may be 2 to 3 days, depending on the temperature that is extant in the community. Of course, in Arizona it is very high, and so the days of larvae period is very short.

When the mosquito becomes an adult, the flood water mosquitos last maybe a week or even less; one feeding cycle maybe the whole

time. However, the most serious vector, which is the one that we see and which I think is more common in the West of this country than it is in the East, that is the Culex tarsalis mosquito and the Culex quinquefasciatus mosquito. These are longer-lived mosquitos. I think the former can live up to 3 weeks or more depending on the ambient conditions, and that means that they can lay eggs several times in their cycle, since once they can bite an appropriate mammal or possibly reptile then they lay eggs; and then another 4 or 5 days later they will do the same thing.

So depending on what the ecology is in the area in which we are talking—and this is the one of the questions that I am going to raise in my discussion—you have a different manifestation of the frequency of infected mosquitos, the probability that an infected mosquito will in fact bite another acceptable host and the probability that mosquito will live to bite again. Infection with West Nile virus is dependent on many different variables.

And the question that I think we need to ask is, how do these variables interrelate? How does temperature, how does rainfall, how does the lifecycle of the mosquito, depending on its ambient conditions, affect the infection rate of other host animals and especially human beings? Because it is highly variable.

Again, we will talk more about that later. But I think it is a critical question in knowing—and for us in public health to know—what is the epidemic going to look like, given a rainy spring, a dry spring, a hot spring, a cold spring? These kinds of questions, if we knew the probabilistic relationship between the multiple factors, would give us an opportunity to make some predictions about how bad the epidemic might be, where we have to focus our efforts, is it larvaciding, is it adultaciding, and so on.

Mr. OSE. I thank you, Doctor, for that clarification. We actually do have a number of questions along that path that we will ask you in the second panel, so I appreciate the clarification.

The reason I asked about the minimum-maximum life spans has to do with, from a public health perspective, how quickly must you act? And Dr. Ostroff and Dr. Fauci, any guidance? I mean, if it breaks out—I mean, you guys have to start—you have to be rolling almost before the first mosquito takes air.

Dr. OSTROFF. Well, Congressman, what I would say is, and I think the folks behind me that do mosquito control for a living would say, doing integrated pest management is most important. You should be taking steps to control mosquito populations during the winter months when you have an opportunity to do so.

It is habitat management. It is larval control. It is many different things. And the earlier you start in the cycle the more likelihood you have of success. Once the mosquito transmission season gets up and rolling, all of us I think would be in agreement that where we get into trouble is when many of those things haven't been done earlier, and then people get into an epidemic situation, and have to resort to tools which we know probably aren't the most effective ways to protect public health, such as using adulticides.

What we would like to see is more mosquito control districts using comprehensive integrated pest management so that many of these steps are potentially averted in the midst of a crisis.

Mr. OSE. Dr. Fauci, anything to add?

Dr. FAUCI. I have nothing to add. Dr. Ostroff said that very well. It is comprehensive, and it is year-round.

Mr. OSE. Dr. Ostroff, this is my last question in this round. Do I recall in your testimony, you said 2.6 percent of the population in certain portions of New York City are infected with West Nile virus?

Dr. OSTROFF. Not infected—had at one point become infected. We have done several surveys after outbreaks have swept through communities to see what proportion of the population actually became infected when West Nile was circulating. We did this in New York. We also did this in Louisiana after a relatively intense outbreak in Louisiana in 2002. And in each of those situations, by doing random surveys of the population and taking blood samples, we were able to determine that between 2 and 3 percent of the population had actually become infected and were now immune.

Mr. OSE. And some percentage of that 2 to 3 percent actually gets the worst result?

Dr. OSTROFF. Correct. We know from surveys that have been done that if you take all comers with West Nile infection, the vast majority of them won't develop any disease at all.

Mr. OSE. The statistic was 80 percent?

Dr. OSTROFF. More than that. More than 90 percent. So only 1 out of every 150 individuals that become infected will develop the most severe forms of the disease. There are another 5 to 10 percent or so who will develop what we refer to as West Nile fever, which is not a nice disease, but it is not a very severe disease that would put you in the hospital.

Also, by looking at blood donors who were infected at the time that they donated the blood, we have been able to determine that 20 percent of those individuals will subsequently become sick, most of them with West Nile fever, and another 1 to 2 percent will develop the more severe forms.

Mr. OSE. So what is the level at which smallpox or the flu or something like that becomes a pandemic? Is it at the level that you are talking about of 1 in 150, or 2 or 3 percent?

Dr. OSTROFF. It is different for every disease. But I would say that the West Nile virus in this country for the last several years has clearly been epidemic as it has moved from place to place to place. When it will convert itself to endemicity so that we won't be in its epidemic waves in the way that we have been seeing is hard to say. We think that it is clearly still in its epidemic phase.

If I was to look at that map and say what is likely to happen in 2005, one would think that it would continue to, in your State of California, move to the north, in areas that haven't yet been very heavily impacted. What will happen in subsequent years is still difficult to say. Because, as was pointed out, it depends on a lot of factors.

What we do know is that it hasn't gone away anywhere. So in every State where this virus has shown up we have seen it at some level year after year after year. So this is a problem we are going to have to continue to deal with into the future.

Mr. OSE. Dr. Fauci, do you have anything to add?

Dr. FAUCI. No. I agree. And if you do comparisons, for example, of diseases like influenza at each given year, 10 to 20 percent of

the population will get infected with influenza, and a fraction of them will have very serious disease.

The numbers that we were speaking about yesterday with the issues that arose yesterday, the 36,000 people a year who die in this country from influenza and about 200,000 get hospitalized, but if you are taking about 10 to 20 percent of 288 million people, that is a lot of people that get infected, and a relatively small number will get seriously ill.

Mr. OSE. Thank you. The gentlelady from Michigan.

The gentleman from Massachusetts.

Mr. TIERNEY. I have a question that may be best reserved for the next panel, but it seems to me that probably two objections to looking to get both permits would be cost and time. So setting cost aside for a second, if time for permitting is a problem, isn't there some way of anticipating where this is going to occur and having some sort of anticipatory process where people get their plans approved and go through the NPDES process? So in the event that there is a need for these pesticides that they are all set and ready to go, as opposed to waiting until they are inflicted with a situation and then going through?

So I guess the relevant question would be, how much time does the permitting process actually take? And maybe Mr. Grumbles can help us with that. And then for the other witnesses included, maybe whether or not it is possible to anticipate a need and get the permitting done ahead of time.

Mr. GRUMBLES. Congressman, on the question of the timing, NPDES permitting can—you know, there are basic variations. There are individual permits which can take years to issue. It is a process.

Mr. TIERNEY. Clearly that won't help then.

Mr. GRUMBLES. No. There are general permits. I think the general permit, it can be a much more expedited, administratively convenient approach. But I think it is a question well put to the regulated community, the applicators in terms of their time constraints or the necessity to go through that additional permitting process and experiences in California or Oregon or Washington where there are clean water permitting authorities being used.

So I think timing—it just varies. It ranges. But certainly it can be viewed as a cumbersome process, particularly from the applicators' perspective if they feel that they have done everything under the FIFRA program.

Just so that you don't think that EPA spends all of its time looking at Clean Water Act jurisdiction, we would like to just highlight some of the things we are doing in terms of developing new products and also revising pesticide labeling. Could I just defer to Adam Sharp?

Mr. OSE. Given the constraints of time, Mr. Tierney is likely to have more questions. Mr. Sharp, could you submit those for the record?

Mr. SHARP. Sure. Thank you.

Mr. TIERNEY. That would be fine with me. Thank you for your offer on that, and we will certainly take a look at them.

[The information referred to follows:]

NOV 30 2004

It is important that the Committee be aware that no new active ingredients for mosquito control have been registered recently. Currently registered adulticides include: permethrin, resmethrin, malathion, d-phenothrin, naled, bifenthrin (for residual surface treatment only), and pyrethrins with piperonyl butoxide. Registered larvicides include Bacillus thuringiensis israelensis (Bti), methoprene, temephos, Bacillus sphaericus, and some oils.

Recognizing the need to develop and streamline the regulatory requirements for new tools to respond to potential public health threats, EPA recently met with representatives from Department of Defense (DOD), Department of Agriculture (USDA), Agency for International Development (USAID), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) to facilitate cooperation and coordination among the federal agencies involved in public health pesticides. The representatives of these agencies discussed ways to pool resources, share information, and encourage development of new techniques and products. Both DOD and NIH are devoting resources to research new methods of control, including finding public health uses for pesticides that are already registered for other purposes. Also participating were representatives from the USDA-sponsored Interregional Research Project No. 4 (IR-4) whose experience with reduced-risk pesticides and information on "minor uses" in agriculture could lend the group expertise in developing similar "minor-use" registrations of pesticides for public health purposes. The committee is scheduled to meet again in January 2005 to continue addressing the need for new public health pesticides as efficiently and effectively as possible.

Mr. TIERNEY. I only say this because I am thinking that, you know, if we should decide and if it is determined that the NPDES process is important—that will have to be something that is ironed out or whatever—the next step is how do you make that process expedited so that it gets the purpose done and doesn't drag people through all of this cost and time and then serves that purpose.

Clearly, the inference from the people, I think we are going to hear on the next panel, is that it is not that way now. That has created some of the problems.

But, Dr. Fauci and Dr. Ostroff, I don't know if you have anything that you want to weigh in on this issue or just leave it for the next panel?

Dr. FAUCI. Leave it.

Dr. OSTROFF. My only comment would be that we don't have as many tools as we would necessarily like to be able to deal with this problem. I mean, this is a battle against this disease and against this virus and against the mosquitos that transmit it; and anything that we can do to facilitate being able to do what is necessary to deal with this battle would certainly be welcome. I don't want any of our public health partners at the State and local level to be going into this battle with one hand tied behind their back.

Mr. TIERNEY. At some point, we ought to weigh what is the danger of pollutants in the water versus the danger of not getting this resolved fast enough. But that is a larger issue.

Mr. OSE. I actually think that is Mr. Grumbles' and Mr. Sharp's central dilemma, is how to work through that.

Mr. TIERNEY. Exactly. Thank you all very much.

Mr. OSE. I have one other question here, if I may; and this is unique. In my neighborhood, one of the local municipal entities is proposing to create a settling basin. This is in Sacramento. We get very hot summers, and we have rain. They want to create a wetlands. If you were living in that immediate area, would you be concerned or not concerned about the creation of this wetlands? Dr. Fauci.

Dr. FAUCI. Environmentally, a lot of people love wetlands. But if you have standing water in a State that has the risk that California has now with West Nile, I would be concerned about providing the macro and micro environment for some rather efficient proliferation of mosquitos. So I would be concerned.

Mr. OSE. Dr. Ostroff.

Dr. OSTROFF. Well, without knowing any of the specifics, it is really difficult to answer that question.

Mr. OSE. I will be happy to give them to you.

Dr. OSTROFF. As somebody that if there is one mosquito in the neighborhood it manages to find me, I would definitely have concerns about the standing water.

Mr. OSE. Thank you.

I want to thank this panel for their testimony and their patience. We will probably have additional questions for submittal to you, which we will do in writing. We would appreciate a timely response so that we can make them part of the record. Again, your testimony has been very illuminating, and we appreciate your participation.

We are going to take a 5-minute recess here while the next panel comes up and joins us.

[Recess.]

Mr. OSE. OK, we are back. Just for safety's sake we are going to go ahead and swear everybody in again. So if you would all please rise.

[Witnesses sworn.]

Mr. OSE. Let the record show the witnesses all answered in the affirmative.

Our second panel, previously introduced, is composed of the following individuals: Mr. John Pape, chief epidemiologist for the Colorado Department of Public Health and Environment; Dr. Jonathan Weisbuch, director of public health from Maricopa County, AZ; Mr. Joe Conlon, technical advisor to the American Mosquito Control Association; Mr. David Brown, who is the Chair of the integrated pest management portion of the Mosquito and Vector Control Association of California; Ms. Wendy Station, who is the founder of Encephalitis Global; and Dr. Marm Kilpatrick, who is a senior research scientist for the Consortium for Conservation Medicine at the Wildlife Trust.

Collectively, welcome. Thank you all for coming.

You have seen how we handled the first panel. We have received your testimony or your statements in writing, and they have been entered into the record. Each of you in turn will be recognized for 5 minutes for the purpose of summarizing your written statement.

We usually go from left to right. Today, we are going to go from right to left on second panel. So, Dr. Kilpatrick, you are first. Welcome. You are recognized for 5 minutes.

STATEMENTS OF DR. MARM KILPATRICK, SENIOR RESEARCH SCIENTIST, THE CONSORTIUM FOR CONSERVATION MEDICINE AT WILDLIFE TRUST; WENDY STATION, FOUNDER, ENCEPHALITIS GLOBAL; DAVID BROWN, CHAIR, INTEGRATED PEST MANAGEMENT, MOSQUITO AND VECTOR CONTROL ASSOCIATION OF CALIFORNIA; JOE CONLON, TECHNICAL ADVISOR, AMERICAN MOSQUITO CONTROL ASSOCIATION; DR. JONATHAN WEISBUCH, DIRECTOR OF PUBLIC HEALTH, MARICOPA COUNTY, AZ; AND JOHN PAPE, CHIEF EPIDEMIOLOGIST, COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Dr. KILPATRICK. Mr. Chairman and members of the subcommittee, thank you for giving me this opportunity to discuss these important issues. My name is Marm Kilpatrick, and I am a senior research scientist with the Consortium for Conservation Medicine.

The Consortium is a collaboration between Wildlife Trust, a conservation NGO, the USGS's National Wildlife Health Center, and three universities—Harvard, Tufts and Johns Hopkins. The Consortium is a leader in the field of conservation medicine, which explores the links between human health, wildlife health and ecological health.

I am a disease ecologist working on West Nile virus through a project funded with Federal and private foundation grants. My testimony focuses on four major points: First, the efficient allocation of resources to control West Nile virus during mosquito season; sec-

ond, the prediction of disease hot spots at least a year ahead of time; third, the sharing of data between scientists and government; and, finally, the spread of mosquito-borne pathogens over oceans.

First, concerning resource allocation, our research group has developed a risk assessment or framework that allows for the comparison of a West Nile virus epidemic between locations at different spatial scales. This risk measure is easy to describe and understand, which should facilitate its use by resource managers in a range of settings. Our risk measure is based or incorporates information on human density, mosquito abundance, and prevalence data collected by surveillance efforts and published information on mosquito feeding behavior and vector competence.

In short, it is a prediction or an estimation of the impending number of human West Nile virus infections based on the current state of mosquito populations. It offers important advantages over resource allocation strategies that do not include unbiased information on the intensity of disease between areas. Its use could improve the efficiency of control efforts during mosquito season by allocating limited financial resources to the areas that need it most.

Second, if we can predict West Nile virus hot spots at least a year ahead of time, we can implement effective but slower-acting strategies such as education outreach and the development of integrated mosquito control plans.

However, hot spot prediction requires an understanding of what determines spatial variation and disease intensity. Unfortunately, our understanding of the basic ecology of West Nile virus is limited. As a result, additional funding for research is urgently needed to determine, among other things, the relative importance of mosquito abundances, the composition and previous exposure of the bird community, and climatic effects on disease transmission.

Third, our understanding of West Nile virus would be greatly facilitated by the increased sharing of data between health departments and scientists working on this disease. The mosquito abundance and infection prevalence data collected by county and State health departments is extremely valuable for understanding spatial and tempo of variation in disease intensity, but, unfortunately, is rarely available to planners and scientists. Although there are some privacy and property value concerns that impede data sharing, it should be possible to work with local health departments to address these issues.

One strategy that may be effective is to aggregate the data to a level that maintains its usefulness for research and planning while also addressing the privacy and property value concerns. If surveillance data can be made available, the creation of an open access data base to archive the data would greatly facilitate research and understanding.

Fourth, and finally, recent work by our group suggests that the introduction of mosquito-borne diseases from other continents to North America and the spread of West Nile virus to Hawaii is likely to occur through the accidental transport of mosquitos on airplanes.

Research suggests that the most promising and politically feasible strategy to reduce the number of live mosquitos on airplanes is the use of a residual insecticide coating on the inside surface of

airplane cargo holds, where over 80 percent of mosquitos are usually found. This strategy achieves significant reductions in mosquitos and avoids the politically difficult issue of using insecticides in airplane passenger cabins.

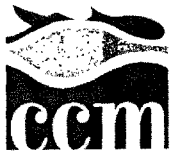
However, implementing this strategy requires compliance by airlines, the air transport industry, and the military, which is unlikely to occur without government intervention. Nonetheless, urgent action is necessary to prevent the introduction of new pathogens. In particular, the introduction of West Nile virus to Hawaii could have strong negative consequences for Hawaii's public health, tourism, and a long list of critically endangered birds.

In summary, I believe tools are available to improve the efficiency of our control efforts, but additional data sharing, research funding, and proactive regulatory action are necessary to meet the challenges of combating West Nile virus.

Once again, thank you for your time and the opportunity to discuss these issues.

Mr. OSE. Thank you, Dr. Kilpatrick. I do want to compliment you. You were very specific on four approaches, and that is exactly the kind of feedback we look for up here: specific, pointed, boom. So thank you.

[The prepared statement of Dr. Kilpatrick follows:]



Consortium *for* Conservation Medicine
at Wildlife Trust

Testimony of Austin Marmaduke Kilpatrick, PhD

Before the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs of the
Committee on Government Reform
U.S. House of Representatives

Hearing on Current Challenges in Combating West Nile Virus

October 6, 2004
Washington, D.C.

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity and time to discuss these important issues. My name is Marm Kilpatrick, and I am a Senior Research Scientist with the Consortium for Conservation Medicine at Wildlife Trust. The Consortium is a unique collaboration among Harvard Medical School's Center for Health & the Global Environment, Johns Hopkins Bloomberg School of Public Health, Tufts University's School of Veterinary Medicine's Center for Conservation Medicine, the U.S. Geological Survey's National Wildlife Health Center, and Wildlife Trust. Wildlife Trust is a global organization dedicated to promoting innovative conservation science, linking ecology and health, and empowering local conservation leadership. We are a pioneer in the field of conservation medicine, which looks at the links between ecological health, wildlife health and human health, and the emergence of diseases such as AIDS, SARS and West Nile virus.

I am a disease ecologist working on West Nile virus as a part of a project funded with Federal and private foundation funds. We have been trapping and testing birds and mosquitoes for West Nile virus at nine sites throughout the Baltimore-Washington area over the past two years.

My testimony represents my opinion and experience on how best to combat the West Nile virus epidemic. Because I am a scientist and a grantee of federal research funds, I am concerned with how to facilitate increased understanding of West Nile virus transmission and how to use this information to reduce future West Nile virus epidemics.

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The CCM strives to understand the link between anthropogenic environmental change, the health of all species including humans, and the conservation of biodiversity.
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There are four major points to my testimony:

I. The allocation of the limited resources available for control of West Nile virus could be improved by basing allocation on a quantitative assessment of the relative risk of human cases at the local, county and state levels using a framework developed by our research team.

II. Our ability to predict future West Nile virus hotspots critically depends on understanding what determines virus transmission at the local scale, which requires additional research.

III. Our understanding of West Nile virus would be greatly facilitated by increased sharing of data between scientists and health departments at the county, state and federal level.

IV. The spread of West Nile virus to Hawaii and the introduction of other mosquito borne diseases from other continents to North America is likely to occur through the accidental transport of mosquitoes on airplanes and requires urgent actions to avoid future epidemics.

I. Resource Allocation

In the past, it has been difficult to predict which areas will be the epicenters of West Nile virus outbreaks. This is because the virus has been expanding into new areas and because it is difficult to compare the relative risk of human West Nile virus cases between areas at the local, county or statewide scales. However, this year (2004) has brought West Nile virus to the West Coast and except for parts of the Northwest, it is now present in most of the U.S., and has been established for several years in some states. In the past, surveillance resources were allocated primarily to determine the presence or absence of West Nile virus in each location over time. However, research and monitoring over the past four years suggests that rather than being present in some areas and absent in others, it is present in most areas but at different intensities. As a result, a more effective approach to assessing the risk of a human epidemic would focus surveillance activities on determining the intensity of the disease in different areas over time, as is suggested by current CDC guidelines for Surveillance, Prevention, and Control.

In addition, recent research by our group has produced a risk analysis measure that enables the comparison of the risk of human West Nile virus infections between locations at any spatial scale. This makes it possible to allocate limited West Nile virus control funds to the places where the risk for a human epidemic is the greatest.

The risk measure is easy to describe and understand, which should facilitate its use by resource managers in a range of settings. It is an estimate of the number of West Nile virus-infectious bites by all the mosquitoes in a location on humans. At a point in time the risk of a human epidemic is calculated as the product of three characteristics of the mosquitoes in an area and the human population density:

= (Mosquito Density) x (% WNV infectious) x (% of diet from humans) x (human density)

Estimating the risk of human West Nile virus cases from this technique is possible using data or approximations from previously published research and information that is currently collected by mosquito surveillance efforts. As a result, it does not require additional funds to estimate. It can be used at the state level to allocate resources between counties, or at the county level to allocate effort at the local scale.

The risk measure has some limitations and is an approximation, but it represents an improvement over current resource allocation protocols based on the presence or absence and timing of West Nile virus in samples collected from surveillance activities. The shortcomings of current resource allocation efforts are threefold. First, the likelihood of finding West Nile virus infected birds, mosquitoes, horses or humans is largely dependent on the effort expended. Second, many surveillance programs curtail activities such as dead bird monitoring after finding their first few West Nile positive birds, which makes it impossible to gauge the intensity of the avian epidemic. Finally, allocating resources differentially to West Nile positive or negative locales ignores important differences in disease intensity that are captured in the risk measure discussed previously.

II. Prediction of future West Nile virus hotspots

A critical step in reducing the intensity of future West Nile virus epidemics is predicting which areas will be most affected months in advance. This will allow slower effective control measures to be carried out, including education outreach, the development of integrated mosquito control plans, etc. However, due to limited resources, effective control requires focusing on a subset of areas that are most likely to suffer from a West Nile virus outbreak. Research conducted to date suggests that many factors are likely to impact the intensity of West Nile virus epidemics, including mosquito abundances, previous exposure of the bird community, the species composition of the bird community (through differences in the propensity of infected birds to infect biting mosquitoes), and temperature (through effects on mosquito development, survival, and viral development in mosquitoes). As a result, predicting future West Nile virus hotspots requires information on the relative importance of these factors.

Unfortunately, our understanding of West Nile virus ecology is in its infancy. Additional research along several lines is greatly needed. A recent funding initiative by the CDC will improve our understanding in several areas, but additional funds are needed for basic West Nile ecology research that will lead to the prediction of future West Nile virus hotspots.

III. Data sharing

Our understanding of the spread of West Nile virus across the U.S., and the long-term persistence and variability of this disease would be greatly facilitated by increased sharing of data from the last four years of surveillance activity. Although the CDC's West Nile virus reporting database ArboNET represents a substantial step forward in efforts to coordinate disease surveillance on a national level, it suffers from two critical shortcomings. First, the data that are collected, the number of West Nile positive mosquito pools, dead birds, veterinary cases and

human cases, suffer from biases associated with the effort that was expended by each area reporting West Nile positive samples. Secondly, ArboNET is missing two key pieces of information, the abundance and West Nile virus infection prevalence of mosquitoes. Mosquito surveillance is generally coordinated by county health departments, and there are often privacy or property value concerns that make department officials hesitant to share mosquito abundance or West Nile virus infection prevalence. Nonetheless, it should be possible to aggregate the data to a level that maintains the usefulness of the data for planning and resource allocation while also addressing privacy and property value concerns. Finally, creation of a database holding past, present and future data collected by ArboNET in an open-access format that facilitates use by scientists and epidemiologists would greatly increase the number of people researching this topic.

IV. Introduction of West Nile virus and other mosquito borne diseases

The transport of mosquito borne pathogens across oceans is likely to increase along with the travel and shipment of goods. Our research group has recently developed a framework that allows for a quantitative assessment of the risk of introduction of a mosquito borne virus from one area to another by different pathways. Application of this framework suggests that the most likely pathway of West Nile virus introduction into Hawaii will be infected mosquitoes being transported on airplanes. We performed a similar analysis for possible West Nile virus introduction into the Galapagos from Ecuador, which yielded the same results; infected mosquitoes on airplanes represent the highest risk. Both analyses suggested that introduction via mosquitoes on airplanes was at least ten times more likely than any other pathway. As a result, actions that can substantially reduce the number of live mosquitoes on airplanes will be most effective in decreasing the introduction of West Nile virus, and likely other mosquito borne pathogens. Research suggests that the most promising and feasible strategy to reduce the number of live mosquitoes transported on airplanes is the use of residual insecticide coatings on the inside surface of airplane cargo holds. Because over 80% of hitchhiking mosquitoes are found in cargo holds, this strategy achieves significant results while avoiding the politically difficult issue of using insecticides in airplane passenger cabins. However, implementing this strategy would require compliance by the airline and air transport industries and the availability of properly licensed residual insecticides. Neither are likely to occur in time to prevent the introduction of West Nile virus to Hawaii without intervention or facilitation by the EPA and other regulatory bodies.

In summary, I believe many of the challenges we face in combating West Nile virus epidemics can be overcome by integration of existing research and policy, increased data sharing between several levels of government and scientists, increased research to understand the basic ecology of West Nile virus, and the generation of West Nile virus hotspot maps. Finally, preventing the introduction of West Nile virus to Hawaii, and the introduction of other mosquito borne pathogens to North America, is likely to require actions to reduce the number of mosquitoes transported on aircraft.

Thank you again for the opportunity to appear before the Subcommittee. I would be happy to answer any questions you may have.

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MISSION AND GOALS

Wildlife Trust is a global organization dedicated to promoting innovative conservation science, linking ecology and health, and empowering local conservation leadership.

