REAL-TIME ASSESSMENT OF THE FEDERAL RESPONSE TO PANDEMIC INFLUENZA

HEARING

BEFORE THE

SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

OF THE

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REAL-TIME ASSESSMENT OF THE FEDERAL RESPONSE TO PANDEMIC INFLUENZA

Tuesday, October 27, 2009

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY,
Washington, DC.

The subcommittee met, pursuant to call, at 2:05 p.m., in Room 311, Cannon House Office Building, Hon. Yvette D. Clarke [Chairwoman of the subcommittee] presiding.

Present: Representatives Clarke, Richardson, Luján, Thompson (ex-officio), Lungren, and Broun.

Also present: Representative Jackson Lee.

Ms. CLARKE. Good afternoon. I would like to thank our witnesses for appearing before us today.

The Homeland Security Committee has long been concerned with the state of our preparedness to deal with pandemics. Today, our subcommittee turns its attention to the Federal response to the re-emerging threat of pandemic influenza.

Over the weekend, President Obama declared a National emergency with respect to the 2009 H1N1 influenza pandemic. This action underscored the gravity of the situation.

Although we went into this pandemic better prepared than we had been in the past, we were not fully prepared to meet the pandemic when it started this year. Going into this pandemic, we knew that, No. 1, our early warning and detection systems were inadequate; No. 2, some key planning activities were incomplete; No. 3, we didn't have a good approach to provide health care under pandemic conditions; and, No. 4, our levels of preparedness for pandemic influenza were unclear.

Unfortunately, our failure to develop these systems, activities, and policies cost us during the response. For instance, the pandemic started in North America, the one place we were not looking for it. We did not have an early warning. The alarm sounded only when people started to die. We did not have the luxury of time to observe the virus before the pandemic started; and, to the surprise of the community, the virus turned out to be H1N1, not the H5N1 virus that causes avian influenza.

We have made it through the first phase of our pandemic and are now entering the second. The Department of Homeland Security, the Department of Health and Human Services are our leading Federal response efforts. It is clear that DHS Secretary Napolitano and HHS Secretary Sebelius have set the tone for responding

to the pandemic with their strong leadership and commitment to the Nation. We commend them, and we commend you.

But the pandemic has shown us where our public health security infrastructure is weak in the same way that the natural disasters show us where our physical infrastructures are vulnerable. The pandemic has shown us that we need to improve biosurveillance, pandemic disaster assistance, real-time recording of lessons learned, public messaging, and the security of our pharmaceutical system.

In these areas, I believe that the National Biosurveillance Integration Center needs more information and participation. The FEMA disaster assistance policy on pandemic human influenza needs to be updated. The DHS lessons learned information sharing system needs to be better utilized. Influenza messaging needs to be deconflicted and clear, and our pharmaceutical system needs to be better secured against the introduction of counterfeits.

Our Federal departments and agencies should be commended for positive steps forward. Indeed, our system improvements have already been made, communication between and among countries have improved, and I am pretty sure that the United States knows more about what is going on in Mexico and Canada now than it did before, and vice versa.

Communication between and among agencies have improved. For example, the Department of Health and Human Services is not putting out guidance on school closures without first consulting with the Department of Education. More guidance regarding personal protective equipment, school closures, and high-risk groups needing vaccination has been provided. Some additional plans, particularly response plans, have been finalized and communicated.

The H1N1 vaccine has been developed, and what we have been able to produce of it is beginning to be distributed. The DHS lessons learned information sharing system has shifted from gathering information, from exercises, to collecting some real-time information; and law enforcement agencies are specifically addressing the threat of the H1N1-related counterfeit pharmaceuticals through such entities as the Intellectual Property Rights Coordination Center.

But we still have work to do. We now have the obligation to strengthen at least some of the weaknesses in our National response. To do that, we in Congress need concrete information from you. We need information from your departments and agencies and need concrete recommendations and resources—that need concrete recommendations and resources from us. The Legislative and Executive branches must work together to improve our response efforts and save as many lives as we can during this pandemic.

I will be submitting a longer statement for the record; and I look forward to hearing from you, all of you, our witnesses here today.

[The statement of Ms. Clarke follows:]

STATEMENT OF CHAIRWOMAN YVETTE D. CLARKE

OCTOBER 27, 2009

I. INTRODUCTION

Although the United States became acutely aware of the incidence of H1N1 cases in April 2009, the disease was already present in other parts of the world. Out-

breaks were soon noted in many countries, creating epidemics. Subsequently, the World Health Organization declared an influenza pandemic in July 2009, when Phase 5 was attained (see Figure 1 below). To date, cases of the disease have been reported by every U.S. State and territory, and in many countries throughout the world.

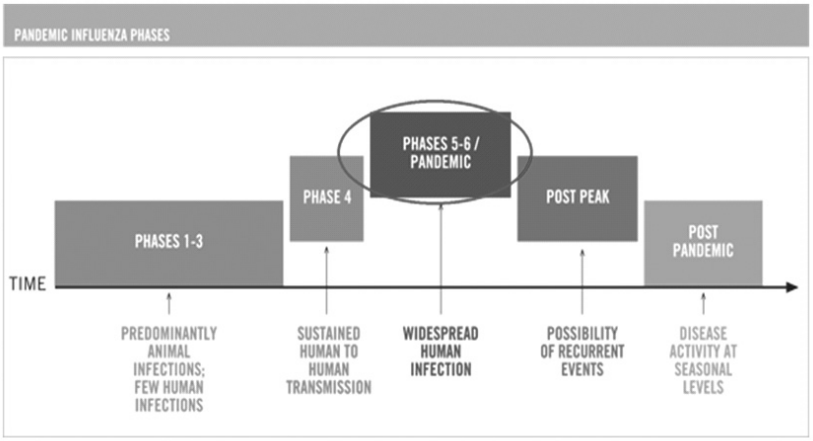

Figure 1: World Health Organization Pandemic Phases

A. Data Lacking, But H1N1 Assumed to be Everywhere

It is likely that every country in the world has cases of H1N1 occurring within their borders, but difficulties in testing, diagnosis, and reporting prevent us from knowing for sure. When influenza pandemics occur, we move away from laboratory testing of all suspected cases, and instead, assume that everyone that is presenting with influenza-like-illnesses (ILI) are infected with the pandemic strain of the disease—in this situation, H1N1 influenza. Laboratory testing does continue in those countries (such as the United States, Canada, Australia, the United Kingdom, many of the countries in the European Union, and Russia, that possess sufficient laboratory capacity and capability to test various groups of patients to determine with what disease they are afflicted. To-date, the vast majority of patients presenting with ILI in the United States and worldwide are indeed infected with H1N1.

B. 2009–H1N1 Disease is Widespread, But Not as Severe as 1918–H1N1

The severity of the current pandemic is clearly not as bad as it was in 1918. There are a number of theories about why this may be the case. First, levels of health and hygiene are better now than they were in 1918. Second, public health, medicine, and health care delivery are all much more advanced. Third, although the strains of influenza are the same—H1N1—there may be differences in the way genetic components are behaving and expressing themselves.

However, despite the overall lower severity, people with certain underlying conditions are developing very serious illnesses. As of 1 October, 28 pregnant women have died, and the rate of pediatric (under the age of 18) deaths is rising, 86 having died to date. We also still do not understand exactly why H1N1 caused so many deaths in Mexico.

C. We Will Never Know Exactly How Many People Were Exposed to H1N1

We have questions about the disease—why it causes severe illness and death in some but not in others, exactly how many people were and are being exposed, how fast it spreads, the nature of our immune response, etc. These questions will need to be answered by scientifically valid data. However, as stated above, laboratory, diagnostic, and reporting capacity differs in countries around the world and in States and territories throughout the United States. We went into this pandemic lacking in these areas, and as a result, we will never have an entirely accurate picture of what is happening and what will happen in the future.

II. WEAKNESSES REVEALED BY PANDEMIC INFLUENZA

One of the characteristics of large-scale disasters is that they reveal weaknesses in society and its critical infrastructures. Disaster management theory suggests that

these weaknesses should be strengthened in order to mitigate the effects of the next disaster before it occurs.

The same holds true for a large-scale disease event such as pandemic influenza. Since April 2009, the pandemic caused by the H1N1 influenza virus has revealed a number of weaknesses in the infrastructures affecting public health, safety, and security. Many were identified by committee staff previously in a report, entitled "Getting Beyond Getting Ready for Pandemic Influenza," issued in January 2009.[1]

A. Early Warning and Detection Inadequate

Biosurveillance efforts are lacking throughout the United States and the world. Committee staff identified three deficiencies in January: (a) Information used to inform U.S. decisions was not uniformly collected or derived; (b) integration of biosurveillance information from throughout the Government was insufficient; and (c) biosurveillance early warning was unsatisfactory.

Biosurveillance information in the United States comes from a variety of sources, such as hospitals, physician's offices, pharmaceutical companies, drug stores, and clinics. However, the collection of this information is not uniformly collected or derived. This means that information is collected from and reported by some organizations and not others, and that derivative products from that information vary according to local and State needs for those products. As a result, we do not have a complete or entirely accurate picture of what is happening with any disease occurring in the United States, unless the number of people becoming ill is very low and the disease is of such great interest that there are mandatory reporting requirements.

States also have the right to determine which diseases are of greatest interest to them, and add some additional reporting requirements as they see fit. Further, although some reporting requirements are mandatory, there are few penalties for not reporting and the requirements are not vigorously enforced. Lastly, information coming from the States to various Federal departments and agencies has never been integrated sufficiently, despite the creation of the National Biosurveillance Integration Center (NBIC) at DHS.

As a result of these deficiencies here in the United Sates and throughout the world, we did not have early warning of the H1N1 outbreaks. The United States only started paying significant attention after cases began to appear in California and Texas, belatedly realizing that the virus causing disease in these cases and those in Mexico was the same—the H1N1 influenza virus. We could have known sooner, had we been: (a) Paying more attention to what was occurring, particularly in our neighboring countries of Mexico and Canada; (b) implementing long recommended systems to collect and analyze information from all our health care delivery, military, and diplomatic establishments; and (c) integrating what information the Federal Government did manage to collect. We did not detect this disease as soon as we could have.

B. Execution of Key Planning Activities Incomplete

Key planning activities were not executed, or were executed incompletely or improperly prior to the beginning of the pandemic in April 2009. Committee staff identified five deficiencies in January: (a) Key stakeholders were not consulted when the National Strategy for Pandemic Influenza and its Implementation Plan were developed; (b) synergies between and among the National Strategy for Pandemic Influenza and the other National strategies were not identified; (c) planning guidance given to the States and territories was inadequate; (d) evidence of pandemic influenza planning for the Federal departments and agencies was scant; and (e) private sector continuity of operations plans were lacking. As a result, when the pandemic started in April, public and private sector entities were not able to respond efficiently and effectively because many did not have plans to execute in the first place.

The Bush administration had not identified synergies between and among the National strategies, and it is unlikely that the Obama administration has had time to do so, yet. If a terrorist event were to occur during this pandemic, we would not know how these strategies should be applied simultaneously, when one takes precedence over another, etc. This of particularly concern if the terrorist event is an act of bioterrorism. Resources that may ordinarily have been available if such an event were to occur in non-pandemic conditions are now becoming scarce.

When the H1N1 pandemic began in April 2009, many Federal Departments and agencies had not completed their plans for responding to pandemic influenza. Some, like DHS, had attempted to complete their planning, but their plans were hung up

[1] The report can be found on the committee website at: *http://www.homeland.house.gov/SiteDocuments/20090114124322-85263.pdf*.

in review processes that occurred too close to the change in administration. As a result, many of these Federal plans were incomplete, unapproved, or altogether missing as late as July 2009. The strategy for DHS itself was only finalized in October.

Some strategies for the Federal departments and agencies are available at Flu.gov (and previous to the inception of that site, PandemicFlu.gov). However, many are not posted there. Some are not yet completed—others are done, but not posted. Some (among them, DHS) make the argument that the information to be found in these plans is too sensitive for public release, but the argument lacks validity when one sees that the Department of Defense has posted its plan there. There are two reasons it is important for these Federal plans to be posted: (a) Doing so is part of Government accountability; and (b) access to these plans allows non-Federal Governmental entities as well as the private sector to understand what the Federal Government has planned to do during a pandemic, thereby allowing them to establish realistic expectations.

The Federal Government still has not comprehensively posted its plans, nor did it issue adequate guidance in advance of the pandemic. As a result, States, territories, Tribes, localities, and the private sector were not able to complete the best plans possible. They did not and do not know what all to expect from the Federal agencies regarding Federal activities and which resources could be made available. As of now, they are doing the best they can with the planning and resources information they do have at their disposal. This accounts for at least some of the incongruity in Federal and non-Federal response efforts to date. Although everyone understood that some guidance could not be issued until the pandemic started (needing to be based on the exact virus, for example), other guidance could and should have been developed in advance (such as that regarding the distribution of pandemic vaccine). Planning efforts continue in the midst of responding to this pandemic in both the public (including Federal) and private sectors.

C. Challenges Posed By Key Medical Response Requirements Partially Addressed

Pandemics challenge the ordinary practice of medicine, particularly in the most developed countries in the world, where medicine is also highly developed and expectations exist for the best possible care at all times and in all circumstances. Committee staff identified four deficiencies in January: (a) Difficult issues (such as the need to establish a different standard of care under pandemic conditions) were identified but left unaddressed by the Bush administration; (b) hospital resource and priority management (including triage) was problematic; (c) pharmaceutical interventions were limited; and (d) recommendations for non-pharmaceutical interventions were lacking or confusing.

As hospitals and other health care delivery establishments are rapidly running out of medicines, equipment, space, and time to treat those suffering from the H1N1 disease—as well as those that are ill or injured otherwise—they are put in the extremely difficult position of having to try to deliver the highest level of health care. This is becoming increasingly difficult, and soon will be impossible. Some States, for example, are running out of hospital space altogether. For them, it is impossible to deliver the highest level of care if doing so requires a patient to be in a hospital. In order for doctors and other medical personnel to not be held liable for providing what would be considered substandard care under ordinary circumstances, it is necessary for a different standard of care to be developed quickly and communicated to providers throughout the country.

Related to this is the need to triage patients differently as they come into health care establishments—how they are physically handled (to minimized exposure to others and themselves), where they are treated and in what order they are treated are all different under pandemic circumstances. This was completely foreseeable, but never addressed in advance. To date, the only guidance that has come out regarding both resources and triage is that those patients that present with influenza-like-illness (ILI) should be assumed to have been infected with H1N1.

Unless the pandemic was caused by a strain of influenza that also happened to be part of the seasonal influenza targeted virus group—thereby allowing the seasonal vaccine to confer some amount of partial immunity—we knew that we would have to develop the pandemic vaccine after the virus had been identified. Attempts had been made to create broad-spectrum vaccines, and vaccines that were termed pre-pandemic vaccines (created by guessing that H5N1/avian influenza variants would cause the pandemic). Additionally, funding has been provided to create new vaccine technologies (e.g., cell-based instead of egg-based), but those technologies were not and still are not available. So going into the pandemic, we did not have H1N1 vaccine (having guessed incorrectly that H5N1 would cause the pandemic).

We also did not have a sufficient supply of antiviral medications, because we did not have enough stockpiled and because H1N1 was found to be resistant to two of the four antivirals that had been effective in the past in treating influenza. Insufficient supplies also further exposed the Nation to the threat of counterfeit pharmaceuticals and medical equipment.

There are two main types of non-pharmaceutical interventions that are applicable to pandemics: (a) Protective equipment, and (b) protective actions. In the case of protective equipment, Members of the committee are well aware of what happened in terms of guidance and availability. If guidance was developed in advance, it was not communicated adequately to the American workforce (including that at DHS). There is no reason this should have occurred. Regardless of the exact genetic composition of an influenza virus, physical properties are similar enough to have been able to create guidance for the use of personal protective equipment for any of these viruses. The same can be said for protective actions. Shortfalls also occurred when guidance regarding what to do in particular situations and places by particular professions had not been developed in advance.

The blame cannot be placed entirely on the shoulders of the CDC (specifically the National Institute for Occupational Safety and Health, part of the CDC) or the Occupational Safety and Health Administration (OSHA). All agencies should have taken what guidance was available from the CDC and OSHA and applied it to their own personnel and circumstances. Neither the DHS Office of Health Affairs nor the DHS Office of Safety and Environmental Protection (part of the DHS Management Directorate) tailored CDC guidance to the specific worksite requirements of the DHS components in advance of the pandemic.

D. Levels of Preparedness for Pandemic Influenza Unclear

As we went into the pandemic, we were not sure as a Nation how prepared we were. Committee staff identified four deficiencies in January 2009: (a) Measurement of and reporting by the Executive Branch was not altogether suitable; (b) reporting under the Bush Administration was inconsistent; (c) the Federal priority on pandemic influenza preparedness had been lowered; and (d) the example set by Executive Branch Departments and agencies working together poor.

Although not all planning was completed for all levels of Government and the private sector in advance of the pandemic, some planning had occurred. For example, the Implementation Plan for the National Strategy for Pandemic Influenza contained hundreds of actions, accompanied by conditions and standards for completion. Unfortunately, not all of the conditions and standards matched the actions, some standards were impossible for responsible agencies to meet on their own, some conditions were based on a different type of situation (a pandemic caused by avian influenza and starting somewhere other than North America), and some standards were not even provided (for example, there were no deadlines associated with the tasks assigned to the non-Federal governmental and private sector entities responsible for executing them). As a result, it was not been possible to accurately measure how prepared we were for a pandemic. Although the Bush administration had been reporting that most and then all of the Federal activities had been completed or ongoing, there was no way to really be sure because of the Implementation Plan was inherently flawed.

Even if we accepted that the all of the conditions and standards matched the activities perfectly, the Bush administration had not been reporting activity status periodically or according to a schedule. After two reports, priorities were changed and the Bush administration chose to focus its efforts on addressing other threats, delegating more of the responsibility for pandemic influenza preparedness to the Federal departments and agencies. Unfortunately, the Bush administration's White House had been monitoring task completion, and they neglected to delegate the responsibility for this monitoring to another Federal entity. As a result, we became less—not more—sure of how prepared we were. The Obama administration was left with a flawed system, poor measurement, and delayed monitoring when it took over. It also eradicated the Office of Health and Biodefense, eliminated the position of Special Advisor to the President that had headed this office and decided to rely entirely on Federal detailees to address pandemic preparedness. Shortly thereafter, the pandemic started.

Prior to the beginning of the pandemic, it was clear that some of the Federal departments and agencies were not working together to prepare for such a large-scale disease event. This carried on for months, requiring additional leadership from President Obama to overcome. A glaring example was that of the Department of Education having not worked significantly with the Department of Health and Human Services (HHS) on school closure guidance. It was only after the CDC/HHS issued guidance that recommended school closure without the benefit of input from

the Department of Education regarding county funding mechanisms (where counties receive funding on the basis of how many children actually show up to school) and the behavior of children when they are not in school (continuing to congregate elsewhere in the community) that these Federal agencies realized they had to work together.

III. SYSTEMIC IMPROVEMENTS IN THE RESPONSE

A. Communication Between and Among Countries and Agencies Improved

When the H1N1 outbreaks were occurring in Mexico in the Spring, the United States was not very aware of what was going on. Part of this was due to an administrative situation, in which Canada was testing specimens for Mexico (the Canadian Centers for Disease Control and Prevention in many ways have capacities equivalent to that of the U.S. CDC, but were charging Mexico less for the service of laboratory testing). There was no reason or mechanism in place for information to be reported to the United States about what was going on in a different country. However, it rapidly became clear to all three countries that some amount of information needed to be shared in order to protect the citizenry of North America. Since then, there has been greater information sharing, and it is likely that after the pandemic, these information-sharing mechanisms will remain in place. This is what occurred between Canada and the United States during the SARS epidemic of 2002–3.

Communications and information sharing has also improved between and among various U.S. and international agencies. Many of these organizations learned the hard way that creating guidance or policy in a vacuum very quickly resulted in outcry from others in the community or those in the community that were on the receiving end of conflicting or incomplete guidance. Although it is still tempting for Federal departments and agencies to issue guidance and policy on their own—in order to make decisions and provide information as quickly as possible—most seem to have learned that either time needs to be invested in advance or more time will be spent subsequently in adding additional information and fixing problems. The best examples of this are the much-improved communications between the Department of Education, HHS, and DHS.

B. Additional Guidance Provided

Although there were many pieces of guidance missing when the pandemic started in April 2009, the Federal Government was (relatively) quick to identify those needs and fill them as quickly as possible. In some case, it was necessary to wait for research or testing to be done, but on the whole needed guidance was developed and distributed. Additionally, some guidance was also modified as time went on and more was learned about the H1N1 disease—how it spread, what underlying conditions were exacerbating the illness, etc. For example, although there were initial difficulties in understanding what personal protective equipment was necessary for those DHS personnel working on the border and ports of entry (e.g., CBP and TSA) that came in contact with many people entering and exiting the country, the need for tailored guidance seems to have been resolved. It is important to note, however, that the tailored guidance was developed mostly by the CDC working directly with the component agencies in DHS—as opposed to the DHS Office of Health Affairs or the DHS Office of Safety and Environmental Programs.

More guidance has been, and continues to be, provided to the States, territories, and private sector by the Federal Government. Where the Federal Government failed to provide adequate planning guidance, it is providing more now in the way of guidance for response. In some cases, where the Federal Government has still not provided guidance—such as that regarding different standards of care or how best to conduct triage under pandemic conditions, the States, territories, and private sector are slowly developing their own criteria and are not allowing themselves to be paralyzed by the lack of Federal guidance.

C. Some Additional Plans Finalized and/or Posted

Since April 2009, more Federal plans have been posted on Flu.gov. Before April 2009, the Department of Defense, HHS, and the Department of Veterans Affairs had posted their departmental strategic plans for pandemic influenza. Since April 2009, the following Department and agencies have also posted plans regarding pandemic influenza in general or H1N1 specifically (although none are strategic plans): Department of Education (re: pandemic emergency planning guidance), DHS (re: critical infrastructure), Department of State (re: international assistance), Environmental Protection Agency (re: EPA actions to prepare), OSHA (re: workplace infection control), U.S. Fire Administration (re: planning guidance to first responders), and the National Highway Traffic Safety Administration (re: planning guidance for

EMA and 9–1–1). DHS has also supposedly finalized its 2009–H1N1 Influenza Implementation Plan, but it has not yet been forwarded to the committee.

D. Vaccine Developed and Distribution Beginning

HHS, working with its subordinate agencies [CDC, the Food and Drug Administration (FDA), and the National Institutes of Health (NIH)] and private sector vaccine manufacturers has developed H1N1 vaccine and began distribution of the vaccine to central distribution points in October. While the pandemic justified fast tracking the vaccine's development and use (via the FDA Emergency Use Authorization), NIH simultaneously has been conducting the studies one would hope and expect to see with any new vaccine. For example, one such study addressed simultaneous inoculation with both the seasonal influenza and H1N1 vaccines (finding that full immune response occurred to both immunizations and that there were no additional ill effects). The ordering system for the vaccine seems to be working well and the States and territories have not yet reported any problems. The only problem noted so far is that the predictions for how much vaccine would be available by this time were off, but it was expected that the predictions would more than likely were not going to be exact, given the inherent vagaries of egg-based vaccine production.

E. Lessons Learned Information Sharing System in Place

The Lessons Learned Information Sharing (LLIS)[2] system is under the direction of the National Protection and Programs Directorate at DHS. The purpose of the secure website is to collect lessons learned, after-action reports, etc., from exercises and actual events and foster communication among the first responder community that is its primary audience. LLIS has been in place since 2004, and pandemic influenza information was added to the site in 2007. LLIS conducts research and provides information regarding those aspects of previous influenza pandemics, other infectious disease outbreaks, and bioterrorism preparedness and response that would be applicable to the problem of pandemic influenza. Some lessons learned, best practices, good stories, practice notes, and other information that would be useful in preventing, detecting, preparing for, responding to, and recovering from pandemic influenza can be found here. However, the system is limited in its dependence on input from organizations outside of the standard first responder community and does not have medical personnel on staff. LLIS is currently does not possess a truly medical platform.

F. Anti-Counterfeiting Activities Occurring

A number of Federal agencies are responsible for addressing the threat from counterfeit pharmaceuticals and medical equipment, including the Federal Bureau of Investigation (FBI), the FDA, and U.S. Immigration and Customs Enforcement (ICE). Where there is a border connection, however, ICE has the lead, with broader jurisdiction than their other Federal law enforcement counterparts. Additionally, due to lack of funding, the FDA often hands cases over to ICE for the agency to investigate. ICE has taken a significant leadership role in the arena, creating the Intellectual Property Rights Coordination Center (IPR Center) under its auspices. Personnel from ICE and a number of other Federal agencies, including but not limited to Customs and Border Protection (CBP), FBI, and FDA are present there with full-time and some part-time representation. Shortly after the pandemic began in April 2009, leadership at the IPR Center decided to expand some of its on-going efforts to stem the tide of counterfeit pharmaceuticals into the United States, and included the requirement that investigators and officers look for counterfeit antivirals and vaccine as part of these operations. Since the summer, CBP, ICE, and the FDA—under the auspices of the IPR Center or as part of their individual agency activities—have seized H1N1-related counterfeits.[3]

IV. WEAKNESSES IN THE CURRENT PANDEMIC RESPONSE

A. Biosurveillance Remains Weak

Going into the pandemic, the public and private sectors were well aware of the flaws and deficiencies in our National biosurveillance efforts. We have hundreds of different public health and health care systems reporting on any number of diseases, events, types of laboratory data, types of epidemiological data, etc.—as well hundreds of other systems reporting biological and medical intelligence, bioterrorism and biocrime law enforcement information, and military weapons and material-related information. The problem is not that we lack information and data. The prob-

[2] See *www.llis.gov*.

