SUMMARY REPORT
of the
NATIONAL BIODEFENSE SCIENCE BOARD
PUBLIC TELECONFERENCE
August 14, 2009

PARTICIPANTS

National Biodefense Science Board Voting Members

Patricia Quinlisk, M.D., M.P.H, Chair
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John S. Parker, Major General (Retired), M.D.
Andrew T. Pavia, M.D.
Eric A. Rose, M.D.
Patrick J. Scannon, M.D., Ph.D.

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Joseph Annelli, D.V.M., Animal and Plant Health Inspection Service, U.S. Department of Agriculture
Diane Berry, Ph.D., Chief Scientist, Director, Threat Characterization and Countermeasures, Office of Health Affairs, Department of Homeland Security
Bruce Gellin, M.D., M.P.H., Director, National Vaccine Program Office, Office of the Secretary, Office of Public Health and Science, U.S. Department of Health and Human Services
Rosemary Hart, Special Counsel, Office of Legal Counsel, U.S. Department of Justice
Peter Jutro, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency
Carol D. Linden, Ph.D., Principal Deputy Director, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services
Aubrey Miller, M.D., Office of Counterterrorism and Emerging Threats, Office of the Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services (designated by Boris Lushniak, M.D., M.P.H.)
COL. John Skvorak, D.V.M., Ph.D., Commander, U.S. Army Medical Research Institute for Infectious Diseases, U.S. Department of Defense

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Erin Fults, Scientific/Technical Writer
Don Malinowski, M.S. Program Analyst
Jomana Musmar, M.S. Policy Analyst
Brook Stone, M.F.S., LT, U.S.P.H.S., Program Analyst

CALL TO ORDER

CAPT Leigh Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense Science Board (NBSB)

CAPT Sawyer called the public teleconference to order at 12:03 p.m. and called the roll. She noted that the teleconference was convened in order to allow the Board to receive current H1N1 activity updates from the representatives of the U.S. Department of Health and Human Services (HHS) and other HHS Federal Advisory Committees. CAPT Sawyer reviewed the Federal Advisory Committee Act (FACA) rules. NBSB Chair Patricia Quinlisk chaired the meeting.

OPENING REMARKS

Nicole Lurie, M.D., M.S.P.H., Assistant Secretary for Preparedness and Response (ASPR), Rear Admiral, U.S. Public Health Services (USPHS), U.S. Department of Health and Human Services

Dr. Lurie said that since the last meeting of the NBSB, her office has established a very robust H1N1 Task Force with the goal of coordinating issues that touch on H1N1 across agencies. CAPT Clare Helminiak is chairing the task force, subdivided into 4 pillars: surveillance/situational awareness, mitigation measures, medical care, and vaccines. Dr. Lurie said that the NBSB recommendations were taken to the Secretary for consideration, and task orders have been issued accordingly; for example, expediting vaccine production with minimal clinical data. Dr. Lurie also mentioned the recent press indicating the initial challenge faced with developing the potency reagents necessary to standardize the antigen content to formulate vaccine for fill and finish. Several sets of reagents are now being used, and manufacturers will now be able to formulate, fill, and finish their vaccines. Also, as afore mentioned, clinical trials planned for August 1 have begun and are on schedule with sufficient volunteer participation. Dr. Lurie said that the Department has been pleased with the recommendations on disaster mental health and concluded that she was looking forward to the results of the NBSB's discussion today.

AGENDA OVERVIEW AND GOALS

Patricia Quinlisk, M.D., M.P.H., Chair, National Biodefense Science Board

Chair Patty Quinlisk moved directly into introducing the first speaker, Dr. Daniel Jernigan from CDC.

UPDATES FROM U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ON H1N1: H1N1 SITUATIONAL UPDATE

Daniel B. Jernigan, M.D., M.P.H., Deputy Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services

Dr. Jernigan noted that the CDC was no longer presenting case counts on its Web site, but that they were working with state health departments in collecting and reporting the numbers of laboratory-confirmed hospitalizations and deaths. The cumulative numbers of cases are continuing to increase but the overall trend is not rising as it has been in the past. Influenza surveillance indicators for outpatient influenza-like illnesses (ILI) show an increase in the amount of people going to the doctor through the summer above what normally would be expected. Also, the percent of outpatient visits for ILIs decreased

slightly but remain above what is normal for this time of year. Two notable areas that have had increases in ILI clinical visits have been Florida and North Carolina. These areas will be followed up with to determine which subtype of the virus is circulating, and if there are other causes of ILIs that might be driving those numbers up. The overall rates for adult and child hospitalization remain low so far. The proportion of deaths attributed to pneumonia remain within the bounds of what is expected in the summer.

In terms of the virus itself, subtype surveillance demonstrates that 100 percent of specimens characterized at CDC and at state public health labs are the pandemic H1N1 virus. Thus far, CDC has not reported any resistant cases in the United States. As of August 12, the World Health Organization (WHO) reported 177,457 lab-confirmed cases and 1,462 deaths coming out of at least 168 countries. The epidemiologic and clinical characteristics of infections evaluated in the Southern Hemisphere appear to be similar to what has been seen in United States so far.