The extinction of species across the globe is accelerating, directly or indirectly, due to human activities. To address this problem, Wildlife Trust trains and supports a network of scientists around the world to save endangered species and their habitats and to protect the health of ecosystems that are vital to life on earth. The key to conservation success is long-term local involvement. No other science-based conservation organization is focused on developing local conservation expertise and action consistently and in an integrated fashion with communities on the ground, around the world.

Wildlife Trust is a conservation science innovator, and has leveraged research expertise and innovation through a series of strategic alliances. We pioneered the field of Conservation Medicine, a new discipline that addresses the link between ecological disruption and wildlife, livestock, and human health and survival. Lyme Disease, AIDS, and West Nile Virus are examples of diseases that impact humans and wildlife. Together with our Consortium for Conservation Medicine partners at Tufts Veterinary School, Harvard Medical School, the Johns Hopkins Bloomberg School of Public Health, and the USGS National Wildlife Health Center, we are building this new trans-disciplinary science by bringing together teams of veterinarians, wildlife epidemiologists, public health experts, ecologists, and physicians to address the complex environmental sequences of events that result in the spread of pathogens and the emergence of new diseases like SARS.

Wildlife Trust was founded in 1971 by British naturalist and author Gerald Durrell. Building on our 33 years of international experience, our work in the United States includes programs in metropolitan New York, New Jersey, Connecticut, Pennsylvania, Florida and along the coast of the Southeastern U.S. Projects include investigating the important role carnivores such as coyotes play even in urban landscapes, examining environmental contaminants in sea birds, researching patterns of West Nile Virus infection, evaluating the effectiveness of sanctuaries for protecting the endangered Florida manatee, and determining the sustainability of manatees' winter habitat.

Wildlife Trust's current annual budget is approximately $5.7 million. Headquarters for Wildlife Trust, a 501(c)3 nonprofit organization, are located on Columbia University's Lamont Doherty Earth Observatory campus in Palisades, New York. Wildlife Trust is governed by a volunteer board of directors, and has offices in New York, Pennsylvania, and Florida.

For more information contact Anne Metcalf or Amy Wolfrum at Metcalf Federal Relations, 703.519.3983.

Mr. OSE. Ms. Station, thank you for joining us today.

Ms. Station is the founder of Encephalitis Global and is here to talk not only about those who might have died from West Nile virus or its associated diseases but in part also about those who survive it and the consequences thereof.

You are recognized for 5 minutes.

Ms. STATION. Thank you, Mr. Chairman. Good morning to yourself and the subcommittee members and guests here today.

As you know from my testimony, I am an encephalitis survivor. I am here today to proudly speak on behalf of encephalitis survivors, caregivers and their loved ones.

Encephalitis impacts the whole family. Today, I speak in one voice for all of these families, asking you to please recognize encephalitis. Hear more, learn more, understand what it means.

Encephalitis is inflammation inside your brain. Encephalitis has changed my life. I cannot clearly verbalize. I cannot clearly and verbally express the ideas in my head. I cannot think of the right words to make conversation. I am neurologically disabled, and I struggle to express my thoughts and my ideas.

Yesterday, on arrival here in Washington, DC, my good spouse and I—that is, my husband and I—we went for a walk, then stopped into an informal restaurant for dinner. We got chatting with a young couple who had a new baby. They sat at the table beside us. They asked why we were here. When I told them why I was invited to this hearing, the young mother said to me, "tell them, explain it clearly. I am so worried for my husband, for myself, and now for our young son. You tell them that something must be done so that we don't have to be so scared."

I am here today to speak for my friends and for families like the one I met just yesterday. I thank you very much for the honor of your recognizing my Web site, Encephalitis Global. I work daily to help society be aware and to help families and friends cope with this disabling disease and thank you, sincerely, for this opportunity to do so.

Mr. OSE. Thank you, Ms. Station. We are pleased you are able to join us.

[The prepared statement of Ms. Station follows:]

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Testimony of Wendy Station
Founder, President of Encephalitis Global

A Hearing of The House Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
on
Challenges in Combating the West Nile Virus

Washington, DC
October 6th 2004

Introduction

On a sunny April morning back in 1999, I sat down at my desk in our local municipal government offices, for the very last time. I had been trying to shake a minor headache all morning. Finally, I told my co-worker that I'd have to go home. That's the last thing I remember for the next four weeks. I don't recall driving home. I don't recall being miserable to my family in the following days. And, I don't recall my own husband taking me to our local hospital's emergency room, and telling them, "something isn't right about Wendy."

It was my amazing good fortune that one of the medical professionals suggested that I may be suffering from encephalitis, which is the inflammation of the brain. I was whisked into treatment, and my life was saved. Unfortunately, while this amazing doctor was saving my life, my family was struggling to learn more about encephalitis. The searched our local library, the internet, asking friend -- no one seemed to really understand.

Once I came home, my problems multiplied. My parents were babysitting me as my husband went to work and our children went to school. On that first morning home, I was seeking a spoon to stir my coffee. I went searching through a pile of newspapers, asking the dog, and checking in the freezer. As I was heading outdoors in the rain to search the backyard for a spoon, my mother had to show me where the spoons were kept -- in my own kitchen drawer. This was just one piece of knowledge that I to re-learned. It was only one of hundreds.

I am legally disabled and I was reassessed earlier this year as disabled. Prior to my viral encephalitis (non-vector borne), I worked in our local government engineering department. I was also trained and qualified to take local Brownies and Girl Guide groups on overnight camping trips, and enjoyed doing so.

October 6, 2004
Prevention and Treatment of Mosquito-borne Diseases

I used to welcome international exchange students to live in our home, and I designed and operated a program titled, "Hello Canada", teaching living skills and the English language to new Canadians. And, now? Post encephalitis? Now, I am a 49 year old woman, with the brain of an 89 year old woman. I forget things. I get flustered. I get confused. I tire easily. My husband and children take turns, "keeping an eye on me." My life is typical of any survivor of encephalitis, no matter how one contracts it. Thanks to the West Nile Virus, there are thousands of people who share the same life as I.

Since I became ill, I have noticed that society looks at me, and says, "Wendy looks okay. She must be okay." This can be so very frustrating for any survivor and not to be taken seriously. To assist you today in taking me seriously, I would like to share part of my neurological evaluation.

> "Mrs. Station has been left with permanent cognitive dysfunction in the form of decreased short term memory, decreased attention span, decreased concentration abilities. Mrs. Station's personality has been permanently changed as a result of this. She is required to be medicated for the anxiety attacks which have developed as a result of encephalitis. Mrs. Station is not able to work, and will probably never be able to work at a job either part time or full time permanently, due to these ongoing cognitive deficits that have left her permanently disabled. It is probable that she will not notice any improvement in the future.

Since then I have learned that encephalitis is an acute infection and inflammation of the inner area of brain itself. This is in contrast to meningitis, which is an inflammation of the layers covering the brain. The damage done by encephalitis is permanent. Encephalitis is often the result of vector borne diseases, in particular the West Nile Virus. Recovery from encephalitis is often professionally measured in a two-year time span, as neighbouring areas of the brain struggle to re-learn skills and abilities that have been lost. This struggle can have a variety of success.

There are different types of encephalitis, including St. Louis Encephalitis, La Cross encephalitis, Eastern Equine Encephalitis, Western Equine Encephalitis, Rasmussen Encephalitis, Herpes Simplex Encephalitis – and now West Nile encephalitis, the newest arrival. Organisms that transmit disease from one animal host to another are called vectors. Mosquitoes are vectors for the transmission of encephalitis from small creatures — usually birds and rodents — to humans. Dan Dubno of CBS News recently reported a fact that is already known to much of the world, that *"According to Florida A&M University, mosquitoes "cause more human suffering than any other organism -- over one million people die from mosquito-borne diseases every year."* (Sept 23, 2004)

In the year 2000, I was capable to return to my computer at home, and I began searching for information about encephalitis. I found that there was only one registered charity in the WORLD for encephalitis, located in the United Kingdom. I contacted them by email to see if they would spread to North America, and they replied, "We will do England, Wendy. You can do the rest of the world." Thus, my website, "Encephalitis Global" was born. Thanks to the efforts of one of our members, who is a lawyer, we are incorporating Encephalitis Global into a non-profit corporation and seeking tax exempt status as a charity in the United States.

October 6, 2004
Prevention and Treatment of Mosquito-borne Diseases

In the last few years I have sought out encephalitis survivors, often traveling great distances to spread awareness. For example, on a weekend in July 2001, my Goodspouse[1] drove me on a 1,000 mile round trip, so I could speak on stage, in the local Community Center in Hermiston, Oregon. The audience was a large gathering of friends and family, getting together as a fundraiser to help support a local farmer who was hospitalized with encephalitis. Apparently, he was not the only one in his area who had been recently diagnosed. Another time, we took a break from a holiday, to meet with a family in Ft. Lauderdale Florida, where the young father had been recently diagnosed. Since the West Nile epidemic began in the United States, I have seen more and more encephalitis survivors.

In addition to my travels, my modest website has become an information reference used by a number of very well known resources on the internet, including the following:

- The Health on the Net Foundation in Switzerland includes Encephalitis Global, and has accredited us with their Honour Code... their highest rating, which confirms we follow their guidelines. - Honour Code Accredited
- In my own country, the National Library of Canada medical sciences includes Encephalitis Global as 616.832 Encephalitis Global.
- Here in the United States, the National Organization for Rare Diseases (NORD) offers Encephalitis Global as an 'organization related to encephalitis.' This means that I'm available, 24/7, to offer information and support.
- Cornell University Environmental Risks Program (West Nile) includes Encephalitis Global in their West Nile Resources section.
- CBS News 48 Hours Medical Mysteries did focus on encephalitis in one of their programs... now, Encephalitis Global is included in their website, as an information reference.

In 2001, the encephalitis community on the internet decided that it was time for us to get together. It did take twelve months to carefully organize the first annual international FACES (Friends And Caregivers Encephalitis Survivors) Conference here in North America, held in Ottawa, Canada in September 2002. The following year, our Conference was held in Las Vegas, Nevada. The third annual international Conference proudly took place earlier this summer in Enfield, Connecticut. This third Conference was included in the CDC Emerging Infectious Diseases (Volume 10, No. 7, July 2004, Page 174) Upcoming Infectious Disease Activities. Each Conference is a heartwarming meeting for survivors, caregivers and loved ones, and has welcomed guests from India and the United Kingdom, as well as from the United States and Canada. Attendees share information and support, and learn more from our excellent guest speakers about prevention, treatment and post-encephalitis coping strategies.

A Guest Speaker at our Conference, David W. Moskowitz, MD, is the Chairman, CEO and Chief Medical Officer for GenoMed, Inc. GenoMed is a company that uses its expertise in genomics to improve clinical outcomes. They announced recently (June 10 2004) that USA's second case of West Nile virus encephalitis has responded promptly to its treatment approach. Dr. Moskowitz states that, "viral encephalitis involves two players: the virus and the host. Not every person infected with the same virus has the same reaction to it. For example, only about one third of people with West Nile virus 'fever' go on to develop full-blown encephalitis. And no more than 30% of people with WNV encephalitis die. Why are some people unluckier than others?"

[1] This nickname, Goodspouse, was at first a term I used to refer to my husband, Rick, to respect his privacy when discussing my life online. Now, it has become a basic nickname used with respect for any spouse of an encephalitis survivor.

October 6, 2004
Prevention and Treatment of Mosquito-borne Diseases

Since North America began suffering from the West Nile Virus epidemic, members at Encephalitis Global shake their heads in wonder and disbelief when they hear folks moan and cry and try to second guess the need for that "annoying mosquito spraying." This NIMBY (not in my back yard) approach does unfortunately only display one side of the story. One can analyze the pro's and con's of any situation. Is it possible that some folks have more focus on saving the local insects, than protecting their family?

Over and over again, the public is told of how few people actually display symptoms of infection from West Nile. The public is also told about how few fatalities there are after the touch of encephalitis. Unfortunately, the media takes little or no interest in the survivors of encephalitis - people who are struggling to face life itself, after surviving this horrible disease, whether caused by a mosquito or other causes. In 2003, The CDC website reported 264 deaths from West Nile virus, PLUS **2,866 cases of West Nile neuroinvasive disease.** (Neuroinvasive Disease refers to severe disease cases, particularly West Nile meningitis and West Nile encephalitis.) By September 27th 2004, the CDC's website had reported 53 fatalities, plus 593 **cases of West Nile Neuroinvasive Disease in 2004.** When will people take note of these survivors, and start to care about THEIR fate?

Fortunately, some in the media do not just focus on fatalities. This past summer, the Arizona Republic's *News Update* reported:

> Thirty-seven people in Maricopa County have tested positive for West Nile virus, up from 20 last week. Twenty-eight have developed meningitis or encephalitis, swelling of the brain or spinal column. Five have West Nile fever, a milder form of the mosquito-borne disease. Victims range from age 21 to 86. Men outnumber women, 26 to 11. *"The concern is that it's doubling every week," said Michael Murphy of the Arizona Department of Health Services.* (Jun. 25, 2004 12:00 AM)

These survivors struggle with memory loss, where a fiancée is heartbroken when her intended really does not remember her, or the promise that they shared. A man's anger with himself, when his spouse is now the solo family bread-winner. Young people, who now face their education with frustration, as their peers move ahead and leave them behind. Or even a farmer, who can no longer return to his fields. Frankly, I have met a number of examples in each of these statements.

Post encephalitis symptoms may include any...or all... of the following:

- impaired memory - Difficulty committing information to memory; following a conversation, processing ideas through a specific modality (e.g., speaking but not writing); recalling appointments; recalling facts, such as definitions or technical terms.
- difficulty solving problems - difficulty organizing time, breaking large tasks down into smaller parts, and deciding where to start when tackling large tasks.
- Cognitive functions - difficulty recognizing objects (even close friends and family), picking out details, or completing tasks requiring visual-spatial abilities.
- A decrease in executive functions - With frontal lobe damage, it is common that higher order cognitive functions, such as reasoning and judgment are affected.
- Communication difficulties, trouble expressing thoughts - : If the motor functions of the brain are injured, then clear speech can be difficult to generate. However, the brain may also have difficulty transferring thoughts into speech or interpreting incoming speech.
- An increase in irritability and a decrease in tolerance for frustration;
- Symptoms of depression, social withdrawal, and learned helplessness;

- The tendency to display excessive or inaccurate emotional responses to events, the tendency to overreact
- Occasionally, the areas of the brain responsible for the initiation, coordination, and feedback of the body's movements are affected. These changes can occur in a number of forms, including reduced motor speed, spastic or rigid movements, body tremors, reduced hand-eye coordination, or poor balance. Individuals may also experience periodic seizures that involve a temporary loss of consciousness and/or muscular convulsions.
- Increased fatigue
- Poor coordination of movements
- Dizziness and loss of balance
- Frequent headaches or nausea
- An inaccurate assessment of ability
- Impulsivity
- Poor judgment

What is encephalitis? When asking a number of encephalitis survivors this question, they come up with a number of responses, including:

- Encephalitis is infection or inflammation of the substance of the brain, as opposed to meningitis, which is infection of the lining of the brain.
- Encephalitis is an illness that has changed my life forever for the worse. Nobody understands what encephalitis is, what it does to you, and, that it leaves you permanently disabled in ways they'll never be able to relate to.
- Ever find your tomatoes in your closet? Your newspaper in the freezer and it is dated a month earlier? Ever feel like you are trapped inside your body? Do your friends and family members tell you often that you have told them the same things over and over? You don't remember doing it? These are some of the challenges associated with living with encephalitis.
- People argue and say, "Memory loss? That's nothing! I forget stuff all of the time!" To which I reply, "Yes. You forget things two or three times a day. I forget things, two or three times an hour. Every hour."

There is very little research offered to the public, which notes the impact of West Nile in North America. Following are quotes from two studies.

Ohio State University Extension Fact Sheet (2003) http://prevmed.vet.ohio-state.edu/docs/wnvfact.pdf
"In a recent study it was found that of those cases that were hospitalized, half reported problems one year after their illness. Reported symptoms include headache, concentration problems, fatigue, and movement disorders. There is no specific treatment for West Nile Virus encephalitis or fever. All care is supportive, including hospitalization, respiratory support, and intravenous fluids. No vaccine or antiviral medication has been developed to prevent or treat this infection in humans. Primary prevention includes protection against mosquito bites, reducing residential mosquito breeding sites, and mosquito control efforts."

One study reported only 37% of patients who had West Nile encephalitis made a full recovery. The full recovery referred to physical, functional, and cognitive areas. New York State Department of Health and Hygiene media release (August 2004) http://www.nyc.gov/html/doh/html/public/press04/nyam-0812.html informs us that, "Nearly two-thirds of severely infected patients, especially elderly, still suffer physical and mental impairments 12 months after falling ill with West Nile."

The Casper Star Tribune **(Casper, Wyoming - Saturday, September 25, 2004)** carried an article titled "Colorado West Nile Cases Down." This sounds so very encouraging, until you read the article, which interviews a West Nile survivor.

> Glennia Milonich still gets bad headaches, nose bleeds and moments when she cannot see, ever since a mosquito infected her with West Nile virus on her front porch in Berthoud a year ago. ... Milonich, 39, was diagnosed with encephalitis and now has heart damage and swelling on the left side of her body that can keep her from walking. Medical tests have cost her about $18,000, she said.

Input from encephalitis survivors

Encephalitis Global is not just a site for finding links to learn about encephalitis and how it is transmitted to people through vectors such as mosquitoes and the West Nile Virus. It is a means by which survivors can share their experience with others. It helps put survivors and their families in contact with others for support and understanding. I have come in contact with numerous survivors of West Nile encephalitis and I speak for them and for others who have contracted this disease, whether from mosquitoes, or through other means. The following is just a brief selection of stories from my internet site written by folks touched by encephalitis:

- "Dear Wendy, I am so glad to hear that officials may soon be addressing this problem. My state is Texas. I was diagnosed with West Nile Fever and Encephalitis in August of 2003. I was 67 at that time. I was critically ill in ICU for over a week and then hospitalized several more. Since coming home my progress has been slow but ongoing. I had memory loss, balance problems, several falls, extreme fatigue/weakness, sleeplessness, numbness, muscle spasms and weakness in my right lower extremities and recurrent low grade fever. I still have most of these symptoms, but to a lesser degree as time passes. I still do use a cane to help me other than for very short distances here in the house. The impact of the illness has certainly been great in regard to my ability to carry out my previously normal activities and of course has impacted my family and my friends. We walk with faith that recovery is on the way and try to be patient and optimistic. Thanks you for all you have done to help so many people and best wishes for your continued involvement and efforts. " Sincerely, EF

- My sister was told West Nile and then St. Louis Encephalitis from a mosquito. Pray you don't get bitten because the medical world chalks you up for dead. You will not get the proper care and you will not get anything you are entitled. Your family will suffer along with you trying to understand and deal with the medical people with little or no success and the law will allow you to die while the medical people go about their merry way. Horrible but true. So if you have the misfortune of contracting this disease pray you recover quickly. Theresa M.

- *(I was diagnosed with...)* "WEST NILE ENCEPH when I woke up on my 50th birthday, 1 year ago, in Wyoming. My lasting symptoms: brain damage causing coordination, short term memory and personality changes. I work part time at my old job, I cannot climb stairs. I have graduated up to a cane from bedridden at its inception without good physical and occupational rehabilitation I wouldn't be where I'm at. Costs to a patient can become astronomical because insurance carriers will not cover rehab, neurological exams and tests are continuing for me." Craig.

- "I can't sue a mosquito, so I'm not. I thought that, as a partner in a fine Boston firm, who worked very hard all my life, I wouldn't have financial problems. I'm on a fixed income now, getting about a third of

what I made before and I'm lucky to have that. My problems range from profound fatigue, paralysis, sight problems, horrible headaches, tremors, myoclonus, seizures, gait problems, speech problems and unbelievable cognitive problems that people who don't know you just can't understand. I can't read out loud, understand conversation if it's with more than one person, remember a phone number, remember where I'm going, read a map, do my bills by myself. My work capacity in my brain is very small and if anyone interferes with what I'm doing, I can't go back to it. That's called no resistance to short term interference. The problems go on and on and interfere with my ability to work as a lawyer. While my general intelligence is in the 99th percentile, I test in the 1 percent on listening comprehension, things that get interfered with, etc, etc." Judith A.

I understand we are here today to talk about West Nile, but I really believe it is important for people to understand that the threat from mosquito-borne diseases is not limited to West Nile. Over the last few years, news has covered West Nile because it is the most recent epidemic. What about future epidemics from other mosquito-borne diseases? The following are brief quotes from survivors of mosquito-borne encephalitis other than West Nile.

- "Hello, My name is Charles H. Fletcher. I am a survivor of Viral Encephalitis. It is very hard for me to put in words all the ways this illness has affected my life and that of my family. I do not remember much of my hospital experience, but the doctors told me that I died twice in the first 24 hours. I was in Intensive Care for 5 days, then a regular room for 2 more. 2 days after arriving home, I suffered a stroke on the way to my doctor. I tried to return to work in January, but due to recurring, severe headaches (one lasted over a month) I felt it was no longer safe for me to operate any vehicle. Since that time my wife has taken a job at a convenience store, and I have been diagnosed with sleep apnea (which I think is a result of the encephalitis). Now I have to have oxygen forced thru my nose to keep me breathing while I sleep. This has put a tremendous strain on our financial situation, and we have to choose between feeding our three children or paying bills. I have had almost perfect credit until this illness struck me. The worst part is that the doctors are just guessing, because there have not been enough studies or testing of this illness. Please excuse any grammatical errors, this illness has also affected my memory and just about everything else. I am definitely not the same person I was before. I live in Mt. Olive, Illinois, I was diagnosed with St. Louis Encephalitis in October 2003', I was 38 years old. Evidently I was bitten by a mosquito near home in the week before I was admitted to Memorial Hospital in Colorado Springs, Colorado. It seems that I also am having problems following simple instructions and I have trouble concentrating. I hope this makes some kind of sense to you and that it will help someone to decide to put more funds into finding out ways to help people in my situation. I would gladly participate in any studies to help myself and anyone else that has been afflicted with Encephalitis and I pray everyday for all the families it affects. Sincerely, Charles H. Fletcher"

- "I came down with meningoencephalitis in 1992 after I was bitten by a mosquito. Initially I was taken to a chiropractor by my mother, and the chiropractor eventually arranged to have me admitted to Barrow Neurological Institute, in Phoenix, where I stayed for about 2 weeks. The day of release, the doctor told me he thought I was going to be 'ok', and I believed him. I had no idea what the unknown virus had done to my brain, or that I would have residual problems as a result of my illness.
My main problems were short term memory, loss of executive skills, short attention span, dememtia, depression, and basically feeling like my brain was in a fog. I used to love to read, but after e, I barely cracked a book since 1992! I used to be a pretty good chess player too, but that was wiped out also, since I had no problem solving skills left. I avoided situations where I would have to 'put my mind' to it, since I could no longer depend on my mind. The doctors never explained to me what happened to me, or if they did I don't remember. They should have written it down for me, since my short term

memory was affected so severely. Everything about encephalitis was always a great big mystery to me. I felt like my old life was gone, and it was quite lonely after encephalitis, since I was no longer able to engage in mentally stimulating conversations, rather I would 'keep it simple' and just get by with shallow conversation. I would not be able to keep up in a group conversation, and it was very frustrating.

- I learned everything I know about 'e' in Encephalitis Global and Ingrid's Yahoo Enceph Group. I found these sites after a 'relapse' of the residuals which took over my life 9 years post e. Now I know the dreaded effects of stress, and I have had to move back near family to avoid a very stressful place where I was living. I am so grateful for all the information and support I have gotten from these groups, I feel like I have a grip on my situation, living with 'e '." Kimberly M.

- "I was working with a girl who had EEE from mosquito bite, I have often thought of her through the years no idea if she is still alive. She was bitten in 1990 and was permanently on a vent and was wheelchair bound. She could move her face to make faces at you but that was basically it. She also had damage to her internal organs due to seizures which caused a sway in her lower back pushing the spine forward and shifting the organs around. She was five years old then born normal and basically her life was over she would never do anything for herself." Annette

- "I had St. Louis Encephalits in 1964. Was in a coma for one month. Ran a fever of 106-110 for two weeks. Since them I suffer from MAJOR HEADACHES. On a daily basis on a scale of 1-10 it is an 8. On a really bad day the pain will be at least 15. I then go to the hospital for a shot of demoral. I also have seizures. It is thought that the virus has laid dormant over the years and may be trying to kick back in like the polio virus. To date I have yet to find a physician who knows to much about this virus. It appears that they know more about the ebola fever than encephalitis." Pamela L, Lamar, Colorado

- "Hi Wendy, I had viral encephalitis which I got from mosquitoes. I got it when I was 2 and now I am 29 years old. I had to learn to walk and talk all over again. It has affected my speech, my balance, my coordination (especially eye and hand.), my fine motor skills are slow and I have learning disabilities and some mental health problems. (mostly depression) I n school, for a few years, I was in special classes. I was in speech therapy for 13 or 14 years. I thin it has impacted my adult life allot even though it has been 25 years. Sometimes when people can't understand what I am saying or I can't do something cause I can't balance or due to my fine motor skills, I feel alone and embarrassed. I am lots better then I was when I was younger but some days are still hard. I don't remember what it was like before I was sick and I am glad for that cause I think, for me, it would be harder. I understand everyone who has had this illness. It is frustrating somedays." Barb

- *(Bevan in California responds...)* " What A Difference~ ONE BUG Can MAKE! Especially A Dirty Little Mosquito! Evidently, I was "bitten" in the Fall Of 1975 in San Francisco, California. RESIDUALS?:Massive Head Trauma~(Brain Damage), Headaches, Sleep Deprivation, Unstable Body Chemistry, Diminished Memory~ (Short & LONG Term), No "Executive Function", Constant CONFUSION, Inability To READ, Diminished "Social Style", "Stroke Like" Symptoms, Diminished ATTENTION Span, Emotional INSTABILITY. IMPACT?: Sheesh ..... Lost Job, Lost INCOME, Almost Turned into a "Vegetable", Lost Wife & Family.