[3] Investigations regarding these counterfeits are on-going. Therefore, no further specifics are available at this time regarding quantities and value seized.

lem is that we lack the ability to gather/collect, combine/integrate, and analyze the enormous amount of information to which we could or do have access.

The DHS National Biosurveillance Integration Center (NBIC) was established by this committee to address the need for integration, but it is up to the Federal departments and agencies to gather/collect and in some cases, analyze this information in advance of sending it on to DHS. However, NBIC has not provided products of value to the Department or to the rest of the Federal Government. Funding has not been high enough (about $8 million over fiscal year 2009 and again over fiscal year 2010), because NBIC has not performed well since its inception and appropriations has not been willing to provide additional funding.[4] The committee must seriously consider the notion that if NBIC could not provide value during this pandemic, it would not be able to provide value during a bioterrorist event.

The CDC has demonstrated another major weakness in biosurveillance. Although it has gathered what information it can from a variety of sources, none of its products provide an accurate picture of what is truly going on with the disease in the United States. In some cases, they reported information but did not take immediate action to fill gaps revealed by that information. For example, the CDC produces a map of the United States in their FluView system (see Figure 2 below). This map shows how the disease is spreading geographically in the States and territories, as reported by sentinel epidemiologists.

Notice how the U.S. Virgin Islands (USVI) is shown not to be reporting. After weeks of committee staff asking why this was the case (when the USVI was reporting data for other charts within the CDC FluView) it was ascertained that the USVI lacked an epidemiologist who could do the sentinel reporting required for the map. Subsequently, the CDC decided to send one of their own Federal epidemiologists to the USVI to make these reports (and hopefully train others from within the USVI in epidemiology as well). However, as you can see from this most recent map, as of 10 October, almost 6 months after the start of the pandemic, the USVI still was not reporting.

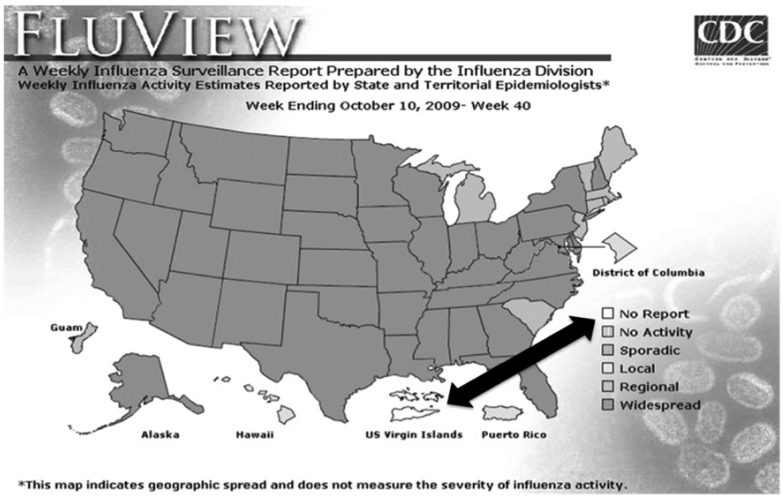

Figure 2: CDC FluView – Geographic Spread

B. FEMA Disaster Assistance Policy on Pandemic Influenza Not Yet Updated

The Robert T. Stafford Disaster Relief and Emergency Assistance Act authorizes Federal assistance to public and private not-for-profit entities affected by catastrophes following a Presidential declaration of an emergency. The Stafford Act is administered by FEMA, which can draw from a Disaster Relief Fund to provide assistance for eligible activities. The Stafford Act's applicability to infectious disease threats—whether natural (such as an influenza pandemic) or intentional (such as a disease caused by an act of bioterrorism) has been a matter of debate. CRS con-

[4] Some estimate that NBIC will not be able to do what it needs to do unless it is funded at ten times the current level.

cluded that emergency assistance under the Stafford Act could be provided if a major disaster is declared as a result of a pandemic. There is no precedent for such a declaration.

FEMA issued Disaster Assistance Policy 9523.17 Emergency Assistance for Human Influenza Pandemic (DAP 9523.17P), that describes Stafford Act assistance that may be provided during an influenza pandemic.[5] The committee sent a letter to the Department, suggesting that DAP 9523.17 be updated and that various aspects be revisited and clarified. First, DAP 9523.17 used avian influenza predictions as the basis for its policy. Second, reimbursement for such activities normally associated with natural disasters (such as search and rescue operations) are included but it is hard to imagine pandemic circumstances that would warrant search and rescue. Third, there is confusion between lack of reimbursement for increased administrative costs associated with medical surge and the reimbursement for temporary medical facilities that would only be necessary if there was a need for medical surge, carrying with it administrative costs. The letter was sent to the Department on 13 August 2009. Committee staff has communicated with various entities (such as FEMA and the Office of Health Affairs) within DHS on numerous occasions since then, but DAP 9523.17 has yet to be updated. Some hospitals throughout the country are running out of hospital space now. It is necessary to get this policy updated well before the President declares emergencies due to pandemics, so that States and territories know in advance what they can expect to get reimbursed.

C. DHS Lessons Learned Information Sharing System Underutilized

The Pandemic All-Hazards Preparedness Act of 2006,[6] required the creation of LLIS-Health, recognizing that there was a need for public health and medical lessons learned, after-action reports, etc. should be collected and provided in a secure area for emergency medical and health professionals. HHS was given the responsibility for gathering and providing information for the site, and it was supposed to have been built on the same platform as the existing LLIS site. LLIS-Health has not been created to date. DHS has added some health and medical information to the site (such as the pandemic influenza page referred to above). However, there is not a large amount of information currently present.

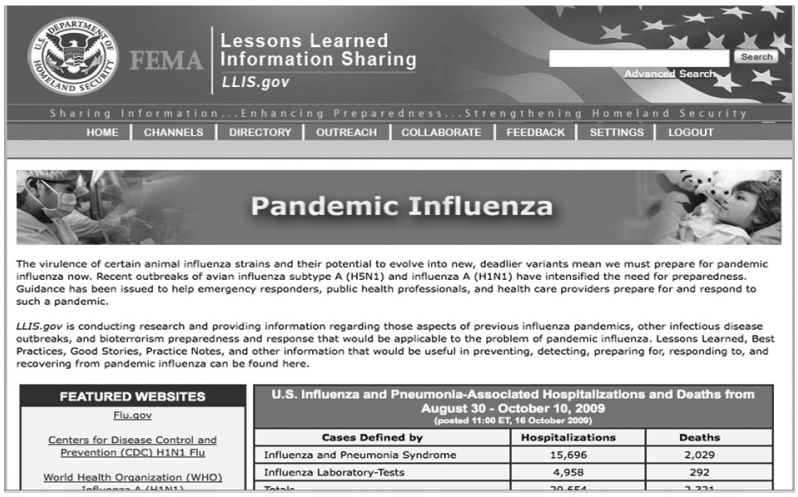

Figure 3: Pandemic Influenza Screen Capture from LLIS.gov

Committee Members have made many comments about the need for lessons learned from infectious disease events, including but not limited to pandemic influenza, to be collected and centralized in a site such as LLIS. Although DHS is to be commended for obtaining and putting what information it can into the existing system, HHS should follow through and either create LLIS-Health or add to the information already present in LLIS currently. We do not want to miss the oppor-

[5] FEMA, "Emergency Assistance for Human Influenza Pandemic," Disaster Assistance Policy 9523.17, March 31, 2007. See: *http://www.fema.gov/government/grant/pa/9523_17.shtm.*

[6] Public Law No. 109–417.

tunity to identify and record lessons learned from this pandemic as it is occurring. We will need this information when it comes time to update (and in some cases complete) the pandemic preparedness plans that were and should have been used to respond to this pandemic.

D. Influenza Messaging Confusing

Although some thought had been given to public messaging regarding pandemic influenza, and some messages were developed by the Federal Government (most by HHS, with some by DHS), it appears that little thought was given to the possibility of having to issue messages regarding seasonal influenza occurring at the same time as pandemic influenza. There is a great deal of confusion regarding simultaneous vaccination with both the seasonal vaccine and the H1N1 vaccine. It may have been necessary to conduct studies to determine whether the vaccine developed for the pandemic would interact adversely with the seasonal vaccine, but there are only so many outcomes—either there is no problem (which would have resulted in a set of messages stating exactly that and encouraging people to get both simultaneously if necessary), or there is a problem (which would have resulted in a set of messages warning people not to take both at once, and providing strict guidance as to how long to wait in between, which to get first, etc.).

The Federal Government has not engaged in a significant public information campaign, using messages and a particular spokesperson (such as the U.S. Surgeon General). As a result, localities and their businesses are providing whatever information they have about vaccines, school closures, personal protective equipment, etc., to prevent the spread of the H1N1 virus.

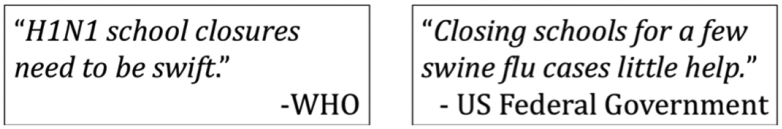

Figure 4: Easily Confused, Seemingly Conflicting H1N1 Messages

Although the need for coherent, comprehensive, and unified messaging has been discussed for years regarding these and other aspects of pandemic influenza, disasters, and other events for which the public would require information in order to take the best possible actions, very little seems to have been implemented. The public must be considered a partner in the endeavor to prevent illness and death due to pandemic influenza. The public cannot do so, however, if it is not armed with the right information.

E. Pharmaceutical System Vulnerable to Counterfeiting

Federal law enforcement agencies (such as ICE, CBP, and the FBI) and agencies with small contingents of law enforcement personnel (such as FDA) have indeed expanded on-going operations to look for and seize H1N1-related counterfeit medications (such as antivirals and vaccine). However, high demand and desperation drive criminals to produce more counterfeit pharmaceuticals and consumers to seek pharmaceuticals outside of normal sources if they are not available when and where they think they should be.

Many illegitimate on-line pharmacies look very legitimate, and fool consumers into purchasing pharmaceuticals that are counterfeited but often look like the real thing. The FDA recently issued a warning to the Nation, urging people to be very cautious about ordering H1N1 drug products over the internet and telling the public that these were unapproved and/or illegal. ICE has been investigating the use of the internet for crime, and these investigations have included ordering counterfeit pharmaceuticals on-line, bringing pharmaceuticals over the border illegally, etc. However, the proliferation of websites has outpaced the ability of ICE and other Federal law enforcement agencies to check each site and what it is selling.

Figure 5: Screen Capture of Website Selling Questionable Tamiflu

More must be done to protect unsuspecting consumers from ordering or otherwise obtaining counterfeit pharmaceuticals, knowingly or unknowingly. It is one thing to purposely obtain pharmaceuticals using illegal practices—this is a crime that should be stopped, and both dealers and consumers must be investigated and prosecuted. It is another to unknowingly obtain pharmaceuticals that are believed to be real, either over the internet or introduced into pharmacies that we believe to be secure. The pharmaceutical supply chain, wholesaler systems that are not regulated and monitored as closely as they should be due to lack of State and local personnel and funding, and the internet are all vulnerable. These vulnerabilities allow criminals to sell counterfeit pharmaceuticals, taking advantage of both demand and desperation during this pandemic.

V. CONCLUSION

We have the opportunity to strengthen at least some of the weaknesses in our National response. To do that, we need concrete information and your departments and agencies need concrete recommendations and resources. The Legislative and Executive Branches must work together to improve our response efforts and save as many lives as we can.

Ms. CLARKE. The Chairwoman now recognizes the Ranking Member of the subcommittee, Mr. Lungren of California.

Mr. LUNGREN. Thank you very much, Chairwoman Clarke, and a welcome to our witnesses.

In this second hearing of our committee on the subject of pandemic influenza, I do look forward to hearing about the challenges we have encountered thus far and our Federal response to this pandemic influenza, what gaps we have discovered, what steps you have taken to correct them, and what corrective strategies will be needed in the future. It would be a great benefit to us to have that in as much detail as possible.

At our July 29 meeting, we examined the near-term outlook for the developing national response to pandemic influenza. Today, we have a chance to see how well we have performed thus far in meeting the challenges and overcoming many of the obstacles that were forecast at that earlier meeting.

I believe I can speak for all of us here today to say the illness and the fatality numbers are very disturbing, with the CDC report-

ing more than 1,000 people in the United States having died from the 2009 H1N1 influenza, with more than 100 of them being children. At the same time, I recognize how many we have that die on an annual basis from regular flu strains, and I think we ought to put that into context and not forget that as well.

I also recall when I was a member of the executive branch in the State of California how different it is from being a Member of the legislature where we often come up with great ideas and then kind of wipe our hands and go off to solve another problem and don't realize perhaps some of the ambiguities, uncertainties, and nuances of what we have asked the Executive branch to do. So I do understand why it is not as easy as putting it on paper for those of you to go forward and actually perform your duties.

Nonetheless, we have an obligation to have serious oversight, and that is what this committee and subcommittee is doing. Going forward, I think we would all agree that we must develop safe and effective vaccines in a timely manner and generate confidence in their use. We must enhance research on vaccines for at-risk populations such as pregnant women and young children, and there is always the cry to correct the delays in the supply chain that have been witnessed I think just about every time and even now.

I would ask this question: A decade into the 21st century, how is it acceptable that we have not commercialized advanced non-egg-based manufacturing for these vaccines? Is there something that I don't understand? Is there something we can do on the Congressional side? Is there a need for great resources to be directed for that? All of this, no matter what your answer, would require resources and commitment from the administration, the Congress, and the private sector.

We should also be concerned about developing significantly better diagnostic technologies for the detection and tracking of these novel flu strains. So I look forward particularly Dr. Lurie's testimony to learn why H1N1 vaccine production has been delayed and why it is still such a challenge to accurately and quickly diagnose influenza strains, whether at the doctor's office or our Nation's ports of entry.

I welcome the Department of Homeland Security's newly appointed Chief Medical Officer, Dr. Garza. Now that the President has declared the H1N1 outbreak a National emergency, I am looking forward to hearing from Dr. Garza on how well DHS is protecting its own workforce and how DHS and the Department of Health and Human Services are coordinating their influenza prevention efforts.

In addition to the human element of any disease, a sick population is a burden on our entire medical system. High workforce absenteeism slows business productivity and impacts the availability of critical State and local government services and this at a time when our economy is at a very, very delicate position.

This pandemic is now a declared National emergency, and I look forward to hearing from today's witnesses what challenges they had to overcome, the lessons they have learned in addressing this H1N1 influenza outbreak, and what advice and counsel they can give us as to how we can work even more closely together in the future to overcome some of the obstacles that remain.

I thank you, Madame Chairwoman, for this hearing.

Ms. CLARKE. Thank you, Mr. Lungren.

The Chairwoman now recognizes the Chairman of the full committee, the gentleman from Mississippi, Mr. Thompson, for an opening statement.

Mr. THOMPSON. Thank you, Madame Chairwoman, for convening this hearing to assess the Federal response to pandemic influenza.

Pandemic influenza is not a new phenomenon. Historically, there have been others; and by the time H1N1 pandemic began this year, we were well overdue.

Although the disease caused by the H1N1 strain of influenza is not as severe as it could have been, we remain concerned. It is already infecting human beings. Pediatric deaths are increasing. Pregnant women are also dying. We realize that if further mutations occur, as often happens with influenza viruses, the death rate could become much higher. As it is, every country in the world has been affected, and global society has changed.

Prior to April 2009, work was on the way to prepare for pandemic influenza. However, even though we knew that an influenza pandemic was coming and that we feared the consequences of such a disease, we were not prepared as a Nation. This committee knew that pandemic influenza would greatly affect the security of our Nation and homeland. It is for this reason that I made oversight of the pandemic preparedness a priority and the oversight of pandemic response a requirement.

Coming into this pandemic, it was clear to the committee that early warning, detection, and biosurveillance were inadequate. Execution of key pandemic planning activities was incomplete. A different standard of care under pandemic conditions had not been identified. Triage rules under pandemic conditions had not been modified. Pharmaceutical interventions were limited. Recommendations for the use of personnel, protective equipment, and other nonpharmaceutical interventions were lacking. Pandemic preparation preparedness was poorly measured, and the Federal departments and agencies were not working together as well as they could have been.

However, the pandemic did start in April. No matter how prepared we were or were not, the Nation and the world stopped preparing and started responding.

In January of this year, before the pandemic started, I instructed the Majority staff of this committee to release a report: "Getting Beyond Getting Ready for Pandemic Influenza." In that report, we made a number of key recommendations for the Nation to become prepared. Some of them have been implemented. For example, we have seen Federal departments and agencies work better together to respond to this pandemic. The CDC is issuing new health care delivery guidance, and a number of response plans have been completed.

However, we are also seeing predictable problems occur during the pandemic response. Many public and private-sector entities are having difficulty reporting how the disease is affecting them or what resources they need. We do not have a truly accurate picture of how the disease is affecting the Nation or the world. Coordination between and among agencies still need to occur, even within

the Departments such as Homeland Security and the Health and Human Services. Hospitals are still determining what the acceptable level of care should be under pandemic conditions. We are still hobbled by the limitations of an egg-based vaccine production. Criminals are infiltrating the pharmaceutical system and trying to sell counterfeit antivirals and vaccine, and confusing messages are still going out to the public.

The Obama administration is working to address these shortcomings while the response to H1N1 pandemic is occurring. We know how hard this is to do, and this committee stands ready to work with the administration in this important endeavor. As leaders, we all share the responsibility to address this threat and fight this pandemic. I, again, as Chairman of the committee, look forward to working with all of the departments as well as other Members of the committee on addressing this as best we can, but we need to do it in a planned, coordinated fashion.

I yield back.

Ms. CLARKE. Thank you, Mr. Chairman.

My colleagues on the subcommittee, we have been joined by the gentlelady from Texas, Ms. Sheila Jackson Lee, a Member of the full committee; and I am asking unanimous consent for her participation here today.

Seeing no objection, so ordered.

Other Members of the committee are reminded that, under the rules, opening statements may be submitted for the record.

[The statement of Hon. Richardson follows:]

STATEMENT OF HONORABLE LAURA RICHARDSON

OCTOBER 27, 2009

Mister Chairman, thank you for convening this very important hearing today focusing on the Federal response to the pandemic influenza. I appreciate your commitment to this very important and timely issue. I would also like to thank our witnesses for taking the time to appear before Congress today.

This is a very timely topic given the recent announcement that vaccines for the H1N1 virus will not be ready as soon as expected. We have all read the local newspaper reports, both in Washington and our respective districts, with stories of people waiting in line for hours to receive vaccines that quickly run out in the face of high demand.

For example, let me tell you about a case in my home State of California. Cindy Nexon Filsinger of San Fernando Valley says she has not been able to obtain flu shots for her two young children. She has driven around fruitlessly to local pharmacies and called her family's pediatrician repeatedly, only to be told, "We are out," and "We don't know when to expect the next shipment." Mister Chairman, this is simply unacceptable. Worried families deserve answers and peace of mind about the health of their children.

In the spring, this subcommittee convened a panel about preparations for a pandemic. It is clear that we still have some lessons to apply to the current situation with regard to the H1N1 virus and its rapid spread around the country.

The 37th Congressional District of California, which I am privileged to represent, is one of the most diverse districts in the country. My district is located in Southern California, home to Samoans, Cambodians, Hispanics, and countless other ethnic groups. While we are dealing with a shortage of vaccines all over the country, it is important that we do not overlook minority communities as well. I hope to hear from our witnesses on the protocols in place for outreach and education. Minorities need to have equal access as well to vaccines and other health information.

But the time for action is certainly sooner rather than later. According to the CDC, H1N1 is present in all 50 States, but widespread in 46 States, including California. But in California, just 1.7 million doses of H1N1 inoculations have been delivered out of 20 million expected this season. It is clear that despite the advance warning and early calls to action, we are still under-prepared for the H1N1 virus.

And it is chilling to think what would happen in the event of a bio-terrorist attack, which would certainly come with little to no warning.

I am pleased that this hearing will focus on the efforts to strengthen the weaknesses in public health, safety, and security revealed by this virus. Clearly, the Federal Government still has work to do in terms of preparation and coordination. I look forward to bringing back positive information and answers to the worried families of my district, as well as hearing from our distinguished panel of witnesses on public outreach with regard to education about the virus, vaccine availability, and basic tips on containing the spread of this virus.

Thank you again, Mr. Chairman, for convening this hearing. I yield back my time.

Ms. CLARKE. I welcome the panel of witnesses.

Our first witness, Dr. Alexander Garza, I understand likes to be called Alex—or doesn't mind—is the Assistant Secretary of the Health Affairs and Chief Medical Officer of the Department of Homeland Security. Welcome.

Prior to joining DHS, Dr. Garza spent 13 years as a practicing physician and medical educator. He most recently served as the Director of Military Programs at the ER–1 Institute at the Washington Hospital Center and has served as the Associate Medical Director of EMS for the State of New Mexico and the Director of EMS for the Kansas City, Missouri, Health Department. He is a war veteran, and we commend him for his service in Senegal and Iraq.

Our second witness is Dr. Nicole Lurie. Dr. Lurie is the Assistant Secretary for Preparedness and Response for the Department of Health and Human Services. The subcommittee is well familiar with the work she did at the RAND prior to returning to HHS, where she served previously as the Principal Deputy Assistant Secretary of Health.

Welcome.

Our third witness is Mr. Richard Serino, Deputy Administrator for the Federal Emergency Management Agency. Mr. Serino brings over 35 years of experience in State and local emergency management and EMS to FEMA and the Department. Prior to coming to FEMA, Mr. Serino was Chief of Boston EMS and Assistant Director of the Boston Public Health Commission.

Our fourth witness is Ms. Marcy Forman, Director of the ICE Intellectual Property Rights Coordination Center. Prior to taking on this directorship, Ms. Forman was the Director of the ICE Office of Investigations, overseeing the largest investigative arm of the Department of Homeland Security. Ms. Forman was responsible for spearheading a number of important initiatives, including Operation Cornerstone and Operation Community Shield.

We thank all four of our witnesses for their service to the Nation and for being here today.

Without objection, the witnesses' full statements will be inserted into the record. I now ask each witness to summarize his or her statement for 5 minutes, beginning with Dr. Alexander, Alex, Garza.

STATEMENT OF ALEXANDER GARZA, M.D., CHIEF MEDICAL OFFICER AND ASSISTANT SECRETARY FOR HEALTH AFFAIRS, DEPARTMENT OF HOMELAND SECURITY

Dr. GARZA. Thank you.

Good afternoon. I want to thank Chairman Thompson, Chairwoman Clarke and Ranking Member Lungren and the distin-

guished Members of the subcommittee for the opportunity to testify before you today.

As you know, this is my first testimony before the committee as the Department of Homeland Security Assistant Secretary and Chief Medical Officer. I welcome the opportunity to address this body, and I am pleased to be here alongside Dr. Lurie from HHS as well as my colleagues from the Department of Homeland Security.

The current H1N1 pandemic is unique in that there is no Ground Zero, no city or State where it is most likely to make landfall, and no discrete beginning or end. It will not destroy buildings, but its effect will be widespread, prolonged, and have the potential to disrupt the normal functioning of communities. To this end, DHS and OHA have focused our efforts on protecting the people and the country from the ramifications of the H1N1 pandemic.

The principal tasks of the Office of Health Affairs regarding the current pandemic are providing information, analysis, and advice in support of Secretary Napolitano, co-leading the DHS H1N1 planning effort, helping ensure that the DHS workforce is protected, and serving as the lead representative of DHS in the interagency coordinating bodies.

DHS has a dual mission intersecting at National security. While we are intimately involved with National planning and response efforts, we are also internally developing policies and procedures to protect our workforce so they may continue to safeguard our country. Together with our interagency partners, DHS has led a strong Federal response. We have learned from our experiences and have implemented changes to improve our response for the Fall wave and in the future.

The key lessons observed and learned that I would like to highlight are interagency coordination, planning, workforce protection, and communications. The Spring outbreak illustrated the necessity of a strong interagency coordination. We have worked closely with our Federal partners, including my colleague, Dr. Lurie, at ASPR, the Department of Health and Human Services, the Centers for Disease Control and Response, and the Department of Education, as well as the White House.

In addition to working horizontally, we have integrated vertically by working with our State, local, Tribal, and territorial governments, as well as the private sector and faith-based communities in providing guidance. Our Office of Intergovernment Programs conducts weekly calls and meetings with the homeland security advisers across the country. Our National Protection Programs Directorate coordinates with critical infrastructure representatives. This, just to name a few. We will continue to collaborate and push information across at all levels.

As my experience in the Army has taught me, plans must be flexible enough to adapt to the tactical reality on the ground. The Department has learned this as well from the H1N1 pandemic. While we originally planned for a worst-case scenario, that being a pandemic influenza originating outside of the continent, we realized the situation was different and were able to adapt and maneuver to the challenges of the current reality. We tested our internal coordination and planning by conducting tabletop exercises with

DHS senior leadership, including the Secretary and the deputy secretary. This provided an opportunity for the Department to identify how to meet our mission-critical functions while protecting employees during an influenza pandemic outbreak.

As I mentioned earlier, we have a dual mission where one complements the other. The Department of Homeland Security has over 200,000 personnel, of which 80 percent are operational. The size of our operational force is second only to the Defense Department and equivalent to the size of the Marine Corps. OHA and DHS have acted aggressively through several different mechanisms to ensure that our forces are protected. We have disseminated evidence-based guidance directly to the employees and posted this on our internet. In addition, we spearheaded the acquisition of personal protective equipment and antiviral medications. By performing these functions, we are helping assure that the threat of the current pandemic will not influence the security posture of the Nation.

Because our job at DHS is to ensure a coordinated Federal response, information sharing is essential. Our National Biosurveillance Integration Center provides situational awareness via the biosurveillance common operating picture to State and local fusion centers. We integrate and disseminate critical information to our law enforcement and emergency managers across the country. As we move forward through the Fall flu season, we continue to build on the strong relationships we have formed across all levels of Government and the private sector.

Again, I would like to thank you for the opportunity to testify before you today, and I look forward to any questions that you may have. Thank you.

[The joint statement of Dr. Garza, Mr. Serino, and Ms. Forman follows:]

PREPARED JOINT STATEMENT OF ALEXANDER GARZA, RICHARD SERINO, AND MARCY FORMAN

Chairwoman Clarke, Ranking Member Lungren and Members of the committee. The Department of Homeland Security (DHS) thanks you for taking the time today to discuss the National response to 2009–H1N1 flu. The DHS Office of Health Affairs (OHA), the Federal Emergency Management Agency (FEMA) and Immigration and Customs Enforcement (ICE) are key players in DHS efforts to ensure the Nation is prepared for the effects of 2009–H1N1 influenza.

At this time, the Nation has a solid idea of the scope and severity of the outbreak. However, we are still watching to see what changes will occur during regular flu season, if any, as the seasonal flu strains circulate concurrently with the 2009–H1N1 virus. DHS has worked in close collaboration with the Department of Health and Human Services (HHS) and other agencies to lead a strong response since the initial appearance of 2009–H1N1 flu in the Spring, and we have implemented changes to continually improve our response now and in the future.

LESSONS LEARNED AND ACCOMPLISHMENTS

As a result of what we learned in the spring about H1N1, the Federal Government has updated its response plans, enhanced our community mitigation planning and guidance, and improved a range of our abilities. We have effectively pre-deployed antiviral medications, and we have created and disseminated messages that help the public understand what the Nation is facing. These improvements are not only critical to our H1N1 response, but are also critical to responding to future pandemics when they occur.

Specifically, the Department and other Federal agencies had been planning for an influenza pandemic for many years, and especially since 2005. However, we learned this past Spring that much of what actually occurred in the H1N1 outbreak did not

align with prior avian flu planning. Since the spring, DHS has led interagency efforts to develop and implement H1N1-specific preparedness and response planning activities. On Aug. 25, 2009, the Secretary of Homeland Security signed the *DHS 2009–H1N1 Influenza Implementation Plan,* which identifies specific component roles and responsibilities, and directs all DHS components to develop plans that address key preparation and response actions, performance of mission essential functions, workforce protection, continuity of operations, and communications with key stakeholders during the H1N1 influenza outbreak. We also worked with the Department of State to clarify the status of international border operations under provision of the Security and Prosperity Partnership of North America's Plan for Avian and Pandemic Influenza.

INTERAGENCY COORDINATION

Throughout the response to H1N1, DHS has engaged closely with Federal interagency partners, including the Department of Health and Human Services (HHS) and its Centers for Disease Control and Prevention (CDC), the Department of Education, the Department of State, and the White House. DHS has also worked with State, local, Tribal, and territorial governments and with the private sector to help mitigate and monitor the spread of this illness.

Our partnerships with HHS, including the HHS Assistant Secretary for Preparedness and Response (ASPR), and other Federal departments and agencies continue to play a critical role in our efforts. The National 2009–H1N1 Summit, held on July 9, 2009, brought together the Secretaries of DHS, HHS, and Education, other Federal officials and experts, staff from Governors' offices, State, Tribal, and territorial health, education, and emergency management/homeland security officials, and National organizations to discuss H1N1 response realities and potential Fall scenarios. The summit was condensed into a webcast for city, county, and local officials and released on Aug. 4, 2009, to update local officials on the status of H1N1, resources available and expectations going forward.

In addition, DHS, HHS, and CDC to provide updated guidance to help multiple segments of the private sector and academic community prepare for and respond to 2009–H1N1. DHS, HHS, and the Department of Education released updated guidance for the K–12 education community on Aug. 7, 2009; updated business guidance from DHS, HHS, and the Department of Commerce followed on Aug. 19, 2009; and guidance for higher education institutions came the following day. In conjunction with the business guidance, DHS, HHS, and the Small Business Administration also produced a small business guide on H1N1 preparedness.

GUIDANCE TO DHS EMPLOYEES

DHS has one of the largest operational workforces in the Federal Government. The health and safety of this workforce continues to be a primary priority of DHS leadership. Therefore, OHA stockpiled personal protective equipment (PPE) and antivirals in advance of any influenza outbreak. Currently PPE is pre-positioned at over 120 DHS locations and field offices Nation-wide. Our antivirals are stored in a pharmaceutical warehouse, fielded across the operational workforce sites, and are prepared to be deployed as required by DHS components.

Throughout the H1N1 response, the Management Directorate and OHA provided DHS employees with new and updated guidance on a number of topics. This guidance has been disseminated to components, is available to all employees on the DHS intranet, and includes information on seasonal influenza and 2009–H1N1 vaccines, influenza antiviral medications, low- and medium-exposure risk occupations, mandatory use of respirators for high- and very high-exposure risk occupations, fit testing and fit checking of respirators, and human resources flexibilities for employees as well as supervisors and managers. We will continue to provide our employees with guidance based on the best science available.

THE OFFICE OF HEALTH AFFAIRS

For the past 3 years, OHA has led the Department's pandemic preparedness activities, placing it in a position to assume an appropriate leadership role when the pandemic occurred. OHA stood up a Decision Support Cell at the first reports of an outbreak, and worked directly with our interagency partners to provide information needed by DHS leadership to coordinate the Federal response. OHA also serves as the DHS representative to interagency coordinating bodies focused on 2009–H1N1.

OHA is co-leading the DHS 2009–H1N1 planning effort in cooperation with the DHS Office of Operations Coordination (OPS). The office also plays a critical role in protecting the DHS workforce, particularly higher-risk employees. OHA provides health and medical guidance to operational components, and has stockpiled PPE

and antivirals for DHS employees. To test our internal coordination for workforce protection, OHA conducted an Assistant Secretary level 2009–H1N1/Pandemic table top exercise on Sept. 10, 2009. The exercise was designed to provide an opportunity for DHS offices and components to identify how they will continue to meet their essential functions while protecting employees during an influenza pandemic event. The forum validated operational relationships, the soundness of Secretarial decision-making processes, and roles and responsibilities of DHS components, confirming that DHS must continue to confront long-term pandemic-related continuity issues head on.

BIOSURVEILLANCE

OHA, through the National Biosurveillance Integration Center (NBIC), integrates and analyzes biological surveillance information from multiple Federal, State, local, and private sector partners. NBIC provides senior DHS leaders a clear, comprehensive picture of on-going incidents and/or outbreaks, both domestically and overseas, and provides the continuing capability to maintain cross-domain analysis and impact assessments of the novel 2009–H1N1 influenza pandemic.

Recognizing the potential consequences of 2009–H1N1 infections on multiple critical infrastructure areas of the United States, NBIC engaged with the National Infrastructure Simulation and Analysis Center (NISAC) to assess potential outbreak characteristics and infrastructure impacts of a resurgent novel-H1N1 virus. The results of the assessment effort were analyzed and reviewed by an aggressive and thorough interagency process that engaged all NBIC Member Agencies and additional Federal participants (including the Departments of Energy, Education, and Labor). The assessment was based on the best scientific snapshot of the outbreak in June and assumed no mitigation efforts. NBIC is now working with HHS and other departments and agencies to conduct an updated assessment that takes into account updated assumptions and mitigation strategies. DHS will use this information to continue to inform Federal Government planning and preparedness.

INCIDENT MANAGEMENT

DHS has taken an aggressive, proactive approach to 2009–H1N1 incident management operations. FEMA has staffed and trained 56 Incident Management Assistance Teams—Advance (IMAT–As) to provide direct Federal support to any State or territory upon a Governor's request. The primary mission of an IMAT–A is to rapidly deploy to an incident or at-risk venue, provide leadership in the allocation and provision of Federal assistance, and to coordinate and integrate an inter-jurisdictional response in support of the affected State(s) or U.S. territory(s). The IMAT–As will support efforts to meet the emergent needs of State and local jurisdictions; possess the capability to provide initial situational awareness for Federal decision-makers; and support the initial establishment of a unified command. In addition, last month, FEMA activated the National IMAT East to provide a dedicated coordination cell for the 2009–H1N1 national response. This cell coordinates with the DHS National Operations Center and the HHS Secretary's Operations Center, facilitates information collection and dissemination; is prepared to receive and evaluate requests for assistance from States and other Federal agencies; and is ready to expand as needed.

For the 2009–H1N1 influenza pandemic, Secretary Napolitano elected to replace the National Pandemic Influenza Principal Federal Official (NPI–PFO) field teams with reconfigured 2009–H1N1 Regional Coordination Teams (RCTs). Secretary Napolitano has outlined clear missions for the 2009–H1N1 RCTs, which will:

- Serve as a conduit between the many Federal agencies engaged in the 2009–H1N1 response efforts and our various partners in the States;
- Identify and, through the established incident management architecture, respond to the Secretary's critical information requirements, enabling the Secretary to make decisions related to her role as the Principal Federal Official for the 2009–H1N1 Pandemic;
- Serve as the Secretary's primary source in the field for awareness of strategic issues related to the 2009–H1N1 pandemic and help broker resolution of significant disputed issues;
- Report through the FEMA Regional Administrator and the Federal Coordinating Officer (FCO). This will ensure that the FEMA Regional Administrators can focus on emergency management and regional administration functions and the FCOs can focus on and lead the administration and coordination of relief at the operational and tactical levels as required by law;
- Assist DHS Component and other Federal interagency leaders in the field to coordinate and collaborate to achieve Nationally directed strategic objectives, in-

cluding those related to entry and exit screening, quarantine, isolation, vaccination, continuity of operations, and continuity of Government.

FEDERAL EMERGENCY MANAGEMENT AGENCY ACTIVITIES

In addition to establishing the IMAT–A teams, FEMA is identifying and addressing potential gaps in Federal response plans, and is providing critical preparedness and response assistance to States and localities.

As a proactive measure at the Federal level, FEMA has shared with HHS a number of Pre-Scripted Mission Assignments (PSMAs) to expedite potentially necessary support to States. In the absence of a declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. 93–288, the PSMAs provide an advance architecture for the scope and cost of Federal support that HHS can use to develop Interagency Agreements (IAAs) between HHS and the Emergency Support Function Departments and Agencies. For example, PSMAs have been established to outline how HHS will seamlessly integrate with the IMAT–A teams, FEMA's Regional Response Coordination Centers and the National Response Coordination Center.

FEMA is also taking the lead in the effort to ensure that the Federal Government can continue operating in the event of significant absenteeism in a major outbreak. The agency's National Continuity Programs (NCP) Directorate has developed and tested its Continuity of Operations for Pandemic to ensure the relevant Federal departments and agencies have the capability to continue supporting disaster activities if pandemic conditions warrant social distancing. NCP has developed planning guidance to address differences in pandemic continuity planning and traditional continuity planning. For example, unlike more traditional continuity planning scenarios, pandemic influenza may be widely dispersed geographically and could arrive in waves that could last several months at a time.

To ensure that all of these Federal planning efforts are well coordinated across all agencies, FEMA has incorporated lessons learned in the Common Operating Picture (COP), within the Homeland Security Information Network (HSIN). The COP is a web-based tool that collects information and provides data to our partners in the Government and in the private sector. To continue updating and improve planning efforts, FEMA provides the DHS Deputy Secretary status updates on a select number of action items, which are included in the Department of Homeland Security Weekly Situation Report. The DHS Situation Report (SitRep) is uploaded to the COP by DHS OPS each week. The DHS weekly SitRep, which provides updated information from responding Federal Departments and Agencies, including HHS, specifically highlights information such as:

- Stafford Act emergency declarations and requests for Federal assistance (to date, there have not been any Stafford Act declarations or requests of DHS pertaining to H1N1);
- Status of Federal-State coordinating elements (e.g. RCTs, ESFs, and IMAT);
- Status of reported school closings;
- Updates from all Federal departments and agencies;
- Impacts, if any, on critical infrastructure and key resources (i.e. absenteeism, operational impact, 7–10 day concerns, mitigation measures, and unique concerns);
- Any specific department or agency updates regarding planning or operational capacity within the four national framework pillars: Mitigation, surveillance, communication, and vaccination.

FEMA is also playing a key role in proactively assisting State and local governments with their H1N1 preparedness and response efforts. For example, the agency's Mass Care Unit is working with State, regional, and other Federal agencies and non-governmental organization partners in the development of a Mass Care (ESF6)/ Emergency H1N1 Planning Guidance Template that will assist States with planning for sheltering, feeding operations, and donations management within an H1N1 environment. The Mass Care/Emergency Assistance Planning Guidance Template provides guidelines for the FEMA regions to support States in their planning efforts for either a pandemic or a pandemic combined with a natural or man-made disaster. Some of the functions included in the template are sheltering, feeding, providing emergency supplies, supporting mass evacuations, facilitating unification, and supporting household pets.

FEMA's National Preparedness Directorate's Center for Domestic Preparedness (CDP) revised the Pandemic Influenza Planning and Preparedness (PIPP) course to reflect new information about the 2009–H1N1 strain along with updated planning considerations. This course is available to State, territory, local, and Tribal homeland security and emergency management professionals.

FEMA's Individual Assistance's Crisis Counseling Program (CCP) is also working with HHS' Single State Medicaid Agencies (SMSA) to develop a contingency plan for administering CCP technology in the event of a mass infectious disease outbreak.

Finally, FEMA's Disaster Assistance Directorate has developed procedures and criteria, under the authority provided in the Stafford Act for requesting assistance from the Federal Government. The President approves all Stafford Act emergency and disaster declaration requests (DAP 9523.17). The Disaster Assistance Directorate has developed guidance titled "Procedure for Evaluating State Requests for Emergency Disaster Declarations for Pandemic Influenza," which is designed to provide States information on factors considered in evaluating State requests for emergency assistance declarations for a pandemic influenza. In addition, FEMA Public Assistance is developing a Disaster Assistance Fact Sheet, entitled "2009–H1N1 Influenza Frequently Asked Questions."

ICE NATIONAL INTELLECTUAL PROPERTY RIGHTS COORDINATION CENTER

Immigration and Customs Enforcement places a significant emphasis on reducing the threat to health and safety posed by the trafficking of counterfeit, unapproved, and substandard pharmaceuticals. Due to the current 2009–H1N1 threat, this emphasis now includes efforts to identify and interdict counterfeit 2009–H1N1 vaccines and other influenza treatment products, such as counterfeit antiviral medications. In addition to the investigative resources of the ICE Office of Investigations, and the Office of International Affairs, ICE spearheaded the establishment of a new National Intellectual Property Rights Coordination Center (IPR Center). The IPR Center now includes representation from all Federal agencies with enforcement jurisdiction over intellectual property (IP)-related crime, including U.S. Customs and Border Protection (CBP), the Federal Bureau of Investigation (FBI), the Food and Drug Administration (FDA)—Office of Criminal Investigations, the U.S. Postal Inspection Service (USPIS), the Department of Commerce, and the Department of Justice Computer Crimes and Intellectual Property Section (CCIPS). Of particular significance is the recent inclusion of Mexico Customs as a partner agency, providing ICE and the IPR Center with the ability to more effectively address cross-border commercial fraud issues between our two countries.

With the reorganization and restructuring into the IPR Center, we have created a true task force environment, bringing together the statutory authority of the partner agencies for a more focused approach to addressing pharmaceutical-related IP crime. The IPR Center develops and receives actionable leads; generates intelligence, seizures, investigations, and initiatives; and conducts outreach and training. One of the primary missions of the IPR Center is the analysis, deconfliction, and coordination of leads received from private industry, counterpart law enforcement agencies, and public avenues. This is accomplished through the sharing of all lead information with agency partners for review and vetting, and is vital to the identification and coordination of existing investigative or interdiction overlaps. To maximize its investigative capabilities, the IPR Center is conducting ongoing investigations of subjects, organizations, and networks exploiting the internet to facilitate the sale and distribution of counterfeit, tainted, and substandard products.

As previously noted, ICE places specific focus on products that present a threat to the health and safety of the U.S. public, which currently include 2009–H1N1 and antiviral medication counterfeit pharmaceuticals. In 2004, ICE developed and implemented Operation Apothecary, which specifically focuses on international mail and express courier services that facilitate the importation of counterfeit and unapproved pharmaceuticals. Operation Apothecary generates information about, and conducts investigations of, subjects and websites involved in the sale and importation of suspect pharmaceuticals.

With the outbreak of 2009–H1N1 earlier this year, ICE and its partners at the IPR Center projected a potential influx of counterfeit influenza products. In response, the IPR Center proactively initiated undercover activity targeting individuals and websites that were offering potential counterfeit influenza treatment products for sale. Even with heightened vigilance, close attention, and thorough investigation, to date ICE has found no evidence of the illicit production or dissemination of counterfeit antiviral medications in the United States. While we have not encountered any counterfeit vaccines or medicines to date, we recognize the potential for the emergence of this threat. ICE will remain diligent in coordinating with our domestic and foreign partners and counterparts on this issue, and will continue to conduct investigative and interdiction activity targeting counterfeit 2009–H1N1 vaccines and other associated pharmaceuticals.

CONCLUSION

In closing, DHS is continuing to address 2009–H1N1 influenza aggressively, as it has since the first appearance of this virus in the Spring. Since that time, we have strengthened our plans and our response capacity as we have learned more about 2009–H1N1, and we have built a strong, coordinated, and effective response. Again, thank you for inviting us to testify on this important issue, and we are happy to answer any questions you have.

Ms. CLARKE. We thank you, Dr. Garza, for your testimony.

I will now recognize Dr. Nicole Lurie to summarize her statement for 5 minutes.

STATEMENT OF NICOLE LURIE, M.D., ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. LURIE. Thank you, Madame Chairwoman, Chairman Thompson, Ranking Member Lungren, and other distinguished Members and guests.

I am Dr. Nicole Lurie. I am the Assistant Secretary for Preparedness and Response. I brought with me for your reading a series of updates on the situation and guidances that have been put out just for your reference.

I thought I would start by describing ASPR's role in general and then move on to talk about what we have been doing with H1N1. So, in general, the role of my office is to coordinate across HHS response and work with the interagencies throughout this pandemic. It is also to stimulate the development of and contract for vaccines and antivirals that have been so essential at combating this pandemic. In addition, we must ensure that we backstop States and communities if they get overwhelmed and request our help. Finally, we have to stay prepared for any other emergency. I will remind you that just a couple of weeks ago we helped out in American Samoa when they were overwhelmed with their tsunami.

H1N1 has been really a public-private partnership from the getgo in response, and I want to give you examples. We have vaccine today because, thanks in large part to the foresight of Congress, we had invested in rebuilding the vaccine infrastructure in the United States. As a result of our avian flu planning, we were able to get out of the blocks quickly, with preexisting contracts with manufacturers already licensed in the United States.

As you know, we have bought enough vaccine for anyone who wants it. While we all know that the vaccine is later than we want it to be, this is a global problem; it is not just a U.S. one. The good news is that at the end of last week States had 16 million doses available to order, and today they have 22 million doses available to order, and there will be more coming every day.

We have stimulated the development of antivirals and have just issued an emergency use authorization for the first-ever intravenous antivirals, and we stockpiled antivirals and personal protective equipment in the Strategic National Stockpile. In the Spring, when the virus first hit, we released about one-quarter of the antivirals from the stockpile as well as N–95 masks to the States. We have replenished that supply, and in the last few weeks we have released about 300,000 treatment courses of liquid pediatric Tamiflu from the stockpile as well as more N–95.

We have partnered closely with the private-sector health care system. Investments in the hospital preparedness program have meant that most health care facilities had exercised all hazards plans, including influenza plans. We have already seen it pay off with places activating disaster procedures, setting up temporary facilities, including tents outside of their emergency rooms. You know, while we first felt scared about that, that is exactly what is supposed to happen in an emergency, and that preserved their emergency rooms for people with true emergencies.

Putting in place a way to pay for vaccine administration has been another accomplishment; and we have partnered very successfully with health insurers, pharmacists, big box stores, the American Medical Association, and public health agencies to get this done. The goal is to be sure that cost is not a barrier for anyone who wants to get vaccinated.

We are working hard in partnership with State and local, Tribal, and territorial agencies on surveillance, on vaccine administration, and on educating the public and working with community groups to get the message out. We talk all the time, formally at least twice a week, with them; and their representatives now are embedded in the Emergency Operations Center of the CDC.

We have also partnered very effectively across the Federal Government, and I would like to highlight just a few of those.

As Dr. Garza said, we work now very closely with DHS. We talk all the time and have coordinated a lot on both the Federal emergency response as well as working with private-sector entities. Similarly, as you pointed out, Madame Chairwoman, we have worked very effectively with the Department of Education around guidance for schools. I would also like to recognize our partnerships with VA and DOD around medical surge and around monitoring vaccine safety.

Let me move on for a minute to lessons learned. In addition I want to say a couple things. The first and most important lesson, chronic underinvestment in public health, whether at the Federal, State, or local level, has real-world consequences; and we can't afford to let this happen again. While surveillance, either about the disease or the status of the health care system, may not always have been as timely as we would like, we have been able to enhance surveillance quickly by collaboration with the health care system and leveraging capabilities of new information technologies.

There is a lot of future promise in those approaches; but, at the same time, biosurveillance, more computers, and fancy IT cannot replace the work of human beings, clinicians, public health scientists, and others who need to track the virus and investigate what is going on on the ground.

Communication remains a challenge; and while it is certainly much better across the interagency, the challenges and speed of the internet means that we need to communicate and respond in new ways tracking down rumors, et cetera.

We are not done with the science, either, in advanced development related to vaccines or building manufacturing capacity in the United States. My fear is that when this is over we will just check the box and decide we don't need to worry about a pandemic for another 30 years.

[The statement of Dr. Lurie follows:]

PREPARED STATEMENT OF NICOLE LURIE

OCTOBER 27, 2009

Good afternoon Chairwoman Clarke, Mr. Lungren, and Members of the subcommittee. I am Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). As Secretary Sebelius emphasized in her testimony before the Senate last week, slowing the spread and reducing the impact of 2009 H1N1 is a shared responsibility and we all need to plan for what would need to be done when the flu impacts our communities, schools, businesses, and homes this fall. I appreciate the opportunity today to discuss our role in response efforts as well as some of the challenges and successes we have encountered in responding to the 2009 H1N1 influenza outbreak.

OVERVIEW OF THE OUTBREAK

Since the initial spring outbreak of 2009 H1N1 influenza, this virus has triggered a worldwide pandemic, and was the dominant flu strain in the southern hemisphere during its winter flu season. Data about the virus from around the world have shown that the circulating pandemic H1N1 virus has not mutated significantly since the Spring. The virus remains similar to the virus chosen for the 2009 H1N1 vaccine, and remains susceptible to the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza), with rare exception. As with seasonal influenza, persons with some chronic health disorders and pregnant women have a higher risk of severe disease. In contrast to seasonal influenza, elderly persons have proven less likely to contract the virus; nevertheless, many elderly persons who do contract the virus have had serious complications, so early treatment with antivirals is recommended for them, as it is for pregnant women and others at high risk for complications, and for anyone who becomes seriously ill.

Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably among school-aged children and young adults. More recently, we have seen widespread influenza activity in almost all States. Visits to doctors for influenza-like illness are much higher than levels expected for this time of the year. We are already observing that more communities are affected than those that experienced outbreaks this past Spring and Summer, reflecting wider transmission and potentially causing greater impact. For example, as of October 10, 2009, 86 pediatric deaths related to 2009 H1N1 flu have been reported to the Centers for Disease Control and Prevention (CDC) since April 2009, a level that has only been seen at the peak of past influenza seasons. During the week of October 4–10, 2009, 11 deaths were reported. In each of the past 3 years, between 46 and 88 children died from seasonal influenza.