- "I'm Dianna S and you know me, but I just read this e-mail and it talks about Encephalitis from a mosquitto bite and that's what caused mine in 1989 and has screwed my life up since then with my

memory problems and losing my job do to my memory loss then few more years and I had to stop working and driving completely cause of the Lupus and Osteoporosis all from the Encephalitis back in 1989 and it's screwed my whole life up so much and I've become a different person from it all and how my life has turned out to be nowadays. I'm sick of it the way my brain works is so crazy I'll do something and regret it when I'm done but at the time it seemed like the right thing to do but it just helped me get through that it of time like drinking a few beers and when stop and go back to water I regret it and wonder why I did it in the first place since I can't taste or smell or nothing I guess I just do it cause of how my life is so boring there's just nothing going on in my life it's pretty much the same day after day. I just don't know what to do anymore."

There are many threats to happiness and health on this planet. But, when we have tools to combat the threat, we would be idiots to not use those tools. Members at Encephalitis Global shake their heads in wonder and disbelief when they hear folks moan and cry about "annoying mosquito spraying!" They cry that the pesticides may hurt our water quality or the scenery. What about the quality of life of survivors? If West Nile is spread by mosquitoes, then we must eliminate the infected mosquitoes.

We are also often told that, "encephalitis is only a threat to the very young, the very old, and those with lower immune systems." NO! Encephalitis is an equal opportunity disease, striking any and all parts of the community! Another media quote assures us "All those killed in New York by the disease were older than 50 and in poor health." Ah... at the age of fifty, we should no longer care? It's a shock in our culture, that in many instances, the only folks who take this topic seriously, are those who have experienced it!

Some sections of society have come to express disdain over the concern of mosquito-borne encephalitis. Perhaps, because it's getting to be a rather tedious and boring subject in the media, some seem to be wishing that we'd just hush up and cease. It seems that every winter, some media quick-wit shouts out a comparison of the fatality impact of influenza in North America, vs. the fatality impact of mosquito-borne virus, then pooh-poohs the need to be concerned about the mosquito. Society needs to understand, that there is MORE to encephalitis, than the fatality head count!

With proper procedures taken, the impact of mosquito-borne West Nile encephalitis can become a much more controlled situation. With proper procedures, mosquito abatement can protect both the environment and lower the mosquito population. It does not have to be one or the other. We must remind society of the integral part our local mosquito control officers play in striving to lighten the impact of mosquito-borne disease. It seems in so many situations, that somehow, the mosquito-control team have become, "the bad guys." Folks who are not educated or enlightened, often vent and spew, without understanding the facts. I hope that in reviewing the auto-biographies submitted by my friends, you will understand my dismay at this foolish attitude.

The key is to share information, and raise awareness. We must focus on reducing the mosquito population, study the creation of a vaccine, and recognize the impact of mosquito-borne encephalitis such as the West Nile Virus. These are not steps taken with loud dramatic panic, but with education, self respect and motivation to protect our loved ones, and ourselves.

I wish to thank the Subcommittee for its patience and courtesy in allowing me to testify here today. I would be happy to answer any questions you may have or to provide additional information. It has been a sincere honour to appear before you.

Wendy Station, Founder
Encephalitis Global www.encephalitisglobal.com

Mr. OSE. Our next witness is Mr. David Brown, who is the Chair of the integrated pest management efforts at the California Mosquito and Vector Control Association.

Sir, welcome to our subcommittee. Appreciate your written statement. It has been read and entered into the record. You are welcome to summarize in 5 minutes.

Mr. BROWN. Thank you, sir.

Good morning, Mr. Chairman and Congressman Tierney. My name is David Brown. I am a member of the Mosquito and Vector Control Association of California, an association comprised of 57 public health agencies responsible for the control of mosquitoes and other vectors in California.

I also co-chair the Association's Integrated Pest Management Committee; and, Congressman, I am also the manager of the Sacramento Yolo Mosquito and Vector Control District, the area where you earlier referred to, the detention basin being developed.

Mr. OSE. That is a coincidence, I am sure.

Mr. BROWN. Since 1999, as West Nile virus has steadily moved west, we have seen its arrival here in California to where, as of October 1, 2004, West Nile virus has been detected in 57 of the 58 counties of California, with over 654 humans infected and 18 deaths.

There have also been 419 equine cases, with 177 of the horses dying from the infection or requiring euthanization. Most of the human infections have been located in the southern part of the State, but as the virus becomes more established we can anticipate Northern California facing serious issues next year as well, and I believe that was discussed and confirmed from the earlier panel as well.

California has what could be characterized as the most comprehensive mosquito control programs in the United States, fully utilizing integrated pest management in our control efforts. California's unique blend, however, of wetlands, agriculture and dense urban populations create a public health challenge when addressing mosquito populations.

However, since we have seen West Nile virus move into California, we have significantly increased surveillance for mosquitoes, cooperating with the California Department of Health Services in a dead bird surveillance program. We dramatically increased control responses in areas where the disease has been detected, and we have increased education to citizens on how they can prevent the disease themselves.

We do have concerns about sustaining and maintaining these efforts, as has already been outlined from the previous panel and in my written testimony. Specifically, issues of funding regarding maintaining our mosquito control efforts as well as the need for clarity of regulations between the Clean Water Act and FIFRA. We are hopeful that we can address some of these issues today.

I want to thank you for the opportunity to provide this testimony, and I will be happy to address questions later.

Mr. OSE. Thank you, Mr. Brown. I appreciate your participation.

[The prepared statement of Mr. Brown follows:]

Good morning, Mr. Chairman and Members of the Subcommittee. My name is David Brown. I am a member of the Mosquito and Vector Control Association of California ("MVCAC"), an Association comprised of 57 public health agencies responsible for the control of mosquitoes and other vectors. I Co-Chair the Associations' Integrated Pest Management Committee, and I am also the Manager of the Sacramento-Yolo Mosquito and Vector Control District. I welcome this opportunity to provide information to this committee regarding West Nile Virus in California, the status of control operations, and some hurdles agencies face regarding maintaining effective control measures now and in the future

West Nile virus was first detected in New York City in 1999. Since that time it has steadily moved west, with California finding its first infected birds and mosquitoes last year. This year, as of October 1, 2004, West Nile virus has been detected in 57 of the 58 counties of California, with 654 humans infected and 18 deaths. There have been 419 equine cases, with 177 of the horses dying from the infection or requiring to be euthanized. Most of the human infections have been located in the southern part of the state, but as the virus becomes more established, Northern California is expected to face serious consequences as well.

Despite having what could be characterized as the most comprehensive mosquito control programs in the United States, California's unique blend of wetlands, agriculture, and dense urban populations create a public health challenge when addressing mosquito populations. Mosquito control districts have significantly increased surveillance for mosquitoes, dramatically increased control responses in areas where the disease has been detected, and increased education to residents in the communities they serve. Many mosquito control districts have already spent their entire operating budgets against West Nile virus and anticipate depleting their reserves, which will leave California facing serious consequences from this and other mosquito-borne diseases next year.

Adequate funding for mosquito control is critical to fully implement control measures that allows mosquito control districts and other interests to work together to provide wildlife habitat, feed our nation and the world, and protect the public health by controlling mosquitoes. Mosquito control districts have been committed to working with our partners in our respective communities to maintain the quality of life the residents of California have come to expect. Adequate funding has not always been available, however, particularly with the budget woes with which California has faced. Continuing to use the most comprehensive and integrated mosquito control measures recognized throughout the world requires adequate and stable funding, and mosquito control districts in California, or areas that require mosquito control, have not had this since Proposition 13 was passed several years ago. This needs to be resolved to protect the residents of California.

The comprehensive methods used to control mosquitoes include the principles of Integrated Pest Management (IPM). These principles include physical, biological, and chemical control. However, due to recently implemented federal regulations and court decisions, the ability for mosquito control districts to fully employ the principles of IPM have been compromised.

For example, there are several issues relative to the Clean Water Act's National Pollutant Discharge Elimination System (NPDES) permitting process that are creating difficulties for public health agencies responsible for mosquito control to adequately perform their jobs. Storm water discharge requirements require the construction of devices that are called "Best Management Practices" (BMP's) that often create habitat for mosquitoes. These BMP's are often densely vegetated swales or devises that are designed to filter runoff water. Unfortunately, they are designed without any consideration for the potential of mosquito development, and provide excellent egg laying sites for female mosquitoes. In addition to this, the lack of maintenance programs either due to insufficient funding or basic disregard result in the need for direct pesticide applications to address mosquito populations. This is completely counterintuitive to their purpose (applying pesticides to water that is supposed be filtered for purity?), and could be resolved by incorporating good design and maintenance programs into the plans that would sharply reduce the need for pesticide applications. It should be noted mosquitoes at these sites has been implicated in the transmission of West Nile virus.

Further complicating this issue are circuit court rulings that some states have interpreted to mean that NPDES permits are required for the application of federally registered pesticides to Waters of the United States. For example, some states in the Ninth Circuit have developed NPDES permits for the legal application of pesticides to

MOSQUITO AND VECTOR CONTROL ASSOCIATION OF CALIFORNIA

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waters, suggesting this is a "discharge" of a "pollutant" to a water way. In California and Washington, there are currently NPDES permits for the application of herbicides, and a separate permit for the application of mosquito control agents. Idaho, also in the Ninth Circuit, does not issues NPDES permits, yet USEPA will not grant them one, which leaves them in double jeopardy

This interpretation will and has had serious implications to mosquito control. Vegetation management is a critical tool used in any comprehensive IPM plan for mosquito control. However, mosquito control agencies in California have discontinued using this tool due to the substantial costs of water quality monitoring required under an NPDES permit for the application of herbicides. In addition, the herbicide permit in California has been challenged in court, claiming current water quality standards have not been met, which would suggest a significant increase in monitoring costs. Public health agencies cannot afford the costs or potential liability, and have abandoned vegetation management in many aquatic sites.

Increased vegetation in aquatic sites tends to lead to increased mosquito development, as well as reduce the effectiveness of overall mosquito control. Dense vegetation reduces the effectiveness of biological control agents (fish cannot adequately seek out and feed upon mosquito larvae), and vegetation inhibits larvicides from reaching the water surface where mosquito larvae reside.

In fact, vegetation management alone will often eliminate the need for mosquito larvicides by allowing wave action to disturb the surface, disrupting the stagnant habitat that mosquito larvae require.

The NPDES permit that exists in California for mosquito control creates further concerns for the future of effective mosquito control. First, the permit currently provides protection for the application of mosquito larvicides, and is silent on the application of pesticides for adult mosquitoes. This is of concern to public health officials, since there is no other effective means of quickly reducing an adult mosquito population in times of serious infestations or epidemics. However, all of the current lawsuits filed under the Clean Water Act in the country against mosquito control operations, most notably in New York and Idaho, have included the applications of both mosquito larvicides **and** mosquito adulticides, exposing public agencies to the threat of litigation we cannot afford.

Mosquito control in the state of Idaho, which is also in the Ninth Circuit, faces an even more troubling situation. Idaho does not administer the NPDES program, relying instead on USEPA to administer and issue NPDES permits. However, a mosquito control district in Idaho, currently facing a lawsuit because of not having an NPDES permit for the application of mosquitocides, has yet to received any notification from the EPA as to whether they need a permit or not for their pesticide applications!

Second, the permitting process has the potential of prohibiting certain larvicides that are currently used for mosquito control .For example, the state of Washington has prohibited a certain larvicide based on dubious "scientific" information, despite objections from public health officials and a complete and thorough registration review by the USEPA. This practice will eventually result in an over-reliance of the only remaining larvicide and promote resistance development in the mosquito population. This is contrary to effective pest management, and California mosquito control professionals, with few remaining larvicides left in the market place, can ill-afford the loss of any tools.

Another issue involving the lack of effective public health pesticides to control mosquitoes in California, where we often share pesticides concurrently used in agricultural operations, is very real. Congress recognized this concern about the lack of public health pesticides by unanimously passing the Food Quality Protection Act. However, provisions in this act addressing the review of current public health pesticides and the need for development of future compounds for public health has never been funded, leaving public health agencies without all of the tools they need.

These issues pose concerns about the future of effective mosquito control to protect the public health for the residents in California. We believe, however, that steps can be taken to address these issues before they become insurmountable.

First, to ensure adequate funding is available for mosquito control, the Mosquito Abatement for Safety and Health (MASH) Act should be fully funded. This legislation, passed and signed into law, has yet to receive any appropriation from congress. One in five people in California are not protected by a mosquito control program, and the state of California, with its own financial woes, does not have adequate funding to address this shortfall. Fully funding the MASH Act would address not only this shortfall in California, but address other states concerns as well.

Second, storm water discharge requirements should fully implement measures to address the potential

growth of mosquitoes from the development of BMP's. Requiring engineers that design these BMP's to work with public health agencies should address not only water quality objectives, but reduce mosquito production as well. An example of how this can work is demonstrated by legislation recently chaptered into law in California. AB 1982, introduced by Assemblymember Lois Wolk, requires the California Department of Fish and Game to incorporate best management practices on land they manage that are designed to preserve wetland values, yet reduce mosquito development. Similar efforts should be made under storm water discharge requirements.

Third, the USEPA should immediately undertake a rulemaking clearly stating that the application of pesticides is not a discharge of a pollutant and therefore is not subject to the provisions of an NPDES permit. The MVCAC has been working with the American Mosquito Control Association (AMCA) to address this situation, and is in full support of a petition put forth by the AMCA to EPA to perform such a rulemaking. To date, the agency has failed to respond to the AMCA s' petition. The "Interim Statement and Guidance" document released by EPA essentially stating that the application of pesticides is not a discharge of a pollutant and therefore does not require an NPDES permit is a good start, but is nothing more than a memo in parts of the Ninth Circuit and has not been given deference by water quality agencies in these states. USEPA should clearly state its position by acting on the petition submitted by the AMCA and immediately perform a rulemaking.

Lastly, congress should fully fund the provisions of the Food Quality Protection Act relative to public health pesticides. This will ensure public health agencies in California and the rest of the country will have the tools they need to do the job they are mandated to perform.

The presence of West Nile virus in California will not be the only threat our residents will face in a global community where diseases can be transported by a single flight of a commercial airliner. Ensuring we have effective control measures in place not unduly hampered by vague regulations or unfunded legislation is of benefit not only to California, but to the rest of the nation as well.

Thank you for the opportunity to address these issues.

MOSQUITO AND VECTOR CONTROL ASSOCIATION OF CALIFORNIA

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Mr. OSE. Our next witness is Mr. Joe Conlon, who is the technical advisor to the American Mosquito Control Association. Mr. Conlon, I have actually waded through your testimony, and I have lots of questions. I am hoping you can summarize and clarify. You are recognized for 5 minutes.

Mr. CONLON. Very well, sir.

Good morning. My name is Joseph Conlon. I am an entomologist serving as technical advisor for the American Mosquito Control Association, a nonprofit organization dedicated to enhancing public health through the suppression of mosquito vectors; and I welcome this opportunity to provide a mosquito control perspective to the deliberations of this committee.

The introduction and spread of West Nile virus in the United States has reawakened an appreciation of mosquitos as vectors of disease. I use the term reawakened advisedly, for mosquito-borne diseases were once quite prevalent in the United States and indeed played a major part in shaping our Nation's destiny. These diseases no longer claim victims in the United States as a matter of course, largely due to the exemplary effort of organized mosquito control agencies in conjunction with an enlightened and effective public health infrastructure.

Best mosquito management practices, when exercised within an integrated framework of surveillance, prevention and control, have demonstrated their effectiveness in combating West Nile virus when employed as a phased response challenge.

The integrated mosquito management methods currently employed by organized control districts in the control of West Nile virus and endorsed by both the CDC and EPA are comprehensive and specifically tailored to safely counter each stage of the mosquito lifecycle. Larval control through water management source reduction, where compatible with other land management uses, is the lynch pin of this strategy, as is use of the environmentally friendly EPA registered larvacides currently available.

When source elimination or larval control measures are clearly inadequate or in the case of imminent disease, both the EPA and CDC have emphasized in a published joint statement the need for considered application of adulticides by certified applicators trained in the special handling characteristics of these products.

The extremely small droplet aerosols utilized in adult mosquito control are designed to impact primarily on adult mosquitos that are in flight at the time of application. Degradation of these small droplets is extremely rapid, leaving little or no residue in the target area at ground level. These special considerations are major factors that favor the use of very low application rates for these products, generally less than 4 grams active ingredient per acre, and are instrumental in minimizing adverse impacts.

Since its inception, the Environmental Protection Agency has regulated mosquito control through the enforcement of standards instituted by FIFRA. This legislation mandated documentation of extensive testing of public health insecticides according to EPA guidelines prior to their registration and use. These data requirements are among the most stringent in the Federal Government and are met through research by established scientists in Federal, State and private institutions.

This process costs a registrant several million dollars per product but ensures that the public health insecticides available for mosquito control do not represent health or environmental risks when used as directed. Indeed, the five or six adulticides currently available are the selected survivors of literally hundreds of products developed for these uses over the years. The dosages at which these products are legally dispensed are at least 100fold and often several thousandfold less than the point at which public health and environmental safety merit consideration.

In point of fact, literature posted on the Web sites of the EPA Office of Pesticide Programs, CDC, American Association of Pesticide Safety Educators and National Pesticide Telecommunications Network emphasizes that proper use of mosquitocides by established mosquito control agencies does not put the general public or the environment at unreasonable risk from runoff, leaching or drift when used according to label specifications.

Even with these safeguards, organized mosquito control agencies often go to extraordinary lengths to accommodate individuals who, for varying reasons, prefer their property not be sprayed with approved public health insecticides.

When surveys indicate the need for adult sprays, they are approved, planned and conducted with special regard to the concerns of chemically sensitive persons. Personal notification of chemically sensitive individuals, the spray times, in addition to using global positioning systems and global information systems technology to reduce the likelihood of drift over unauthorized areas are but a few of the means utilized to ensure mosquito control serves the entire public health spectrum.

The AMCA fully endorses the Clean Water Act's intent of reducing pollutant load in the Nation's clean water while allowing productive use of that resource. However, the AMCA considers NPDES permits attendant to this legislation to be both redundant and unnecessary for the application of public health insecticides specifically registered by EPA under FIFRA.

Furthermore, the excessive fiscal burdens that NPDES permits entail through compliance measures and threat of civil lawsuits will ultimately divert scarce mosquito control resources away from the primary mission of protecting human health while not contributing tangibly to the critical goal of environmental protection.

In January 2003, the American Mosquito Control Association proposed a rulemaking by EPA to exempt mosquito larvacides duly registered under FIFRA for water application from NPDES permit requirement. A clear articulation by EPA of the exemption of FIFRA registered mosquito larvacides and adulticides from these permitting requirements through a rulemaking would both tangibly validate the registration process while obviating further civil litigation.

The EPA currently has this issue under active review, but at some point definitive action by the agency is needed or the citizen suits attendant to CWA will continue to proliferate.

West Nile virus has now accounted for almost 16,000 cases, 622 fatalities, and 48,000 cases of meningoencaphalitis. Those statistics are but a pale shadow of the human experience of this devastating disease. The increase in worldwide tourism and trade virtually

guarantees further challenges from other exotic mosquito-borne diseases such as Japanese encephalitis and Rift Valley Fever in the future.

Should these emerging diseases settle into the American public health landscape, particularly an as unintended consequence of otherwise laudatory environmental policy initiatives, we will have only ourselves to blame, for we have the means to control these diseases within our grasp.

A robust interagency cooperation and design, resourcing and implementation of sustainable mosquito-borne disease programs are cornerstones of this national effort. In conjunction with judicious application of federally registered and NPDES-exempt public health mosquito insecticides when warranted our shared goals of both the health populous and environment can thus be attained—our citizens and our Nation's wildlife deserve no less.

Again, thank you for the opportunity to testify, and I would be most happy to answer any questions.

[The prepared statement of Mr. Conlon follows:]

WEST NILE VIRUS: The Role of Mosquito Control

HEARING BEFORE THE

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON ENERGY POLICY, NATURAL RESOURCES
AND REGULATORY AFFAIRS

TESTIMONY
OF
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ON BEHALF OF
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OCTOBER 6, 2004

Good morning, Mr. Chairman and Members of the Subcommittee. My name is Joseph Conlon. I am an entomologist serving as Technical Advisor for the American Mosquito Control Association (AMCA), a nonprofit organization dedicated to enhancing health and quality of life through the suppression of mosquitoes and other vectors of public health importance. I welcome this opportunity to provide a public health perspective to the deliberations of this committee concerning West Nile Virus and will limit my testimony to mosquito control methodologies that contribute to its control.

The introduction and spread of West Nile Virus in the United States has reawakened an appreciation of mosquitoes as vectors of diseases. I use the term "reawakened" advisedly, for mosquito-borne diseases were once quite prevalent in the United States and, indeed, played a major part in shaping our nation's destiny. Dengue Fever, long a scourge in the tropics worldwide, was in fact first described by Dr. Benjamin Rush in Philadelphia in 1780. Additionally, Yellow Fever caused over 100,000 deaths in 135 separate epidemics in the United States from 1793 until 1900, and as late as 1934, there were 125,566 cases of malaria. These diseases no longer claim victims in the United States as a matter of course largely due to the exemplary efforts of organized mosquito control agencies, in conjunction with an enlightened and effective public health infrastructure. Indeed, the mosquito control profession enjoys a long and proud legacy of community service in its pursuit of improved quality of life and a society relatively free from the ravages of mosquito-borne diseases that have afflicted our country in times past.

Since its introduction into the United States in 1999, West Nile Virus has spread southward and westward at an alarming pace, with a total of almost 15,700 human cases and 650 fatalities as of 24 September, 2004. Approximately 20% of human West Nile cases develop West Nile Fever, whose symptoms include fever, headache, tiredness, and body aches, occasionally with a skin rash (on the trunk of the body) and swollen lymph glands. This condition can last anywhere from a few days up to several weeks. Almost 30% of symptomatic human West Nile cases develop a more severe form of neuroinvasive disease characterized by headache, high fever, neck stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, and paralysis. The neuroinvasive form occurs most often in people over age 50 and some immuno-compromised persons (for example, transplant patients), but can occur at any age in healthy individuals. To date in 2004, a total of 1508 human cases have been reported. Of these, 45 have been fatal, 532 (35%) exhibited neuroinvasive symptoms, and 622 (41%) were classified as West Nile fever. In 2003 a total of 9862 human cases were reported. A total of 264 of these were fatal, 2866 (29%) were diagnosed as neuroinvasive, and 6830 (69%) were classified as West Nile fever.

The costs these cases entail are extraordinary and extend far beyond medical and vector control expenditures. It has been estimated by CDC that the average cost per patient hospitalized with WNV infection in Louisiana in 2002 was $51,826, with the total cost of treatment and control exceeded 69 million dollars. However, these numbers fail to address the additional emotional cost to families of victims of mosquito-transmitted disease, a radically-changed quality of life of the victims and similar issues.

West Nile Virus has wrought havoc with wildlife as well. A total of 208 avian species and 29 mammalian species have been found infected. Although accurate counts of absolute numbers of birds and mammals fatally infected are problematic, the toll for corvids (crows, jays, etc.) is estimated to be in the millions. Horses suffer a 40% mortality rate from infection with this virus. The cost to the horse industry in vaccinations, medical costs, prevention/control measures, and mortality is estimated to exceed one billion dollars.

Great strides have been made in defining the transmission dynamics of West Nile Virus. However, considering that it is a comparatively recent epidemiological phenomenon, there remains much to learn in order to establish and verify baseline data. The cycle involves birds as a reservoir of infection and means of spread through migration, avian-feeding species of mosquitoes amplifying the virus among bird populations, and bridging species of mosquitoes that feed upon both birds and mammals transmitting the virus to humans and equines. At present, 59 of the 176 species of mosquitoes currently recognized in the United States have tested positive for the virus. Of these, generally one species is primarily responsible for transmitting the disease in a particular area. The extent to which other species contribute to the problem is often poorly understood. Each species utilizes preferred aquatic habitats within which to breed. These habitats vary widely, from salt marshes to used car tires. Virtually any collection of stagnant water is fair game, with some species successfully utilizing even soda bottle caps. Factors favoring choice of breeding habitat depend upon the mosquito species involved, topography, climate and human use patterns.

As early as 1905, mosquito control pioneers recognized the value of a diversified approach to control, integrating surveillance, source reduction, personal protection, and chemical and biological control. Early control methods consisted of ditching, draining, and/or filling marshes, applying oils to water to kill immature mosquitoes, and insecticide sprays against adults. Realizing there now existed a means to obtain a measure of public health protection heretofore unavailable, citizen groups began conducting referenda to establish special taxing districts to fund organized mosquito control activities. The first districts were established in NJ in 1912. California and Florida followed suit in 1915 and 1925, respectively. In the ensuing years, mosquito control districts and state agencies were established nationwide. Mosquito control personnel refined their methods through applied research and assisted federal and state agencies in developing certification criteria to ensure conformance to stringent safety standards. Since the 1950's, control programs have progressively adopted the use of nationally registered public health larvicides and adulticides to further exploit mosquito vulnerabilities within an increasingly environmentally friendly context. That tradition continues today. In fact, the American Mosquito Control Association has established a formal partnership with the EPA in investigating means of improving effective mosquito control while reducing reliance upon public health insecticides. This Pesticide Environmental Stewardship Program (PESP) has the full and active support of the entire mosquito control profession.

This success did not come about in a regulatory vacuum. Since its inception, the Environmental Protection Agency (EPA) has regulated mosquito control through enforcement of standards instituted by the Federal Insecticide, Fungicide, and Rodenticide Act. This legislation mandated documentation of extensive testing for public health insecticides according to EPA guidelines prior to their registration and use. These data requirements are among the most stringent in the federal government and are met through research by established scientists in federal, state and private institutions. This process costs a registrant several million dollars per product, but ensures that the public health insecticides available for mosquito control do not represent health or environmental risks when used as directed. Indeed, the five or six adulticides currently available are the selected survivors of literally hundreds of products developed for these uses over the years. The dosages at which these products are legally dispensed are at least 100-fold (and often greater than 1000-fold) less than the point at which public health and environmental safety merit consideration. In point of fact, literature posted on the websites of the EPA Office of Pesticide Programs, Centers for Disease Control and Prevention (CDC), American Association of Pesticide Safety Educators and National Pesticide Telecommunications Network emphasizes that proper use of mosquitocides by established mosquito control agencies does not put the general public or the environment at unreasonable risk from runoff, leaching or drift when used according to label specifications.