Over the next several months, seasonal influenza viruses may circulate along with the 2009 H1N1 influenza virus, and it will not be possible to determine quickly if ill individuals have 2009 H1N1 influenza, seasonal influenza, or other respiratory conditions based on symptoms alone. Because of this, close monitoring of viruses in the United States will be critical to ensure that the best guidance about treatment and prevention of influenza can be provided.

Office of the Assistant Secretary for Preparedness and Response (ASPR)

The Pandemic and All-Hazards Preparedness Act (the Act) designated the HHS Secretary as the lead Federal official for public health and medical response to public health emergencies and incidents covered by the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan, and created the Assistant Secretary for Preparedness and Response. Under the Act, ASPR plays a pivotal role in coordinating emergency response efforts across the various HHS agencies and among our Federal interagency partners.

2009 H1N1 Task Force

In July 2009, the White House National Security Staff (NSS) released the *National Framework for 2009 H1N1 Influenza Preparedness and Response (National Framework)* to ensure a coordinated and focused National strategy. In response, ASPR created the 2009 H1N1 Task Force to: Coordinate and consolidate H1N1 strategic program activities; serve as the focal point for policy coordination; and ensure that HHS's National Framework activities and accomplishments are reported to DHS according to NSS timelines.

The Task Force addresses the National Framework's four key capability "pillars": Surveillance, mitigation measures, vaccination, and communication and education.

The Task Force meets daily with me and the HHS Chief of Staff to review on-going activities to ensure our successful execution of the National Framework strategy. The Task Force has closely collaborated with DHS to establish a Common Operating Picture (COP) for 2009 H1N1, a single display of relevant information to facilitate collaborative planning and to achieve situational awareness.

ESF No. 8 Response Activities

Under the National Response Framework, ASPR is responsible for coordinating the Emergency Support Function (ESF) No. 8 response—Public Health and Medical Services. ASPR provides the mechanism for coordinated Federal assistance to supplement State, local, territorial, and Tribal resources in response to public health and medical care needs during an emergency.

Specifically with regard to the 2009 H1N1 influenza outbreak, ASPR coordinates the interagency public health and medical response activities through a series of twice-weekly Emergency Support Function No. 8 calls. During these calls, HHS regional health administrators and regional emergency coordinators report updates on their regions' pandemic influenza preparedness and response activities. Federal interagency partners, including DHS, also report their activities for group discussion and integration.

Other coordination activities include weekly calls between ASPR and the State health departments to discuss any challenges and issues that might necessitate Federal assistance. ASPR has also conducted calls with intensive care physicians to better understand the clinical picture of patients requiring extensive care in hospitals and to share information and experience to help identify best practices to improve patient outcomes.

Hospital Preparedness

Since its inception in 2002, ASPR's Hospital Preparedness Program (HPP) has provided more than $3 billion to fund the development of medical surge capacity and capability at the State and local level. HPP funds are awarded to State and territory departments of public health, which in turn fund projects at hospitals and other health care entities. As a result, hospitals can now provide more beds; actually communicate with other responders through interoperable communication systems; track bed and resource availability using electronic systems; protect their health care workers with proper equipment; decontaminate patients; train their health care workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises. Over the past 3 years, HPP awardees have been required to conduct at least one pandemic preparedness exercise each year.

Congress's investment in the Hospital Preparedness Program has resulted in our hospitals being better prepared to respond to the current 2009 H1N1 outbreak. In 2007, $75 million was awarded to States and territories specifically for pandemic influenza planning, including pandemic exercises and purchases of equipment, such as ventilators, that would aid in their response to a pandemic. Of the grantees receiving these funds, 79 percent conducted pandemic influenza exercises to hone their preparedness capabilities. In 2009, $90 million was awarded for purchase of personal protective equipment, such as N–95 masks and ventilators. Each program recipient also was required to develop plans for alternate care sites. Pandemic influenza preparedness and development of alternative care sites have been two priorities of the HPP program since the inception of funding.

HPP has required recipients to implement a system of bed counting, called the "Hospital Available Beds in Emergencies and Disasters" (HAvBED). This system requires reports of available beds, including a count of available adult and pediatric general beds and ICU beds, to State and HHS emergency operations centers within 4 hours of request. For the past 6 weeks, HAvBED has been operational and collecting information from States about hospital status that has enhanced our 2009 H1N1 medical surge response needs.

Furthermore, based on the lessons learned from the Spring 2009 H1N1 response, HAvBED was modified to also collect information on emergency department stress and hospital stress. ASPR worked with the HPP grantees, the American Hospital Association and private vendors to develop a core set of measures (including daily census counts and equipment shortages) for the level of stress on the health care system. Within 48 hours of receiving information, we have senior ASPR experts discuss the analyzed data to determine if any hospitals are showing signs of stress or if there are indicators of equipment shortages. On occasions where the data indicates stress, we engage our Regional Emergency Coordinators to work with State health departments in conducting an investigation. To date we have not uncovered

any instances of additional stress due to 2009 H1N1, but we remain vigilant and are prepared to act should the need arise.

Other Activities

ASPR has worked with CDC and Emory University to develop a web-based triage algorithm that enables people with flu symptoms to determine if they need to seek medical care and where this care should be sought. This tool is currently posted on the flu.gov website for public use.

ASPR also worked with the American College of Emergency Physicians (ACEP) to develop 2009 H1N1 influenza guidance for emergency departments and emergency physicians. This tool is available on the ACEP website. *(http://www.acep.org/WorkArea/DownloadAsset.aspx?id=46870)*

ASPR is working with the Society for Critical Care Medicine and is conducting a ventilator survey that will enable HHS to understand how many ventilators are available and where any regional shortages might exist. We are also working with professional organizations to train physicians in taking care of patients on ventilators.

The National Disaster Medical System (NDMS) is training personnel to become vaccinators to assist State and local jurisdictions in that activity. Additionally, NDMS teams have received training on the 2009 H1N1 outbreak and are standing by ready to assist States/locals in the delivery of care to pandemic influenza patients.

RESPONDING TO H1N1

Responding to 2009 H1N1 influenza has provided challenges and valuable lessons that will assist our response efforts going forward. As this emergency unfolded it became clear that significant resources would be necessary to respond to the pandemic with potentially large impacts. Further, based on a number of factors such as State readiness and vaccine effectiveness, we would not be able to plan response requirements with certainty and thus, how resources would need to be allocated. As a result, we greatly appreciated the flexible funding that the Congress provided for these efforts.

As we learn from the experiences of 2009 H1N1, we look forward to working with you to improve strategies to ensure that our Nation has the right assets at the right time to minimize the health impacts of an influenza pandemic, hurricane, or bioterrorism event. The timely access to a flexible response fund has provided us with a nimbleness to quickly augment capabilities—such as hiring personnel on the front line of public health—where the speed of our response translates to lives saved.

Now, I will briefly discuss a few of the challenges we encountered in our biosurveillance efforts, vaccine research and development, antiviral stockpiling, situational awareness, private sector collaboration, and international assistance.

Biosurveillance Efforts

Several additional systems have been put in place or modified to more closely monitor data on the impact of 2009 influenzas. These changes include the following:

- *Enhancing Hospitalization Surveillance*.—Using the 198 hospitals in the Emerging Infections Program (EIP) network and six additional sites with 76 hospitals, CDC monitors a population of 25.6 million to estimate hospitalization rates by age group and to monitor the clinical course among persons with severe disease requiring hospitalization. The EIP sites also track vaccine effectiveness.
- *Expanding Testing Capability*.—HHS continues to support all States and territories with test reagents, equipment, and funds to maintain laboratory staff and ship specimens for testing. CDC serves as the primary support for public health laboratories around the globe and has provided test reagents to 295 laboratories in 147 countries. Accurate testing is essential for monitoring any changes in the virus that may indicate increases in severe infection, resistance to antiviral drugs or a decrease in the match to circulating vaccine strains. To further enhance availability of testing, FDA has evaluated and provided emergency use authorization for several diagnostic tests specific for the 2009 H1N1 virus.
- *Monitoring severe illness and mortality of women who are pregnant*.—Pregnant women are at higher risk of severe disease and death from the 2009 H1N1 influenza virus. CDC is in the process of implementing a new system to collect data on severe illness (intensive care hospitalization) and mortality among pregnant women, which will improve our ability to monitor this group.
- *Aggregate Hospitalizations and Deaths Reporting Activity (AHDRA)*.—Initiated on September 1, 2009, AHDRA collects information from all 50 States to identify hospitalizations and deaths due to influenza or influenza-like-illness (ILI) Nationally and within each State. This new collection activity will contribute to

a more complete picture of the burden of serious influenza and pneumonia illness and deaths during the pandemic and let each State examine trends in the course of the pandemic in their areas.

Vaccine Research and Development

ASPR's investment over the past 6 years in medical countermeasure advanced research and development enabled the Department to complete 2009 H1N1 vaccine development with unprecedented speed. ASPR's Biomedical Advanced Research and Development Authority (BARDA) has worked with industry to build and sustain a domestic manufacturing infrastructure. Under the *HHS Pandemic Influenza Plan* (November 2005), the Department's key goals for vaccine preparedness were:

- Stockpile enough pre-pandemic influenza vaccines to cover 20 million persons in the critical workforce;
- Develop sufficient domestic manufacturing capacity to produce pandemic vaccine for the entire U.S. population of 300 million persons within 6 months of pandemic onset.

To establish domestic pre-pandemic influenza vaccine stockpiles, BARDA supported the development and manufacture of vaccines against different H5N1 avian virus strains. Today, BARDA continues to support a secure supply of raw materials, including eggs for domestic manufacturing of seasonal and novel influenza vaccines and the development and manufacturing of novel influenza vaccine candidates for clinical evaluation. BARDA also provided cost-sharing support to expand the domestic influenza vaccine manufacturing infrastructure by retrofitting existing vaccine manufacturing facilities and building new cell-based influenza vaccine manufacturing facilities. Additionally, FDA was fully engaged with industry to substantially increase the number of U.S. licensed seasonal influenza vaccine manufacturers and their overall production capacity, a necessary infrastructure for pandemic vaccine development and production. It was through the licensed seasonal influenza vaccine framework that we were able to license and rapidly make available H1N1 vaccine.

The rapid responses of HHS agencies, including CDC, the National Institutes of Health, and the Food and Drug Administration, in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by preparedness efforts for influenza pandemics set in motion by the H5N1 outbreak in 2003. Stockpiling for pandemic preparedness began in 2004, with H5N1 vaccine (23 million doses). In 2005 and 2006, the first six contracts for cell-based vaccines were initiated with two manufacturers at a cost of $1.3 billion. In 2007, two manufacturers were contracted for work on adjuvants, which are vaccine-boosting compounds ($137.5 million). Throughout, clinical studies have been supported by ASPR/BARDA and the National Institutes of Health/National Institute on Allergy and Infectious Diseases (NIH/NIAID).

These initial activities to prepare for H5N1 provided valuable lessons that have informed our efforts to respond to the current 2009 H1N1 outbreak. For example, we learned that coordination between ASPR/BARDA and NIH/NIAID was necessary to learn about the immunogenic properties of the virus and to conduct clinical trials. Working with our industry partners, we learned that, just as for seasonal influenza vaccines, one dose of the H1N1 vaccine induces a response that is likely to be protective in adults and older children. We also learned that vaccine distribution through Points of Distribution (POD) should not be the only option. Instead, we need to develop our planning and contractual relationships to allow for flexible distribution—in this case, through a third-party—to 150,000 State-specified locations.

Antiviral Stockpiling

Under the *HHS Pandemic Influenza Plan,* HHS was required to:

- Establish National influenza antiviral drug stockpiles to treat 25 percent of the U.S. population during a pandemic, plus an immediate readiness cache of 6 million treatment courses for containment at pandemic onset;
- Support the advanced development of new and promising influenza antiviral drugs toward U.S. approval; and
- Boost U.S.-based production of antiviral drugs.

To accomplish these mandates, ASPR awarded contracts in 2004–2007 totaling more than $924 million to establish and coordinate the Federal and State pandemic stockpiles of antiviral drugs. We procured 50 million treatment courses for storage in the Strategic National Stockpile (SNS) by the end of 2007, completing the Federal contribution to the antiviral goal. Additionally, using funding provided by Congress, ASPR subsidized States in their purchase of 22 million treatment courses of antivirals towards the 31 million treatment course goal for State stockpiles.

To support antiviral development and manufacturing ramp-up activities, BARDA awarded a contract in 2007 for $102.7 million for advanced development and domes-

tic industrialization of a new influenza antiviral drug. Beginning in 2008, BARDA also solicited and awarded additional contracts for new and combination influenza antiviral drugs. These efforts directly benefited pediatric and critically ill populations.

We know that antiviral resistance is a threat. So our acquisition strategy for additional antivirals needed to be flexible. A lesson learned from the 2009 H1N1 outbreak is that rare cases of H1N1 have been Tamiflu resistant. As a result, ASPR has increased efforts to stockpile an alternative antiviral, Relenza. We also know from this outbreak that children are disproportionately affected by 2009 H1N1 influenza, leading us to procure more pediatric courses of antivirals.

Another challenge presented by 2009 H1N1 influenza is the treatment of critically ill individuals, who potentially may require an intravenous antiviral formulation that requires an Emergency Use Authorization (EUA) from the FDA. Since January 2007, HHS has supported the advanced development of a new antiviral drug, Peramivir, which may be administered intravenously to hospitalized influenza patients. On October 23, an Emergency Use Authorization was authorized by the FDA for the utilization of Peramivir to treat critically ill patients with H1N1 virus infections. In addition, the emergency use of intravenous formulations of two other antiviral drugs, approved already for other indications, is under evaluation.

Situational Awareness

Situational awareness is an essential component of any incident response. During the 2009 H1N1 influenza response, HHS worked very closely with the Department of Homeland Security (DHS) to develop a National Situation Report (SitRep) which is then inserted into the Homeland Security Information Network (HSIN). Working cooperatively, DHS and HHS have modified the SitRep to accurately reflect public health and medical issues. HHS has also been working with DHS to enable State and local public health officials to gain access to the HSIN so they can maintain their situational awareness.

Private Sector Collaboration

HHS has engaged many private sector partners in a series of problem-solving dialogues related to the vaccine dispensing program. The Association of State and Territorial Health Officials (ASTHO) worked with ASPR to convene a series of meetings with America's Health Insurance Plans (AHIP), individual insurers, American Pharmacists Association, retail pharmacy chains, American Medical Association (AMA), National Vaccine Safety Program, and other State and Federal partners. The private sector demonstrated a firm commitment to working through complex issues of vaccine administration, billing processes, and other policy issues that would facilitate a successful vaccine campaign with the goal of providing easy access to the 2009 H1N1 influenza vaccine for every person in the United States who wants it.

Many issues related to vaccine administration, including billing and payment issues, were raised and partnerships with the HHS Centers for Medicare & Medicaid Services and the AMA yielded the development of specific vaccine codes, and unique vaccine administration codes for both Medicare recipients and the privately insured. In addition, the health insurers and pharmacies agreed upon a set of principles for billing practices and payment procedures and developed associated draft templates to support State vaccine program consistency.

International Assistance

There is broad international recognition that the 2009 H1N1 pandemic is a global health challenge. Millions of people around the world have been affected, thousands have died and the virus continues to spread across international borders. Recognizing that 2009 H1N1 infection, like most diseases, knows no borders and that the health of the American people is inseparable from the health of people around the world, President Obama committed to make 10 percent of the U.S. 2009 H1N1 vaccine supply available to other countries through the World Health Organization (WHO). Vaccine will be donated on a rolling basis, as it becomes available, in order to assist countries that will not otherwise have direct access to the vaccine. We are taking this action in concert with international partners: Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, Japan, Germany, and the United Kingdom.

On October 5, we met with the Governments of Mexico and Canada to review current 2009 H1N1 efforts and decided to re-institute the North American Plan for Avian and Pandemic Influenza Coordinating Body to ensure continued international coordination in the areas of human health, animal health, border issues, and emergency management.

CONCLUSION

I want to assure the subcommittee that the administration is taking the public health challenges of 2009 H1N1 seriously and is implementing a comprehensive strategy to monitor and address this influenza outbreak throughout this Fall and Winter. HHS continues to work in close partnership with virtually every part of the Federal Government under a National preparedness and response framework for action that builds on the efforts and lessons learned from this spring.

Working together with Governors, mayors, tribal leaders, State, and local health departments, the medical community, and our private sector partners, the Federal Government has been actively implementing a vaccination program and continues to revise and refine our pandemic influenza plans and activities based on new data and information.

It is important to reiterate that our current level of preparedness and subsequent ability to respond is a direct result of the investments and support of Congress; the hard work of State, local, Tribal, and territorial public health officials; and our partners in the private and not-for-profit sectors. Building strong systems to track and monitor seasonal influenza has allowed us to closely monitor the impact of this novel virus on our communities.

Our Nation's investment in public health infrastructure, particularly at the State and local levels, remains a critical challenge that has real life consequences in peoples' lives. Today, these consequences are impacting our communities, our schools, our workplace, and our homes.

Investments in science and the public health infrastructure will enable us to better prepare and respond to threats, such as 2009 H1N1, that arise in the future. For instance, the President's 2010 budget includes funding for advanced development of antiviral drugs and invests in new vaccine technology. These investments are critical to building the resilience needed to better prepare for a flu pandemic or other public health emergency before it occurs. Moreover, these investments require our continuing attention and commitment over the long-term and should not depend solely on the occurrence of a public health emergency.

Building resilience makes us more secure from a number of public health emergencies—from the current 2009 H1N1 pandemic, to chemical, biological, radiological, or nuclear threats and natural disasters.

Our experience with 2009 H1N1, and the lessons we have learned, demonstrate a need to examine new paradigms for leveraging the public health infrastructure to facilitate proper preparedness, recovery, and response to future disasters.

Thank you for your time and interest. I am happy to answer any questions.

Ms. CLARKE. We are going to have to probably get the rest of your testimony through the questioning. We want to make sure that we get the other witnesses in. But thank you.

I thank you for your testimony, and I would like to now recognize Mr. Richard Serino to summarize his statement for 5 minutes.

STATEMENT OF RICHARD SERINO, DEPUTY ADMINISTRATOR, FEDERAL EMERGENCY MANAGEMENT AGENCY, DEPARTMENT OF HOMELAND SECURITY

Mr. SERINO. Chairman Thompson, Chairwoman Clarke, Ranking Member Lungren, and Members of the subcommittee, thank you for the opportunity to testify on behalf of the Federal Emergency Management Agency.

The issue that we are discussing today is timely and extremely important. As the President indicated on Saturday with his declaration of a National emergency, this administration is taking the H1N1 threat seriously. Even before this declaration, the strong Federal team led by the Department of Health and Human Services assembled to address an outbreak of H1N1.

As a member of this team, FEMA is doing its part to ensuring our communities are prepared. The drive behind this effort is clear: We care deeply for all those who we serve and protect, and our hearts go out to the families of those who have suffered or lost a loved one as a result of H1N1. I want to ensure all of them and

all Americans that the Federal Government is working hard to protect them.

As you know, this is my first appearance on Capitol Hill since I was sworn in as Deputy Administrator last week. Prior to my swearing in, I served as both Chief of the Department for the City of Boston EMS but also as the Assistant Director of Health in Boston. I was proud that Mayor Menino entrusted me to be part of the team to lead the city's effort in preparing for H1N1. I am now looking forward to bringing that experience to bear at a National level.

What we are doing in Boston is similar to what many cities all across America are doing right now. The key to our efforts in Boston was community outreach. We used partnerships with schools, churches, synagogues, temples, businesses, and unions to spread the message of personal protection from the H1N1 virus. We emphasized the simple things but critically important things that you have all heard, but it bears repeating, like washing your hands, covering your cough with your arm, getting vaccinated, and staying home when you are sick. I know that is hard for all of us, but it is important.

We established a medical intelligence center in Boston last year that became a central hub of our efforts. It brought hospitals, EMS, community health centers, law enforcement, businesses into our facility to foster and create cooperation and to build upon the strengths that each member of the team had to offer. For instance, when we were looking to expand our outreach efforts in several neighborhoods, the Boston police who were there were able to assist by using their relationships with dozens of community crime watch groups.

Boston's faith-based community also assisted in our efforts to sponsoring vaccination clinics throughout the city. We used Facebook, Twitter, and other innovative ways to get the message out to the public.

While I am proud of what we were able to accomplish in Boston, I am also now humbled by the responsibilities that I now have as FEMA's Deputy Administrator. Much has already been done, but I am anxious to contribute to the efforts ahead.

In the weeks since my swearing in, I have spent much time studying the plan and efforts that are already under way; and next week I will be traveling to Atlanta with Dr. Garza to meet with the CDC officials. What I have observed so far, the Federal approach to H1N1 is similar to our approach in Boston. Through close coordination and cooperation, we are using unique expertise of numerous Government agencies to respond again as one team.

HHS is the lead agency in the Federal team, but FEMA is playing an integral part. FEMA is assisting State and local governments with their H1N1 planning efforts by developing clear guidance on how to structure emergency mass care operations within an H1N1 environment. We are providing guidance through procedures and criteria for requesting emergency assistance under the Stafford Act, if necessary, the fact sheet that we are sending out to all States and localities for them to know what guidance is available and what they need in case they need to use the Stafford guide.

FEMA is also working to expand and improve coordination between all levels of Government. We created 56 Incident Management Assistance Teams—Advance, or IMAT–As, that can be deployed at the request of a Governor to assist in coordinating Federal assistance during H1N1 emergency. We have developed a number of pre-scripted mission assignments that provide detailed script on how different agencies will interact if called upon in H1N1 emergency. In addition, FEMA has developed and tested a continuity of operations plan to ensure that even during an H1N1 outbreak that the Federal Government still has the capability to support disaster response and recovery activities.

Madame Chairwoman, these are just some of the examples of how FEMA is working with the Department of Health and Human Services in our State and local departments to plan and prepare for an outbreak of the H1N1 virus. It is with my experience in Boston the key to our effort is coordination and cooperation. We are building upon our strengths and expertise of each of our partners to form one unified response. I am looking forward to be part of this Federal team.

I am anxious to work with you, Madame Chairwoman, and the other Members of Congress to ensure that the Federal Government can do all it can do to protect the American people. Thank you for the opportunity to appear before you today.

I am prepared to answer any questions the committee may have.

Ms. CLARKE. We thank you for your testimony.

I now recognize Ms. Marcy Forman to summarize her statement for 5 minutes.

STATEMENT OF MARCY FORMAN, DIRECTOR, INTELLECTUAL PROPERTY RIGHTS COORDINATION CENTER, DEPARTMENT OF HOMELAND SECURITY

Ms. FORMAN. Chairman Thompson, Chairwoman Clarke, Ranking Member Lungren, and distinguished Members of the subcommittee, I appreciate the opportunity to appear before you today.

I currently serve as the Director of the Intellectual Property Rights Coordination Center led by ICE. Prior to me coming to the Center, as noted by the Chairwoman, I served as the Director of the Office Investigations for ICE. During that time, I oversaw the largest investigative arm of the Department of Homeland Security for more than 8,000 employees, to include over 6,200 special agents assigned to 26 Special Agent-in-Charge field offices and 181 suboffices.

It was during my tenure as the Director of the Office of Investigations that I established the current National Intellectual Property Rights Center to stem the flow of counterfeit and tainted goods that were entering the commerce of the United States. This multiagency IPR coordination center, through its shared law enforcement and regulatory partnerships, targets intellectual property crimes globally with a focus on health and safety and a special focus on pharmaceuticals, counterfeit pharmaceuticals.

Because Dr. Garza has provided the committee with a written statement on behalf of all the DHS witnesses before you today, I will forego making a formal statement at this time.

I look forward to answering any questions. Thank you very much.

Ms. CLARKE. I thank all the witnesses for their testimony.

I will remind each Member that she or he will have 5 minutes to question the panel. I will now recognize myself for questions.

Dr. Garza and Dr. Lurie, we knew about H1N1 prior to the outbreaks occurring elsewhere in the world before 2009. How much did we know and how far in advance did we know it, and who do you think—and why do you think, rather, why do you think that we didn't act faster?

Dr. GARZA. Let me make sure I understand what you are asking. Are you asking about when did we find out about the first cases of H1N1?

Ms. CLARKE. Well, we knew about H1N1 prior to the outbreaks.

Dr. GARZA. Yes.

Ms. CLARKE. Because they were occurring elsewhere in the world before April 2009. That is correct.

Dr. GARZA. I believe they were first discovered in Mexico. Correct.

Ms. CLARKE. Do you know how much we knew and how far in advance we knew it, about that outbreak in Mexico or elsewhere?

Dr. GARZA. I am not familiar with the outbreak information.

Ms. CLARKE. Dr. Lurie, do you have any sense of that?

Dr. LURIE. I don't have specific dates. But it is fair to say that, as soon as it was clear that outbreaks of a yet unnamed respiratory disease were going on in Mexico, there was a fair amount of sample sharing, as you know, and the virus was identified. Shortly thereafter, cases were identified in the United States. As you may know, interestingly, it was actually an investigational rapid diagnostic test that was being supported as part of our pandemic planning that helped to pick up one of those very first cases.

Ms. CLARKE. Well, if you look at the timeline, it would seem to me that there would have been a number of steps that we would have taken as a Nation, given our proximity to Mexico, to try to mitigate as much as possible any outbreak here in the United States. Perhaps it could have been happening simultaneously. I really don't know. I don't know what sense you have. I guess that is sort of what I am trying to get at, is what sense do you have of the occurrence that took place basically right next door, how quickly it would spread in the United States? Do you think that we acted fast enough, given what we knew?

Dr. LURIE. Well my sense is—and I wasn't in the Department at the time, but my sense from following this very closely was that we acted on it really as soon as we knew it. As soon as we knew there was a new virus, we were very vigilant. We recognized first cases in the United States early in Texas and in California and with the tragic death of the Texas child. At that time, it was fairly clear that the virus was already likely to be widespread, and that turned out to be the case. You will recall that within a few days many more cases were noticed. So by that time it was also felt to have sort of crossed the border, as it were, and that border closures and other sorts of things would not really have been appropriate under the circumstances.

We did look very carefully at the mitigation measures being imposed by Mexico. We did enhance surveillance very rapidly. As you know, we learned a lot about the virus as it moved around the country and particularly then when it hit pretty hard and forcefully in New York City.

Ms. CLARKE. Let me ask you, Dr. Lurie. As you know from the CDC FluView presentation of influenza data, epidemiologists are providing reports of how widespread H1N1 is in the States and the territories. Although we have reported cases of H1N1, the map shows no report coming from the U.S. Virgin Islands. We understand that this is because the U.S. Virgin Islands did not have an epidemiologist in the territory that can provide the necessary sentinel reporting. Is that true?

Dr. LURIE. I would have to confirm that fact about the U.S. Virgin Islands.

But one of the things that I think has really challenged everybody in this pandemic has been the status of State and local public health. You know, there has been serious underinvestment there for many years. Throughout this pandemic we are in touch with State, local, Tribal, and territorial health departments that are laying off people as we are trying to cope with this epidemic; and so it wouldn't surprise me in the least to hear that there wasn't an epidemiologist there.

Ms. CLARKE. I am sure that you will agree that sending Federal personnel to States and territories to do the jobs that should be done at their level by their own employees is probably not a long-term strategy. What do you think should be done to remedy this problem? This is not the first time that a lack of expertise in the U.S. territories has presented a problem for public health reporting.

Dr. LURIE. That is absolutely right; and I think one of the very important lessons that we are reminded of throughout this pandemic is that a chain is as strong as its weakest link, that we really need to have very strong public health on the ground in States, territories, communities to do the surveillance, to do the epidemiology, to do disease control, and to respond. I think part of the problem is that public health has become kind of invisible over the last several decades.

Ms. CLARKE. Dr. Lurie, I am going to have one of my other colleagues follow up on that question. My time has expired.

I now want to recognize the Ranking Member of the subcommittee, the gentleman from California, Mr. Lungren, for his questions.

Mr. LUNGREN. Thank you very much, Madame Chairwoman.

Being Ranking Member gives you a lot of things to do, and one of them I didn't realize I was going to have, but my friend, Mr. Broun, turned over to me when Mr. Serino was testifying and he said, what language is he talking?

Ms. CLARKE. Boston, similar to Brooklyn.

Mr. LUNGREN. But I have got a guy from Georgia asking me to interpret a guy from Boston. Thank God I am from California where we have no accents whatsoever.

Dr. Lurie, as I said in my opening statement, maybe there is something I don't fully understand. But aren't we using 50-year-old

technology with respect to producing viruses by way of—flu virus in chicken eggs? I remember visiting the CDC several years ago, and there was an indication there that they thought we were developing a new technology that showed promise that would allow us to produce vaccines in the future on a much shorter time schedule. What is the state of that? What do we need to do? Where are we?

Dr. LURIE. You are absolutely right. In fact, we are in year 3 of a 5-year strategic plan to support the development and large-scale manufacturing of vaccines using some of these newer technologies like cell-based technology and recombinant technologies; and, at the same time, we are continuing to invest in even more advanced technologies that hopefully can bring vaccines to market much sooner than that.

Mr. LUNGREN. But where are we on the course? I know we are 3 years through 5 years, but that just tells me we have still got a program going. What is the promise? What do we think we are going to see when?

Dr. LURIE. We do have a program going. You are absolutely right. In November, I think the first U.S.-based cell-based facility will, in fact, open in North Carolina. Unfortunately, it wasn't open in time to make vaccine there for this pandemic. But that is part of the strategy, is both to move toward some mix of egg-based technologies and newer technologies, as well as to have manufacturing capacity in the United States that is robust.

Mr. LUNGREN. Let me ask you about that last part, and this goes to the question that the scheduled H1N1 vaccine production has slipped to 25 percent below the initial Government projections, as I understand it.

On Friday, October 23, only the 14.1 million doses were available to the States. By the end of October, it is estimated that 28 million doses will be ready. But that is falling short of the predicted 40 million. Why were we overly optimistic about how much we would produce? I understood at one time we had certain manufacturers producing the vaccine for regular type of flu that had to move to the other. Is that part of the problem, or is it something else?

Dr. LURIE. Well, I think it has been a series of challenges. We have been working in very close collaboration with the manufacturers throughout this, and we rely on their estimates and what they are able to do to make projections of how much vaccine are available. There have been a couple problems. One has been the amount of vaccine that they have been able to—or virus that they have been able to grow quickly in the eggs. As I think you know, all of the manufacturers really experienced fairly low yield in the beginning, which set back these projections.

At the same time, some of the manufacturers, as they got further on into the manufacturing process, were standing up new filling and finishing lines to put the vaccine from a big vat into syringes or vials to ship out. Some of those had problems in the beginning. They didn't get them up and running as quickly as they thought, even with conservative estimates.

I think the good news now is I think we are through those problems and we are back on track, but no doubt vaccine has been late.

Mr. LUNGREN. Are those problems unique to this circumstance? Are those problems that we would anticipate we would have in the

future if we had to respond in the same way using egg-based as opposed to new technologies?

Dr. LURIE. Great questions.

First, I should say these are problems that we encounter every single flu season. In fact, even growing the seasonal vaccine for this year's flu season one of those three strains was slow to grow and is late, and so the manufacturers were manufacturing seasonal late into the flu season. We hope that with cell-based and with recombinant technologies the idea is to get there faster with more vaccine.

Mr. LUNGREN. Dr. Garza, this may be slightly outside your realm. But I saw a GAO report that had a different slant on the influenza pandemic, believe it or not. It said that concerns exist that a more severe pandemic outbreak than this year's could cause large numbers of people staying at home to increase their internet use and overwhelm the internet providers' capacity. The reason I mention that is that could go specifically to our critical infrastructure in any number of areas, and one of the responsibilities of DHS is to ensure that critical telecommunications infrastructure is protected. So any conversation you have with your operation with the critical infrastructure protection operation of DHS on this question, and is there any insight into what we do in that kind of a situation?

Dr. GARZA. Well, absolutely. That is a serious concern, with absorbing the bandwidth, people who were staying home.

As you know, before the H1N1 pandemic came along, we were planning for a much more serious pandemic in prior years. One of the elements of planning for that pandemic was, of course, anticipating the second and third order effects. One of those was if we have a large amount of absenteeism, if we have a large amount of people staying at home, that they will absorb a majority of the bandwidth and thus make it difficult for the economy to move as well as security. So there has been a lot of effort within DHS at infrastructure protection. We, of course, lended our subject medical expertise to those discussions, and I believe they are actively working on a draft report right now. But it is a little bit outside my expertise.

Mr. LUNGREN. That might be the subject of another hearing. Because those second- and third-level effects could be as devastating to our overall economy as the immediate effect.

Ms. CLARKE. Thank you very much, Mr. Lungren. We will certainly follow up and look into that.

But, at this time, I would like to recognize the Chairman of the full committee, the gentleman from Mississippi, Mr. Thompson.

Mr. THOMPSON. Thank you very much, Madame Chairwoman. I appreciate this hearing which, obviously, is perhaps on the hearts and minds of a lot of people, the subject matter we are talking about.

One of the issues that continue to confront us is, even though we knew certain things around this H1N1 was happening, whether or not as a Government we were prepared. That is still the subject of a lot of discussion. Mr. Serino, let me give you a good example of what I am talking about; and since this is your maiden voyage to the committee, I will kind of give you some future expectations.

FEMA has a policy that has been in place since 2007 with respect to disaster assistance and communities being reimbursed with respect to human influenza pandemic. It is my understanding that we have not updated this policy since 2007. Am I correct?

Mr. SERINO. Well, from what I understand is this fact sheet, that was distributed to all the States, essentially will be the policy. Everything that is in the new policy is in the fact sheet, and we wanted to get this out to the States and to all the regions so they are familiar with all the—that this was—I believe this was brought up to you earlier today and was shared again with all the States and the Governors and the emergency managers throughout the country who, if they needed——

Mr. THOMPSON. Good point. How old is that fact sheet?

Mr. SERINO. I believe this fact sheet is just within the last week.

Mr. THOMPSON. So you understand what I am saying.

Mr. SERINO. I understand very much what you are saying.

Mr. THOMPSON. We have a policy from March 2007 that just got updated recently with respect to this. So that is an issue, and one of the concerns that we have is: How much planning are we really putting into what we do in the event of another situation like this? If you came from Boston, you can imagine how you felt on the other end waiting for word from Washington that was 2007 didn't really reflect what you were addressing.

My concern and a concern of this committee is that, as we go forward, we would like your agency to take particular note of situations like this because of the pivotal role that you play, hospitals, public health entities, a lot of those entities, in the event that something really bad happens, the first line of defense in so much of what we do. But on the back side, we have to reimburse those agencies. I think what you need to look at is whether or not the reimbursement to those State and localities is current. I can tell you that most of it is geared towards hospitals and not toward other things, and that is probably something from a policy standpoint that you need to look at because we now know there are more players in this scenario than just hospitals.

Ms. Forman, counterfeit drugs, we have heard the story of Tamiflu being ordered and God knows what comes back. What can we assure the public in that these counterfeit drugs somehow we are doing our best to prevent that from getting into our system?

Ms. FORMAN. Mr. Chairman, what we can represent to you is that ICE and their law enforcement partners, to include the Food and Drug Administration, Customs Border Protection, the FBI, the Postal Service, and Department of Justice in conjunction with the private sectors, the manufacturers of these true and legitimate pharmaceuticals are working very proactively to target internet sites, to conduct operations within our mail and courier facilities, and to work with our foreign partners to identify the illegitimate manufacturers of these goods so they do not enter the commerce of the United States.

Mr. THOMPSON. So to what degree have you been able to measure success in stemming the flow of these counterfeit drugs?

Ms. FORMAN. We believe as a U.S. Government we have made impact and inroads within identifying the manufacturers of many

of these pharmaceutical goods, the counterfeit pharmaceutical goods, but there is much work to be done.

Mr. THOMPSON. So what other kind of work do you suggest that we do?

Ms. FORMAN. As counterfeit pharmaceuticals and counterfeit goods in general is a global problem, we must work with our foreign counterparts, especially in those countries that are manufacturing a majority of these goods, to work together to identify the manufacturers, to disrupt, dismantle, and prosecute the violators, both foreign and domestic, on those individuals who are penetrating all our borders.

Mr. THOMPSON. So are we doing that?

Ms. FORMAN. Yes, we are doing that.

Mr. THOMPSON. Just for the sake of this committee's information, give me the two top violators of this country.

Ms. FORMAN. Probably the two top violators on counterfeit pharmaceuticals are, No. 1, China and, No. 2, primarily India and countries in Southeast Asia.

Mr. THOMPSON. We are entering a dialogue with those countries to try to prevent it?

Ms. FORMAN. Yes, we are entering in dialogue; and we are working joint operations with both these countries and other countries worldwide to identify, disrupt, and take down the violators.

Mr. THOMPSON. Thank you.

Ms. CLARKE. Thank you, Mr. Chairman.

The Chairwoman will now recognize other Members for questions they may wish to ask the witnesses. In accordance with our committee's rules, I will recognize Members who were present at the start of the hearing based on seniority on the committee, alternating between the Majority and the Minority. Those Members coming in later will be recognized in order of their arrival.

Having said that, I now recognize the gentleman from Georgia, Mr. Broun, for his questions at this time.

Mr. BROUN. Thank you, Madame Chairwoman.

I am pleased the committee is meeting to review and assess the status of H1N1 readiness and prepare for and respond to the pandemic flu. If you all need somebody to interpret, Mr. Lungren has said that he would be glad to. Down in Georgia, I don't have an accent, you all do, and so anyway—but I thank you all for being here.

The DHS national preparedness guidelines and the companion target capabilities list both identify "mass prophylactics capabilities" as one of the core capabilities that communities, the private sector, and all levels of Government should collectively possess in order to respond effectively to a disaster. At the Federal level, the United States has purchased its allotment of antivirals called for by the National Strategy on Pandemic Influenza. I am told that some States have purchased all of their allocations and still have some of that on hand. Several States have purchased far less than would be needed to protect 25 percent of the population, which is the benchmark that was set by NSPI. I am also told that some States have used antivirals from their State stockpiles and have not replenished those supplies.

The target capabilities list suggest that States take several actions to protect the health of the U.S. population by developing procedures for the distribution and dispensing of mass prophylactics and developing processes to ensure that first responders, public health responders, critical infrastructure personnel, and their families receive prophylactics.

For the panel, do you know how many States have established these procedures; and, No. 2, what do you see as the roles of DHS and HHS in encouraging incorporation of these procedures for a public health emergency?

We will start on this end and go down.

Dr. GARZA. Sure. Thank you, sir.

As far as the stockpile of antivirals go, that is mostly regulated by the SNS stockpile at the CDC.

I would hope that a lot of the State and local public health officials would be following the guidance that is set forth by the CDC on when to use antivirals. As we all know, not every situation is the same. Had this pandemic turned out to be a much more virulent or different strain of virus, then I am sure that the CDC and other folks would have taken that into consideration on recommendation on when to use the antivirals.

I am afraid I cannot speak to the different plans that the States have for replenishing their stockpiles, but I would hope that we would all be prudent in following the best advice that the science can give us.

Dr. LURIE. Sure. Thank you for that question.

I think both vaccines and antivirals are certainly kind of targets for talking about the distribution system; and I think throughout this pandemic the decision was made to get antivirals out—I am sorry—vaccines out as well as antivirals out largely in the way that people access them normally through usual flu season, which is through their private providers, through the health care system, through community clinics, and then to be sure that, in addition, we had places stood up by public health departments that people could go both to get vaccines and antivirals. That is turning out to be the case with the vaccine distribution system.

With regard to antivirals, you are correct that not all States originally stockpiled enough antivirals for 25 percent of their populations. But it is also the case right now that the priority is to keep people from getting sick and dying. So the Strategic National Stockpile initially distributed 25 percent of the allocations to the States in a pro rata allocation, and it is responding to State requests as they come in. The goal is to be sure that no child dies or nobody dies because antivirals were not released from the stockpile and made available to people who need them.

Mr. BROUN. Thank you, Dr. Lurie.

My time is about expired. I have more questions that I will submit, but thank you, Chairwoman Clarke, for the time. I yield back.

Ms. CLARKE. I now recognize the gentlelady from Texas, Ms. Sheila Jackson Lee, for her questions.

Ms. JACKSON LEE. Madame Chairwoman, let me thank you very much for your kindness and that of the Ranking Member and the full committee Chairman and my colleagues as well.

I know that the Obama administration, the administration is committed; and I want to thank the witnesses that are here and try to see if we can all get on the same page and be part of the same team.

I want to follow the line of questioning that my colleague, Chairman Thompson, did on the data and the resources or the materials and facts that we have. I am reading from a FEMA disaster assistance policy dated March 31, 2007, so I would commend the Assistant Administrator to have as one of his first tasks, his staff—and I know that you—is the updating of this document. But let me just read these numbers:

It has been estimated that in the United States a Medium Level pandemic could cause 89,000 to 207,000 deaths, 314,000 to 734,000 hospitalizations, 18 to 42 million outpatient visits, and another 20 to 47 million people being rendered sick. The economic impact could range between $71.3 billion and $166.5 billion in damage. But this document was written in 2007.

Another document that I would like to show indicates—and this may be a little earlier. It looks as if it has the picture which shows that H1N1 or influenza is widespread, which I assume led to the President's announcement. So I have the following concerns:

Yesterday, we had a congressional briefing in Texas, in Houston, and it was entitled H1N1. Texas may be the epicenter of the H1N1 virus pandemic, a very large State, a State a year or so ago that had some of the early deaths along with New York, my colleague's State. But to refer you to a direct question, we had an example of a 33-year-old languishing in his apartment for a week and may have gotten Tamiflu but wound up dying after being admitted to the hospital, which reflects on the lack of health care insurance but still it reflects on I think the lack of information.

So I raise these points, and I will ask two questions.

There is some representation by the persons who participated with us yesterday that they need FDA to expedite approval of the PER tests. In our State alone, we do not have enough vaccines; and the question was being asked, when will they get them? So I invite the Assistant Administrator—I would like him to dispatch to Texas as one of the States that you are visiting because of its size.

Pediatricians—private pediatricians, who were also part of this briefing, said they have a spray, but they do not have a vaccine. In the news wire services there is an indication that one out of five children in America will be impacted by influenza. I assume that would include H1N1. Our hospitals are seeing very, very sick children; and there is a CDC DHS rule that nurses cannot come back before 7 days. So let me pose these questions:

Can I have an answer about what you are doing to actually hit home about the seriousness of knowing when to get to the emergency room? Because I think people are dying right now, and I think that we have not coordinated sufficiently so that people can stop dying. I would like to know what you are doing to coordinate.

I would like an answer to the FDA expedite of the PER test as I understand it and the question of the return of health professionals now required to be 7 days. My doctors and hospitals say that they will be completely empty of physicians if they do that.

I will start with Dr. Lurie, and I only have 57 seconds, and then I will go to the Assistant FEMA Administrator. Thank you.

Dr. LURIE. Sure. I think you raised some very important points.

First, let me assure you now that Texas has allocated to it not only the nasal mist vaccine but also injectable vaccine, and injectable vaccine is on the way.

With regard to the messaging about this, I think your point is extremely important. We have been really using all channels to see if we can get the message out that people, particularly who are in high-risk groups and who are sick, need to get treated early with antivirals. That information is on flu.gov. It is in Flu Essentials. All of the State and local health departments are messaging to this. We have been working to outreach to the clinical communities.

In addition, there are several assessment guidelines available on flu.gov and other websites to help people understand that they need to get antivirals early if they are in high-risk groups and what the warning signs are so that we don't have the kinds of tragedies like the ones you mentioned. Some of that material is actually in the Flu Essentials that I provided here.

With regard to the PER test, I think I will have to get back to you about this. But, in general, the guidance is that people should not wait to be tested if they are in a high-risk group. If they are pregnant, if they have underlying chronic conditions, they need to get antivirals and to get them early.

Ms. JACKSON LEE. Did the administrator finish the questions I posed to you? I think the outreach—you are the 9/11 man, if you will. What are you doing to be 9/11? Because people are dying.

Mr. SERINO. There are a number of things that FEMA has done, but I also think it is important to realize that the case you mentioned is really for people—I think you hit the nail on the head. It is about the messaging; and it is also about—it is part of the team, that FEMA is a member of the team and public health is a member of the team, but the citizens are a critical part of the team. One of the key messages I think is for people to check on their neighbors as well. When people—when somebody is home especially by themselves, especially the elderly or somebody has young children in a single-parent family, is to make sure that they check on other people as well.

In addition to that, some of the things that FEMA has been doing is FEMA is able—has worked a number of plans to help throughout the continuity of Government here with all the Federal agencies but also the ability that if needed, and the Government were to request, FEMA is there to add a number of things that are consistent with what I mentioned earlier as well.

Ms. JACKSON LEE. Thank you, Madame Chairwoman.

Ms. CLARKE. I now recognize Mr. Luján of New Mexico for his questions at this time.

Mr. LUJÁN. Madame Chairwoman, thank you very much and thank you very much for this hearing to you and to our Ranking Member.

I heard early on, Dr. Lurie, that we have enough vaccine, that we purchased enough vaccine for what we need right now, that anyone that wants it can get it.

I just want take share a couple of things about New Mexico. The most recent release from New Mexico from our Secretary of the Department of Health, H1N1 influenza is the predominant strain of flu in New Mexico at this time. Visits to health care providers for influenza-like illness increased to approximately 20 percent this week up from approximately 16 percent last week. This is compared to the peak of last year's flu season of 3 percent of all visits to providers. We have had 16 deaths, 468 hospitalizations related to novel H1N1 influenza. When asked what more we need in New Mexico, he said we can always use more vaccine.

So with that being said, in response to that, Dr. Lurie, is it fair to share with my Secretary and the State of New Mexico and the Department of Health that if more is needed more is available for him to bring in?

Dr. LURIE. So what we anticipate is the vaccine will be available for everybody who needs it. It is not now. As I think everyone is aware there have been delays in getting vaccines from the manufacturers out to States. But now there is a pretty steady pipeline of vaccine coming out. Each State gets a share of vaccine based on its population, and New Mexico has been getting doses allocated to it, has ordered doses and is able to vaccinate, and we will keep making vaccine available for as long as people want it.

In the mean time, until vaccine is available, there is a lot people can do. As we were reminded still, the public health messages, wash your hands, cover your cough, stay home if you are sick, terribly important. In addition, the comment I had made to Ms. Jackson Lee about antivirals and getting treated early still stands.

Mr. LUJÁN. Thank you very much, Dr. Lurie.

Dr. Garza, can you tell me what is being done specifically to reach out to tribal leaders across the country? My district in New Mexico, we are home, I believe, to more nations, Tribal nations than any other district in the country, second in population across the United States. What can be said to me to assure me that our tribal leaders are being reached out to?

Dr. GARZA. Yes, I am very familiar with the Indian Tribal country in New Mexico, having traveled from Albuquerque to Santa Fe almost every day to work at the health department in New Mexico. So, a very fast highway, lots of open land, and certainly a lot of Indian Tribes.

So what we have done is our intergovernmental partners have been reaching out to our State, territorial, as well as our Indian health people throughout Government, as well as down to the local level; and they do this by doing weekly phone calls to these leaders. I know that they have also been working with Health and Human Services, specifically with Indian Health Services, to get that message out. I believe they were—if I remember correctly, they were planning to go to the conferences that the major Indian Tribes have every year in order to reinforce that message.

So, in addition to our State and locals, we are making a concerted effort to reach out to the territories and Tribal leaders.

Mr. LUJÁN. Thank you very much.

Looking, Dr. Lurie, back to you, in reading some of the information that was provided to us by staff as well there appears to be a concern with our ability to be able to get the data that is being

put together to be able to harness that data from a biosurveillance perspective and being able to bring that together to share the latest information so we can stay on top of that. Can you talk about what is being done with the coordination from Health and Human Services and how maybe we can improve that?

Dr. LURIE. Sure. I think that is a very accurate perception.

As you know, surveillance really depends both on systems set up by the CDC but the surveillance systems that are available in States and in local governments. It is fair to say that at the outset of this pandemic, and, frankly, throughout it, there are often times that we would like to have information in real time and we don't, whether it is information about how the disease is progressing or how our health care system is doing.

We have very rapidly expanded a lot of on-the-ground surveillance through influenza-like illness reporters on the ground. We have collaborated with the private-sector health care system so that we have now close to real-time surveillance from many emergency rooms throughout the country.

In addition, on the health care system side, we have begun having weekly reports from a system from my office called HAvBED in which hospitals report on a weekly basis their bed availability, how crowded their ICUs are, whether they have ventilators available.

That said, there is a lot more to do. As I said in my oral testimony, I think this has really shown us, No. 1, that harnessing the power of IT and working with a number of private-sector partners we can get a lot further than we have been. But, at the same time, it is not going to replace human beings on the ground, the clinician calling with something funny or needing to track down an outbreak.

Mr. LUJÁN. Thank you very much.

Madame Chairwoman, if I may ask a quick yes-or-no question to Ms. Forman along the lines of the questioning from Chairman Thompson. Have we found that there are counterfeit H1N1 vaccine out there right now?

Ms. FORMAN. No, we have not, but we continue to search.

Mr. LUJÁN. Thank you.

Thank you, Madame Chairwoman.

Ms. CLARKE. I now recognize the gentlelady from California, Ms. Richardson, for her questions at this time.

Ms. RICHARDSON. Thank you, Madame Chairwoman.

Dr. Lurie, are you familiar with the case of the nurse who died in Sacramento who they believe contracted H1N1 from her work environment?

Dr. LURIE. I am not familiar with the details.

Ms. RICHARDSON. Well, ma'am, I think it would be important to do so.

If you read my local paper, which is the Press Telegram, the nurse was in Sacramento, I believe Mercy hospital. We can supply you the information. She was 51 years old, and her name was Karen Anne Hayes. It is believed that she contracted H1N1 in her work occupation and died several days later.

Are you aware that in California the nurses are planning on striking on Friday due to this, of not everyone having masks and so on?

Dr. LURIE. I am aware of that. That is a really tragic situation, yes.

Ms. RICHARDSON. So what are you doing about it?