Even with these safeguards, organized mosquito control agencies often go to extraordinary lengths to accommodate individuals who, for varying reasons, prefer their property not be sprayed with approved public health insecticides. When surveys indicate the need for adult sprays, they are approved, planned and conducted with special regard to the concerns of chemically sensitive persons. Personal notification of chemically-sensitive individuals of spray times in addition to using Global Positioning Systems (GPS)/Global Information Systems (GIS) technology and drift-modeling computer programs to reduce the likelihood of drift over unauthorized areas are but a few of the means utilized to ensure mosquito control serves the entire public spectrum.

Successful West Nile Virus control programs as practiced nationwide today rely upon principles of Integrated Pest Management (IPM). IPM, as the name implies, utilizes a variety of physical, chemical, mechanical, cultural, biological, and educational measures, singly or in appropriate combination, to exploit the mosquito's vulnerabilities and attain the desired level of mosquito control consistent with community needs. Application of these measures is predicated upon surveillance data indicating a need for intervention. In this light, the *sine qua non* of effective, sustainable West Nile Virus control is a sound, comprehensive surveillance program driving intervention efforts. Knowledge of the target mosquito vector allows efficient allocation of control resources specifically tailored to safely counter each stage of the mosquito life cycle. Larval control through water management, vegetation management and source reduction, where compatible with other land management uses, is a prudent pest management alternative - as is use of the

environmentally friendly EPA-approved larvicides currently available. When source elimination or larval control measures are clearly inadequate, or in the case of imminent disease, the EPA and CDC have emphasized in a published joint statement the need for considered application of adulticides by certified applicators trained in the special handling characteristics of these products. The extremely small droplet aerosols utilized in adult mosquito control are designed to impact primarily on adult mosquitoes that are on the wing at the time of the application. Degradation of these small droplets is rapid, leaving little or no residue in the target area at ground level. These special considerations are major factors that favor the use of very low application rates for these products, generally less then 4 grams active ingredient per acre, and are instrumental in minimizing adverse impacts.

Components of contemporary West Nile Virus control programs include the following:

Prevention

Surveillance - A sustained, consistent surveillance program targets vector species, identifies and maps their larval habitats by season, documents the need for control through larval and adult trapping regimens. It thus also monitors the effectiveness of the control program. Appropriate and timely response to surveillance data is the key to preventing human and animal disease associated with WNV. Detection of epizootic transmission of enzootic arboviruses Control activity should be intensified in response to evidence of virus transmission, as deemed necessary by the local health departments.

- Virus Surveillance of Mosquitoes/Birds - Detection of WNV in bird and mosquito populations appears to be the most sensitive early detection system for WNV activity, typically preceding detection of human cases by several days to several weeks. Early-season detection of WNV activity in birds and mosquitoes appears to be correlated with increased risk of human cases later in the season.
    - Surveillance programs based upon dead birds are the most sensitive method of detecting WNV presence in an area.
    - Captive sentinel surveillance typically utilizing chickens and programs based upon free-ranging bird surveillance have both been used. Both of these approaches requires extensive knowledge of local transmission dynamics and may require animal use and care protocols and other authorization permits.
    - Mosquito surveillance based upon trapping remains the primary tool for quantifying the intensity of virus transmission in an area. In addition, these techniques can monitor efficacy of control programs.
        - Light traps and gravid traps remain classical methodologies

- If appropriate, human biting/landing counts can be used to establish accurate data regarding mosquitoes questing for human meals.

- Human Surveillance - Human case surveillance, both passive and active, alone should not be used for the detection of arbovirus activity, except in jurisdictions where arbovirus activity is rare or resources to support avian-based and/or mosquito-based arbovirus surveillance are unavailable.

Public Information and Outreach – Studies have shown that information programs, while crucial to the overall prevention/control strategy, have a moderate effect on modifying population behaviors related to personal protective measures. About half of the population actively attempts to reduce breeding habitats aroound their domiciles. A smaller percentage use repellents due to perceived risk and other complex demographic factors. Nevertheless, programs should include strategies to facilitate protective actions and to address barriers that hinder preventive actions. Effective programs include developing a community task force, interventions to improve access to window screening materials or repellents, and social marketing to reinforce preventive behaviors. These are critical components of any mosquito control program, but cannot, in and of themselves, replace established prevention/control methodologies.

Source Reduction - Source reduction involves the elimination, where possible, or modification alteration of water sources to make them unavailable for mosquito breeding. Removing breeding habitat is the most effective long-term mosquito control where allowed, but modification through the selective use of herbicides to make the habitat unsuitable for breeding is also extremely effective. Source reduction includes activities as simple as the proper disposal of used tires, paint cans and trash, in addition to the cleaning of rain gutters, bird baths, and unused swimming pools by individual property owners. This can also include extensive regional water management projects conducted by mosquito control agencies on state and/or federal lands, where permitted. Source reduction activities can be separated into the following two general categories:

- Sanitation – Cleanup of peridomestic stagnant water sources provides a substantial reduction in biting activity. Educational information about the importance of sanitation in the form of videos, slide shows, and fact sheets distributed at press briefings, fairs, schools and other public areas can be effective in reducing these as breeding habitats. Considering that mosquitoes breeding in these containers tend to feed upon humans in close proximity, they constitute an important disease risk.

- Water Management – Proper stormwater management and both fresh and saltmarsh management are critical and resource-intensive forms of source reduction of important nuisance and vector species. Included in this strategy is

vegetation management through physical removal or herbicide applications within potential habitats to remove means for larvae to escape predation.

Control

Surveillance results drive all facets of the control program. Control ultimately consists of reducing the contact between the vector mosquito and humans. This is accomplished through removing, modifying or treating larval habitats; modification or removal of adult mosquito resting areas, adulticide treatments when indicated; use of repellents. Most Best Management Practices (BMP) utilized in mosquito control districts employ a phased response based upon surveillance data, using only those measures likely to be most effective based upon a variety of bionomic, atmospheric and environmental factors. Such programs should consist of public education emphasizing personal protection and residential source reduction; municipal larval control to prevent repopulation of the area with competent vectors; adult mosquito control to decrease the density of infected, adult mosquitoes in the area; and continued surveillance to monitor virus activity and efficacy of control measures.

The following components may be used concomitantly or at intervals determined by target bionomics, host demographics or environmental factors.

- **Larval Control** – Mosquito larvae, although air-breathers, require a source of reasonably stagnant water in which to feed and ultimately metamorphose into adults. Larval control is extremely efficient, in that the larvae are confined within the aquatic habitat and are usually concentrated. While this makes possible a variety of strategies to effect control, environmental considerations are of paramount concern.
    - Biological Control – this may involve augmentation of natural predator species such as mosquitofish, but may also include cannibalistic species of mosquito larvae, viruses, fungi, bacteria and predaceous aquatic invertebrates.
        - Fish, most notably *Gambusia*, are extensively used throughout the country but their use must generally be cleared with local Fish and Wildlife officials.
        - Augmenting or introducing aquatic predators of mosquito larvae alters the local ecosystem in often unforeseeable ways, and should be done with great caution.
    - Chemical Control – Because chemical larvicides are to be used in sensitive aquatic environments, they are specifically designed to minimize their impact on non-target organisms. They must be applied, by law, only to a predefined target site whose guidelines are specified on the label. To

ensure its effectiveness, the application rate for each larvicide is calculated on the basis of its toxicity profile and degradation characteristics. For example, the application rate for methoprene is calculated to achieve a final concentration in water of between 0.22 to 1.1 parts of product per billion (ppb). This would be equivalent to an initial dose of roughly one drop in an Olympic sized swimming pool. Chemical larvicides roughly fall into the following categories:

- Bacteria such as the various species of *Bacillus* are widely used and extremely effective means of control. They must be ingested by the larvae and therefore are less effective in habitats with high organic loads serving as competeing food sources.
- Insect growth inhibitors constitute insect metamorphosis hormone analogs that prevent the mosquito larvae from molting eventually to the adult stage.
- Surfactants reduce surface tension of the water, making it impossible for the larvae to attach their breathing apparatus, drowning them.

- **Adult Mosquito Control** – Adult mosquitoes, being active fliers in a three dimensional space, present a unique challenge for their control. Control methodologies vary with the species involved, their peaks of activity, known resting areas, and other environmental factors.
  - Elimination of resting areas – Eliminating brush and high grass removes places where mosquitoes avoid dessication during their non-active periods. This makes the immediate vicinity less hospitable for questing female mosquitoes.
  - Personal protective measures – Measures to reduce biting include alteration of schedules to avoid peaks of mosquito activity, proper dress when outside, and use of repellents.
  - Encouragement of natural predation on adult mosquitoes – Use of bats and certain bird species has great public appeal, but has been disappointing in terms of reducing mosquito populations.
  - Chemical control - Modern pest management strategies endorsed by EPA and the Centers for Disease Control and Prevention recommends application of adulticides when surveillance indicates that larval control measures have proven inadequate to prevent imminent disease outbreaks. Certified operators trained in the special handling requirements of adulticides apply them after dusk under specified atmospheric conditions when mosquitoes are most active and non-target species are generally not

at risk. Adulticides are usually applied in aerosol form of extremely small droplets (10 million of the standard 20-micron droplets could fit inside of a BB) so that they remain airborne to impinge upon mosquitoes in flight at the time of application. The minute droplet size also ensures that products dissipate and degrade quickly, to minimize any deposition of active ingredient on the ground or other surfaces. The low application rates of these aerosols—generally less then ¾ ounce of insecticide per acre treated—further minimizes environmental risk.

There is a large body of scientific literature demonstrating significantly reduced trap counts after adulticide applications. Since the size of questing female mosquito populations is crucial to disease transmission, it would be prudent to utilize all approved means to reduce these populations below transmission threshold. Adulticide applications should not be the sole means of control in an urban setting. But that is not to argue that adulticides should not be used at all. Even a 30% kill rate would still have a significant impact on disease transmission.

Adulticides used in the United States fall into two general chemical categories, organophosphates and pyrethroids. The pyrethroids and organophosphates are rotated at specified intervals in mosquito management programs to prevent the mosquitoes from becoming resistant after long-term exposure to a single group of pesticide.

- Only two organophosphates, malathion (Fyfanon) and naled (Dibrom, Trumpet), are in general use for adult mosquito control. Malathion is a popular choice because of its low price, proven efficacy and low level of toxicity (it's less toxic than table salt). Naled is an extremely effective adulticide when applied aerially.

- Pyrethroids constitute the other class of adulticides. Three products currently on the market, resmethrin (Scourge), sumethrin (Anvil) and permethrin (Aqua-Reslin) are produced from a highly potent chrysanthemum extract. These synthetic derivatives have both a longer shelf life and are as much as 50 times less toxic than the natural insecticide, while performing the same function.

The safety profiles of these public health insecticides are undergoing increasing scrutiny because of concerns with how the specialized application technology and product selection protect the exposed public and environment. In fact, well over 200 peer-reviewed scientific studies in various national and international refereed journals since 1980 have documented the safety and efficacy of these public health insecticides at label rates in addition to their application techniques. Despite intense pressures to eliminate the use of public health insecticides. the Centers for Disease Control and Prevention, World Health Organization and other public health organizations agree that it is essential that these products remain available for disease prevention and that editorial or irresponsible misrepresentation of the risks involved not lead to the greater risk of not

having them available when truly needed. They simply must remain available for the control of vectors in the times of even greater public health emergency that are sure to come.

This reasoning, coupled with the spread of WNV into areas without established mosquito control programs, provided impetus for renewed investigation into means to develop functional abatement programs on short notice. Infrastructure shortfalls in capabilities for addressing the threat of vector-borne disease were identified and drove establishment in 2004 of a Mosquito Control Collaborative (MCC), comprised of members of the Association of State And Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO) and U.S. Centers for Disease Control and Prevention. Further motivation for forming the MCC came from the Mosquito Abatement for Safety and Health (MASH) Act (Public Law 108-75). The MASH Act authorizes grants through the Centers for Disease Control and Prevention to states for coordination of mosquito control programs within a state and assisting localities by providing assessment and planning grants. The MASH Act also authorizes operating grants directly to localities that have conducted assessments and have coordinated with the state to prevent mosquito-borne diseases. As of June 1, 2004, Congress had not appropriated any funds to cover the cost of the MASH Act.

Recommendations put forth by the MCC will serve as a resource to states and localities should funds for MASH Act implementation ultimately become available. The AMCA fully supports the MASH Act and requests action to appropriate the funds for its full implementation. The MMC identified four components of effective, sustainable state and local mosquito control programs.

- Timely Planning and Preparation - Developing an effective mosquito control program requires intense preplanning and timely collaboration with a wide range of agencies and jurisdictions. Understanding the structures and roles of the state, local and federal participants, defining equipment needs, workforce and training requirements, identifying legal authority and funding alternatives, and developing strategies for evaluating programs are key elements of any successful planning effort. In anticipation of the potential for future mosquito-borne disease outbreaks, communities should enact statutes permitting legal action to abate mosquito-related public health nuisances. In addition, legislation must be in place to allow creation of and provide funding for municipally-based integrated mosquito management programs. Local jurisdictions can contact their respective state mosquito control associations to provide examples of enabling legislation, generally involving creation of special taxing districts.

- Involve key participants - Governments should identify and engage a wide variety of stakeholders early in the process. Mosquito control issues can be contentious. Therefore, successful programs should identify all points

of view early, present relevant scientific information in a transparent format, and work to a negotiated agreement, where necessary.

- Science should drive the process - There are numerous proven methodologies and practices that guide the best mosquito control programs. All programs need to be based on an identified need that is matched with local and state resources and technically and environmentally sound strategies. Control strategies can focus on preventing the emergence of adult mosquitoes (larviciding), addressing biting stages (adulticiding), and other prevention measures such as breeding pool reduction and bite prevention. The mix of strategies used by each state and local community will vary based on their individual political, legal, environmental, geographic, demographic and resource concerns.

- Public Education - The public has concerns about problems related to mosquito populations and insecticide spraying. Addressing these concerns is critical to maintaining support of the citizenry. Successful programs having the have multi-phase communications plans that educate the public about preventing the breeding of mosquitoes, personal protection guidance, and the various activities of the agencies involved.

Provision of a safe and healthy environment is a core value of my profession. To this end, mosquito control professionals have devoted a substantial amount of their expertise to the development of numerous mosquito abatement strategies that reduce reliance upon public health insecticides. Indeed, provisions of the Clean Water Act (CWA) mandating measures to reduce pollution provide both significant challenges and opportunities to those charged with protecting the public's health. In pioneering the use of integrated mosquito control strategies, mosquito control programs fully endorse the CWA's intent of reducing pollutant load in the nation's clean water while allowing productive use of that resource.

However, even well-designed and maintained mosquito prevention programs will require corrective mosquito control efforts within an IPM context to address mosquito populations escaping natural predation in federal and state wetlands, vernal pools, marshes, etc. Addressing this problem has been complicated considerably by recent rulings rendered by both the 9th and 2nd Circuit Courts mandating issuance of National Pollution Discharge Elimination System (NPDES) permits required by the CWA to mosquito control agencies contemplating use of EPA-registered larvicides and adulticides as part of their integrated mosquito control program. These rulings, in effect, reduce or eliminate incentives for utilizing the full measure of integrated pest management techniques to mitigate mosquito populations due both to permit and water quality monitoring costs borne by mosquito control agencies.

The American Mosquito Control Association is strongly opposed to any interpretation of the CWA that requires NPDES permits be obtained for the legal application of public health mosquito larvicides in accordance with registered label stipulations. The AMCA considers NPDES permits to be both redundant and unnecessary for the application of public health larvicides specifically registered by USEPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) for application to water. Furthermore, the fiscal and logistical burdens that NPDES permits entail through compliance measures and threat of civil suit will ultimately divert scarce mosquito control resources away from the primary mission of protecting human health, while not contributing tangibly to the critical goal of environmental health. As a result, the AMCA believes that such interpretations are both contrary to congressional intent and inimical to public health and safety. In January of 2003, the AMCA proposed a rulemaking by EPA to exempt mosquito larvicides duly registered under FIFRA for water application from the NPDES permit requirement. This could be easily accomplished via EPA interpretation clearly articulating the removal of their status as point-source pollutants. The EPA currently has this issue under active review, but at some point definitive action by the Agency is needed or the citizen suits attendant to CWA will continue to proliferate.

West Nile Virus has now spread to 47 states and the District of Columbia and has now accounted for almost 16,000 human cases, 650 fatalities and 4,800 cases of potentially crippling neuroinvasive disease. While the statistics are startling, they are but a pale shadow of the real human toll exacted by this disease. Its emergence and rapid spread through areas historically lacking functional mosquito control infrastructures has underscored the need for established mosquito control programs to meet unforeseen threats. Indeed, the continued increase in worldwide tourism and trade virtually guarantees further challenges from exotic mosquito-borne diseases such as Japanese B encephalitis and Rift Valley Fever requiring ready control expertise to prevent their establishment and spread. Should these mosquito-borne diseases of man and animals settle into the American public health landscape, particularly as an unintended consequence of otherwise laudatory environmental policy initiatives, we will have only ourselves to blame, for we have the means to control these diseases within our grasp. A robust inter-agency cooperation in the design, resourcing and implementation of sustainable mosquito-borne disease programs is a cornerstone of this national effort. In conjunction with judicious application of federally registered and NPDES-exempt public health mosquito insecticides, when warranted, our shared goals of both a healthy populace and environment can thus be attained.

Mr. OSE. Our next witness is the chief health officer for Maricopa County, AZ, somebody right there in the heart of the struggle on this, Dr. Jonathan Weisbuch.

Welcome to our subcommittee, and you are recognized for 5 minutes. Thank you.

You need to push it so the green light is on. There you go.

Dr. WEISBUCH. Thank you very much for inviting me to testify before your committee, Mr. Chairman. I am Dr. Jonathan Weisbuch from the Maricopa County Department of Public Health and the chief health officer in that county.

Our struggle in 2004 with the West Nile virus I think all of you are familiar with. I am going to discuss four points. First of all, what we knew prior to the epidemic, what we did, and then what we have learned and the questions that we have.

Controlling mosquitos in the greater metropolitan Phoenix area possess unique challenges. Maricopa County is over 9,000 square miles, larger than several States. Its population, 3.5 million, exceeds that of 20 States. While much of Arizona is desert, Maricopa County has built an artificial oasis, the perfect harbor for mosquitos. We have green lawns, golf fairways, lakes, wetlands, irrigation canals, storm sewers, an urban heat island, and the largest number of private home swimming pools in the Nation. We estimate it at the level of 500,000.

During our long hot summer, many of those backyard swimming pools go unused, go unmanaged, and are available for mosquito larva. And we can show this, if we have a copy of the first slide. It's just a map of the area. This is the central part. I guess this doesn't show on there, the central part of Maricopa County, only part of it, about 2,000 square miles, all of which are filled with dense area of human beings; and then we have horses, we have chickens, we have birds, we have a variety of other things, including harborage for mosquitoes.

In late 2002 we estimated that 2003 would be the time in which West Nile would arrive in Maricopa County, but it did not. We then knew that 2004 would be our time. Mosquito disease usually impacts Arizona during our rainy season in late July, and then peaking in August and waning in September as diurnal temperatures decline and mosquitoes become inactive.

We began larvaciding using the management technique that has been described earlier. We began larvaciding our breeding sites in late March 2004 and surveillance of both mosquitoes and animal cases, including human cases, in April. We had a communication package ready to go after our first case in order to inform the public of the situation. But unfortunately, nature in our case did not cooperate. A blood donor was identified on April 24, long before our normal season. The first human case was reported in mid-May. The epidemic was in full swing and by the end of May we had over 60 cases.

Our media message was very simple. We stressed prevention: Clean up your back yard, clean up your neighborhood, report mosquitoes to environmental services, report stagnant swimming pools, use repellent, long sleeves, and stay indoors after dark. As a result the media ran several stories. Complaints increased to the hundreds a day to our environmental control program. We were fortu-

nate that the message did get out; Ninety-eight percent of our residents were aware of the West Nile virus and how to prevent disease; 71 percent had done something; but only 30 percent had ever used repellant. By the end of June we had 150 cases. July was our hot month. Temperatures were over 100 every day. Mosquito trap counts were increased, as did the viral infection rate of mosquitoes. Chickens, horses, and dead birds showed West Nile infection, and 100 new cases of human disease were added to the total, giving us 250 cases by July 31. Half of those cases were encephalitis and meningitis. We had two deaths.

We can show the second slide which is a picture of what the epidemic looked like in the different colors; you have it in front of you. The different colors indicate encephalitis, meningitis fever, and what have you. And the cases reported from blood sampling. We began expanding our larvaciding to the hundreds of green pools that have been reported. Over the course of this last summer we did over 1,000, 1,500 green pools, to larvacide them. We doubled our fogging with anvil 2.2 and then doubled it again before the end of July as we added fogging devices to our fleet.

In late July, with the epidemic raging in Maricopa County, our conference call with CDC discussed the possibility of aerial spraying for the entire 2,000 square miles that I showed earlier. That was a big step we chose not to take.

In August we increased our mosquito traps. We expanded our fogging where the traps showed vector mosquitoes and viruses to be prevalent. We expanded ground fogging tenfold so that by the end of the season we had fogged well over a million acres. That's about 10 times the size of the city of Philadelphia.

West Nile-positive mosquito pools and vector mosquitoes began to decline. Mosquito complaints dropped. Human cases also began to go down. Was this a cause and effect with our spraying and the decline? I cannot say.

There are several other slides that we could show. We can show the case, and the next case would be the—have you got it up there? This is, again, the reported cases slightly different from the cases by the time of onset. But you can see this line over here at the end of the slide which indicates the number of acres that we larvacided. And you can see here in the middle of June we've increased or doubled the number of acres, then we doubled it again toward the middle of July, and then we exploded it as our number of foggers became available to us.

The next slide shows something similar to that which is really the same case reports, but if you can see the small line, that's the proportion of mosquitoes that we trapped which were infected with the virus. And it is the virus in the mosquitoes that causes the disease and you can see that in the outset of our epidemic it was high. It began to decline as we began to do the other efforts of adulticiding.

Map No. 5 indicates, again the total number of—it's hard to see on the slide here, but you have it in front of you. There are 347 cases shown on this slide, the total number that we've had through September, and it cuts across the entire county of Maricopa where every area was infected.

The last slide, of course, is just a summary of the cases that we've discussed.

Deaths, however, continue to increase. We've had six in Maricopa county, one extra one in the State of Arizona. That final case actually was a blood recipient from blood that had been tested and where they had missed the virus so that we would—we were unaware of the fact that the individual had been given tainted blood until we went back and checked.

The 2004 epidemic has taught us a great deal, the interrelationships between the multiple factors that were discussed in the previous panel—the bird migration, over-winter cycles, mosquito infection rates, vertical transmission to larva, seasonal variations in temperature and rainfall, and the particular nature of our own built environment all have an impact and interrelate in the explosion of our epidemic this year.

We think that mosquito traps are probably our best surveillance tool because they give us rapid information about what the vectors are and whether they're infected. And we also recognize that physicians do not always recognize West Nile viruses, either in their cases or in those who have succumbed to the disease. Close surveillance of disease and infectious disease encephalitis and deaths is very important by our epidemiological staff. Stagnant swimming pools are probably our most significant breeding sites. They are extremely difficult to manage. We know little about the impact of pesticides on people, and that ignorance has undermined our ability to assure citizens that the risks of pesticides is worth the benefit of killing adult mosquitoes.

Mr. OSE. Doctor, could you summarize here?

Dr. WEISBUCH. I'm going to summarize. We have a number of questions you have before you. But let me just say in conclusion, our experience with West Nile virus exposed underlying deficiencies in the public health infrastructure that can only be rectified with adequate funding for State and local public health systems and a national investment in the applied research that was described earlier in the earlier panel.

Congress and States should determine how to provide health departments with sufficient fundings to support public health infrastructure so that this and other kinds of health problems can be managed. A small percentage of the $1.5 trillion spent in the national medical system could be allocated to strengthen the public health infrastructure and assure that the health of the public and communities would be preserved in the event of unexpected biological events. Absent the necessary resources, the health of this Nation will continue to be at risk.

And I thank you very much, Mr. Chairman, for the few extra minutes, and I appreciate the opportunity to speak before you today.

Mr. OSE. Thank you, Doctor.

[The prepared statement of Dr. Weisbuch follows:]

West Nile Virus Update

Jonathan Weisbuch, MD, MPH,
Director, Department of Public Health
and
Chief Health Officer
Maricopa County, Arizona

Presentation to
The United States Congress
Committee on Government Reform
Sub-Committee on Energy Policy,
Natural Resources, and Regulatory Affairs

October 6, 2004

West Nile Epidemic in Maricopa County, Arizona
Sub-Committee on Energy Policy, Natural Resources and Regulatory Affairs

Mr. Chairman, Members of Congress:

Thank you for inviting me to share what the Maricopa County Departments of Public Health and Environmental Services have learned as we struggled with the 2004 West Nile Virus (WNV) epidemic .

Controlling mosquitoes in the greater metropolitan Phoenix area poses unique challenges. Maricopa County is over 9000 square miles, larger than several states. Its population, 3.5 million, exceeds that of 20 states. And while much of Arizona is desert, Maricopa County has built an artificial oasis, the perfect harbor for mosquitoes. We have green lawns and fairways, lakes, wetlands, irrigation canals, storm sewers, an urban heat island and the largest number of private swimming pools in the nation-- over 500,000. During our long hot summer, many backyard pools are unused, unmanaged and available for mosquito larvae.

> Slide 1: Urban Density in Central Maricopa County.