Dr. LURIE. First and most important thing we are doing is encouraging health care workers to get vaccinated. As you know, they are in one of those very highest priority groups to get vaccinated. Unfortunately, every year only about 40 percent of health care workers make a choice to get seasonal flu vaccine; and we are hoping that nurses and other health care workers will decide to get vaccinated now.

As you know, there is also a shortage of N–95 masks. The CDC has put out guidance for how to use those N–95 masks most judiciously, how to set up a hospital or health care environment with other kinds of controls to minimize the risk of infection, and in addition is releasing more N–95 masks from the stockpile.

Ms. RICHARDSON. When do you anticipate having all the health care workers have the ability to have an N–95 mask?

Dr. LURIE. I can't tell you exactly. But what I can tell you is that there is a National, in fact, a worldwide shortage of N–95 masks and so——

Ms. RICHARDSON. So—I apologize, ma'am, but I only have 3 minutes left. So if you don't know when, how are you going to figure it out? Are we going to get something else in lieu of it? What steps do you plan on taking to ensure that our health care workers are in a healthy environment? Because if we have an epidemic and more people begin to contract this, if we expect people to be cared for, we have to ensure that those health care workers are cared for as well so they can care for us.

Dr. LURIE. You are absolutely right. First of all, that is why vaccination is so important, because vaccination is the best protection. Similarly, treatment of antivirals for people who get sick and are in a high-risk group is important. Thirdly, as I said, the CDC has put out a fair amount of guidance now about the health care environment, how to work on the ventilation——

Ms. RICHARDSON. Ma'am, my question was, when are we going to ensure that the health care workers have N–95 masks? If we don't have those, when are they going to get some other masks? That is my question. I heard you twice now on the other points.

Dr. LURIE. N–95 masks are being shipped from the Strategic National Stockpile to States this week. I am not sure when they are slated to arrive in California. People who are priority users of N–95 masks certainly include health care workers and particularly those health care workers at the highest risk of exposure.

Ms. RICHARDSON. So can you provide to this committee a rollout plan of how you expect the N–95 mask to be delivered throughout this country? For those that are not going to receive it, what is the plan? Beyond vaccination, beyond all that, do you have another mask that you recommending? Is someone else making the mask? What are you going to do, besides the vaccinations? We get that. But my question is specifically regarding the mask.

Dr. LURIE. We would be happy to provide you information about the National supply, what is in the stockpile, and what has been shipped.

Ms. RICHARDSON. What is the alternative?

Dr. LURIE. What is the alternative? Absolutely.

Ms. RICHARDSON. Okay. Ma'am, my other question has to do with when you talk about if I am in a community where people are potentially striking. We also had a situation. I sit on the Transportation Committee, and TSA was not properly advised of when they could begin to wear the mask, and that was the whole discussion. What have you put in place to assist them as well?

Dr. LURIE. Let me go back and say, first of all, with regard to the health care workers, we believe that for most health care workers that surgical masks provide quite good protection as well. So there are surgical masks also available in hospitals and surgical masks likely to be shipped from the stockpile.

At the current time, TSA and other workers are not in the highest priority groups to receive the limited supply of masks that we have. There are some people with very high-risk exposure who indeed need them. I would refer this question to Dr. Garza, who I know has spent a lot of time working on keeping the DHS workforce healthy in this situation in terms of their purchases of N–95s and their recommendations for their workers.

Dr. GARZA. Yes, ma'am. We have issued guidance to all of our workforce employees about when it is appropriate to wear a mask. We are following along the CDC OSHA guidelines with the high, medium, and low risk.

In addition to that, we have stockpiled N–95 respirators as well as surgical masks for our different components; and so we feel at this moment—and, of course, this is a very fluid situation—and so at this moment, though, we feel like we have adequate supplies to meet our components' needs.

Ms. RICHARDSON. So when is the TSA person allowed to put on a mask?

Dr. GARZA. A TSA person is allowed to put on a mask—we recommend if, following along CDC OSHA guidelines, if they are in close proximity to someone with a known influenza-like illness, then we recommend the N–95 mask. If they are in close proximity to the public where they are going to be interacting a lot and they feel justified to wear a mask being that they are in close proximity, they are certainly welcome to use that and address it with their supervisor.

Ms. RICHARDSON. I will ask further questions. My time has expired.

Ms. CLARKE. My colleagues, I know that we all have additional questions to ask. It is being said that we are going to be having votes probably within the next 15 minutes. So what we will do is just quickly, if there is a burning question for you, have you do your questions as quickly as you possibly can.

Let me just take this time to ask a question to Dr. Lurie about the spreading and the vaccine production. It just seems like the H1N1 is spreading, but the vaccine production and the distribution is lagging behind. Epidemiologically speaking, what will the impact

be on the epidemic curve here in the United States, you know, with this disparity?

Let me just add to that that I just wanted to get a sense of—maybe, Dr. Garza, you would have this information. How is it determined what parts of the Nation received the vaccine at what point in time?

I know that New York City, for instance, is just beginning its vaccination process for children; and it was one of the hot spots very early on. But then I land here in Washington, and the children have been receiving their vaccines for quite some time. So if you can just explain that, why that occurred, and also how what that curve is going to look like if we don't catch up with our production capabilities?

Dr. LURIE. Sure. Well, we certainly are eager to get vaccine out as quickly as possible. The way this works is that every week, depending on how much vaccine has been made and is ready to be shipped to States, it is allocated to States on a pro rata basis according to their population size. Within the States, the State Health Department decides where, in fact, the vaccine needs to go first to get to priority groups; and then it is shipped to over 150,000 sites in the country according to those priorities.

Because in the first couple of weeks only the nasal spray was available and the nasal spray can only be given to certain populations, State and local Health Departments made decisions about how to reach those priority populations, often health care workers or children or college students, by how they could reach the most people quickly. Now that injectable vaccine is available, it, too, is coming out on a pro rata share.

Ms. CLARKE. Have we found any counterfeits in this process, any counterfeit antivirals?

Dr. LURIE. I would let my colleague, Ms. Forman, speak to the counterfeit antivirals.

Ms. FORMAN. Today we have not found any pure counterfeit Tamiflu antivirals pertaining to the flu. What we have found is something referred to as the "gray market", which is legitimate Tamiflu that comes into the United States. However, it was made for a foreign market. It is, in itself, a legitimate product.

Ms. CLARKE. It is our understanding that the FDA did find some counterfeit antiviral. Are you aware of that?

Ms. FORMAN. We have an FDA representative at the IPR Center, and my understanding is what they located was a product that was not counterfeit and did not represent itself to be Tamiflu. It represented itself to treat the flu, which is a fraudulent representation and not a violation per se of counterfeit law.

Ms. CLARKE. Thank you.

Let me recognize the Ranking Member, Mr. Lungren, for his questions.

Mr. LUNGREN. Thank you very much, Madame Chairwoman.

My colleague from California mentioned this case that occurred actually in my district at the Mercy San Juan Medical Center in Carmichael where an otherwise healthy nurse—she was actually a triathlete—died within a few days of contracting the disease, which brings this question. To me, it sounds—and I don't want to misstate this for the record so, Dr. Lurie, if you could respond, it

sounds to me as if you believe the best prophylactic is receiving the vaccine. So I would have two questions.

One is, has there been much resistance in the health care industry about this? I know there was a command in one jurisdiction, and I believe it was the nurses association or health representatives fought that, so they countermanded that.

Do we have sufficient vaccine for our health care workers so that if, in fact, they wished to receive it, we could say to them today, if you wish to have it, and we recommend strongly that you have it, and give at least an example of this one terrible case in my district, we have it readily available to you? Can we say that?

Dr. LURIE. What we can say right now is that vaccine is coming out every day. Health care workers are among the highest priority groups for vaccine, and as soon as it arrives in their community the very best way to protect themselves is through getting vaccinated.

I point out that health care workers generally have a pretty crummy track record of getting vaccinated, and so I would hope that they would do better.

Mr. LUNGREN. We have the situation, as I understand it, where we have, as this lady was, otherwise healthy individuals who are contracting it in very serious ways with very serious episodes of the illness or death, which is very different than the model that we have had before; and that, in the past, the normal course is that, with flus, the highest percentage of people dying are those 65 and older, and now we find the highest percentage of those dying are 25 and under.

I believe that is the case. Correct me if I am wrong.

Dr. LURIE. Yes.

Mr. LUNGREN. If that is the case, what does that mean for a different strategy, if it does, for how we respond to this with these various prophylactics that we have and with the antivirals?

Dr. LURIE. It is a great question.

One of the things that characterizes a pandemic and why we worry about pandemics such as this is because the population affected doesn't have immunity because it is a new virus or new strain that has shown up. That is exactly what makes a pandemic so dangerous and so scary. Almost every pandemic, it kills younger people disproportionately to older people.

So you are quite right. Seasonal flu most often affects older people. This pandemic strain and other pandemic strains most often affect younger people.

So that is why it is so important for us to be able to get to the point where we can manufacture vaccine quickly, to your comments before about the new technologies and get vaccine out quickly. In the meantime, the public health measures, you know, the hand washing and those things and the antivirals, are the most important things that we can do.

Mr. LUNGREN. I know you have been doing this, but it seems to me the message needs to be repeated. This is different from what we usually expect so that the average person may understand, hey, maybe it is more important for my child to get vaccinated than before, and the average healthy health care worker will understand it is more important that they get vaccinated than before, as opposed to them saying, well, we see this every year. The flu comes

along, and the older people die, and I am healthy, and it doesn't bother me.

I know you have said it, but I guess we need to help you repeat it as well.

Dr. LURIE. The more of us that can repeat it together—I very much appreciate the help. It is a terribly important message. It is very important for young people, for health care workers to get vaccinated. It is often hard to talk them into it. I am a physician. I still see patients. It is hard for me to talk my patients into it. It is hard for me to talk the residents that I practice with into it; and yet, at the same time, many people are getting vaccinated, taking steps to protect themselves.

Mr. LUNGREN. Young mothers and pregnant women particularly.

Dr. LURIE. Young mothers and pregnant women, parents of children.

I also want to just say, health care workers have a very special obligation not only to protect themselves but to protect their patients from getting infected when they get sick; and that is a really, really important reason to get vaccinated.

Ms. CLARKE. Let me just—a point of clarification. Ms. Forman, we have recent information from the FDA that warns consumers to use extreme care when purchasing any products over the internet that claim to diagnose, prevent, treat, or cure the H1N1 influenza virus. It came because the FDA recently purchased and analyzed several products represented on-line as Tamiflu which may pose risks to patients. Were you aware of what the FDA found out?

Ms. FORMAN. Yes, I am, ma'am.

Ms. CLARKE. What is your take on it? What would you say to the American people, given what we know about counterfeit pharmaceuticals?

Ms. FORMAN. I would advise the American public to apply due diligence, especially when making purchases over the internet. As we know, the internet has been our friend since inception, but it has also been an enemy. Because you don't see the opposite side of those who are selling these products. These individuals—the American citizens need to be aware that there are fraudsters out there who are trying to sell them a product to make a dollar, and it is all about the money for these individuals and not the health and welfare of our citizens.

Ms. CLARKE. Thank you, Ms. Forman.

I now acknowledge the gentlelady from California for her question at this time.

Ms. RICHARDSON. Dr. Garza, I want to come back to the TSA questions that I was asking you. As I understood you quoting the rules, if a person knows that a person is infected, then, obviously, they can wear the mask. But the TSA worker, nine times out of ten, is not going to know if a person is infected. You said if they feel that they need to, then they are allowed to.

If I am not mistaken, back when this whole thing started, some TSA workers asked to wear masks and were discouraged by their supervisors saying, oh, if you wear a mask you will make other people feel afraid and they won't want to travel and so on.

So what have you done to address that issue of the workers feeling comfortable that if today they want to put on a mask that their

superior or no one else is going to say or put them through the wringer because they feel uncomfortable and want to be protected?

Dr. GARZA. Yes, ma'am. You are absolutely right.

During the initial phases of the pandemic, when there wasn't a lot of information out there, there were some issues with allowing workers to wear masks. Since then, we have updated our guidance to allow them to wear the mask if they feel like they need to.

I would point out, though, that most of our TSA workers are in a low-to-medium-risk category. When I say high-risk, being around somebody who is infected, I realize that you can be around somebody who is infected without the visible signs, but, typically, those are safe for health care workers, EMS workers, and those sorts of populations. But the fact still remains that the guidance that has been issued to DHS would allow a TSA worker to wear a surgical mask if they felt like they need to.

Ms. RICHARDSON. So if I were to walk up to my local airport and say can I see the masks that you have available for workers, there would be sufficient masks for folks to use and that the workers have been communicated to that they can use them?

Dr. GARZA. I can tell you that we have issued the guidance, that we have sent it out Department-wide, and it is up on the internet. As far as individual airports and their procedures and where the masks are, issues like that, I can't speak to that. But we have provided both the information and the material to our component services.

Ms. RICHARDSON. Would you follow up with those airports and I will follow up to this committee?

Dr. GARZA. Absolutely.

Ms. RICHARDSON. Three very quick questions.

Dr. Garza, have you agreed to provide to this committee an update and clarify the FEMA Disaster Assistance Policy 9523.17 Emergency Assistance for Human Influenza Pandemic and communicate the updated policy to this subcommittee within 30 days?

Dr. GARZA. Yes, ma'am.

Ms. RICHARDSON. Dr. Lurie, have you agreed to provide to this committee a LLIS-health or use of the capacity in LLIS to gather and display H1N1 lessons learned within 30 days?

Dr. LURIE. Yes.

Ms. RICHARDSON. Finally, Ms. Forman, have you agreed to provide to this committee within 30 days a report regarding the IPR Center programs to investigate H1N1 related to counterfeit pharmaceuticals and equipment and monthly thereafter until the pandemic is over?

Ms. FORMAN. Yes.

Ms. RICHARDSON. Thank you very much. I yield back.

Ms. CLARKE. Well, I want to thank all of our witnesses.

I think that Congresswoman Richardson has raised in her final line of questioning of the documents that we would like to make sure that we are receiving from you, just that lays out some of the concerns that this committee has about where we are in the state of the build-out of your capacities.

I think you made it pretty clear, Dr. Lurie, that there are some areas that you feel need to be much more robust and you kind of found flatfooted.

Certainly the Ranking Member has talked about the new technologies that we would like to see put forth in terms of production of vaccine. As he has quite rightly said, this is the 21st century. I would like to say we are in the new millennium. The egg-based vaccine production has to be outmoded, and I know that there are technologies already available that should make it possible for us to create vaccine without that sort of antiquated process.

So, having said that, I want to thank you all for being here and for sharing with us your insights into what is taking place. This is real-time assessment of what is happening with this pandemic influenza. Our concern is that we are ready, that we are ready for anything, whether it is H1N1 or anything else that may accompany it, any type of permutation of it or mutation of it or anything that may be detrimental to the preservation of life on our homeland. You are all on the frontline of that. So anything that this committee can do to be partners with you in reaching those goals we are certainly there to be helpful to you.

To everyone, thank you very much for attending. My colleagues thank you very much.

This hearing is adjourned.

[Whereupon, at 3:45 p.m., the subcommittee was adjourned.]

APPENDIX

QUESTIONS FROM CHAIRWOMAN YVETTE D. CLARKE FOR ALEXANDER GARZA, M.D., CHIEF MEDICAL OFFICER AND ASSISTANT SECRETARY FOR HEALTH AFFAIRS, DEPARTMENT OF HOMELAND SECURITY

Question 1. In your testimony, you stated that the Office of Health Affairs "spearheaded the acquisition of personal protective equipment and antiviral medications" for the Department of Homeland Security. How did the Office of Health Affairs spearhead this?

Answer. OHA has provided oversight and direction for the DHS Fiscal Year Pandemic Emergency Supplemental (Pub. L. 109–148) since it was appropriated in fiscal year 2006. Much of that appropriation was identified to provide for the protection of the DHS workforce. Personal protective equipment (PPE), including respirators, surgical masks, disposable gloves, garments, hand sanitizer, and splash goggles, was purchased and distributed to the DHS components for pandemic stockpiles. Furthermore, 258,400 courses of antiviral medicine were purchased and stockpiled in a secure pharmaceutical warehouse location for future needs.

In addition to purchasing and stockpiling the PPE and antivirals above, OHA has spearheaded establishing large procurement vehicles that will serve all DHS Components. This will include blanket purchase agreements (BPA) and indefinite delivery indefinite quantity (IDIQ) contracts, which will be pre-negotiated and competed in advance. This will ensure quick, efficient means for the Components to acquire these critical items.

Currently, 15 BPAs are in place for the use by the DHS Components, to purchase surgical masks, hand sanitizer, splash goggles, disposable gloves and disposable garments. Additional DHS-wide contract vehicles are currently in the procurement process for the purchase of respiratory protection devices.

Question 2. In your testimony, you stated that you would follow up with airports throughout the United States regarding sufficient availability and numbers of masks that TSA employees could wear voluntarily. What were the results of your following up with these airports?

Answer. TSA received 600,000 N–95 respirators/surgical masks in 2007 as part of its pandemic planning stockpile allocation from OHA. In 2008, TSA received another 400,000 N–95 respirators/surgical masks. In 2009, at the request of OHA, a contract for 7 million surgical masks was awarded on May 1, 2009, at the beginning of the H1N1 outbreak. Of that quantity, 1 million was allocated and delivered to the TSA distribution center for allocation among its locations. The sum total of masks and respirators delivered is 2 million. In September 2009, TSA ordered an additional 5.4 million surgical masks. TSA has allocated these items to its personnel as directed by TSA's Acting Administrator.

TSA pre-positioned N–95 respirators at 148 airports and TSA Field Offices. Many of these airports serve as "hubs" in the "hub and spoke family" of airports. A hub may serve 10 or more smaller spoke airports. Airports receiving respirators allotments include locations in all 50 States and Guam, Puerto Rico, and the Virgin Islands. Allotments were distributed by TSA in accordance with the personnel count at each location.

All TSA airports were sent a 14-day supply of PPE. If airports require additional PPE, they can request it and it will be shipped from the TSA warehouse in Springfield, VA. OHA has regular communications with the TSA health and safety department, and TSA has not reported any shortages of respirators or requested additional PPE.

Similar quantities of respiratory protection (masks and respirators) have been issued to CBP and ICE personnel, many of whom also serve in airports around the Nation.

Question 3. What can be done to improve communications and information exchange between the United States, Canada, and Mexico regarding important public

health security issues? What is the role of the Office of Health Affairs' Office of International Affairs and Global Health Security in this regard?

Answer. "Diseases do not honor international borders," is a long-standing public health axiom that has recently been validated yet again in the novel 2009 H1N1 pandemic. The United States, Canada, and Mexico are acutely aware of this principle and have worked together to develop an integrated approach to public health security.

The most visible product of this collaboration is the August 2007 North American Plan for Avian and Pandemic Influenza (NAPAPI), originally developed as part of the Security and Prosperity Partnership, but now continued under the auspices of the North American Leadership Summit (NALS). NAPAPI provides a framework for emergency communications among the three countries. It creates a multi-disciplinary coordinating body with representatives from human and animal health, foreign affairs, and security agencies. This body is charged to meet and communicate regularly on important issues surrounding avian and pandemic influenza.

On October 5, 2009, the DHS Deputy Secretary led a U.S. delegation to a trilateral meeting of the United States, Canada, and Mexico. The purpose of the meeting was to focus on the security issues brought about by the present H1N1 pandemic. The NAPAPI coordinating body was relatively dormant during the change in administrations, and one of the key results of this meeting has been to reinvigorate both the plan and the coordinating body.

The Office of International Affairs and Global Health Security (OGHS) within the Office of Health Affairs (OHA) for DHS maintains an active and vibrant relationship with the DHS attachés, the HHS Liaison Officer, key international contacts within HHS, health officials in DOS, and selected health policy individuals in the governments of Canada and Mexico. During the Spring wave of the pandemic, OGHS gleaned important health information from these various sources and then worked with other resources within OHA to shape this information into a context that assisted our Assistant Secretary in his role of advising the DHS Secretary and the FEMA Administrator. We were able to glean subtle health information and translate that into impacts on aspects such as work absenteeism, critical sector functionality, and impact of community mitigation measures, which proved to be valuable facts for our Secretary and the FEMA Administrator to use in their decision-making process for the domestic emergency response.

Question 4. Which Federal Departments and agencies participating in the National Biosurveillance Integration Center (NBIC) are providing detailees who work at the NBIC on a full-time or part-time basis? How many are working on H1N1 currently?

Answer. The U.S. Department of Agriculture (USDA) is the only Department that continues to provide one full-time equivalent (FTE) detailee to NBIC. The USDA-assigned detailee supports 2009–H1N1 and all other biosurveillance-related taskings on behalf of NBIC and in coordination with USDA. The Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) provided a detailee to NBIC in the past. No HHS/CDC detailee has been provided since March 2009.

Question 5. Are all participating Federal departments and agencies providing surveillance information to the NBIC—on H1N1 and/or other diseases? Which departments and agencies are providing H1N1 information?

Answer. Agencies providing H1N1 information (as well as information on other diseases and events) to NBIC on a non-routine basis are:

- Department of Agriculture;
- Department of Health and Human Services;
- Department of State;
- Department of Defense.

All of the reports provided to NBIC are finished products.

The H1N1 Operational Planning Team (OPT) receives H1N1 information from the following sources:

- Department of Health and Human Services;
- Department of Agriculture;
- Department of State;
- Department of Defense;
- Department of Education;
- Department of Labor;
- Department of Transportation;
- Veterans Affairs;
- Treasury Department;
- American Red Cross.

An NBIC analyst participates in the OPT's daily operations and therefore has access to the information provided directly to the OPT.

- The following agencies are not National Biosurveillance Integration System (NBIS) member agencies. Their data is shared with NBIC via the OPT: Department of Education, Department of Labor, and the Department of Treasury.
- The Department of Transportation (DOT) is an NBIS participant, but does not have a signed NBIC Memorandum of Understanding. DOT data is shared with NBIC via the OPT.
- The following organizations are not NBIS member agencies but may still be data sources of H1N1 biosurveillance related information. If such information is shared with the OPT, the NBIC–OPT analyst has access to that information. These organizations include: The American Red Cross.

Question 6. What do you think can be done right now to improve NBIC performance while the H1N1 pandemic is occurring?

Answer. To improve the performance of the National Biosurveillance Integration Center (NBIC) during the current 2009–H1N1 pandemic, NBIC Member Agencies (NMAs) should expeditiously assign detailees. In addition, NBIC should have unfiltered access to the NMAs' biosurveillance source data and access to appropriate subject matter experts that support 2009–H1N1 analysis. With direct access to such information, NBIC capability to provide cross-domain integrative analysis and critical infrastructure impact assessments would immediately increase.

The following Federal agencies are providing 2009–H1N1 information (as well as on other diseases and events) to NBIC:

- Department of Agriculture;
- Department of Health and Human Services;
- Department of State;
- Department of Defense.

Question 7. What is the current budget of NBIC? What is the budget for fiscal year 2010? How much would you estimate is going towards H1N1 biosurveillance efforts?

Answer. Congress appropriated $8 million for the National Biosurveillance Integration Center (NBIC) in fiscal year 2009, and $8 million for fiscal year 2010. NBIC funding supports a number of 2009–H1N1 efforts, including surge support as well as staffing for the DHS 2009–H1N1 Operational Planning Team. Additionally, NBIC has funded the National Infrastructure Simulation and Analysis Center (NISAC) to conduct modeling of economic and infrastructure impacts of the 2009–H1N1 pandemic.

NBIC estimates costs of on-going 2009–H1N1 biosurveillance efforts for fiscal year 2009 and fiscal year 2010 at $2.0 million.

Question 8. How does the DHS Office of Health Affairs work with the DHS Office of Intelligence and Analysis on public health security issues, including the H1N1 influenza pandemic, if at all?

Answer.

- The Office of Health Affairs (OHA) is actively supporting DHS Office of Intelligence and Analysis (I&A) on the Health and Medical Intelligence/Information Sharing program. OHA has detailed personnel to I&A, provides subject matter expertise, and provides support through a network of health and medical professionals in the public health and health care community.
- I&A works closely with the 72 designated State and large urban area fusion centers and has 60 officers in processing or deployed to these fusion centers, which creates an information-sharing environment that serves stakeholders' information needs and builds interoperability. By partnering with I&A, OHA has been able to leverage those relationships and formulate policies, guidance, and strategies to provide outreach, advisory services, training, and a variety of coordination and education activities. This partnership allows for a maximization of OHA efforts to enhance existing relationships with the health community and promote the appropriate exchange of health security information and intelligence between all homeland security partners. Additionally, OHA has detailed an individual to DHS I&A's State and local program office to develop this program, which emphasizes the strong and effective partnership between OHA and I&A.
- OHA is also partnering with I&A to develop mechanisms to share appropriate WMD and health-related threat information with fusion centers and partners in the health community. The intelligence and analytic products produced by I&A and the National Center for Medical Intelligence (NCMI) are particularly important to fusion centers, State and local law enforcement, and other public safety partners, as well as their public health and health care partners. I&A's Chemical, Biological, Radiological, Nuclear and Health (CBRNH) Branch's

health security team is a founding partner, co-located with the Deputy Director of Homeland Security at NCMI. I&A/CBRNH and NCMI provide individual and co-authored all-source intelligence analysis for medical intelligence threats to the homeland, and are able to disseminate them as appropriate to Homeland Security partners. OHA also embedded an I&A/CBRNH intelligence analyst within OHA's 2009 H1N1 Flu Incident Management Cell (IMC). This afforded OHA senior leadership prompt access to intelligence and analytical products concerning the H1N1 outbreak.