1) Planning for West Nile began in 2002:

In December 2002, using information from earlier outbreaks, we planned for surveillance, mosquito control, and public communication. We expected WNV

in late 2003. The virus did occur in birds in late 2003, but no human cases were confirmed that year; 2004 would be our time.

Mosquito borne arboviruses usually impact Arizona during our rainy season in late July, peaking in August and waning in late September as diurnal temperatures decline and mosquitoes become inactive.

Surveillance began in April. We employed mosquito traps, sentinel chicken flocks, dead bird evaluation, horse cases reports, blood bank screening for WNV, death certificate review, and infectious disease reports. We expected our first human cases in mid-summer. Larviciding of the 6000 known mosquito-breeding sites began along with fogging in areas with high mosquito counts. Public communication materials were ready for the media.

2) The Epidemic:

Nature did not cooperate. A blood donor with a positive test for West Nile was identified on April 24, and the first human case was reported in mid-May. The epidemic had begun.

We initiated a large scale public education campaign encouraging citizens to:

- **Clean up their own back yards and their neighborhoods.**
- **Report mosquito complaints to Environmental Services,**
- **Identify and report mosquito breeding sites,**

- **Identify stagnant swimming pools,**
- **Use prevention measures, repellent, long sleeves, stay indoors after dark.**

We were successful:

- **Complaints to Vector Control increased to hundreds daily,**
- **A June poll showed that 98% of residents were aware of West Nile Virus and how to protect themselves and their neighborhoods; 71% had done something, but only 30% had used insect repellent even once.**
- **The media produced several stories on the outbreak.**

July was our hottest month.

- **Ambient temperatures exceeded 100 F every day**
- **Mosquito trap counts increased**
- **All sentinal chickens became infected**
- The **Mosquito Infection Rate (MIR)** reached 2 to 4%, four times epidemic rates
- **The number of cases reported weekly exceeded 35.**
- **By July 31, human cases exceeded 200, half being neuro-invasive.**
- **We had 4 reported deaths.**

>Slide 2: Weekly Cases

Larvicide use expanded as hundreds of "green" pools were reported; ground fogging with the pesticide, Anvil 2-2, doubled, and than doubled again as we added units to our fleet. In late July, CDC recommended aerial spraying.

We chose to increase the number of mosquito traps and expand our ground fogging in areas where traps yielded vector mosquitoes and virus. As ground fogging increased in August, the number of WNV positive mosquito pools and vectors mosquitoes (Culex Quinquefacienatis and Culex Tarsalis**) declined. Mosquito complaints also dropped.**

> Slide 3: Case Load after Fogging

> Slide 4: MIR after Fogging

> Slide 5: Map of WNV Cases

> Slide 6: WNV Disease Breakdown (October 1, 2004)

Human case reports also dropped in August, but fatalities continue to be reported, 4 at the end of July and 7 on September 30. Several cases are still under intensive care. A delay of two months and more between infection and death is not uncommon. Clinicians do not always identify the cause of death based upon positive WNV lab reports; therefore, mortality figures may not represent the full extent of the epidemic.

3) What we have learned to prepare for 2005:

- **The WNV epidemic in Maricopa County is not over; it did not conform to the normal mosquito and arbovirus pattern.**
- **Many parameters effect time and place of the outbreak, including:**
  - **migration patterns of birds,**
  - **the over-winter cycle of mosquitoes,**
  - **seasonal variations in temperature and rainfall,**
  - **the peculiar nature of the Maricopa County urban environment**
- **The interrelationship of these many factors is largely unknown**
- **Our best surveillance tool is the mosquito trap; We will use 200 next year**
- **Physician do not always identify WNV as the cause of death**
- **Close surveillance of death certificates is necessary to identify WNV deaths**
- **Stagnant swimming pools of unknown location may be our most significant breeding sites.**
- **Stagnant pools are difficult to manage**
- **We must find an efficient way to identify pools, or we will be forced to depend on vector control that includes pesticides.**
- **The absence of data on the human impact of pesticides undermines our ability to assure citizens that the risks associated with spraying are very low compared to the risk posed by the virus.**

4) Questions for the future:

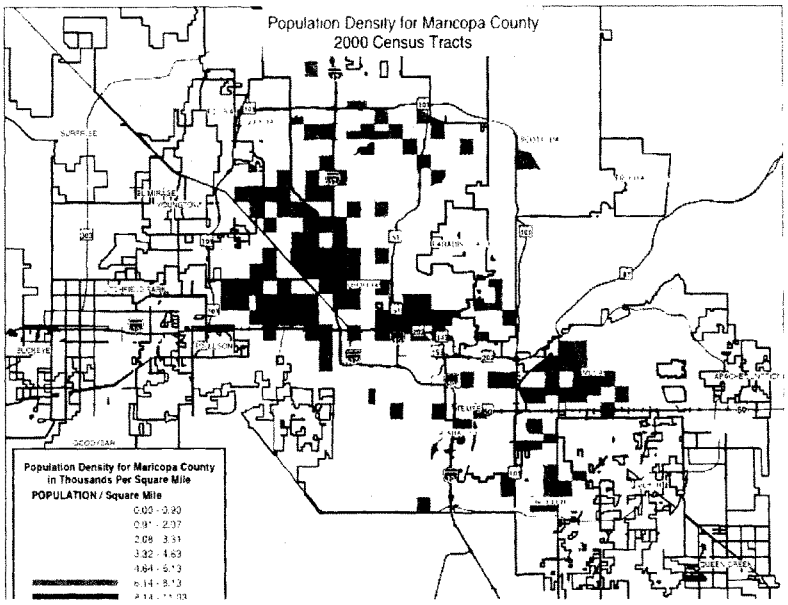
- **What are the interrelationships between the parameters that define WNV?**
- **Can a mathematical model be built to help state and local health departments predict an outbreak and plan for action?**
- **Does the virus hide in birds, mosquitoes, or some other animal during the winter; how does it survive?**
- **What triggers the explosive multiplication of virus in birds and mosquitoes?**
- **Is a human vaccine justified or will herd immunity prevail?**
- **What is needed to change people's behavior as well as their knowledge**
- **Where will resources come from to help local health agencies prepare for WNV and other threats?**
- **What proportion of the population may suffer acute sensitivity to any specific pesticide — a critical factor in risk-benefit analysis for spraying.**

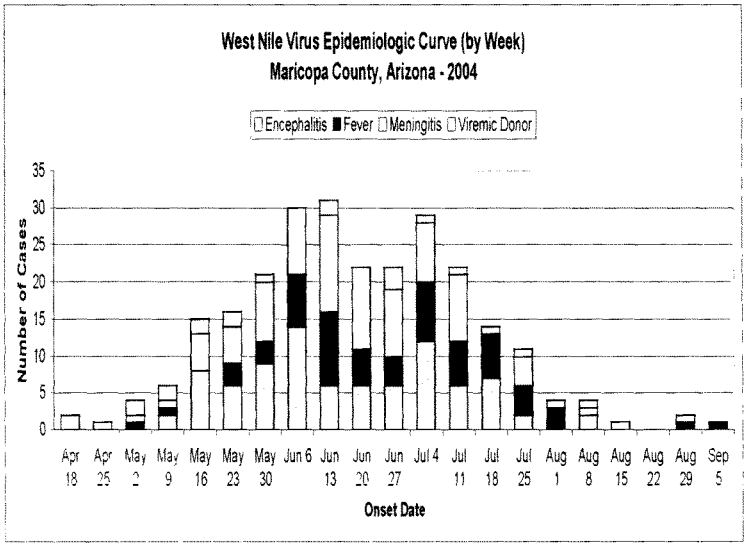
The Congress, the Centers for Disease Control, the EPA and other government agencies must find resources to study these questions. When any epidemic unfolds, public health decision makers need trigger points to know when to take specific action.

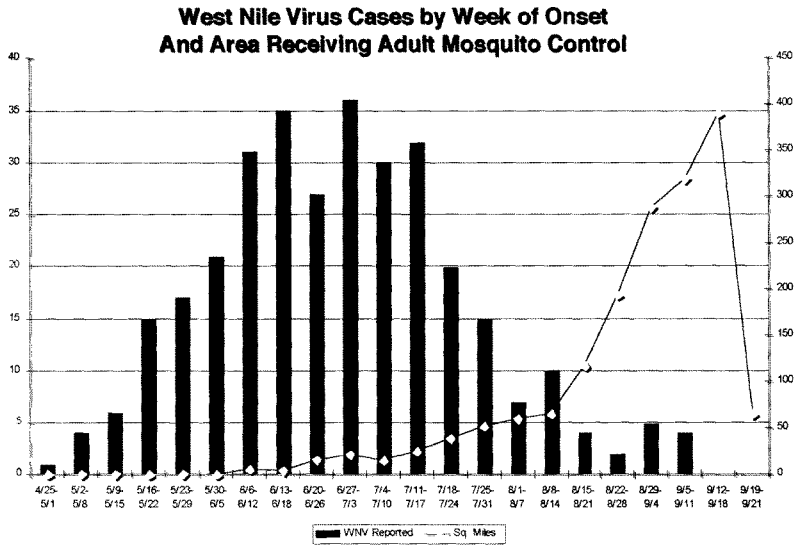
5) Conclusions:

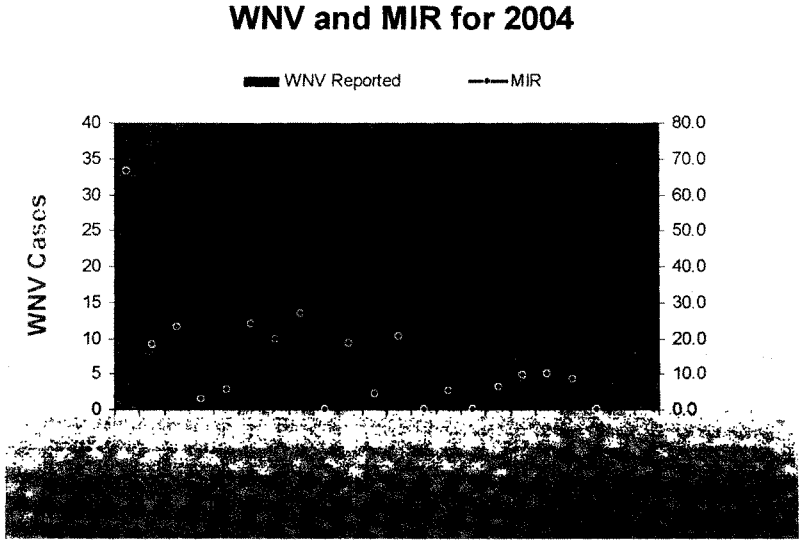
Our experience with West Nile Virus exposed underlying deficiencies in the Public Health infrastructure that can only be rectified with adequate funding of state and local public health systems and a national investment in applied research for public health. Congress and the states should determine how health departments will receive adequate funding to support the public health infrastructure under a set of professional standards that will assure that the public is protected. A small percentage of the monies spent in the national health and medical care system specifically allocated to strengthen the public health infrastructure would assure that the health of the public and of communities would be preserved in the event of unexpected biologic events. Absent the necessary resources, the health of the nation is at risk.

Thank you for the opportunity to meet with you today sharing with you that which we have learned about a major outbreak of disease in central Arizona.


Population Density for Maricopa County
2000 Census Tracts
Population Density for Maricopa County
in Thousands Per Square Mile
POPULATION / Square Mile


West Nile Virus Epidemiologic Curve (by Week)
Maricopa County, Arizona - 2004
Encephalitis
Fever
Meningitis
Viremic Donor
Number of Cases
0
5
10
15
20
25
30
35
Apr 18
Apr 25
May 2
May 9
May 16
May 23
May 30
Jun 6
Jun 13
Jun 20
Jun 27
Jul 4
Jul 11
Jul 18
Jul 25
Aug 1
Aug 8
Aug 15
Aug 22
Aug 29
Sep 5
Onset Date


West Nile Virus Cases by Week of Onset
And Area Receiving Adult Mosquito Control
40
35
30
25
20
15
10
5
0
450
400
350
300
250
200
150
100
50
0
4/25-5/1
5/2-5/8
5/9-5/15
5/16-5/22
5/23-5/29
5/30-6/5
6/6-6/12
6/13-6/19
6/20-6/26
6/27-7/3
7/4-7/10
7/11-7/17
7/18-7/24
7/25-7/31
8/1-8/7
8/8-8/14
8/15-8/21
8/22-8/28
8/29-9/4
9/5-9/11
9/12-9/18
9/19-9/21
WNV Reported
Sq. Miles


WNV and MIR for 2004
WNV Reported
MIR
WNV Cases
40
35
30
25
20
15
10
5
0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0

West Nile Virus Update

Dr. Jonathan Weisbuch, Director
Maricopa County Public Health Department

Presentation to
The United States Congress
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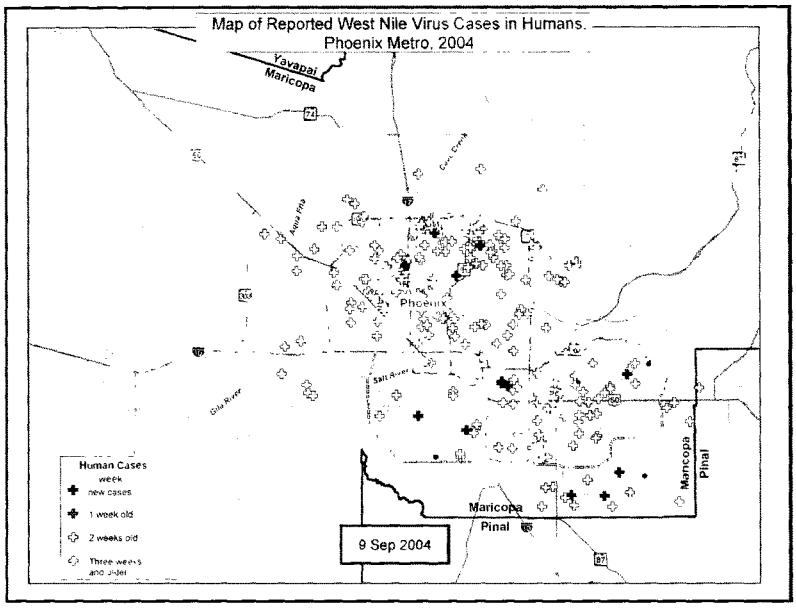
October 6, 2004



Disease Severity
Maricopa County Cases

Neuroinvasive disease:	**185**
West Nile Fever:	**69**
Viremic Donors:	**25**
Unknown:	**68**
Deaths:	**6**
Total Cases:	**347**

Estimated 25,000 Infections

Based on MCPHD Case Classification Criteria

Mr. OSE. Our final witness on the second panel is John Pape who is an epidemiologist for the Colorado Department of Public Health and Environment. He too has been at the center of significant efforts dealing with West Nile virus. Sir, welcome to our panel. We have received your statement. It has been entered into the record. I have read it and I'd be happy to recognize you for 5 minutes for the purpose of a summary.

Mr. PAPE. Thank you, Chairman. On behalf of the Colorado Department of Public Health and Environment, our local health partners, and the citizens of Colorado, I'd like to thank the committee for this opportunity to share THE Colorado experience with West Nile virus.

As is well known, since its introduction into New York City in 1999, this virus has marched rapidly across the country resulting in large outbreaks in each of the last 3 years. Thus our experience in Colorado is not unique. Many States have felt the bite of West Nile virus.

I would also like to take this opportunity to thank our partners at the Centers for Disease Control and Prevention whose technical and financial support were absolutely crucial to our response to West Nile virus. Without the CDC investment in laboratory and public health infrastructure, Colorado would not have been prepared to respond when West Nile entered the State in 2002.

Additionally, as has been discussed earlier, the collaborative research between CDC, State and local health agencies, academia, and private industry have been critical to our understanding and response to this emerging infection. By the time West Nile virus reached Colorado in August 2002, relatively few human cases had been reported in Eastern States and there was considerable uncertainty as to what West Nile virus would do in the Western United States. In preparation, Colorado enhanced its comprehensive surveillance system, upgraded laboratory capacity and launched Fight the Bite-Colorado, a multifaceted public education campaign focused on personal protection to avoid mosquito bites.

In consideration of time, I will not reiterate the details of the 2003 epidemic in Colorado that resulted in 2,947 cases and 63 deaths; actually 64, as one of our patients died just this week. This information IS provided in written testimony. However, it is important to note that neighboring States in Nebraska, South Dakota, Wyoming, were hit just as hard as Colorado in 2003 and that has been discussed in these hearings. Other States have experienced West Nile epidemics, including Arizona and California this year. So this is a national issue.

Colorado was the first State to make a conscientious effort to investigate all patients who were diagnosed with any illness from West Nile virus, not just the more severe illnesses of meningitis or encephalitis. This effort has advanced our knowledge on the clinical spectrum of West Nile infection which is still not completely defined. Personally I know several people who were infected last year. For most, fortunately, the illness lasted a couple of weeks, followed by a full recovery. However, the middle-aged daughter of a longtime friend and public health colleague was not so fortunate. She was infected, developed encephalitis and paralysis in one leg. A year later she is still severely affected, and subsequent testing has

demonstrated permanent brain damage that has left her unable to work or care for her daughter. For some people, infection with this virus is a life-altering event, and that is why prevention is so critical in our response to West Nile virus.

Colorado's prevention efforts revolved around three areas: surveillance to identify high areas of risk of virus activity; public education on personal prevention measures; and encouraging local community-based mosquito control. All three components are necessary.

We do need to improve our public prevention messages to encourage citizens to take personal precautions. Many people heard these recommendations but did not take actions to protect themselves. In the semi-arid climate of Colorado, nuisance mosquitoes are not a widespread problem like other more mosquito-prone areas of the country, and thus mosquito infrastructure is not as well developed or extensive, if it exists at all, in many areas of the State.

Based on health department recommendations, many jurisdictions expanded or implemented mosquito controls. Others did not. Reasons for not implementing control varied, but generally held to four themes: tight budgets with competing community needs; uncertainty as to the impact of West Nile virus and the benefit of mosquito control; the stance that if people took personal precautions such as repellent use, mosquito control was unnecessary; and vocal opposition to mosquito control from some members of the community with a potential of lawsuits.

In particular, adult mosquito control—that is, spraying—is controversial. And although a survey found the majority of Coloradans would support spraying in the face of an epidemic, there are many constituencies out there that will oppose such action under any circumstance.

Congress could take several steps to assist State and local agencies in addressing mosquito-borne disease problems and removing barriers to local control efforts. Foremost, as has been discussed at these hearings, would be resolving the contradictory Federal laws that could potentially result in a district complying with pesticide regulations under FIFRA, but then being sued under provisions of the Clean Water Act. And we've gone through that—this committee's gone through that.

Pesticide regulation should be incorporated under one law, a law that encourages development of new, effective, environmentally friendly mosquito control products and methods.

Second, the Mosquito Abatement for Safety and Health Act, which was passed and signed into law 2 years ago, has never been appropriated. Funding the MASH Act would provide communities with startup funds from a matching grant to initiate mosquito control that would then be maintained by local resources.

And, finally, the funding provided from CDC for West Nile surveillance prevention and research was critical to our preparedness and response to the epidemic. Continued funding support of research and basic public health infrastructure at national, State, and local levels is imperative. As we've seen with the outbreaks of

West Nile virus, with monkey pox, with the continuing threat of bioterrorism attack, a strong public health system remains vital to the health and security of U.S. citizens. Thank you.

Mr. OSE. Thank you, Mr. Pape. I appreciate your testimony.

[The prepared statement of Mr. Pape follows:]

Colorado Department
of Public Health
and Environment

House Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
West Nile Virus: The Colorado Experience

Written Testimony for October 6, 2004 Hearing
Submitted by John Pape, Epidemiologist
Colorado Department of Public Health and Environment

Since its introduction into New York City in 1999, West Nile virus (WNV) has marched unimpeded across the continent. Its anticipated arrival in Colorado occurred in August 2002. This was rapidly detected by the comprehensive surveillance system Colorado had in place to monitor mosquito-borne virus activity across the host range including birds, mosquito vectors, mammalian hosts and humans. By the end of the 2002 mosquito season, surveillance had demonstrated that WNV had spread throughout the state. The stage was set for the subsequent 2003 Colorado epidemic that resulted in 2947 reported human cases and 63 deaths.

The Colorado Department of Public Health and Environment (CDPHE) in cooperation with local health departments has conducted surveillance for mosquito-borne arboviruses (Western equine encephalitis (WEE) and St. Louis encephalitis (SLE)) since 1988. With the assistance of federal WNV grants through the Centers for Disease Control and Prevention (CDC), this surveillance program was upgraded and expanded to include testing for WNV. It is important to note that without this infusion of funding, the continuation of Colorado's existing encephalitis surveillance program was in doubt. The existing program was using 15-20 year-old salvaged hospital lab equipment and its shoe-string budget would not permit expansion or upgrading. Federal funding permitted laboratory equipment to be upgraded and automated procedures developed to allow the lab to add WNV testing, increase accuracy and process more samples in less time without adding additional staff. A local health department lab was certified to conduct human testing to provide surge capacity for high volume human testing at the state lab. Six regional local health department labs were upgraded to facilitate rapid screening of dead birds and mosquito pools at the local level.

By the summer of 2002, a comprehensive surveillance system was in place to monitor for mosquito-borne viruses and the arrival of WNV. Communicable disease surveillance systems are absolutely necessary for detecting and responding to communicable disease outbreaks, emerging infectious diseases or a bioterrorism event. The Colorado WNV surveillance program tracked the spread of the epidemic across the state, identified areas of high transmission risk to help direct mosquito control activities and provided surveillance updates, maps and human case data to local health departments, mosquito control districts, and the public on a real-time basis. Animal and human surveillance data were compiled from 10 instate laboratories, and several private commercial labs, and provided in daily summary reports to local health departments, the media and the public. Updates were posted on the CDPHE website daily at: <http://www.cdphe.state.co.us/dc/zoonosis/wnv/wnvhom.html>.

In addition to enhancements of the surveillance program and laboratory capacity, Colorado prepared for West Nile virus by training local health department, city and county staff in mosquito surveillance and control, encouraging the expansion of local mosquito control programs and developing WNV prevention activities. The state mosquito-borne virus response plan was updated to provide recommendations for response activities to local agencies based on surveillance findings. A training workshop was developed on mosquito biology, identification and control with an emphasis on hands-on training to identify samples of mosquito larvae and adults. Information on WNV was provided to thousands of professionals in Colorado including presentations at several large physician conferences, the Colorado Veterinary Medical Association, Colorado Environmental Health Association and Colorado Animal Control Officers Association conventions. Physician guidance on the recognition and diagnosis of WNV infection was sent to all hospitals, infectious disease physicians and many medical providers via Colorado's Health Alert Network (HAN) system. Town meetings were held throughout the state to discuss WNV, local mosquito control efforts, and personal prevention strategies people can use to protect themselves.

Prevention efforts revolved around the "Fight the Bite Colorado" educational campaign that emphasized personal responsibility in preventing infection. Education centered around the four Ds: Dawn/Dusk (when mosquito that transmit the virus are feeding), Dress (use of protective clothing), DEET (use insect repellents containing DEET) and Drain (eliminating standing water around the home). These steps were promoted for citizens to use in preventing mosquito bites and mosquito breeding on private property. This educational effort included community presentations, a public, toll-free telephone hotline, website <www.FightTheBiteColorado.com>, pamphlets, posters, wallet cards and other educational materials emphasizing the 4 Ds message. During the 2003 epidemic, the website had over 500,000 hits, the hotline responded to over 12,000 calls and pamphlets (250,000), posters (20,000) and wallet cards (500,000) were distributed by agencies and organizations around the state.

The surveillance and public education systems were in place by the start of the 2003 WNV transmission season. In Colorado, the mosquito season runs from May through late September. WNV arrived late in the 2002 season, and although it caused a large disease outbreak in horses and spread throughout the state, only 14 human cases were reported. In retrospect, areas with the most WNV animal activity in 2002 were the hardest hit the following year.

A common question in 2003 was why was Colorado hit so hard? First, it is important to note that several surrounding states were hit just as hard. Nebraska, South Dakota and Wyoming all had human case rates that exceeded Colorado's rate. However, Colorado's significantly larger population produced higher total numbers, and CDPHE's ability to update case numbers daily gave the impression that Colorado was affected more than its neighbors. The other point to note is that states count human WNV cases differently. In prior years, most states only counted cases of neuroinvasive diseases (i.e. meningitis or encephalitis) but not the less severe WNV fever. Colorado, in accordance with CDC guidelines, made a conscious effort to investigate and report all patients who were diagnosed with an illness from WNV.

There were several factors that resulted in the WNV epidemic of 2003. First, is the second year phenomenon, a theory that the virus arrives late the first season, becomes established in the area and has the entire second season to amplify to high levels in the bird-mosquito-bird cycle due to a lack of immunity in the local bird population. This pattern was observed in 2002 (Illinois/Ohio/Michigan/Louisiana/Mississippi), 2003 (Colorado, Nebraska, South Dakota, Wyoming) and in 2004 (Arizona, southern California). The second, and probably primary factor for Colorado, was ideal weather conditions for mosquito production. Mosquito populations were at record levels in 2003, exceeding levels from the past 10-15 years, even in areas with established mosquito control programs. Third, the western U.S. is home to a species of mosquito, Culex tarsalis, that is the most highly efficient

transmitter of WNV found to date. Finally, in the semi-arid climate of Colorado, nuisance mosquitoes are not a major problem and nuisance mosquito control is not routinely conducted as in other areas of the country. Thus, mosquito control infrastructure is not well developed or extensive, if it exists at all, in many areas of the state.