- OHA has worked closely with I&A's CBRNH Branch on the Homeland Security Presidential Directive (HSPD)—21 to fulfill paragraphs 34 and 35. OHA and CBRNH worked collaboratively on HSPD–21 paragraph 34 by producing an unclassified briefing for non-health professionals that outlines public health risks posed by catastrophic health events (including WMD attacks). OHA and CBRNH also worked with HHS on HSPD–21 paragraph 35 to initiate the appropriate step necessary for qualified State and local health officials to obtain security clearances, which will allow them to receive access to classified threat information when applicable.
- To prepare for the start of the 2009–2010 flu season and to address several of the flu vaccine issues currently in the media, OHA and I&A coordinated with each of the I&A deployed regional managers to hold a series of conference calls for officials from across the country—to include law enforcement, emergency services, fusion center directors, and public health. During these regional conference calls, DHS health experts from OHA and I&A's Health Intelligence team provided an update on H1N1 and the Health Security Intelligence Enterprise (HSIE) and Medical Intelligence, and answered local-level questions.

Question 9. Please describe how the NBIC has been obtaining information and data to create its products, including the Biological Common Operating Picture (BCOP)? How is H1N1 addressed in the BCOP?

Answer.

- NBIC collects reported information from a variety of sources using a tool called the Biosurveillance Common Operating Network (BCON). BCON pulls information from open-source media and Government reports that are sent to NBIC.
- After internal evaluation, information is then presented to the interagency at 1300 on a daily basis for review, further conversation, and analysis by subject matter experts from all member agencies.
- After a concurrence is reached on the information, it is then combined into a report by the NBIC analysts and geo-located on the Federal BCOP and the NBIC portal on the Homeland Security Information Network (HSIN). The Federal BCOP is accessible only to NBIC's Federal partners and contains information on H1N1 and other worldwide biological events of interest.
- This process is echoed for the State, local, Tribal, and territorial BCOP, which focuses solely on H1N1 at this time. Each report of significance is posted on the BCOP. This version of the BCOP will be made available to the H1N1 Operational Planning Team (OPT) to post on its HSIN portal to provide information to individuals across the Government as well as to State, local, Tribal, and territorial entities.
- NBIC generates a separate report for each H1N1 item of interest. Examples of past reports include the following:
  - Reports of co-infections with H1N1 and dengue;
  - An overview of H1N1 in the Ukraine;
  - Descriptions of H1N1 mitigation measures;
  - Reports of H1N1 in animals worldwide;
  - Reports of resistance to antiviral drugs.

Question 10. Should mobile hospitals (made of tents, vehicles, or otherwise) be used to help hospitals overwhelmed by H1N1? What advice has the Chief Medical Officer given to the Secretary of Homeland Security and/or the FEMA administrator in this regard?

Answer. Given the nature of a pandemic, the need for surge capacity due to hospital overload could be expected to impact all hospitals in a given region, possibly even at the National level. Planning for hospital surge falls within the jurisdiction of the Department of Health and Human Services (HHS). However, the Chief Medical Officer of DHS provides advice to the Secretary and FEMA administrator on a range of pandemic preparedness and response issues, and keeps DHS leadership informed of health and medical critical infrastructure and key resources impacts.

Many States have purchased mobile field hospital units based upon the scenario of an unanticipated disaster or incident that would require a rapidly assembled platform upon which to care for ill or injured citizens. These field hospitals could provide additional bed space to assist in the relocating of hospital inpatients, especially

those less acutely ill. We have seen some successful deployments of these units scattered around the Nation during this pandemic. Mobile medical units can offer another option, and as they were specifically designed with providing patient care in mind, they are often better suited physically and ergonomically for this function than retrofitting a lecture hall to serve as a patient care area.

Question 11. How will lessons learned that address many areas relevant to H1N1 be identified, collected, recorded, and communicated to the many customers seeking that information? How do you recommend this occur? How will this information be added to the DHS Lessons Learned Information Sharing system, if at all?

Answer. DHS has already recorded lessons learned and is working to implement changes to enhance our pandemic response now and in the future. DHS will collate, report, and record the information using the DHS Lessons Learned Information Sharing system and the H1N1 Common Operating Picture. DHS will work with the National Security Staff, the Department of Health and Human Services, and other departments and agencies to coordinate and encourage participation in the interagency lessons learned effort.

Question 12. How does DHS identify vulnerabilities in the pharmaceutical supply chain? Is the NBIC gathering any information relevant to H1N1-related pharmaceuticals in the supply chain? If not, why not, and how would you go about giving NBIC such a mission?

Answer. The National Biosurveillance Integration Center (NBIC) utilizes reports issued from the Department of Homeland Security (DHS) National Operations Center (NOC), intelligence sources, and open sources that detail existing threats to the Nation's transport, storage, and delivery of pharmaceuticals. Drawing information from these reports, NBIC monitors for signs of distress resulting from the 2009–H1N1 pandemic—including perceived shortages of desired supplies. Although NBIC does not currently have the capability to monitor specific supply chain vulnerabilities, NBIC regularly scans open-source materials and U.S. Government contacts for indirect evidence of pharmaceutical supply chain dysfunction.

The present NBIC mission—to provide early cueing on biological events of National significance—is sufficiently broad to permit NBIC to examine supply chain vulnerabilities in cooperation with DHS component offices, sector-specific agencies and other relevant Government agencies, specifically DHS Office of Infrastructure Protection (IP), and the Departments of Health and Human Services (HHS), Transportation (DOT), Commerce (DOC), and Justice (DOJ). NBIC does not have authority to require agencies to respond to NBIC queries regarding either surveys of vulnerability status or to perceived threats to these vulnerabilities, but this information can be shared on a cooperative request basis. Since the production, transportation, and consumption of pharmaceuticals are all "lagging-indicators" of a bio-related event, NBIC's current resources and capabilities have been more intensely focused on precursor biosurveillance data-streams and indicator analysis. NBIC successfully executes all statutory functions with regards to cross-domain biosurveillance analysis and assessments. Planned improvements to interagency information sharing technology such as the National Biosurveillance Information Sharing Environment (NB–ISE) will span lingering capability gaps that limit NBIC's ability to fully engage with National Biosurveillance Integration System (NBIS) Federal partners and will empower NBIC and NBIS engagement with State, local, Tribal and territorial agencies and entities as well as private sector participants.

IP assesses vulnerabilities in the pharmaceutical and other critical supply chains through the Critical Foreign Dependency Initiative (CFDI). CFDI identifies foreign infrastructure critical to the public health or economic and National security of the United States through an inter-agency process led by DHS, working in close collaboration and coordination with the Department of State, the intelligence community, and public and private infrastructure protection community partners. CFDI is the international component of the Department's larger National Critical Infrastructure Prioritization Program (NCIPP), which identifies and prioritizes nationally and regionally critical infrastructure.

QUESTIONS FROM CHAIRWOMAN YVETTE D. CLARKE FOR NICOLE LURIE, M.D., ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Question 1. In your testimony, you stated that, "investments in the hospital preparedness program have meant that most health care facilities had exercised all hazards plans, including influenza plans." What data do you have to back up this observation?

Answer. Cooperative agreement funding made through the Hospital Preparedness Program (HPP) to State/territory departments of public health to improve surge ca-

pacity and enhance community and hospital preparedness for public health emergencies has improved the ability of participating health care facilities Nationally to conduct drills and exercises, test HPP funded sub-capabilities, and participate in State-wide and regional exercises. We measure their progress every year. Nationally, 4,541 hospitals participated in an exercise or incident during the fiscal year 2007 reporting period, and 3,975 hospitals developed improvement plans based on after-action reports.

Question 2. In your testimony, you stated that you would have to confirm that the U.S. Virgin Islands (USVI) had not been reporting information expressed in the CDC FluView map regarding how widespread the H1N1 disease was because the USVI did not have an epidemiologist that could do such reporting. Have you confirmed this was and/or is the case? Has the CDC provided an epidemiologist of their own to provide such reporting from the USVI? Has that epidemiologist been replaced, and if so, why? What is the long-term plan to help the USVI and other U.S. territories establish and maintain long-term, resident, epidemiological capacity?

Answer. Due to lack of a robust surveillance system in the U.S. Virgin Islands (USVI), it is difficult to collect data that can be loaded into FluView. CDC deployed a public health advisor to the USVI the second week of September and a second epidemiologist was sent the last week in October, and has been reporting since November 16. The staff is expected to stay for 4 to 6 months, or until they have trained others.

USVI has been able to define its current outbreak as "sporadic" and this status was included in FluView, beginning Monday, November 23. USVI also now is able to collect lab-confirmed flu data from St. Croix, which will include both inpatient and outpatient information. It is expected that they will begin reporting on a weekly basis. Until recently, USVI did not have adequate manpower to conduct surveillance activities; they are still limited in what they will be able to accomplish due to manpower and system limitations.

In addition to deploying the epidemiologist and public health advisor, staff from CDC's Influenza Coordination Unit has provided technical assistance to the USVI health department. This technical assistance began prior to the 2009 H1N1 outbreak and will continue after the resolution of the event to ensure that USVI is able to build its surveillance capacity for influenza and other diseases.

Question 3. In your testimony, you stated that you would provide a roll-out plan to the committee regarding N–95 mask delivery throughout the United States, the plan for those that are not slated to receive N–95 masks, whether HHS is recommending another type of/alternative mask, whether other manufacturers are making N–95 masks, information about the National supply of N–95 masks, what masks are in the stockpile and how many, what has been shipped. Please provide this information to the committee.

Answer. On October 19, 2009, the Secretary approved the Strategic National Stockpile Release Strategy for N–95 Respirators. The Strategic National Stockpile (SNS) contacted all 62 project areas to determine each one's desire and readiness to receive its pro rata allocation of 75 percent of the remaining N–95 respirators held in the SNS. Fifty-nine project areas requested their pro rata allocations. Three project areas were not ready to receive their pro rata allocations; SNS will hold their N–95s in inventory. Including the spring deployment for the H1N1 response, SNS has shipped 84.5 million N–95 respirators and has 20 million N–95 respirators remaining in inventory.

The commercial, national supply chain of N–95 respirators is unable to keep up with current demand. Reports received from N–95 manufacturers and distributors indicate that product from current production cycles is committed, and suppliers report significant difficulty filling new orders. As a result, manufacturers and distributors have been forced to implement allocation strategies to attempt to meet new demand. It is unclear at this time if demand for N–95 respirators is due to increased use of products or due to facilities increasing inventory in anticipation of need.

Other classes of disposable respirators (e.g., N–99s, N–100s), which are similar in appearance to N–95s, can be considered for use by health care workers. Alternatives to disposable respirators, such as powered air purifying respirators (PAPRs), or elastomeric half-mask and full face piece respirators, also can be considered, especially in settings such as procedure rooms (e.g. bronchoscopy suites) where higher-risk activities such as aerosol-generating procedures are intermittently performed, and in facilities that have prior experience with these respirators. More information on respiratory protection associated with pandemic H1N1 influenza is available at: *http://www.cdc.gov/h1n1flu/masks.htm.*

To most effectively reach respirator users, CDC's National Institute for Occupational Safety and Health (NIOSH) has developed a web-based clearinghouse of respirator information, in conjunction with the October 14, 2009 release of the CDC

Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel, which is available at *http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm.* The purpose of this web page is to provide NIOSH-verified information to help facilities identify suppliers of respiratory protective equipment and dispel user confusion due to misinformation and lack of knowledge on performance, selection, acquisition and use of various respirator types.

Question 4. What can be done to improve communications and information exchange between the United States, Canada, and Mexico regarding important public health issues such as the H1N1 influenza pandemic?

Answer. The outbreak of novel influenza A/H1N1 in North America in April 2009 provided a real world test of the preparedness work of Canada, Mexico, and the United States, including efforts under the North American Plan for Avian and Pandemic Influenza and the precepts of the revised 2005 International Health Regulations (IHR's). In this regard, rapid information sharing among the trilateral partners occurred early in the event and was maintained. Under the IHR (2005), all countries are obligated to notify the World Health Organization (WHO) of all events that may constitute a public health emergency of international concern (PHEIC), including human influenza caused by a new subtype. A simultaneous notification process has been established, requiring Canada, Mexico, and the United States to simultaneously notify their trilateral partners when they notify the WHO of a potential PHEIC under IHR (2005). All three countries met this obligation during the H1N1 event. In addition to this initial, formal information sharing, the United States hosted conference calls with Canada, Mexico, the Pan American Health Organization (PAHO) and the WHO to exchange epidemiological and other public health information during the H1N1 event.

Currently, we are in the process of establishing an HHS and Inter-Agency Health Working Group under the aegis of the North American Leaders Summit and, as mentioned in my testimony, re-instituting the North American Plan for Avian and Pandemic Influenza (NAPAPI) Coordinating Body. As we continue to strengthen our collaborations against emerging infections with pandemic potential (particularly with H1N1 and other potential novel influenza virus outbreaks), we will be focusing on further enhancing trilateral North American communications and information with our partners in Canada and Mexico by:

(a.) Reviewing existing emergency coordination and communication mechanisms and enhancing the exchange of detailed operations plans;

(b.) Identifying opportunities to exercise trilateral or bilateral pandemic influenza preparedness and response planning to include information-sharing strategies and communication planning that would strengthen the broader emergency response and contingency plans;

(c.) Establishing and testing mechanisms for communication among institutions according to specific functions for exchanging epidemiological information;

(d.) Strengthening operating procedures/processes for the sharing of laboratory information before and during an emergency;

(e.) Establishing public health liaison exchange with Mexico (Note: We already have exchanged public health liaison officers between HHS and the Public Health Agency of Canada); and

(f.) Enhancing information-sharing on stockpile planning.

Additionally, we intend to continue to engage in discussions with Canada and Mexico to enhance trilateral and cross-border communication among agencies and jurisdictions to improve emergency coordination regarding risk communications, public messaging, and health alert notifications.

Question 5. Do you agree that laboratory testing for H1N1 is necessary—that if we had the additional capacity to test more specimens, we should, in order to better characterize the spread of the disease, how it mutates (if at all), etc.?

Testing for 2009 H1N1 is desirable but is not necessary for all specimens if it is known that the strain is circulating in the community. In epidemic or outbreak situations, testing is usually confined to specimens from severe cases or high-risk individuals to determine the best course of treatment. The type of testing done at the State and territorial laboratories only identifies the virus and does not yield information about mutation. Full virus characterization to detect antigenic or genetic variation is only conducted in reference laboratories such as CDC that are equipped to do this sort of high complexity testing. In clinical settings, testing is most important when it changes clinical treatment, such as in hospitalized patients.

Question 6. If you agree that if we had more lab capacity we should use it to test for H1N1, then why are we not using available labs such as the NIH-funded Regional Biocontainment Laboratories and other available labs to test until they, too, are testing at full capacity?

Answer. In addition to the test developed by the CDC, the FDA has issued Emergency Use Authorizations for an additional nine tests for the detection of H1N1, including those developed by the DoD, large clinical reference laboratories, and commercial companies. This greatly increased testing capacity has eased the surge in demand on the CDC and public health laboratories and allowed them to concentrate on surveillance rather than diagnostic testing for H1N1 infection. CDC is in the process of setting up increased testing capacity at the Regional Biocontainment Laboratory located at the University of Texas laboratory in Galveston. In addition, the CDC Dengue Branch in San Juan, Puerto Rico now has now been equipped and trained to do real-time PCR diagnostic testing for influenza, allowing it to serve as a resource in emergency situations for Caribbean Territories and Nations.

Question 7. What can be done now to improve collection, analysis, and reporting of H1N1 biosurveillance information at HHS?

Answer. CDC has a long history of collecting robust data to monitor and understand the spread of influenza. CDC continues to collect, analyze, and report data from various sources. As a result of the 2009 H1N1 pandemic, several new systems or enhancements to existing systems also have been put into place. These include:

- *Enhancing Hospitalization Surveillance*.—CDC has greatly increased the capacity to collect detailed information on patients hospitalized with influenza. Using the 198 hospitals in the Emerging Infections Program (EIP) network and six additional sites with 76 hospitals, CDC monitors a population of 25.6 million to estimate hospitalization rates by age group and monitors the clinical course among persons with severe disease requiring hospitalization. The EIP sites also track vaccine effectiveness.
- *Expanding Testing Capability*.—Within 2½ weeks of first detecting the novel 2009 H1N1 virus, CDC had fully characterized the new virus, disseminated the information to researchers and public health officials, and developed and begun shipping to States a new test to detect cases of 2009 H1N1 infection. CDC continues to support all States and territories with test reagents, equipment, and funds to maintain laboratory staff and ship specimens for testing. In addition, CDC serves as the primary support for public health laboratories around the globe and has provided test reagents to 295 laboratories in 147 countries. It is vital that accurate testing continue in the United States and abroad to monitor any changes in the virus that may indicate increases in severe infection, resistance to antiviral drugs, or a decrease in the match to circulating vaccine strains.
- *Monitoring severe illness and mortality of women who are pregnant*.—Pregnant women are a group known to be at a higher risk for seasonal influenza. Similarly, data indicate that pregnant women also are at higher risk of severe disease and death from the 2009 H1N1 influenza virus. CDC is in the process of implementing a new system to collect data on severe illness (intensive care hospitalization) and mortality among pregnant women, which will improve our ability to monitor this group.
- *Aggregate Hospitalizations and Deaths Reporting Activity (AHDRA)*.—To supplement several well-established influenza surveillance systems, CDC introduced an interim data collection activity to augment information on hospitalizations and deaths in 2009. This supplemental activity collects information from all 50 States to identify hospitalizations and deaths due to influenza or influenza-like-illness (ILI) Nationally and within each State. Jurisdictions now can report to CDC either laboratory-confirmed or clinical pneumonia counts of hospitalizations and deaths. Initiated on September 1, 2009, this new collection activity contributes to a more complete picture of the burden of serious influenza and pneumonia illness and deaths during the pandemic and lets each State examine trends in the course of the pandemic in their areas.
- *Health Care System Readiness*.—HHS is also using multiple systems to track the impact of the 2009 H1N1 pandemic on our health care system. The HHS Assistant Secretary for Preparedness and Response (ASPR) and CDC are in constant communication with State health officers and hospital administrators to monitor stress on the health care system and to be prepared in case Federal medical assets will be necessary to augment State and local surge capabilities. To date, State and local officials have been able to accommodate the increased patient loads, but this is something we need to monitor very closely, and we need to be prepared to respond quickly if the situation warrants.

Question 8. How will lessons learned that address many areas relevant to H1N1 be identified, collected, recorded, and communicated to the many customers seeking that information? How do you recommend this occur?

Answer. ASPR is currently collecting lessons learned and best practices from the entire Department and once collected, will begin processing them through the HHS

Corrective Actions Program (CAP) which will conduct a thorough root cause analysis and identify specific actions necessary to improve response plans and operations. To date, we are in the final stages of an H1N1 reconstruction based on a wide variety of information reporting products (e.g., situation reports, briefings, separate reports and incident action plans) and in-person interviews with HHS personnel who were actively engaged in the initial H1N1 response operation. HHS will write a report that includes a narrative of the reconstruction and an analysis of key issues. We are investigating scope, scale, and feasibility of conducting a formal After-Action Conference with applicable stakeholders that would include State and local representation (currently this is unfunded). At the conclusion of this we will conduct an HHS Corrective Actions Program Working Group to address identified issues and develop an improvement plan. Based upon the outcomes of the work group, we will look to identify best practices and lessons learned that capture expertise and innovation in the H1N1 response and post them to the Federal Emergency Management Agency's (FEMA) Lessons Learned Information Sharing (LLIS) website.

Question 9. In your testimony, you promised to provide to this committee the status of LLIS-Health (which was mandated in the Pandemic All-Hazards Preparedness Act) or use of the capacity of the DHS Lessons Learned Information Sharing system within 30 days of the hearing. What is the status of LLIS-Health or the use of DHS–LLIS capacity?

Answer. Supporting the LLIS-Health/DHS–LLIS capacity, HHS/ASPR has responded to the PAHPA requirements through the following:

The LLIS was established as a vehicle to provide an on-line clearinghouse for best practices related to exercises and events.

- Vast numbers of awardees have supplied promising practices in this area to the Lessons Learned Information Sharing (LLIS) secure portal through DHS.
- HPP has access to LLIS to view awardee submissions.
- While several submissions for health care exist, there is a relative paucity of entries on emergency preparedness, especially from the public health and health care systems perspective.
- Health care is supported on DHS–LLIS with over 20,000 entries.
- Currently there are:
  - 7,720 entries for public health;
  - 1,605 entries for medical surge;
  - 7,851 entries for medical;
  - 1,649 entries for vaccinations.
- Since PAHPA legislation in 2006, up through the present, HPP has been collecting data related to:
  - Exercises/Drills;
  - Corrective Actions/Improvement Plans;
  - Executive Summaries.
- HPP will continue to encourage LLIS submissions:
  - DHS and HHS have been collaborating through the DHS–HHS Coordinating Committee to get AARs for health care loaded into LLIS and allow awardees more access and increase transparency.

Question 10. When did the FDA start addressing the potential for H1N1 antivirals, vaccines, and other related medicines and equipment to be counterfeited and tainted? How did the FDA change its operations to accommodate this particular threat?

Answer. When the H1N1 virus first emerged as a public health threat and the Secretary of Health and Human Services declared a public health emergency at the end of April, FDA immediately put a proactive strategy in place to actively and aggressively target, investigate, and take enforcement action against counterfeit products, as well as products FDA has not approved or cleared, that falsely claim to diagnose, prevent, treat, or cure the H1N1 flu virus. In addition, FDA put measures in place to inform the public about its efforts in this area so that consumers could protect themselves and report suspect products to the agency.

To achieve its objective to combat fraudulent H1N1 products, FDA has, to date:

- Issued more than 80 Warning Letters to more than 85 websites covering about 145 products via the internet with a 48-hour response time. These warnings are the result of frequent internet surfs conducted by staff across FDA's product Centers, the Office of Criminal Investigations (OCI) and the Office of Enforcement (OE).
- Achieved a compliance rate of approximately 80 percent, meaning that the violative H1N1 claims that appeared on the websites have been modified or removed, that the website no longer exists, or that the violative product with fraudulent claims is no longer offered for sale to the public.

- Established a single H1N1 reporting form for the public to report fraudulent products, websites, or suspected criminal activity.
- Posted a searchable database on FDA's website which includes a list of all websites that received Warning Letters and the products covered by those warnings.
- Initiated further investigations for possible civil or criminal enforcement actions when appropriate.
- Analyzed several products purchased over the internet that purported to be anti-viral treatments for the H1N1 flu virus. Worked with Internet Service Providers (ISP) to shut down websites that illegally offered fraudulent H1N1 products for sale to the public. Launched an H1N1 Fraudulent Reporting Widget.
- Conducted numerous interviews with the print, radio, and broadcast media, and issued four press releases, to inform the public about FDA's efforts in this area.

Question 11. What else can and should be done to counter the threat from H1N1-related counterfeit and tainted pharmaceuticals right now?

Answer. FDA remains vigilant in its efforts to counter the threat from H1N1-related counterfeit and fraudulent products and continues to use civil and criminal enforcement and communication as effective tools to protect the public health, achieve credible deterrence and prevent illegal H1N1 products from proliferating throughout the marketplace.

Question 12. How does HHS determine the authenticity and integrity of medicines and medical equipment in the National stockpile?

Answer. The Strategic National Stockpile (SNS) consults with FDA regarding the regulatory status of products proposed for procurement, as well as on issues affecting products currently in the SNS, including storage, labeling, and shelf life. The products in the SNS are manufactured and stockpiled in accordance with current Good Manufacturing Practices. There are quality control procedures in place to ensure that the Division of Strategic National Stockpile's receipt, handling, and storage of drugs, vaccines, and devices meet these defined standard practices.

Question 13. How does HHS identify vulnerabilities in the pharmaceutical supply chain?

Answer. FDA, including its Office of Criminal Investigations (OCI), in collaboration with the Assistant Secretary for Preparedness and Response (ASPR) and CDC, identifies vulnerabilities in the pharmaceutical supply chain through various sources, including information gathered from domestic and international law enforcement partners, industry, consumers, health care professionals and our regulatory counterparts.

Question 14. What impact would the release of large quantities of substandard counterfeit pharmaceuticals (such as substandard antivirals) to the public have during an influenza pandemic when there is not yet enough vaccine available?

Answer. Substandard, counterfeit, or fraudulent products present a significant threat to the public health. They may not prevent the transmission of the virus or offer effective remedies against infection. Likewise, they could give consumers who unknowingly take them a false sense of protection and cause them to delay or fail to seek legitimate medical care. More seriously, they put consumers at an increased risk of suffering life-threatening adverse events from possible dangerous drug interactions or from contaminated, impure, super-potent, or sub-potent ingredients.