The 2003 epidemic "began" on June 4 with the collection of the first WNV positive dead bird. Over the next 6 weeks, surveillance showed increasing numbers of positive birds and mosquitoes in eastern Colorado especially along the Arkansas and South Platte River drainages and in the northeastern counties. WNV outbreaks are explosive and progress rapidly. By mid-July, large numbers of birds, mosquitoes and horses were testing positive daily. Although no human cases had yet been confirmed, the surveillance data showed that an epidemic was imminent. The first human case was reported July 21 and reported cases rapidly escalated during subsequent weeks. Due to unusually warm fall weather, mosquito activity continued into October, 2-3 weeks past the normal end of the season. A total of 2947 human cases were reported, including 234 cases of encephalitis, 388 cases of meningitis and 2325 cases of WNV fever. At one county hospital, 10% of all admissions from July – September were patients with WNV. Ultimately, 63 Coloradoans died. Uncounted and not fully appreciated are the patients who have experienced prolonged recoveries or suffered permanent paralysis or brain damage.

Recommendations had been made, in anticipation of WNV arrival, to counties, cities and other local jurisdictions to implement integrated mosquito control programs with a focus on eliminating breeding sites and conducting larval control. Adult mosquito control (spraying), was recommended when surveillance data indicated a human outbreak was imminent. While some jurisdictions enhanced existing control programs or implemented mosquito control, many others did not. Reasons for not implementing mosquito control varied, but generally held to four themes: tight budgets with many competing community needs, uncertainty as to the impact of WNV and the benefit of mosquito control, vocal opposition to mosquito control with the potential of lawsuits from segments of the community, and the belief that if people took personal precautions, such as repellent use, mosquito control was unnecessary.

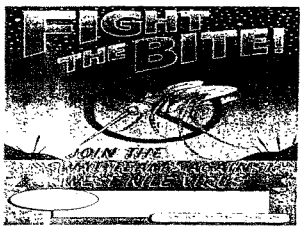
The concern over lawsuits was a topic of discussion at many meetings. It was observed that many communities in other states had been sued for initiating emergency mosquito control activities in response to WNV outbreaks. Although most of these lawsuits were successfully defeated, the defense effort and cost for communities was considerable. In addition, there was concern that a 2001 federal court ruling (Headwaters, Inc. vs Talent) could be a possible avenue to file a lawsuit against a mosquito control district. Although the irrigation district was in compliance with all EPA Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) regulations regarding herbicide use, they were successfully sued under separate EPA Clean Water Act regulations for failure to have a National Pollution Discharge Elimination System (NPDES) permit. It is widely believed this ruling could be broadened and used against mosquito control districts if pesticide spray could potentially drift into water. Many local officials felt this put them in a no-win situation if they implemented mosquito control in their communities.

By early 2003, WNV had been in the country for only four years and our knowledge of what this virus would do was very limited. Although there were large outbreaks in the Midwest in 2002, relatively few human cases had been documented in the previous three years (1999-2001). There was no experience with WNV in the western U.S. Thus, in July 2003, given the lack of experience with this virus and tight budgets, it was difficult to convince local officials that emergency funding for mosquito control, especially highly controversial spraying, was warranted based on a few hundred dead birds. But the lessons of 2003 did not good unheeded. In 2004, when surveillance detected a potential epidemic developing in a western Colorado county, local health and elected officials quickly initiated mosquito spraying and significantly reduced the risk of WNV transmission and human cases in their communities.

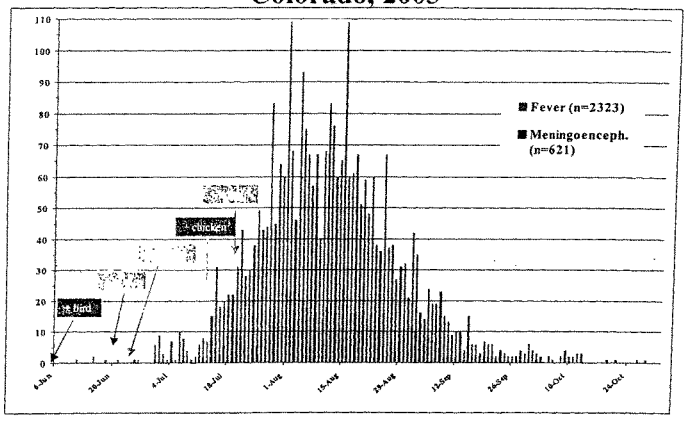
Congress could take several steps to assist state and local agencies in addressing mosquito-borne disease problems and removing barriers to local mosquito control efforts. Foremost, would be modifying contradictory EPA regulations and incorporating all pertinent pesticide regulations under one law. Secondly, the Mosquito Abatement for Safety Health (MASH) Act, passed and signed into law 2 years ago, has never had an appropriation. The MASH Act was designed to provide matching funds to local agencies to develop mosquito control programs. Funding this program would provide communities with start-up funds to initiate mosquito control programs that would then be maintained by local funds. Finally, the funding provided by CDC for WNV surveillance and prevention efforts was critical to the state's preparedeness and response to the epidemic. Continued financial support of basic public health infrastructure at the national, state and local level is imperative.

The Colorado experience with WNV during the past three years has been learning opportunity for Colorado and scientists across the country. A collaborative effort of local, state and federal health officials, tracked of the 2003 epidemic. Over 2600 of the 2947 reported patients with WNV were rapidly interviewed, providing data that has expanded our understanding of WNV infections. For example, it became apparent that WNV fever for many people was a severe, prolonged illness with duration averaging 23 days. This finding was in contrast to the "mild, flu-like illness" message that had been previously promoted. Numerous studies have been initiated with CDC (long-term neurological sequelae, blood transfusion transmission and effectiveness of blood bank screening tests, effect of WNV infection in pregnancy, hospitalization outcome, impact of mosquito control on transmission), University of Colorado Health Sciences Center (cerebral spinal fluid parameters, cause of deaths, risk of complications in immunosuppressed patients) and state/local health departments (illness duration, clinical description of WNV fever, high incidence of rash, reasons for non-repellent use). These studies increase our understanding of the impact of WNV infection in the United States and facilitate improved prevention efforts, such as addressing reasons that citizens don't use repellents for personal protection.

Colorado continues to adapt its surveillance and prevention efforts, as it is clear that WNV will be a continuing problem. The Colorado experience demonstrated that effective tracking of a large communicable disease outbreak can be accomplished, experience that can be applied to future emerging infections outbreaks, pandemic flu or a bioterrorism attack. Such a response however, cannot be turned on and off as needed. It requires continued commitment to fund and maintain viable public health infrastructure in this country. As the recent outbreaks of WNV and monkeypox have demonstrated, and with the continuing threat of a bioterrorist attack, a strong public health system remains vital for the health and security of U.S. citizens.



Onset Dates of Human West Nile Virus Cases, Colorado, 2003



Human Epidemiological Curve (cases by onset date) in relation to the first positive surveillance specimen

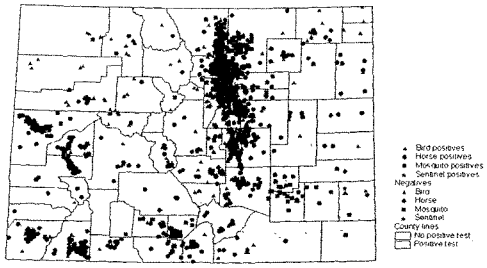
Comparison of WNV Surveillance Testing by Year, Colorado 2002-04

	2002	2003	2004*
Birds	138/889 (15%)	766/1575 (49%)	50/340 (15%)
Horses	380/810 (47%)	604/1100 (55%)	25/180 (14%)
Mosquitoes	15/362 (4%)	639/2703 (24%)	160/3558 (4%)
Human Cases	14	2947	227

* Provisional data as of 9/10/2004

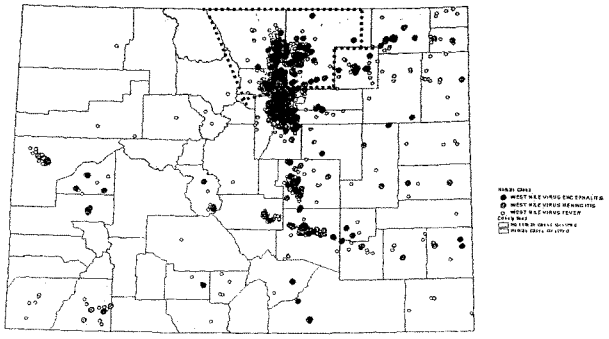
Number of specimens positive for WNV/ total number of specimens tested (% Positive)

Colorado West Nile Virus Surveillance
Updated October 15, 2003



Distribution on WNV surveillance testing in 2003. On average animal surveillance specimens were positive an area 2-3 weeks prior to the first human cases. Shaded counties had a positive specimen.

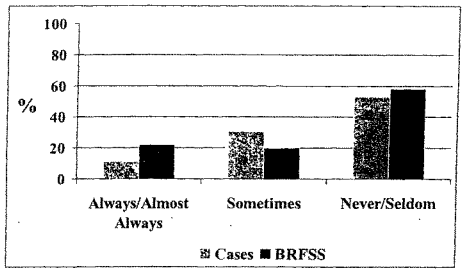
Colorado West Nile Virus
Human Cases
Updated January 29, 2004



N = 2,944

Geographic distribution of Colorado Human WNV cases in 2003
Three counties in the highlighted (.....) area accounted for 46% of the total cases (dots are several layers deep).

Reported Repellent Use



Comparison of reported repellent use from 2003WNV patient interviews (n=2601) and participants in Behavioral Risk Factor Surveillance System (BRFSS) survey conducted Nov/Dec, 2003 (n=600)

Reasons Why People Didn't Wear DEET Repellents

10. Not sure why I didn't use repellent
9. Too lazy/ didn't have time
8. Used other methods to avoid mosquito bites
7. Smells bad
6. (tie) Didn't have repellent / Mosquitoes don't bite me
5. Don't go outside
4. Concerned about health effects of DEET
3. Forgot
2. Don't see mosquitoes where I live
1. Not worried/ not at risk (36% gave this answer)

Results from the Behavioral Risk Factor Surveillance System survey conducted Nov/Dec, 2003

Mr. OSE. OK. We went from right to left with our public statements. We're going to go from east to west on our questions. Mr. Tierney, you're recognized.

Mr. TIERNEY. Thank you, Mr. Chairman. And I'm going to be brief because I have to leave. And I mean no ill intent toward the panel here. I thank you for your testimony, which has been read with some interest.

Dr. Kilpatrick, let me just ask a couple of quick questions. You talked about the need for better evaluating where resources for preventing and combating West Nile viruses are most needed. Can you explain why it's important to look at information that goes beyond just the number of positive human West Nile virus cases in a given area?

Dr. KILPATRICK. Yes. Thank you for the opportunity to address that. I think as several of the speakers have suggested, putting resources in place before human infections take place is the only way to kind of prevent them. And so if there can be a framework that can predict the risk of a human epidemic, then you can put the resources in those places to try to stop things from happening ahead of time.

Mr. TIERNEY. You made some comments about the data base needed to be improved. Can you add some specifics on that and tell us how more comprehensive data would be helpful to your efforts and other researchers' efforts?

Dr. KILPATRICK. Yes, definitely. So in my view, the two most important pieces of information in terms of assessing the risk of a West Nile virus epidemic are the mosquito abundances and the infection rates of those mosquitoes. And currently, unfortunately, those two pieces of information are not part of Arbonet, which is the CDC's data base. And my experience has been those are not part of that because of issues I discussed having to do with county health departments not wanting to provide those data for either privacy or property value issues. But if those two pieces of information could be brought together in a data base that would be available for planning either on a statewide or a countrywide level, that would immensely help us in understanding and predicting where epidemics would occur.

Mr. TIERNEY. Is it the general consensus from our individuals? Mr. Pape.

Mr. PAPE. Well, we actually use that data in Colorado, what Dr. Kilpatrick was talking about, both the mosquito populations, the make-up of mosquitoes—because some species are better at transmitting this than others—and mosquito infection rates. And we calculate those. I'm not sure of the value at a national level because this is such a focal disease.

If you look at the information in my written statement, 46 percent of our cases last year occurred in a very small area of the State. It was a very focused area. And you would find some cities that were hit very hard, and 20 miles down the road another town had much lower activity due to environmental factors and other things in play.

So we really look at that data at the State level but focus more on the local picture, because it does provide you with evidence of

how bad the activity is this year, or how much human risk may be present.

Mr. TIERNEY. So would you argue against putting that information on CDC's data base?

Mr. PAPE. I don't think there's any problem with it from our end. We have that data available and could easily transmit it to CDC with the rest of the data we provide through Arbonet. For us it would not be an issue.

Mr. TIERNEY. You don't think you'd get any resistance with respect to the property value issue or things of that nature?

Mr. PAPE. No, not at this point.

Mr. TIERNEY. Dr. Weisbuch, you wanted to say something?

Dr. WEISBUCH. Yes. We have accumulated the same information. We've augmented it with meteorologic data in terms of the temperatures and the amount of the rainfall in different sections of the communities so that we can combine all of the several factors, hopefully, in some kind of a mathematical model, which I think is what's being done. And I would look forward to using that and sharing our data with either CDC or with the Harvard-Tufts-BU group that's doing this work.

I asked in the beginning who can project for me from what we already know in April when we had our first couple of cases who can tell me how big this is going to be? We didn't have that capability. And I think that others in the future would like to have it so that we would know where to focus our efforts, where to do our larviciding, where to place our traps. I think putting the large number of mosquito traps out early in the scene is critical so that you know which mosquitoes are out there, because some of them are very good transmitters, as I mentioned earlier in the hearing, and others—and then knowing in each of those mosquitoes what the prevalence of infection by virus is critical. Then you can focus your larviciding. You can focus your ground fogging, and you don't have to go to the more general fogging that is so difficult for the population, or at least members of the population, to accept. I mean, we've had as many arguments with the citizenry on our ground fogging as we've had about the disease itself. And I think that's something that needs to be addressed in this epidemic as well.

Mr. TIERNEY. Thank you. I yield to the chairman.

Mr. OSE. Will the gentleman yield?

Doctor Kilpatrick has in his testimony a formula for calculating the risk of a human epidemic, and I'm curious whether the other witnesses have seen that formula. Have any of you seen the formula he laid out?

Dr. KILPATRICK. It's just in the progress of being published right now, so I would guess that most people probably have not.

Mr. OSE. All right. I'm trying to get to the model that Dr. Weisbuch was talking about, so——

Mr. TIERNEY. I yield back and thank the witnesses for the testimony.

Mr. OSE. I thank the gentleman.

Mr. Pape, on page 3 of your testimony, you make some interesting observations. I want to step through them. You state that opposition to mosquito control, with the potential of lawsuits from seg-

ments of the community, was one of the reasons certain Colorado localities did not implement mosquito control in 2003. And it's your contention that many local officials felt that this particular dynamic put them in a no-win situation. How did Colorado resolve this matter?

Mr. PAPE. Well, again, mosquito control in Colorado, as I think most of the country, is really a local decision item. It's locally funded and the citizens who pay through tax for the benefit of mosquito control receive that benefit. At several of our meetings, both with meetings we had with Colorado County Commissioners Inc., with our vector mosquito control associations, this issue of adulticide spraying comes up, and it's a very controversial issue. There's a lot of things that play into it. But clearly, in many communities, the feeling was that if they went ahead with it, went ahead with spraying in the face of opposition from some of these constituencies, that they would be opening up their community to a potential lawsuit. And so they would be putting out money to do the control, and then they would have to put out additional money to fight the lawsuit, from taking action that they felt was going to benefit the health of the people. It basically has been resolved by communities deciding was that risk worth it and voting whether they would enact or not enact mosquito control.

One of the things I think is interesting is that in many communities the decision was made in the winter months, during January February when we were doing all our planning, doing all our discussions, that we were not going to do mosquito control. And yet, come mid-August when the community was faced with a couple hundred cases and the fifth person had died, suddenly there was a big public outcry to do something. And of course, by this time it's too late to gear up any type of effective measures. And I think that lesson was learned by many of the communities because a lot of those that opted out of doing any control last year, this year opted to do some.

Mr. OSE. I mean, we had a long conversation with Mr. Grumbles about—from the EPA about the certainty provided under a regulation as opposed to a lack of enforceability under guidance. Would EPA issuance of a rule properly vetted under the Administrative Procedures Act and Congressional Review Act and all that, would the issuance of that rule be helpful or hurtful from your perspective in the field in treating this problem?

Mr. PAPE. It clearly would be helpful because any barrier that we can remove from a local community to take a preventative measure or to take some action would be helpful and move things along. This was discussed, this problem with the Clean Water Act and the requirement for an NDPES permit, at some length with a variety of our mosquito control agencies and communities. And certainly it was a concern.

Mr. OSE. Dr. Weisbuch, down in Maricopa County, same question.

Dr. WEISBUCH. Yes. We didn't have that same kind of concern. For some reason the—I think Arizona has a unique situation, and that is that the counties have the full responsibility, granted from the State Department of Environmental Protection, to carry out the vector control services that county feels is necessary.

During this last summer, some counties actually chose not to do any spraying of any kind. Maricopa, of course, has chosen to do limited spraying for several years. And this year we chose to do broad spraying. We did, however, have to gain support from our supervisors from the Maricopa County Board of Supervisors, who are our policymaking board, and without that support we would never have been able to spray. Four out of the five were in strong support of using an adulticide in order to cut back on this epidemic when we had over 300 cases in the middle of August. One of the supervisors, however, was strongly opposed to using adulticiding, and I think next year we may have more political pressure and certainly more pressure from the community itself against spraying. And I think we'll probably have to make a much more complex argument of the value for spraying. And that argument will have to include the cost of a death, the cost of illness, the cost of injury, as described earlier, all of which must play into the model for making a risk assessment: Is it valuable to spray or not?

But I would emphasize Mr. Pape's point, that early intervention with larvacides, identifying the pools, identifying the breeding sites, identifying places where the mosquito lives over the winter, are all extremely important; and that's something which we've been doing, but we realize that the swimming pools themselves are clear areas that we have to address and we haven't in the past.

Mr. OSE. Dr. Kilpatrick, in terms of the discussion we had with Mr. Grumbles as it relates to the issuance of a narrowly crafted rule focusing on public health, do you think the certainty that would come from that would be helpful or not helpful in these issues?

Dr. KILPATRICK. I guess I would suggest that due to the time scale in which these problems present themselves, additional regulatory hurdles certainly are going to slow down efforts to try to reduce the problem when it happens. So I would think that certainty would in fact, as suggested by the other panel witnesses, help our efforts in combating this problem.

Mr. OSE. Mr. Brown, Mr. Conlon, you guys have in the field—I mean, your membership and what have you deals with this. What's your feedback on this same question?

Mr. CONLON. From a nationwide perspective there aren't any mosquito abatement districts that I'm aware of nationwide that are awash in money. They're all operating pretty much at the margins. Anything we can do to free up resources for them to do the preventive nature of their work is something we should pursue. Mosquito abatement districts outside the 9th Circuit are looking at this quite closely, because they can see this becoming writ large, and then they're going to be fighting rear-guard actions against that ad infinitum.

And I think it's the statement that's being made of federally registered insecticides being de facto pollutants that's really got them scared, because this drives an emotive response from antipesticide activists that's going to keep mosquito abatement districts in a defensive role, and it's going to divert resources from where they really should be used.

Mr. OSE. Well, I think the diversion of resources is an important point because the vector control district has X amount of money.

They can either spend it to address the problem or they can spend it to defend themselves legally. You can't spend it for both.

Now Mr. Brown, in Sacramento or central valley California, if I read my history correctly—and I guarantee you I've studied it well—that particular portion of the country at one time, 150 years ago, was a wetland. So you're kind of like at ground zero on this stuff.

Mr. BROWN. Yes, sir. And in fact as you well know, California has undertaken great lengths to try to restore much of the wetlands in our central valley which creates a potentially serious issue as West Nile virus moves its way up through the State into northern California.

To underscore a little bit what Mr. Conlon mentioned, we're very concerned about the vague rulings right now coming out of EPA relative to the NPDES permitting process. I can tell you that the State of California has clearly stated that it is nothing more than a memo and therefore does not require any deference. We believe that the next step, minus any congressional action taken, would be for U.S. EPA to perform a rulemaking, as has been previously suggested.

Mr. OSE. If I understand correctly, you have from the Attorney General a statement that guidance is nonbinding and—I mean, it's gone to that level.

Mr. BROWN. That's correct.

Mr. OSE. It's gone to that degree of activity. So the issuance of a rule may very well solve the 9th Circuit problem.

Mr. BROWN. Correct.

Mr. OSE. All right. Before I leave that point, you're from Sacramento.

Mr. BROWN. Yes, sir.

Mr. OSE. If you lived across from a site where someone was going to build a settlement basin, would you be happy or unhappy, given the consequence that might arise? I'm going to keep asking until you answer yes or no, so you might as well just give up now.

Mr. BROWN. Well I've never been one to give up. So, in my capacity as the director of the district in Sacramento, I would go to great lengths to ensure that proper integrated pest management programs were in place to alleviate my concerns of mosquitoes being developed at that site. If I did not have that opportunity to do that, or if I had regulations put in place that prevented me from doing that, I can tell you I would be very unhappy.

Mr. OSE. Now, you did talk about best management practices in your statement at length. And you also talked about the severe fiscal constraints that you operate under in the State of California for funding. Does the Sacramento Yolo vector district have adequate resources today to deal with the challenges it faces?

Mr. BROWN. Currently we believe that our district does. Understanding that, as what was mentioned in the previous panel, this is a disease that is within a naive population, so we aren't completely confident that we'll be able to reduce the mosquito population below levels that will result in transmission to humans. However, with the data that we've accumulated so far, we feel confident that we can reduce the numbers of mosquitoes so that it won't be as serious as in other parts of the country.

Mr. OSE. One of the things California does is, it very comprehensively addresses environmental questions far beyond what perhaps happens in other States. One of those issues that we deal with is the preservation of wetlands for sound policy reasons. Do you see any correlation between a focus on preservation of wetlands, a successful preservation thereof, and the potential for a rise in the level of West Nile virus incidents?

Mr. BROWN. The short answer is, yes, I do. However, I don't think it has to be. I think that given the science that we know today, that we can restore many of our wetland values and yet reduce the numbers of mosquitoes that may come from those sites. Unfortunately, as is often the case and as you mentioned previously, 150 years ago California was a—certainly the central valley was a broad wetland, if you will. And for many reasons, mosquito control being one of them, a lot of them were drained. We have since recognized that the values of wetlands suggest that we should restore many of those wetland habitats. However, knowing why we conducted some of the draining that we did in the past, I think we can introduce the principles that would reduce mosquito populations, yet still enhance and restore many of the wetlands that we've lost.

Mr. OSE. Your point being that it's one thing to build them. It's another thing to keep them in proper functioning order.

Mr. BROWN. Correct. Correct.

The CHAIRMAN. Now, Ms. Station, in your experience how do—I just want to be able to share this with my neighbors and constituents, of course—how do survivors of West Nile virus feel about some of the regulatory challenges and protests against the use of ground foggers or aerosol sprays?

Ms. STATION. They're very dismayed. Once you've been touched or had encephalitis touch you, touch someone in your family—they're frustrated with this no more spraying that's going on everywhere and all the fuss that's going on. So much of society and so much of the media is talking, as we're talking today, about what will we do in the future? Well, what can we do to fix this? So little attention has been paid to the people who've already been touched. I'm hoping that everyone here will include my Web site in references on their own Web sites so that the hundreds of people that are now coping with this debilitating disease can turn to someone for help.

Mr. OSE. Well, now, Dr. Fauci and Dr. Ostroff, earlier in their written statements, clearly indicated that there's no curative medical treatment. I mean once you have it, you have it. That's the way it is. Even though they're working on some vaccines that would prevent a person from catching it.

I guess my question would be perhaps directed to Dr. Weisbuch, the incidence of which people contract the disease and don't develop the really serious symptoms, what is that incidence? And then conversely, what is the incidence within the naive population that people do contract the disease and develop the very serious symptoms?

Dr. WEISBUCH. That's a complicated question because I think it varies or has varied across the country as I've looked at some the data. In the Maricopa County experience this year, we had 347

identified cases, laboratory confirmed, of illness. Approximately half of those only had fever with no residual whatsoever. We're following up on all of them to determine over the next 6 to 9 months to a year whether or not any other sequelae occur. But the other hundred and whatever, 50 or 60 individuals who suffered either a meningitis attack or an encephalitis attack, or both, that group obviously has the highest potential for long-term sequelae. We don't know at the present time what proportion of that group will, in fact, have residual 6 months, 9 months, a year from now. We're going to be following those. We do know that six of those individuals or actually seven have died as a result of the disease. And we also know that there are about a half a dozen or maybe a dozen who are still in intensive care units with all of the various ramifications of paralysis, coma, loss of sensitivity, inability to breathe normally, and so on. And we're expecting that some of that group will also succumb to the illness.

One of the most interesting things that we've found in reviewing our six death certificates is that at least two of these individuals succumbed from what the physician called a respiratory paralysis. But when x-rayed, and in one case autopsied, there was no real evidence of a pneumonia. And so it appears that the virus is infecting the central aspect of respiration in the pons of the brain, where the individual is just dying from a respiratory disease as a result of their not moving their diaphragm, sort of like what polio used to do 50 years ago.

These kinds of things need further evaluation and I think further research. We don't know the overall impact, long-term impact of this illness. It's only been a what, a 5-year problem. And I think that's—I think maybe Dr. Pape has other——

Mr. PAPE. I would agree with that. We took an effort in 2003 to look at the full clinical spectrum of illness. If you look at data from earlier years from other States, they primarily were reporting meningitis and encephalitis, which was what the national guidelines recommended at that point. We tried to look at the full spectrum which is one of the reasons we had a large number of cases. Eighty percent of our cases were the West Nile fever. And what we found is there's not a, you know, nice even break where you have fever and then you break, now you have meningitis. It's a full spectrum from people who are ill a couple of days with fever, to some people who had prolonged fever—our average duration of people who had West Nile fever, the milder illness, was 23 days. That's they were sick, they had fever, they had aches, they had all these other symptoms, and it took them 2 or 3 weeks to get their strength back to be able to go back to work or function.

As you get into, as Dr. Weisbuch talked about, the more severe manifestations, we actually had our 64th patient die this week, who has been in the ICU with respiratory paralysis since last August. And essentially this is identical pathologically to what we used to see with the polio epidemics in the fifties. It's a poliomyelitis that affects various nerves. And depending on which nerves the virus destroys, depends on whether your respiratory system get paralyzed; is it your arm, is it a leg, is it some cognitive function because of damage to those areas of the brain? And so there is really a wide spectrum of illness.

We've actually got a couple of papers that we're working on that will be out shortly, scientific papers looking at exactly that question: What are the long-term ramifications, what are some of the clinical manifestations with this infection?

Mr. OSE. You're not making a very good case for this settling basin across the street from my house.

Mr. PAPE. Well, if you were to ask me that question about the settlement basin, I would say I wouldn't have opposition to it, provided part of their plan is, as Dave Brown pointed out, was that they're going to do some kind of mosquito control. And, in fact, we have seen those problems, I think other States have experienced it, where for instance we have a wetlands. One city I know in particular has a federally protected wetlands on the border of their city that they will not allow—are not allowed to do any control on. And so they have a buffer zone of control between the city and that wetlands area, because they get a lot of mosquitoes coming off of the wetland since it's protected as natural, and we don't want to get rid of the fish food or the bat food or things like that.

I won't argue the validity of that point because I tend to be fairly environmentally sensitive myself. But I think there are situations where, in the case of that catch basin, it would be beneficial to be able to go and put some larvacide into it.

Mr. OSE. All right. I want to come back to this particular question. I want to ask Ms. Station something, and that is that you indicated in your statement that a lot of people don't take vector-borne diseases very seriously because historically there's been a very low number of deaths and the large portion of those people who get infected, they have a relatively minor sickness.

Now, how do we get the message out that there's a certain group of people where the impact of that sickness is severe? How do we get that out? I mean, you're talking to some folks who are on the front lines here. Help me help you, so to speak. How do I do that?

Ms. STATION. How do we do it? Any way possible, sir. I spend 12 hours a day on the computer. I started my Web site in the year 2000. I write to newspapers. I've got a newspaper article that was published here in, oh, just within the past week that was—I just got in the mail yesterday. I go on talk shows. I was on a talk show radio, I believe it was in Minnesota last year. I pound the pavement. And that seems to be the only way to get the message out.

I see here, Ohio State University says in a recent study it was found people who were hospitalized last year with encephalitis, with West Nile encephalitis, they have reported problems 1 year after their illness including headaches, concentration problems, fatigue, movement disorders.

Let's see, New York State, they did a study saying nearly two-thirds of severely infected patients still suffer physical and mental impairments 12 months after falling ill. So I would do anything I could.

Mr. OSE. Excuse me. All right. Like Pavlov's dog, we all learn what the bell means. What we've got is a 15-minute vote that's just been called on the floor, followed by a 5-minute vote. So we're going to have to move quickly here.

Mr. Brown, I want to come back to this issue on this catch basin. It is admittedly across the street from my house, but my neighbors

and constituents have a concern about it. Now, this area is within the 9th Circuit, and if I understand correctly, under best management practices, a treatment with either a larvacide or an adulticide would be part of an integrated pest management system. But in California that would require an NPDES permit for application thereof. Am I correct on that?

Mr. BROWN. At least for the larvacide. It's one of the concerns about the vagueness of the ruling that we have currently in California. There is an NPDES permit for the application of larvicides in California. It is silent to date on an application of an adulticide. It has raised concerns, as has already been mentioned, about the potential of litigation for the use of an adulticide in and around that area you refer to. And could you give me the address of that area, by the way?

Mr. OSE. Yes. Del Paso Regional Park at the very east end of the city. But it is also 9th Circuit case law that an NPDES permit will be required for the application of a larvacide.

Mr. BROWN. For a larvacide. Yes, sir.

Mr. OSE. Right. OK.

Dr. WEISBUCH. Does that include biological larva sites? I mean, we use fish and we use a particular bacterium, Bacillus thuringiensis, I think.

Mr. OSE. I believe it's restricted to the——

Dr. WEISBUCH. To the oils.

Mr. OSE. To the organophosphate classification.

Mr. BROWN. It is for the application of any registered pesticide. So the larvacide you're referring to, Bacillus thuringiensis, is a registered larvacide and would therefore require an NPDES permit as defined under the 9th Circuit.

Dr. WEISBUCH. I'm glad we don't have that in Arizona.

Mr. OSE. And absent an NPDES permit, you can't apply the larvacide.

Mr. BROWN. Without fear of litigation.

Mr. OSE. OK. Now, I have a significant number of additional questions here for each of you in turn. But we're not going to be able to get to them verbally here. As I indicated to the first panel, we will send those questions to you in writing. We would appreciate a timely response. I believe the record stays open for 10 days for Members and what have you who have been in attendance, in part or not, to submit additional questions. Those will be forwarded to you.

I do want to thank you all for taking the time to come and testify. This is one of those interesting, as I said earlier, interesting intersections between public health, the environment, and science that gets very little play because it's highly technical and it requires some thought.

I would urge you to stay on your message. I mean, stay at this. The MASH Act by Senator Gregg of New Hampshire—eventually it will get funded. Unfortunately, it may be after 600-odd people have died and untold thousands have been infected. But stay on this.

And California in particular, this is an issue I think of significant concern because of what the likely consequence of next spring will bring.

Mr. Conlon, Mr. Brown, what you do across the country makes a difference. Dr. Weisbuch, Mr. Pape, what you do in Arizona and in Colorado is appreciated. Ms. Station, Dr. Kilpatrick, we thank you for your suggestions and your input. We'll send you the questions. This panel is excused and this hearing is adjourned.

[Whereupon, at 12:51 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

October 15, 2004

BY FACSIMILE
The Honorable Benjamin H. Grumbles
Acting Assistant Administrator
Office of Water
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Mr. Grumbles:

This letter follows up on the October 6, 2004 hearing of the Government Reform Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, entitled "Current Challenges in Combating the West Nile Virus." As discussed during the hearing, I am enclosing questions to be completed for the record.

Please send your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building by November 6, 2004. If you have any questions about this request, please call Counsel Danielle Hallcom Quist at 226-2067. Thank you for your attention to this request.

Sincerely,

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural
Resources and Regulatory Affairs

Enclosure

cc The Honorable Tom Davis
The Honorable John Tierney

Q1. Citizen Lawsuits. On July 11, 2003, the Environmental Protection Agency (EPA) issued an "Interim Statement of Guidance on Application of Pesticides to Waters of the United States in Compliance with FIFRA." Notwithstanding this nonregulatory, nonbinding guidance document, local vector control districts still face the threat of lawsuits under the Clean Water Act (CWA).

(a) What actions will EPA take to lessen the threat of citizen lawsuits under the CWA?

(b) In light of the pending litigation in Gem County, Idaho, what steps can local vector control districts take to protect themselves from citizen lawsuits?

(c) Since EPA's guidance is not binding on non-Federal entities, in States where EPA administers the National Pollutant Discharge Elimination System (NPDES) permit program, will EPA issue an NPDES permit upon request in order to protect vector control districts from potential lawsuits under the CWA? If not, why not?

Q2. Final Guidance. EPA issued its interim guidance for public comment in the Federal Register on August 13, 2003 (68 FR 48385). Public comments were due on October 14th, i.e., a year ago.

(a) Does EPA intend to finalize its interim guidance? If so, when?

(b) If so, will the final guidance mirror the interim guidance?

(c) If not, what are the expected substantive changes?

Q3. Formal Rulemaking. Under the Congressional Review Act, all agency documents, including guidance documents, with any general applicability or legal effect are subject to Congressional review before they can be issued or take effect. Therefore, EPA's interim guidance is merely advisory for non-Federal parties. As a consequence, during the Subcommittee's October 6, 2004 hearing, I asked you whether EPA would initiate a rulemaking to clarify under what circumstances vector control districts do or do not need to obtain a NPDES permit for use of both aquatic and aerial spray pesticides to control mosquitoes. You responded, "perhaps." Please explain the following:

(a) In 2003, why did EPA initially issue interim nonbinding guidance in lieu of an interim rule?

(b) In 2003, why did EPA believe that nonbinding guidance was more appropriate than a formal rule with general applicability and legal effect under the Administrative Procedure Act?

(c) On what date will EPA make a decision on whether to promulgate a rule?

Q4. Wetlands. In the West, wetlands, both healthy and degraded, often provide prime habitat for mosquitoes infected with the West Nile Virus (WNV).

(a) In light of the Bush Administration's policy of "no net-loss of wetlands," how does EPA intend to assist local vector control districts and public health officials in minimizing the public health threat posed by wetlands, especially wetlands located adjacent to suburban and rural populations?

(b) How does EPA suggest local vector control districts manage vernal pools and other bodies of water considered to be under the jurisdiction of the CWA?

Q5. Pesticide Availability. Vector control districts voice concern over the limited number of lower risk larvicides and adulticides available to control mosquitoes carrying the WNV. What steps has EPA taken to support the development of new and reduced risk public health pesticides?

October 15, 2004

BY FACSIMILE
The Honorable Benjamin H. Grumbles
Acting Assistant Administrator,
Office of Water
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Mr. Grumbles:

This letter follows up on the October 6, 2004 hearing of the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, entitled "Current Challenges in Combating the West Nile Virus." Please respond to the enclosed followup questions from Congressman Dennis Kucinich for the hearing record.

Please hand-deliver the agency's response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building not later than November 5, 2004. If you have any questions about this request, please call Subcommittee Counsel Danielle Quist at (202) 226-2067. Thank you for your attention to this request.

Sincerely,

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

Enclosure

cc: The Honorable Tom Davis
The Honorable John Tierney

Questions for the Record
For Benjamin Grumbles, Acting Assistant Administrator, Office of Water, Environmental Protection Agency
From Representative Dennis J. Kucinich
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

Hearing on "Current Challenges in Combating the West Nile Virus"

October 6, 2004

What risk assessments have been done for the widespread effects of spraying pesticides on drinking water or wetlands that will increase under the Interim Guidance? If none, who will weigh the risks and benefits of the exemptions to CWA regulation proposed in the Interim Guidance? How will local conditions be considered in order to yield more accurate risk assessments or more efficient risk abatement?

Have you done or do you plan to do an environmental impact analysis on the act of exempting pesticides from CWA regulation as you are proposing? If you do not, who will?

If the SDWA does not require testing for most if not all of the pesticides used against WNV-bearing mosquitoes, and the CWA, which provides for prevention of contamination of water supplies from pollutants like pesticides, will be circumvented under the Interim Guidance, how will drinking water sources be protected from pesticide contamination? Since there are no requirements to test drinking water for the relevant pesticides, how will you know determine whether the spraying resulted in drinking water contamination?

If there is a reliance on FIFRA to provide protection of health and the environment, how will the endocrine disrupting effects of the relevant pesticides be considered?

Are there any mechanisms in place to receive and/or investigate reports about misguided or otherwise ill-suited mosquito management practices?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 24 2004

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Doug Ose
Chairman
Subcommittee on Energy Policy,
Natural Resources and Regulatory Affairs
Committee on Government Reform
U. S. House of Representatives
Washington, DC 20515

Dear Chairman Ose:

Enclosed, for insertion in the hearing record, are the Environmental Protection Agency's responses to the questions that you forwarded to the Agency following the October 6, 2004 hearing entitled "Current Challenges in Combating the West Nile Virus."

If you have any questions about the enclosed materials, please do not hesitate to contact me, or your staff may call Tom Dickerson of my staff at 202-564-3638.

Sincerely,

Charles Ingebretson
Associate Administrator

Enclosure

EPA'S RESPONSES TO FOLLOW-UP QUESTIONS FROM THE OCTOBER 6, 2004 HEARING REGARDING WEST NILE VIRUS

Questions from Chairman Ose

Q1. Citizen Lawsuits. On July 11, 2003, the Environmental Protection Agency (EPA) issued an "Interim Statement of Guidance on Application of Pesticides to Waters of the United States in Compliance with FIFRA." Notwithstanding this nonregulatory, nonbinding guidance document, local vector control districts still face the threat of lawsuits under the Clean Water Act (CWA).

(a) What actions will EPA take to lessen the threat of citizen lawsuits under the CWA?

(b) In light of the pending litigation in Gem County, Idaho, what steps can local vector control districts take to protect themselves from citizen lawsuits?

(c) Since EPA's guidance is not binding on non-Federal entities, in States where EPA administers the National Pollutant Discharge Elimination System (NPDES) permit program, will EPA issue an NPDES permit upon request in order to protect vector control districts from potential lawsuits under the CWA? If not, why not?

EPA's Interim Statement and Guidance issued on July 11, 2003, provides that, for pesticides applied to waters of the U.S. in compliance with the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA), an NPDES permit is not required in two circumstances described therein. EPA sought public comment on this Interim Statement and Guidance. It is completing review of the comments received and expects to issue a final guidance by this December. Until the Interim Statement is made final, it is EPA's position that the application of pesticides in compliance with relevant FIFRA requirements in the circumstances described in the Guidance is not subject to NPDES permitting requirements under the CWA, as described in the Interim Statement.

Since EPA issued the Interim Guidance, we are only aware of one Clean Water Act lawsuit alleging the discharge of pollutants without a NPDES permit that has been filed against a mosquito control district. While EPA can not prevent citizens from filing lawsuits against vector control districts, EPA hopes that the courts that hear such cases will uphold EPA's interpretation of the CWA. Agencies' interpretations of statutes they administer are entitled to judicial deference.

Vector control districts that need additional assurances should consult EPA regional offices. Some States have made a NPDES general permit available for vector control districts. Although EPA believes that permits are not needed in the two circumstances described in the Interim statements, authorized States are permitted to adopt more stringent requirements than the minimum requirements of the CWA. The only permit application that EPA has received to date has been from the Gem County Mosquito Abatement District. EPA has communicated with representatives of GCMAD in an effort to learn whether its mosquito control activities are limited to the two circumstances identified in the Interim Statement and Guidance. If so, an NPDES permit would not be required. If GCMAD's activities are not limited to those two circumstances, EPA will consider whether it is appropriate to issue a permit and/ or to provide additional guidance. Similarly, EPA will review future permit applications and decide on appropriate action.

Q2. Final Guidance. EPA issued its interim guidance for public comment in the Federal Register on August 13, 2003 (68 FR 48385). Public comments were due on October 14th, i.e., a year ago.

(a) Does EPA intend to finalize its interim guidance? If so, when?

(b) If so, will the final guidance mirror the interim guidance?

(c) If not, what are the expected substantive changes?

EPA intends to finalize the guidance by December 30, 2004 or shortly thereafter. The Agency plans to complete the review of the public comments and will consider these comments in its deliberation on the final guidance.

Q3. Formal Rulemaking. Under the Congressional Review Act, all agency documents, including guidance documents, with any general applicability or legal effect are subject to Congressional review before they can be issued or take effect. Therefore, EPA's interim guidance is merely advisory for non-Federal parties. As a consequence, during the Subcommittee's October 6, 2004 hearing, I asked you whether EPA would initiate a rulemaking to clarify under what circumstances vector control districts do or do not need to obtain a NPDES permit for use of both aquatic and aerial spray pesticides to control mosquitoes. You responded, "perhaps." Please explain the following:

(a) In 2003, why did EPA initially issue interim nonbinding guidance in lieu of an interim rule?

(b) In 2003, why did EPA believe that nonbinding guidance was more appropriate than a formal rule with general applicability and legal effect under the Administrative Procedure Act?

(c) On what date will EPA make a decision on whether to promulgate a rule?

The guidance sets forth EPA's interpretation of the statute, which is an appropriate subject for a guidance document. Furthermore rulemakings are resource and time intensive. For example, to revise its regulations, EPA generally must develop analyses that estimate the impact that the proposal and any alternatives would have on costs, governments, small businesses and reporting requirements.

By issuing the Interim Guidance, EPA was able to quickly clarify its position that NPDES permits are not required to apply aquatic pesticides in compliance with FIFRA in the two circumstances described in the guidance.

Once it has finalized the Interim Guidance, EPA will consider the need for a rulemaking.

Q4. Wetlands. In the West, wetlands, both healthy and degraded, often provide prime habitat for mosquitoes infected with the West Nile Virus (WNV).

(a) In light of the Bush Administration's policy of "no net-loss of wetlands," how does EPA intend to assist local vector control districts and public health officials in minimizing the public health threat posed by wetlands, especially wetlands located adjacent to suburban and rural populations?

We would note at the outset that the Administration's policy is to increase net wetlands acreage, not just avoid net loss, and EPA is committed to that goal. It is critical to understand the virus transmission, mosquito life cycle, preferred habitats and seasonal trends of mosquito species in a particular area to discuss the real risk of the virus posed by wetlands to humans.

Healthy wetlands sustain numerous species of mosquito-eating fish, amphibians, insects and birds. Together, these species form a balanced predator-prey relationship that helps to limit mosquito populations. Sometimes, however, even healthy wetlands may harbor large numbers of mosquito species that carry West Nile Virus. Therefore, it may be necessary to use appropriate mosquito control measures to prevent West Nile disease transmission.

Before making a decision to use pesticides, local public health and vector control officials, along with wetland managers should first perform a surveillance to determine where and if control is necessary, where mosquitoes are produced, and if mosquitoes are carrying the virus. Not all species of mosquito carry West Nile virus, not all species of mosquito feed on humans, and not all species of mosquito live in wetlands. Under the interpretive guidance issued in 2003, pesticides (larvicides and adulticides) may be applied directly to waters of the United States (including wetlands) without a NPDES permit if it is done according to label instructions.

The Agency for Toxic Substance and Disease Registry (ATSDR) and the United States Department of Health and Human Services (HHS) are working to provide guidance to local public health officials and vector control districts on safe and effective means of vector control. Additionally, EPA has published a fact sheet and made presentations to the American Mosquito Control Association to better help the public understand the relationship between wetlands and the West Nile Virus.

(b) How does EPA suggest local vector control districts manage vernal pools and other bodies of water considered to be under the jurisdiction of the CWA?

If surveillance indicates that mosquito control measures are deemed appropriate and necessary for a particular water body, vector control districts may apply pesticides directly to and over the water body. EPA's July interim guidance states that the application of pesticides directly into and over U.S. waters, in compliance with FIFRA requirements is not subject to NPDES requirements.

Q5. <u>Pesticide Availability</u>. Vector control districts voice concern over the limited number of lower risk larvicides and adulticides available to control mosquitoes carrying the WNV. What steps has EPA taken to support the development of new and reduced risk public health pesticides?

Recognizing the expanding need to develop new tools to respond to potential public health threats, EPA recently met with representatives from Department of Defense (DOD), Department of Agriculture (USDA), Agency for International Development (USAID), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) to facilitate cooperation and coordination among the federal agencies involved in public health pesticides. The new committee discussed ways to pool resources, share information, and encourage development of new techniques and products. Both DOD and NIH are devoting resources to research new methods of control, including finding public health uses for pesticides that are already registered for other purposes. Also participating were representatives from the USDA-sponsored Interregional Research Project No. 4 (IR-4) whose experience with reduced-risk pesticides and information on "minor uses" in agriculture could lend the

group expertise in developing similar "minor-use" registrations of pesticides for public health purposes. The committee is planning to meet again in January 2005, to continue addressing strategies for developing new public health pesticides as efficiently and effectively as possible.

Questions from Representative Dennis J. Kucinich

Q.1 What risk assessments have been done for the widespread effects of spraying pesticides on drinking water or wetlands that will increase under the Interim Guidance? If none, who will weigh the risks and benefits of the exemptions to CWA regulation proposed in the Interim Guidance? How will local conditions be considered in order to yield more accurate risk assessments or more efficient risk abatement?

The interim statement and guidance interprets the Clean Water Act in a manner consistent with how the statute has been administered for more than 30 years. EPA does not require NPDES permits solely for the direct application of a pesticide to target a pest that is present in or over a water of the United States, where the application is consistent with relevant Federal Insecticide, Rodenticide and Fungicide Act (FIFRA) requirements, nor has it ever stated in any general policy or guidance that an NPDES permit is required for such applications. Risk assessments have been done for malathion, naled, and prallethrin (not yet registered). Permethrin, pyrethrin, resmethrin, and d-phenothrin (sumithrin) risk assessments are on-going in keeping with the reregistration schedule for these chemicals. Levels in drinking water and effects on the ecology of wetlands are considered and evaluated during the EPA risk assessment process.

Pesticide registration is based on a nationwide risk assessment and EPA's risk management process under the FIFRA is designed to ensure that, no matter where they are used, pesticides do not pose greater ecological or environmental risks than the benefits they provide. Potential effects on human health through drinking water exposures are evaluated through a risk assessment and management process based on conservative assumptions about extent, rate and frequency of pesticide use. We believe these pesticide risk assessment processes lead to sound and protective decisions to protect water resources from pesticides.

Q.2 Have you done or do you plan to do an environmental impact analysis on the act of exempting pesticides from CWA regulation as you are proposing? If you do not, who will?

The interim statement and guidance interprets the Clean Water Act in a manner consistent with how the statute has been administered for more than 30 years.

Q.3 If the SDWA does not require testing for most if not all of the pesticides used against WNV-bearing mosquitoes, and the CWA, which provides for prevention of contamination of water supplies from pollutants like pesticides, will be circumvented under the Interim Guidance, how will drinking water sources be protected from pesticide contamination? Since there are no requirements to test drinking water for the relevant pesticides, how will you know determine whether the spraying resulted in drinking water contamination?

Under the Food Quality Protection Act of 1996 (FQPA), EPA may authorize the presence of pesticide residues in food only if "aggregate exposure" would be safe. FQPA defines aggregate exposure as including both dietary exposures and all other non-occupational exposures. EPA has implemented this provision by combining food and drinking water exposures with exposures to pesticides used in and around homes, schools, parks, and other similar locations. This rigorous risk assessment technique produces decisions that are protective of water resources.

Before registering a pesticide, EPA requires a company to conduct over a hundred different studies to assess a wide variety of potential human health and environmental effects associated with use of the product, as well as potential exposure. These studies include tests to evaluate whether a pesticide has the potential to cause adverse effects or to contaminate surface water or ground water. EPA uses these data to develop "conservative" estimates of potential exposure through drinking water (i.e., estimates that are not likely to understate potential exposure), which are then incorporated into the human health risk assessments for each pesticide.

Q.4 If there is a reliance on FIFRA to provide protection of health and the environment, how will the endocrine disrupting effects of the relevant pesticides be considered?

EPA requires companies to conduct extensive testing of their pesticides to evaluate the potential effects of these substances on humans, aquatic life and wildlife. These tests include short and long term studies that evaluate the potential of a pesticide to cause reproductive or development adverse effects. In addition, as required by FQPA, EPA initiated the Endocrine Disruptor Screening Program (EDSP) to develop an additional screening program for pesticide chemicals and environmental contaminants for their potential to affect the endocrine systems of humans and wildlife. EPA is developing the screening program, which will be based on appropriately validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects that can lead to adverse reproductive or development outcomes. The 1996 amendments to the Safe Drinking Water Act authorize EPA to screen substances that may be found in sources of drinking water for endocrine disruption potential.

Q.5 Are there any mechanism in place to receive and/or investigate reports about misguided or otherwise ill-suited mosquito management practices?

Yes. There are several mechanism in place:

- Every pesticide label includes the statement, "It is a violation of federal law to use this product in a manner inconsistent with its labeling." The conditions of proper use are derived from risk assessments prior to registration. The pesticide label is essentially "the law," requiring the users to handle/apply the product exactly as directed. The purchaser or user of any pesticide assumes all legal responsibilities for the use of the product. Any departure from label directions is an illegal use of the pesticide.

- The States have primary responsibility for the oversight of proper use of pesticides and to investigate misuse. When enforcement actions are necessary, EPA works with State lead agencies and coordinates action as needed.

- EPA is preparing a new guidance to registrants and others concerning the Agency's labeling statements for pesticide products used for wide-area applications to control adult mosquitoes. These recommendations help clarify some labeling statements. The new language will help public health mosquito control officials optimize mosquito control techniques while ensuring that use of these products will not pose unreasonable risks to public health or the environment.

EPA relies on the existing public health infrastructure of State and local public health departments, State departments of agriculture, EPA regional offices, poison control centers, EPA-sponsored National Pesticide Information Center, and health care professionals to report trends in pesticide-related cases. EPA routinely evaluates the adverse effects information reported to the Agency to determine if further investigation and mitigation measures are necessary. Under FIFRA section 6(a)(2), pesticide registrants are required by law to inform EPA about harmful effects of their products. Information reportable under this provision includes not only new information derived from scientific studies, but also reports of incidents of harmful effects resulting from the use of pesticide products. When administered properly in a mosquito control program, insecticides pose a low risk for acute, temporary health effects among persons in areas that are being sprayed and among workers handling and applying insecticides. EPA works with the States, pesticide manufacturers, and mosquito control officials to promote the safe use of pesticides, as well as promoting the adoption of reduced-risk pesticides.

October 15, 2004

BY FACSIMILE
Mr. David Brown
Sacramento/Yolo Mosquito
Vector Control District
8631 Bond Road
Elk Grove, CA 95624

Dear Mr. Brown:

This letter follows up on the October 6, 2004 hearing of the Government Reform Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, entitled "Current Challenges in Combating the West Nile Virus." As discussed during the hearing, I ask you to please respond to the following questions:

1. Mosquito Abatement in Northern California.
   (a) What are typical conditions favorable for mosquito habitat?
   (b) What distance can a mosquito fly during its lifetime?
   (c) Under what circumstances do vector control districts use pesticides to kill mosquitoes and destroy their habitat?

2. NPDES Permit. How does California's permit requirements under the National Pollutant Discharge Elimination System (NPDES) impact the vector control association's ability to utilize:
   (a) herbicides, larvicides and adulticides to kill mosquitoes, larvae and their respective habitat?
   (b) pesticides in a timely manner?, and
   (c) the most effective pesticides applications?

3. EPA's Nonregulatory Guidance. To your knowledge, has any State been hindered in any way by the Environmental Protection Agency's (EPA's) July 2003 nonregulatory guidance, including being subject to any lawsuits? If so, how? Would an EPA rule solve this problem?