Question 15. Once information has been obtained by FDA that counterfeit or tainted pharmaceuticals have been found in the system, how is that information communicated to the public health community? How is this information communicated to other Federal agencies that may be investigating or could come across counterfeit pharmaceuticals in the course of their own investigations or activities?

Answer. FDA uses a variety of communication tools to disseminate important information to the public. These include press releases, consumer updates and many different "List Serves" and "RSS Feeds" through which stakeholders who are interested in specific public health topics can receive timely, regular updates when the agency issues information in their areas of interest.

FDA will also distribute information about counterfeit drugs through the agency's Counterfeit Alert Network (CAN), a network of National organizations, health professionals, consumer groups, and industry representatives. The goal of this network is to disseminate alert messages to a wide audience about specific counterfeit drug incidents in the United States and measures that can be taken to minimize exposure. In the event of a confirmed counterfeit case in the United States, FDA will send an alert to these partners. The agency also will send partners a notice if a counterfeit incident is confirmed elsewhere in the world that could affect U.S. partners.

FDA's Office of Criminal Investigations (OCI) is responsible for liaison contacts with all local, State, and Federal law enforcement agencies on matters related to

FDA-regulated products, including counterfeit, adulterated, or misbranded drugs and vaccines. All questions from law enforcement counterparts concerning fraudulent and/or counterfeit H1N1 countermeasures can be directed to OCI Headquarters for assistance and further investigation.

In addition, FDA has established a single reporting form whereby any member of the public can report suspected fraudulent/counterfeit products or criminal activity associated with H1N1. This form is available at the following link: *http://www.accessdata.fda.gov/scripts/email/oc/oci/flucontact.cfm.*

Question 16. In your testimony, you state that HHS is " . . . in year 3 of a 5-year strategic plan to support the development and large-scale manufacturing of vaccines using some of the newer technologies like cell-based technology and recombinant technologies . . .". Please provide this strategy to the committee.

Answer. The U.S. pandemic preparedness strategy for establishing a domestic manufacturing surge capacity to produce sufficient pandemic vaccine for the entire United States within 6 months of pandemic onset involves an integrated approach utilizing vaccine development and U.S.-based manufacturing facility building. Advanced development of new influenza vaccines using tissue culture, recombinant DNA, and molecular technologies is the foundation for providing more flexible and robust ways to manufacture influenza vaccines. Further advanced development of antigen-sparing technologies for existing and new influenza vaccines using adjuvants provides opportunities to expand the vaccine supply at different points towards the final surge capacity goal. Coupling the enhancement of existing U.S.-based manufacturing facilities that produce egg-based influenza vaccines with the building of new domestic facilities that will manufacture cell-, recombinant-, or molecular-based influenza vaccines is the natural extension of vaccine advanced development that achieves the U.S. pandemic vaccine surge capacity goal.

Question 17. We know egg-based vaccines experience varying levels of ability to grow. How is the need for new technology to develop vaccine being addressed at HHS? What else needs to happen? What else does BARDA need? How much longer do you think it will be before we have better, non-egg-based technology to produce vaccines?

Answer. At the present rate of vaccine development and building of new vaccine manufacturing facilities as described strategically above, the U.S. pandemic preparedness vaccine goal may be reached in 2012. In 2005–06 HHS supported advanced development of six cell-based programs. In 2009 a down selection of contractors was planned due to lack of performance or inconsistency with the manufacturers' business models. Presently, three of the original six contracts remain active and continue to make progress. Two of these vaccines are nearing completion of final clinical testing and are expected to seek U.S. licensure in 2010–11. One of these two companies has started to build a plant for the production of cell-based vaccines here in the United States with assistance from HHS. This facility may be available for vaccine production in less than 2 years in a pandemic emergency. Other cell-based vaccine candidates are earlier in the development pipeline.

In June 2009, HHS made its first award for advanced development of a recombinant vaccine. Recombinant and molecular technologies are not dependent on the ability to grow the virus in an egg or a cell to manufacture vaccine and thus may be available much sooner after pandemic onset. It is projected that this first program will be licensed for use in the United States in 3 years. A second request for proposals (RFP) was released in September 2009 to support additional recombinant and molecular influenza vaccine candidates; multiple proposals were received for review with contract awards expected early in 2010.

In early 2007 HHS made awards for three antigen-sparing technology programs. These technologies reduce the amount of vaccine needed to vaccinate a person and thus increase the total supply. These technologies are in late stage development with H1N1 vaccines and are expected to seek U.S. licensure in 2010.

As part of our efforts to augment existing and nearly completed influenza vaccine manufacturing facilities, HHS plans to issue a RFP in early 2010 to further support construction of a U.S. vaccine manufacturing facility implementing new cell-, recombinant-, or molecular-based technologies. Additionally, we plan to pursue new vaccine production technologies and technologies that expedite the vaccine production and delivery process, such as new and faster ways to measure vaccine potency that will provide better estimates of vaccine production. Together, these programs of advanced development and building domestic manufacturing infrastructure will enable the United States to meet its pandemic preparedness vaccine goals in the next 3 years.

Question 18. How has new information on how the H1N1 vaccine is growing in eggs modified projections of how much vaccine will be available, and by when?

Answer. Prior to the release of materials for vaccine testing, the estimates of vaccine production were based on experience with viruses that grow poorly for vaccine production, like H5N1, and feedback from the manufacturers from alternative assays they were using to gauge the productivity over the summer. After the FDA/CBER released the materials for vaccine testing in mid-August, accurate numbers for what was being produced became available. These results showed the poor growth of the initial virus seeds and therefore reduced the projections for the amount of vaccine that was produced over the summer. Projections for the number of doses that could be available during the early stages of the immunization campaign were reduced to reflect this realization. The manufacturers have now made improvements in their production process for H1N1 vaccine and production is now meeting the initial estimates.

Question 19. Should HHS have told everyone that so much vaccine was going to be available by mid-October? What should HHS have done differently?

Answer. While firmly based in both scientific information from the vaccine manufacturers and experience in making influenza vaccines, the initial projections and statements on the vaccine supply raised public expectations too high. The poor growth of the virus contributed to a 2- to 3-fold reduction in the number of doses received early in the vaccination program. Other unforeseen factors including a prolonged seasonal influenza vaccine manufacturing campaign by 40 days, home countries taking priority for vaccines, and start-up delays in new vaccine production lines caused delays in vaccine availability in October and November 2009.

HHS strives to meet the public's need for transparency and expectations with available facts. HHS has asked manufacturers to publicly disclose their projections, and is posting them on flu.gov.

Question 20. Has influenza vaccine production reached maximum capacity? If so, and the virus mutates, how would the current production apparatus be modified? What would the Nation do for new vaccine? Would the currently produced seasonal and H1N1 vaccines provide any partial immunity?

Answer. All manufacturers are at or near their maximum production capacity for influenza vaccine production.

If the virus were to mutate significantly, a new virus seed would need to be generated and shared with the manufacturers so they could produce a matched vaccine. We would work with manufacturers to dedicate their production and filling lines to this new vaccine. Once this new vaccine was produced and released for use it could be used to immunize the public.

Sera from recently immunized subjects can be studied to see if the seasonal and H1N1 vaccines offer any partial immunity. This should also include sera from clinical studies in which subjects received H1N1 vaccines with adjuvants. Adjuvants are additives that can be added to vaccine to increase the body's immune response and may broaden the immune response to afford protection against related influenza viruses that an unadjuvanted can not or can only partially protect against.

QUESTIONS FROM CHAIRWOMAN YVETTE D. CLARKE FOR RICHARD SERINO, DEPUTY ADMINISTRATOR, FEDERAL EMERGENCY MANAGEMENT ADMINISTRATION, DEPARTMENT OF HOMELAND SECURITY

Question 1. What is the status of updating FEMA Disaster Assistance Policy 9523.17 for Human Influenza? The committee understands that guidance was released in October, but that this guidance does not replace this policy. During the hearing, the committee asked that the updated and clarified policy be communicated to the committee within 30 days of the date of the hearing. Please provide this to the committee within the requisite time frame.

Answer. FEMA is currently in the process of updating FEMA Disaster Assistance Policy 9523.17 for Human Influenza and expects to have it completed as soon as possible; however, appropriate agency and Departmental review is necessary. FEMA has the support of DHS and the administration in this effort.

In the interim, on October 27, 2009, FEMA issued a fact sheet with guidance on the available assistance and guidelines for requesting that assistance. FEMA has shared that document with Congressional Members and staff.

We are working as quickly as possible to finalize the policy, but must ensure agency and Departmental review.

We will issue it as soon as possible, and will ensure the committee receives a copy of the finalized policy.

Question 2. What is the total amount of tentage that FEMA possesses? How much is being used for other emergencies and disasters currently?

Answer. Total—4280.

- Distribution Centers (DCs) within the contiguous United States—0.

- DCs outside the contiguous United States—4,280.
  - DC Pacific-Guam—1,411 (types: Yurts, Disaster Relief Shelters and Catomas).
  - DC Pacific-Hawaii—2,869 (types: Colemans and Catomas).
  - DC Caribbean-Puerto Rico—0.

Recently, 1,300 tents were sent from DCs Pacific to support American Samoa.

Question 3. What is the specific status of the tents in storage in Maryland? How much tentage is resident there? Have any of those tents been used since they were produced and stored during the previous administration?

Answer. FEMA does not have any tents in storage in Maryland. Tents are only stored outside the contiguous United States as previously shown in the answers to prior questions.

Question 4. What do you think of the use of mobile hospitals (made of tents, vehicles, or otherwise) when hospitals are overwhelmed by disease events such as the H1N1 pandemic? How many mobile hospitals does FEMA own?

Answer. The Department of Health and Human Services is the appropriate agency for recommending the protocol, if any for using mobile hospitals.

FEMA has maintained a Federal Medical Contingency Station (FMCS) since January 2007 when the National Disaster Medical System (NDMS) returned to the Department of Health and Human Services. Although FEMA expended resources to manage this medical asset, the FMCS was never used.

There is a Memorandum of Agreement between FEMA's FMCS and the North Carolina Department of Human Services to transfer FEMA's FMCS to North Carolina. FEMA Region IV and the States within that Region have developed a plan to incorporate the FMCS by assigning it to North Carolina, and making it available to other States via the Emergency Management Assistance Compact. North Carolina accepted the FMCS when it was delivered in Spring 2009.

Question 5. How will lessons learned that address many areas relevant to H1N1 be identified, collected, recorded, and communicated to the many customers seeking that information? How do you recommend this occur? How will this information be added to the DHS Lessons Learned Information Sharing system, if at all?

Answer. DHS has already recorded lessons learned and is working to implement changes to enhance our pandemic response now and in the future. DHS will collate, report, and record the information using the DHS Lessons Learned Information Sharing system and the H1N1 Common Operating Picture. DHS will work with the National Security Staff, the Department of Health and Human Services, and other departments and agencies to coordinate and encourage participation in the interagency lessons learned effort.

QUESTIONS FROM CHAIRWOMAN YVETTE D. CLARKE FOR MARCY FORMAN, DIRECTOR, INTELLECTUAL PROPERTY RIGHTS COORDINATION CENTER, DEPARTMENT OF HOMELAND SECURITY

Question 1. In your testimony, you promised to provide to this committee a report regarding Intellectual Property Rights Coordination Center programs to investigate H1N1-related counterfeit pharmaceuticals and equipment—within 30 days of the hearing and monthly thereafter until the pandemic is over. Please provide this information in the requisite time frame.

Answer. The National Intellectual Property Rights Coordination Center provides as an attachment its report (as of November 20, 2009) regarding its operational activities that investigate all counterfeit pharmaceuticals and equipment, including those related to H1N1. Reports will be provided monthly thereafter until the pandemic is over.

[The information follows:]

IPR CENTER REPORT ON H1N1 EFFORTS

Background

This report sets forth the information requested by the U.S. House of Representatives Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, from the National Intellectual Property Rights Coordination Center (IPR Center) during the October 27, 2009, hearing on the topic of "Real-Time Assessment of the Federal Response to Pandemic Influenza." This report was to be submitted within 30 days of the hearing, with additional monthly reports until the pandemic threat is over. The information below is the initial report regarding the IPR Center's programs that investigate H1N1-related counterfeit pharmaceuticals and equipment.

Since the inception of the H1N1 pandemic during the spring of 2009, the IPR Center partner agencies [1] have coordinated three different initiatives to address the threat posed by the potential importation and distribution of counterfeit H1N1 antiviral and vaccine products, as follows:

1. Operation Apothecary.—The IPR Center coordinates monthly surge inspection operations under Operation Apothecary, which targets subjects and organizations utilizing international mail to facilitate the importation and distribution of counterfeit pharmaceuticals. The latest operations have focused directly on counterfeit H1N1 antivirals and vaccines.

2. Undercover Operations.—The IPR Center mobilized the capabilities of its certified undercover operation to identify internet-based websites and individuals involved in the sale of purported anti-viral products (Tamiflu). Purchases of these on-line Tamiflu products were conducted in an undercover capacity to determine their authenticity and identify any health and safety concerns, as well as identify investigative and enforcement targets.

3. Partnership with the Industry.—The IPR Center continues to coordinate with industry partners who are involved in the manufacture of antivirals, such as Tamiflu, to identify all viable leads that may assist in a criminal investigation or interdiction effort.

Monthly Report to Congress

Operation Apothecary:
- Packages Examined—460.
- Antiviral Found—0.
- Counterfeit Antiviral Found—0.

Undercover Operation:
- Counterfeit Antiviral Received—0.

Referrals From Industry:
- Counterfeit Antiviral Leads—0.

Question 2. To what degree and how has ICE been able to measure success in stemming the flow of counterfeit pharmaceuticals?

Answer. Operation Apothecary is an ICE-led interagency health and safety initiative with U.S. Customs and Border Protection (CBP) and the U.S. Food and Drug Administration (FDA) that targets counterfeit pharmaceuticals that are purchased on the internet and imported into the United States via international mail branches and express consignment couriers (e.g. FedEx, UPS, etc.). ICE measures the success of Operation Apothecary through the utilization of metrics designed to track arrests, indictments, convictions, and seizures as a result of reactive and proactive cases initiated. Since inception in 2004, Operation Apothecary has resulted in 1,205 seizures of counterfeit pharmaceuticals valued at more than $2.2 million and initiated 229 investigations that have resulted in 68 arrests, 99 indictments, and 67 convictions.

Operation Guardian is an ICE-led interagency health and safety initiative that targets substandard, tainted, and counterfeit products imported into the United States that pose health and safety risks to the American public. During fiscal year 2009, Operation Guardian generated 394 seizures of harmful products valued at more than $3.3 million and initiated 166 investigations that have resulted in 26 arrests, 22 indictments, and 23 convictions.

In addition, ICE, through the National Intellectual Property Rights Coordination Center (IPR Center), works with various interagency partners engaged in the targeting and interdiction of counterfeit pharmaceuticals including the Federal Bureau of Investigation, CBP, FDA, and U.S. Postal Inspection Service. ICE and its partners collect, analyze, and reconcile data associated with seizures and discoveries at U.S. ports of entry and in locations away from the U.S. border, as well as information from State and local law enforcement and prosecutorial agencies concerning investigations and prosecutions. As an example, the IPR Center leverages criminal enforcement authorities under the jurisdiction of FDA to help ICE, FDA, and CBP in surges under Operation Apothecary and other health and safety investigations involving counterfeit, substandard, and unapproved pharmaceuticals. In these surges, ICE and its partner agencies conduct operations at ports of entry, international mail facilities, and express courier consignment hubs in which they search packages to secure intelligence and investigate leads.

Question 3. Should lessons learned regarding H1N1-related counterfeit pharmaceuticals be identified, recorded, and added to the DHS Lessons Learned Informa-

[1] Partner Agencies: U.S. Immigration and Customs Enforcement; U.S. Customs and Border Protection; Federal Bureau of Investigation; Food and Drug Administration; Department of Commerce; Department of Justice Computer Crime and Intellectual Property Section; U.S. Postal Inspection Service; Mexican Revenue Service.

tion Sharing system or some other system? If the latter, which system? How will these lessons learned be identified, collected, recorded, and communicated to the many customers seeking that information? How do you recommend this occur?

Answer. The ICE-led Intellectual Property Rights Coordination Center (IPR Center) is dedicated to sharing lessons learned through a number of different mechanisms. As a multi-agency effort, the IPR Center oversees and participates in criminal and civil investigations. ICE and the IPR Center utilize a vast network of established law enforcement and regulatory contacts that are involved in criminal enforcement and targeting to further identify, record, and share H1N1-related counterfeit pharmaceuticals information. Although the vast majority of the information received by the IPR Center is deemed law enforcement-sensitive, the IPR Center has also created a mechanism to document and respond to leads provided by private industry and the public.

In addition, the IPR Center also has a robust training and outreach program, focused on domestic and international training initiatives for our law enforcement and regulatory partners. ICE's Outreach and Training Unit at the IPR Center coordinates domestic and foreign training efforts with the U.S. Patent and Trademark Office, the Department of State, the Department of Justice, and the World Customs Organization. This training allows for enhanced information sharing between law enforcement and the private sector.

The information learned regarding counterfeit pharmaceuticals should not be included in the DHS Lessons Learned Information Sharing system as this would not be the best way to share information with other Federal, State, and local agencies in the United States, or with agencies throughout the world. The IPR Center believes it is using the best mechanisms to share information.

Question 4. How does ICE draw upon medical and public health information it might need as it investigates cases involving counterfeit or tainted pharmaceuticals? Is this different than with other types of cases?

Answer. ICE and the IPR Center leverage all available resources to identify appropriate subject matter experts to facilitate and support lines of inquiry and investigation that involve elements of medical and public health information. The IPR Center works with the ICE National Incident Response Unit (NIRU) and other ICE programs to consolidate and share information concerning interdicted and seized counterfeit or tainted pharmaceuticals and their possible impact on the public health. Additionally, the IPR Center utilizes NIRU to facilitate interaction with the Department of Homeland Security's Office of Health Affairs (OHA) and the U.S. Department of Health and Human Services Centers for Disease Control and Prevention.

The efforts that ICE and the IPR Center put forth in leveraging all available resources are recognized in standard operational protocols that the IPR Center utilizes for all investigations.

Question 5. Please explain how the Intellectual Property Rights Coordination Center addresses counterfeit pharmaceuticals, grey market pharmaceuticals, etc. What other resources does the Center need to execute these missions?

Answer. The National Intellectual Property Rights Coordination Center (IPR Center) addresses counterfeit pharmaceuticals in a variety of ways, including the following:

Operation Apothecary.—Operation Apothecary is a health and safety initiative that targets counterfeit pharmaceuticals that are purchased on the internet and imported into the United States via international mail branches and express consignment couriers. Under Operation Apothecary, IPR Center partner agencies conduct monthly surge inspection operations at targeted facilities looking for commercial quantities of counterfeit product. Information is gathered from the surges for use in targeting websites, international shippers, and drop-shippers (individuals who receive large amounts of contraband and distribute it in smaller amounts) operating in the United States.

Leads.—The IPR Center partners with industry and National and international law enforcement counterparts to generate leads targeting subjects, organizations, and networks involved in the manufacture, sale, smuggling, and distribution of counterfeit pharmaceuticals. Upon receipt of viable leads, the IPR Center deconflicts the target information among all partner agencies, coordinating investigative overlap to ensure a focused and effective approach to disrupting and dismantling the criminal activity. The leads are then distributed to the appropriate agency or ICE field office for investigation.

Investigations.—The IPR Center also has the capability to conduct undercover investigations targeting subjects, organizations, and networks that exploit the internet to facilitate the sale of counterfeit pharmaceuticals. Through these efforts, the IPR Center generates and enhances leads for investigative action in the field either by

ICE or partner agencies, or retains viable lead information for investigations. The IPR Center investigates violations and utilizes Department of Justice Computer Crime and Intellectual Property Section attorneys to prosecute cases in the Northern District of Virginia.

Relative to gray market pharmaceuticals, the IPR Center does not conduct enforcement actions to address the importation of these products; however, these products are subject to seizure based on not being approved by the FDA for consumption in the United States. Gray market pharmaceuticals are produced abroad without authorization and payment but are imported into unauthorized markets. In either circumstance, the product does not present a counterfeit, substandard, or tainted threat.

Question 6. When did the Intellectual Property Rights Coordination Center start addressing the potential for H1N1 antivirals, vaccines, and other related medicines and equipment to be counterfeited, tainted, entered into the grey and black markets, etc.? How did the Center change its operations to accommodate this particular threat?

Answer. During Spring 2009, in concurrence with the increased concern over the potential H1N1 pandemic, the National Intellectual Property Rights Coordination Center (IPR Center), in conjunction with our partner agency the Food and Drug Administration—Office of Criminal Investigation (FDA–OCI), initiated efforts to address the potential threat of importation and distribution of counterfeit, tainted, and unapproved H1N1 antivirals, vaccines, and related medicines. The IPR Center mobilized the capabilities of its certified undercover operation to identify internet-based websites and individuals involved in the sale of these violative products. Through these efforts, the IPR Center identified numerous websites offering antivirals through outside of the legitimate pharmaceutical supply chain, in particular Tamiflu. Purchases of these questionable Tamiflu products were conducted in an undercover capacity to determine their authenticity and identify any health and safety concerns.

In addition, the IPR Center and its partner agencies coordinated a surge inspection operation at the JFK International Mail Facility to target counterfeit antivirals. The IPR Center partner agencies reviewed the efforts of their field components to identify any investigations or enforcement actions relating to this area of concern. These surge operations are continuing on a monthly basis to identify the presence of antivirals entering the United States via the mail/express consignment environment. No counterfeit Tamiflu was found during the operation. Additional interdiction and undercover investigative efforts have been made to identify any counterfeit H1N1 vaccines entering the United States, with negative results.

Although there have been no counterfeit antivirals discovered since the emergence of H1N1, there are other products that have been encountered during investigations and surge operations that are frequently confused for counterfeit. These products fall into two primary categories:

Fraudulent.—While there are a significant number of herbal, homeopathic, and other types of substances encountered that purport to treat the effects of or cure influenza, they in fact do not. By claiming to accomplish something they do not, these products are fraudulent in nature, but not counterfeit. As they are unapproved supplements, the assessment, review, and regulation of these products fall under the purview of FDA.

Non-U.S. Licensed ("Gray Market").—Undercover and interdiction activity have resulted in the identification of a significant number of Tamiflu products entering the United States. These products are licensed by Roche, the maker of Tamiflu, for manufacture and consumption outside of the United States. These products are not approved by FDA for consumption in the United States. They are not counterfeit, but are subject to seizure by Customs and Border Patrol based on not being approved by the FDA for consumption in the United States.

Question 7. What else can and should be done to counter the threat of H1N1-related counterfeit pharmaceuticals right now?

Answer. ICE recognizes that increased knowledge via the appropriate and timely dissemination of clear, concise, and accurate information is the strongest most reliable tool in the U.S. Government's arsenal against the threat of H1N1-related counterfeit pharmaceuticals. ICE supports any improvements to processes for National, State, regional, and local dissemination of information about the harm of counterfeit H1N1-related anti-virals and the risks of obtaining pharmaceuticals via unproven or unregulated sources. Public information and increased awareness campaigns have the ability to reach wide audiences quickly, and can have almost immediate impact on consumer decisions.

Question 8. How does ICE identify vulnerabilities in the pharmaceutical supply chain? Is this something that the Intellectual Property Rights Coordination Center should do itself?

Answer. ICE does not monitor or investigate breaches/vulnerabilities of the legitimate pharmaceutical supply chain. The U.S. Food & Drug Administration and the U.S. Drug Enforcement Administration have the authority and the subject matter expertise concerning breaches of legitimate pharmaceutical supply chains. The IPR Center regularly consults with the pharmaceutical industry and other law enforcement agencies in order to identify recent trends in the manufacturing, smuggling, and distribution of counterfeit pharmaceuticals. ICE and the IPR Center, through investigative and interdiction efforts, attempt to identify, disrupt, and dismantle subjects, organizations, and networks that are involved in the smuggling and distribution of counterfeit pharmaceuticals which threaten the health and safety of unsuspecting consumers.

Question 9. Once information has been obtained by ICE that counterfeit, tainted, and/or diverted pharmaceuticals have been found in the system, how is that information communicated to the public health community? How is this information communicated to other Federal agencies that may be investigating or could come across counterfeit, tainted, and/or diverted pharmaceuticals in the course of their own investigations or activities?

Answer. In all ICE investigations of counterfeit, tainted, and/or diverted pharmaceuticals found in the system, including those that result from interdictions at ports of entry, international mail branches, and during or as a result of other law enforcement operations, information is released to the public health community through proper channels with approval from the ICE Office of the Assistant Secretary. Any information that is deemed releasable to the general public is coordinated through the ICE Office of Public Affairs.

Where it becomes necessary for ICE to share information with Federal, State, and local entities, the IPR Center can disseminate information via several established working groups including regularly-scheduled multi-agency operational deconfliction meetings, the ICE-led Operation Guardian Working Group, and established channels of communication through the IPR Center's Outreach and Training Unit. In all instances, information is disseminated in an efficient manner, with recurring dialogue between agencies. Since the IPR Center is a multi-agency effort, many of the primary Federal law enforcement and prosecutorial agencies are on-site and able to immediately receive and share this information.