Please send your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building by November 5, 2004. If you have any questions about this request, please call Counsel Danielle Hallcom Quist at (202) 226-2067. Thank you for your attention to this request.

Sincerely,

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

cc The Honorable Tom Davis
The Honorable John Tierney

SACRAMENTO-YOLO
MOSQUITO
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DISTRICT

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November 8, 2004

Congressman Doug Ose
Chairman
Subcommittee on Energy Policy
Natural Resources and Regulatory Affairs
2157 Rayburn House Office Building
Washington DC 20515-6143

RE: Follow up questions to October 6th Testimony

Dear Congressman Ose:

Please find enclosed my responses to questions you had following the hearing on October 6th entitled "Current Challenges in Combating the West Nile virus". Please let me know if I need to provide further information.

Sincerely,

David Brown
IPM Chair
Mosquito and Vector Control
Association of California

Mosquito Abatement in Northern California

(a) What are typical conditions favorable for mosquito habitat?

Typical conditions can range from artificial containers that hold water, such as buckets, wading pools, and ornamental ponds, to natural or manmade sources such as wetlands, rice fields, storm water detention basins, or other similar sites. The latter sites are often characterized by dense vegetation (more than 50% in the site) that inhibit biological control or larvicidal control.
Mosquitoes that are responsible for the transmission of West Nile virus in California are generally found in sites that have water with a high organic content and/or dense vegetation.

(b) What distance can a mosquito fly during its lifetime?

There are over 50 species of mosquitoes in California. Some species will fly only a few hundred yards, while other species will fly over 10 miles. Typical flight ranges for Culex species of mosquitoes responsible for West Nile virus are approximately 1-5 miles. It is not uncommon for a host-seeking mosquito to fly a few miles from where they develop to seek a blood meal.

(c) Under what circumstances do vector control districts use pesticides to kill mosquitoes and destroy their habitat?

Mosquito control districts conduct mosquito larvae and mosquito adult surveillance to determine when mosquito populations reach levels ("thresholds") that require remedial action. When these threshold levels are met, Vector Control districts use the principles of Integrated Pest Management to reduce the mosquito population. These principles include physical control (modifying or eliminating the site) or biological (the introduction of mosquitofish or some other predator). When these cannot be used or will not work, chemical applications are made that are targeted to control mosquito larvae in the water or adult mosquitoes in the air.
One component of chemical control that is related to physical control is the use of herbicides to reduce vegetation in an aquatic site. By reducing vegetation in an aquatic habitat, it provides more opportunities for biological control to work and can reduce the overall need for future pesticide applications. This practice is currently not practiced in California due to excessive costs related to the NPDES permit for herbicide applications.

NPDES Permit

How does California's permit requirements under the National Pollutant Discharge Elimination System (NPDES) impact the vector control abilities to utilize:

(a) herbicides, larvicides and adulticides to kill mosquitoes, larvae, and their respective habitat?

No mosquito control district is currently using herbicides as a part of their integrated pest management program due to the expense of complying with the current NPDES permit for herbicide applications to surface waters. The current permit in California for larval

control of mosquitoes has no provision for any new larvicide, instead placing a reliance on listed larvicides that may eventually result in resistance to this short list of public health pesticides. California's current permit is silent on the use of adulticides.

(b) Pesticides in a timely manner? And

Most of the larvicides listed in the permit may be used in a timely manner. However, at least one public health pesticide registered in California could not be used without extensive pre- and post- monitoring conducted.

(c) The most effective pesticides applications?

The permit does not allow the use of all public health pesticides that are registered in California unless certain monitoring requirements are met. Mosquito control districts cannot use at least one product that is registered in all other states without extensive pre- and post- monitoring.

EPA's Nonregulatory Guidance

To your knowledge, has any State been hindered in any way by the EPA' July 2003 nonregulatory guidance, including being subject to any lawsuits? If so, how? Would an EPA rule solve this problem?

At least one mosquito control district in Idaho has been sued under the Clean Water Act, claiming the need for an NPDES permit, in spite of EPA issuing an "Interim Statement and Guidance Document" in July of 2003. Idaho does not administer the NPDES program, instead relying on USEPA to administer the program for them. To date, USEPA has not issued an NPDES permit to Idaho mosquito control districts, nor do they claim mosquito control districts need one.

In California, State Water Resource Control Board Officials claim the "Interim Statement and Guidance" document is nonbinding, and in many cases nothing more than a "memo". The State of Washington has excluded certain pesticides from being used in their NPDES permit, despite the issuance of the Interim Statement and Guidance document from USEPA. This is contrary to sound integrated pest management methods that rely on a rotation of public health pesticides to avoid resistance in a mosquito population.

Members of California Mosquito Control Districts firmly believe that absent any legislative change, USEPA should perform a rulemaking that clearly states that pesticides applied by mosquito control agencies to control mosquitoes or their habitat are not the discharge of a pollutant as defined under the Clean Water Act and therefore are not subject to NPDES requirements.

October 15, 2004

BY FACSIMILE
Dr. Stephen M. Ostroff
Deputy Director, National Center for Infectious Diseases
Centers for Disease Control and Prevention
Department of Health and Human Services
1600 Clifton Road, Mailstop C12
Atlanta, GA 30333

Dear Dr. Ostroff:

This letter follows up on the October 6, 2004 hearing of the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, entitled "Current Challenges in Combating the West Nile Virus." Please respond to the enclosed followup questions from Congressman Dennis Kucinich for the hearing record.

Please hand-deliver your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building not later than November 5, 2004. If you have any questions about this request, please call Subcommittee Counsel Danielle Quist at (202) 226-2067. Thank you for your attention to this request.

Sincerely,

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

Enclosure

cc: The Honorable Tom Davis
The Honorable John Tierney

Questions for the Record
For Stephen Ostroff, Deputy Director, National Center for Infectious Disease
Centers for Disease Control and Prevention
From Representative Dennis J. Kucinich
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

Hearing on "Current Challenges in Combating the West Nile Virus"

October 6, 2004

In general terms, please explain the program of oversight carried out to track possible adverse effects to human health or the environment from exposure to pesticides used for mosquito control.

Follow up question for the Centers for Disease Control and Prevention from the October 6 Government Reform Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs hearing: "Current Challenges in Combating West Nile Virus"

Question: In general terms, please explain the program of oversight carried out to track possible adverse effects to human health or the environment from exposure to pesticides used for mosquito control.

Studying Pesticide Exposure
CDC does not conduct a coordinated nationwide surveillance program or activity monitoring adverse human health effects from the application of mosquito control pesticides. However, CDC's National Center for Environmental Health (NCEH) has conducted specific, targeted studies assessing exposure to mosquito control pesticides (Mississippi 2002, Virginia and North Carolina 2003). Most recently, CDC has conducted three studies, each of which concluded that human exposure to pesticides had not increased as a result of spray activities:

- To evaluate the risk from exposure to pesticides used in public health spraying to control West Nile Virus, CDC researchers assessed people's exposure to mosquito-control pesticides applied in Mississippi to control the mosquito vector of West Nile Virus (WNV). CDC compared urinary levels of permethrin metabolites in people living in areas that were sprayed for mosquitoes with levels in people living in areas where spraying for mosquitoes was not done. Results showed that the people living in the vicinity of spraying of mosquito-control pesticides had the same level of pesticides in their urine as those who were not exposed to these pesticides.

- CDC investigated the relationship between mosquito control spraying and pesticide exposure (not related specifically to WNV) in two studies, one in North Carolina and one in Virginia. On September 18, 2003, Hurricane Isabel blew ashore at Cape Hatteras, North Carolina, bringing high winds and pouring rains to North Carolina, Virginia, West Virginia, Pennsylvania, Delaware, Maryland, New Jersey, New York, and the District of Columbia. The severe weather conditions produced massive flooding, and state health officials became concerned about an increase in mosquitoes. In an effort to control the mosquito population, North Carolina and Virginia began aerial spraying of the pesticide naled. CDC obtained urine samples from 150 volunteers in neighborhoods where the spraying occurred in North Carolina and Virginia. CDC's environmental health laboratory staff analyzed the samples for metabolites of organophosphorus and pyrethroid insecticides. The data indicated that no increased exposures resulted from the public health pesticide applications. A final report of the study was provided to the state health department.

Following the hurricanes in Florida this year, CDC conducted a fourth study evaluating these exposures, with slightly different parameters. Results of this study are pending.

Surveillance of Illnesses Associated with Pesticide Exposure
CDC's National Institute for Occupational Safety and Health (NIOSH) provides technical and financial assistance to state health departments that conduct acute pesticide poisoning surveillance, with an emphasis on illnesses in workers. Currently, we obtain data from the nine states that conduct pesticide poisoning surveillance. In 2003, CDC published an MMWR report on this subject using data from state partners. The report can be found at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5227a1.htm.

In addition to collecting annual data from states on acute pesticide poisoning, CDC also asks states to promptly notify NIOSH of pesticide events that meet one of the following criteria:
a. events that result in a hospitalization or death;
b. events that involve 4 or more ill individuals;
c. events that occur despite use according to the pesticide label, or;
d. events that indicate the presence of a recurrent problem at a particular workplace and/or employer.

Poisoning Surveillance through the American Association of Poison Control Centers (AAPCC)
CDC and ATSDR monitor calls made to poison control centers reporting adverse health effects from exposure to any toxins or poisons through AAPCC's Toxic Exposure Surveillance System (TESS), which is the only comprehensive poisoning surveillance database in the United States. The TESS annual report for 2003 is available on the Internet and breaks out poisonings due to pesticides: http://www.aapcc.org/2003.htm.

Toxicological Profiles of Pesticides
The Agency for Toxic Substances and Disease Registry, CDC's sister agency, compiles summaries of toxicologic information and studies of health impacts from exposure to hazardous substances most commonly found at Superfund hazardous waste sites. Included in these are toxicological profiles for pesticides used in mosquito control for West Nile Virus. They are malathion, pyrethrins and chlorpyrifos (links attached with summaries called "toxFAQs").

In addition, ATSDR has prepared a document on health impacts of exposure to a variety of pesticides used in mosquito control. The document is in final clearance.

Toxicological Profiles:
Chlorpyrifos: http://www.atsdr.cdc.gov/toxprofiles/tp84.html
toxFAQ: http://www.atsdr.cdc.gov/toxprofiles/tp84.html
Malathion: http://www.atsdr.cdc.gov/toxprofiles/tp154.html
toxFAQ: http://www.atsdr.cdc.gov/tfacts154.html
Pyrethrins: http://www.atsdr.cdc.gov/toxprofiles/tp155.html
toxFAQ: http://www.atsdr.cdc.gov/tfacts155.html

October 15, 2004

BY FACSIMILE
Mr. John Pape
Epidemiologist
Colorado Department of Public Health & Environment
4300 Cherry Creek Drive South
Denver, CO 80246

Dear Mr. Pape:

This letter follows up on the October 6, 2004 hearing of the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, entitled "Current Challenges in Combating the West Nile Virus." Please respond to the enclosed followup questions from Congressman Dennis Kucinich for the hearing record.

Please hand-deliver your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building not later than November 5, 2004. If you have any questions about this request, please call Subcommittee Counsel Danielle Quist at (202) 226-2067. Thank you for your attention to this request.

Sincerely,

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

Enclosure

cc: The Honorable Tom Davis
The Honorable John Tierney

Questions for the Record
For John Pape, Epidemiologist, Colorado Department of Public Health and Environment
From Representative Dennis J. Kucinich
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

Hearing on "Current Challenges in Combating the West Nile Virus"

October 6, 2004

What provisions have been made to explore and emphasize non-pesticide approaches to mosquito abatement? What is your budget for considering such alternatives? For example, what is your budget allocation for eliminating standing water throughout your jurisdiction? What is being done to ensure least toxic pesticides are used before more toxic pesticides?

Questions for the Record
For John Pape, Epidemiologist, Colorado Department of Public Health and Environment
From Representative Dennis J. Kucinich
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

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What provisions have been made to explore and emphasize non-pesticide approaches to mosquito abatement? What is your budget for considering such alternatives? For example, what is your budget allocation for eliminating standing water throughout your jurisdiction? What is being done to ensure least toxic pesticides are used before more toxic pesticides?

Answers for the Record
For Representative Dennis J. Kucinich
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs
From John Pape, Epidemiologist
Colorado Department of Public Health and Environment

Hearing on "Current Challenges in Combating West Nile Virus"
October 6, 2004

What provisions have been made to explore and emphasize non-pesticide approaches to mosquito abatement?

The Colorado Department of Public Health & Environment (CDPHE) and local health departments launched an educational campaign, Fight the Bite Colorado (www.fightthebitecolorado.com), as a major component in our response to West Nile virus. The focus of the campaign was on personal protective measures citizens could take, specifically methods to avoid mosquito bites and eliminating mosquito-breeding sites on private property. Elimination of standing water on property was one of the primary measured emphasized in the 4 D's recommendation (Drain standing water) on all Colorado West Nile virus prevention public information.

CDPHE does not engage in any direct mosquito abatement activity. CDPHE does advocate a multi-faceted approach to mosquito abatement with an emphasis on larval control via elimination of water sources and use of biological based larvicides. In literature and presentations to communities, CDPHE recommends the use of pesticides for adult control only in the face of an impending outbreak. The state's seven level Arbovirus Response Plan does not recommend initiation of adult pesticide-based mosquito control until levels 6 (epidemic imminent) or 7 (epidemic in progress). County and city mosquito abatement operations have emphasized the identification and mitigation standing water as one component of control. One county passed an emergency ordinance requiring property owners to treat mosquito producing, standing water on their property by either elimination of the source or use of larvicides.

The use of other approaches to mosquito abatement, such as the use of larvae eating fish, building bird and bat houses in a neighborhood, or using non-pesticide mosquito products (i.e. carbon dioxide traps, bug zappers) can be important components of a integrated mosquito control program. However all of these methods have limitations and none can significantly reduce mosquito populations or transmission of WNV in a community. Such approaches are encouraged and utilized whenever feasible, but are not considered a stand-alone solution.

What is your budget for considering such alternatives? For example, what is your budget allocation for eliminating stating water throughout your jurisdiction?

CDPHE does not conduct direct mosquito control activities. The CDPHE budget is allocated to surveillance activities to track the virus and assess the human health risk, to conduct human testing and to fund the public education campaign. The majority of the budget is provided to local health agencies for conducting these activities, including elimination of standing water as part of the educational campaign. Breakdowns on how much is specifically used for mitigation of standing water are not available.

What is being done to ensure the least toxic pesticides are used before more toxic pesticides?

As stated, CDPHE emphasizes larval control as the most cost-effective, environmentally friendly approach to mosquito control. This can partially be done with standing water elimination, but must be supplemented with other larval control methods for breeding sites that cannot be eliminated. This includes the introduction of native larvae eating fish when possible or the use of biological larvicides (BTI, insect growth hormone and surfactants). When adult pesticides are used they are required under EPA and state law to be used in accordance with the label requirements and at the lowest dose needed to do the job. Adult mosquito control for disease control is recommended only as a last resort, when an outbreak in imminent, under the Colorado Arbovirus Response Plan.

October 15, 2004

BY FACSIMILE
Dr. Jonathan Weisbuch
Director of Public Health
Maricopa County Department of Public Health
1825-45 East Roosevelt Street
Phoenix, AZ 85006

Dear Dr. Weisbuch:

This letter follows up on the October 6, 2004 hearing of the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, entitled "Current Challenges in Combating the West Nile Virus." Please respond to the enclosed followup questions from Congressman Dennis Kucinich for the hearing record.

Please hand-deliver your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building not later than November 5, 2004. If you have any questions about this request, please call Subcommittee Counsel Danielle Quist at (202) 226-2067. Thank you for your attention to this request.

Sincerely,

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural
Resources and Regulatory Affairs

Enclosure

cc: The Honorable Tom Davis
The Honorable John Tierney

Questions for the Record
For Jonathan Weisbuch, Director, Department of Public Health and Chief Health Officer, Maricopa County, Arizona
From Representative Dennis J. Kucinich
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

Hearing on "Current Challenges in Combating the West Nile Virus"

October 6, 2004

What provisions have been made to explore and emphasize non-pesticide approaches to mosquito abatement? What is your budget for considering such alternatives? For example, what is your budget allocation for eliminating standing water throughout your jurisdiction? What is being done to ensure least toxic pesticides are used before more toxic pesticides?

Maricopa County
Department of Public Health
Jonathan B. Weisbuch, M.D., M.P.H.
Director/Chief Health Officer

1845 East Roosevelt Street
Phoenix, Arizona 85006-3642
Phone: (602) 506-6609
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Divisions:

Epidemiology/Bio-Defense Preparedness and Response
Chronic Disease & Tobacco Control
Community Development & Minority Health
HIV/HCV Services
Maternal, Child & Family Health
Public Health Clinical Services

Health Constellation:

Animal Care & Control
Correctional Health
Department of Public Health
Environmental Services
Human Services
Medical Examiner's Office

November 5, 2004

Doug Ose
Chairman
Subcommittee on Energy Policy, Natural
Resources and Regulatory Affairs
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Chairman Ose:

Attached is the response from Jonathan B. Weisbuch, M.D., M.P.H., Director, Department of Public Health by your request in response to a question from Dr. Weisbuch's Congressional Testimony on October 5th, hearing on "Current Challenges in Combating the West Nile Virus".

Please call me at 602-506-6609 if I can assist you in any other way.

Sincerely,

Susan Attiah

Susan Attiah
Assistant to Jonathan B. Weisbuch, M.D., M.P.H.

What provisions have been made to explore and emphasize non-pesticide approaches to mosquito abatement? What is your budget for considering such alternatives? For example, what is your budget allocation for eliminating standing water throughout your jurisdiction? What is being done to ensure least toxic pesticides are used before more toxic pesticides?

1. **Question: What provisions have been made to explore and emphasize non-pesticide approaches to mosquito abatement?**

Response: We initiated an extensive media campaign mirroring the Centers for Disease Control's "Fight The Bite". Our own "Fight The Bite" campaign focused on messages that included backyard breeding prevention and elimination, using personal protection including using insect repellants and reporting mosquito problems to our vector control office. We conducted press conferences, town hall meetings and gave presentations. We produced 250,000 mosquito brochures, 40,000 door hangers and 20,000 posters to distribute to the public.

To date we have had:

4	Press Conferences
61	Public Information / media releases
65	Media Appearances
27	Public Presentations

We provided mosquito-eating fish for free to anyone who requests them. We use larvicides that are non-toxic to humans and wildlife.

2. **Question: What is your budget for considering such alternatives?**

Response: We budgeted $65,000 of our emergency funds for brochures. Staff time spent on presentations and interviews came from normal personnel budgets, and one time approved funds.

What provisions have been made to explore and emphasize non-pesticide approaches to mosquito abatement? What is your budget for considering such alternatives? For example, what is your budget allocation for eliminating standing water throughout your jurisdiction? What is being done to ensure least toxic pesticides are used before more toxic pesticides? - Continued

3. **Question: What is your budget allocation for eliminating standing water throughout your jurisdiction?**

Response: Currently we have no dedicated funding allocated to eliminate standing water or source reduction. We have spent $138,584 for treatment of standing water, nuisance water and green swimming pools through larviciding. City governments and homeowners associations are responsible for eliminating standing water on public right-of-ways and other common areas.

4. **Question: What is being done to ensure least toxic pesticides are used before more toxic pesticides?**

Response: The Environmental Services Department carefully explored and examined all available mosquito control chemicals including botanicals before making a decision to use synthetic pyrethriod pesticides, Sumethrin and Permethrin for adult mosquito control. This class of pesticides is considered by the majority of mosquito control agencies to be the least toxic available for adult mosquito control

West Nile virus: Drought, Climate Change,
And Diseases of Wildlife
Testimony
October 6, 2004

Committee on Government Reform
Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs

Paul R. Epstein, M.D., M.P.H.
Center for Health and the Global Environment
Harvard Medical School

West Nile virus (WNV) is playing a particularly sinister role in nature. Following its explosive debut in NYC during the drought and heatwave of 1999, WNV abated and incubated. Then, during the hot, dry summer of 2002, West Nile made a furious and voracious dash across the nation, establishing itself in 44 states, DC, and five Canadian provinces. In 2002 WNV encephalitis afflicted 4,161 people and claimed 277 lives. WNV also performed a dazzling array of new tricks, demonstrating its ability to infect via blood transfusions, organ transplants, pregnancy and probably breast milk.

Of greatest concern, however, WNV has spread to 230 species of animals, including over 130 species of birds, and it is carried by 37 species of mosquitoes.

Not all animals fall ill from WNV, but the list of hosts and reservoirs includes: dogs, cats, squirrels, bats, chipmunks, skunks, rabbits and reptiles. (Florida alligators may have eaten infected birds or were perhaps bitten by one of the 36 species of mosquitoes that can carry WNV.) Avian deaths increased five-fold over 2001, and 12 times as many horses -- 14,515 -- became ill. Eight Humboldt penguins died in Milwaukee's Zoo and a monkey succumbed in Toronto in 2002.

The domination of urban landscapes by "generalist" birds -- like crows, starlings and Canada Geese – may contribute to the spread of West Nile, along with the numerous mosquito breeding sites, like old tires and stagnant waterways. (On the positive side, declines in crow populations may have provided ecological space for the return of rarer birds to urban centers. This needs further study.) But spring and summer droughts, it seems – especially when compounded by warm winters and reduced snowpack/spring runoff – cause urban-dwelling, bird-biting mosquitoes to flourish; amplifying the levels of virus circulating in nature. These *Culex pipiens* -- unlike malaria-bearing *Anophelines* that thrive after rains – breed abundantly in the shallow pools of organically–rich water that remain in drains during dry spells. Heatwaves accelerate the maturation of viruses inside mosquitoes, and predators of mosquitoes – like dragonflies, darning needles and amphibians – decline during drought.

Fortunately, an animal vaccine is available, and newly released condors are being inoculated to stave off their "second" extinction in the wild.

But WNV has spread to the Caribbean, and it is a leading suspect in the 10-fold drop in several bird species in Costa Rica over the past year., and horses have died from WNV in El Salvador (2002) and in Mexico (2003); the latter in clear association with drought. Monitoring of birds and in Brazil and other nations of Latin America must be considered to develop early warnings that allow timely, environmentally-friendly public health interventions.

The population impacts on wildlife and biodiversity have not been adequately evaluated. The impacts of declines in birds of prey could ripple through ecological systems and food chains, and could in itself contribute to the emergence of disease.

Declines in raptors – condors, owls, hawks, eagles, kestrels and marlins – could have dramatic consequences for human health. (Some raptors have died, but the population-level impacts are as yet unknown.) These birds of prey are our guardians for they prey upon wayward rodents and keep their numbers in check. When rodent populations "explode"– when floods follow droughts, forests are clear-cut, or diseases attack predators – their legions can become prolific transporters of pests and pathogens.

The list of rodent-borne ills includes: Lyme disease, leptospirosis and plague (all bacteria), hantaviruses and arenaviruses – like Lassa fever, Guaranito, Junin, Machupo and Sabia viruses, associated with severe hemorrhagic fevers in humans.

By way of a parallel, vultures in India have declined some 95%! in the past several years (most likely from consuming refuse contaminated with a toxic medication). Absent these primary recyclers of carrion, feasting feral dogs are spreading rabies to humans.

In the summers of 2003 and 2004 cases of WNV concentrated in Colorado, then California and Arizona – areas that experienced prolonged spring drought (and summer wildfires). The eastern part of the US (where a cold snowy winter occurred in association with the North Atlantic freshening and North Atlantic High, plus continued warming of tropical waters) has had relatively calm two seasons. (Note: both the Pacific and the Atlantic Oceans were in anomalous states beginning in the late 1990s. The state of the Pacific the "Perfect conditions for drought" (Hoerling and Kumar 2003) in many parts of the globe.

The sixth consecutive year of drought (considered the worst in 500 years!) has just ended in the eastern US. Climate change is projected to generate more prolonged and intense droughts (along with more intense precipitation events). As the oceans and land surfaces warm, greater evaporation dries out land surfaces while ocean warming fuels generate more intense downpours. But with warming at high latitudes, polar and Greenland ice is melting and more rain is falling near the poles. The combine cooling and freshening of surface waters in the North Atlantic and in parts of the Pacific are creating the "perfect conditions for drought. All the world's oceans are anomalous and the deep warming, melting of ice and increased water vapor are creating more turbulent and severe weather the word over. The costs of such extremes are mounting.

Meanwhile, climate is changing; humans are contributing; biological systems are responding; and extreme weather events are increasing in frequency and intensity. These are the four primary conclusions of the 2001 Intergovernmental Panel on Climate Change, Third Assessment Report (Houghton, et al. 2001).

Since the publication of that report we have learned that: 1. Carbon dioxide is building up in the atmosphere at an accelerating rate; 2. The pace of warming is quickening; 3. The cryoshere (polar and alpine ice) is shrinking much faster than it was just several years ago; 4. The deep ocean under the North Pole is warming faster than previously measured (1°F over the past year); 5. Circumpolar (and cross ocean) winds are accelerating as polar ice shrinks (e.g., polar vortices are tightening); and 6. The pace of very extreme events is rising sharply (Epstein and McCarthy *in press*).

Extreme weather events are the primary way in which climate change affects our health, ecological systems and the economy. Increased weather volatility accompanying climate change also has implications for the sensitivity of the climate system to abrupt shifts, shocks and surprises. A changing "shape of the curve" in the distribution of weather extremes has implications for the global economy in general and especially for the financial sector.

Reference

Epstein, P.R. and J.J. McCarthy, *in press*. Assessing climate stability. Bull. Amer. Met. Soc.

Hoerling, M., and A. Kumar, 2003: The perfect ocean for drought. *Science* **31**: 299: 691-694.

Houghton, J.T., Y. Ding, D.J. Griggs, M. Noguer, P.J. van der Linden, X. Dai, K. Maskell, and C.A. Johnson, 2001: IPCC Working Group I Third Assessment Report: *Climate Change 2001: The Scientific Basis*. Cambridge University Press, New York, NY.

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