H1N1 VACCINES

Robin Robinson, Ph.D, Director, Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Dr. Robinson said that the vaccine strategy has three elements: vaccine development, vaccine manufacture, and vaccine administration. The vaccine manufacturers and the National Institutes of Health (NIH) have each started their clinical trials. All five manufacturers have received their seed. The manufacturers have received their potency assay reagents so that now they can start to determine over the next week how much vaccine they have already produced, and that will inform them to start the fill-finish manufacturing of the inactivated subunit vaccines.

Regarding live-attenuated vaccine, the virus grew well and the Department is still anticipating the campaign to begin mid-October. The Department has already purchased 109 million doses from the five manufacturers. Dr. Robinson said the initial estimate of 120 million doses being ready for October has been revised to 45 million doses, with at least 20 million doses being produced for each subsequent week..

There are several reasons why the Department has less doses produced than anticipated: the virus's production yields are less than with seasonal flu; there is a limited number of fill-finish sites; one of the manufacturers, CSL in Australia, had obligations in its home country of manufacture; and one of the manufacturers has had problems finishing one of their strains which has impacted the Department's timelines by four to six weeks. HHS is working with State and local health departments to stay updated.

H1N1 VACCINE PLANNING

Jay Butler, M.D., Program Director, H1N1 Vaccine Task Force, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

In his update, Dr. Butler highlighted four areas: vaccine distribution, assessment of the number of doses administered and coverage, safety monitoring, and communications.

The vaccine will be distributed in a manner similar to federally-purchased vaccines provided through the Vaccines for Children Program. Vaccines from the manufacturers will be shipped to a central distributor who will fill the orders for vaccines. The orders will then be sent to the distributor under the direction of State and Territorial Health Officers. Vaccine record cards will be provided for each recipient by CDC, and the Vaccine Information Sheet (VIS) will be available for download from the Internet.

Regarding monitoring and coverage, Dr. Butler said that the number of doses administered will be tracked for two reasons: 1) to provide a rough estimate of a denominator of persons who are vaccinated in order to evaluate any early reports of adverse events, and 2) to determine the performance of vaccine delivery to specific age groups for whom the vaccine is recommended. The Countermeasures Response Administration (CRA) will be used to track the number of doses administered. The National Immunization Survey (NIS) and the Behavioral Risk Factor Surveillance System (BRFSS) will assess the increases in doses.

The third topic that Dr. Butler addressed was safety monitoring. Several mechanisms will be used to monitor vaccine safety. The Vaccine Adverse Events Reporting System (VAERS) will function as a method of signal detection to collect numerator data on moderate or severe reactions after vaccination. The Vaccine Safety Datalink (VSD) will be used to assess the prevalence of signals detected in vaccinated and unvaccinated persons and compare these rates with expected background rates. VSD is a population-based surveillance using eight participating managed care organizations that represent approximately three percent of the U.S. population. This system is intended to achieve the goal of near real-time surveillance for adverse events. Specific projects are being focused on Guillain-Barre Syndrome surveillance and monitoring using the Emerging Infectious Disease program sites.

The final area that Dr. Butler touched on was communications. The goals of H1N1 communication include providing situational awareness, transparency, engaging partners, setting realistic expectations, enlisting public participation, and discussing implementation and additional concerns. Methods of communication will include print, broadcast, and Web-based media. A journalistic workshop on influenza is also planned to provide the media answers from influenza subject matter experts.

ANTIVIRALS
Robin Robinson, Ph.D
Dr. Robinson said that the Department has taken NBSB's recommendations to look at the investigational antiviral drugs. The Department is discussing and meeting to talk about whether these products could be available and how much would be needed initially for procurement.

Regarding the Strategic National Stockpile (SNS), Dr. Robinson indicated that the Department should have a little over 100 million treatment courses of the antivirals by the fall. States have acquired more than 2 million treatment courses in addition to the 11 million courses that were deployed to them in early May. Manufacturers are working

three shifts a day, seven days a week to provide more treatments that would be available into the New Year.

DIAGNOSTICS
Daniel B. Jernigan, M.D., Ph.D.
Dr. Jernigan followed up on several issues concerning diagnostics. Dr. Jernigan said that the Department is trying to focus the testing of Public Health Laboratories on surveillance testing rather than providing clinical testing capacity. The Department also recognizes that clinical hospital laboratories may also be under-resourced to provide expanded diagnostic capacity. Outside of assays that are either Food and Drug Administration (FDA) 510(k) cleared, or are under an Emergency Use Authorization (EUA), the development of laboratory-developed tests are also likely to be available. An EUA for Focus Technologies' (Quest Laboratories) H1N1 pdm PCR assay will be available through Quest commercial laboratories nationally, and may be distributed to other laboratories. CDC is currently completing validation of swine, and five-target assays on the Roche LightCycler to submit to the FDA for an EUA. Overall, the Department is trying to increase the number of places that can do surveillance and clinical testing.

With regard to rapid tests, it was previously stated that existing rapid diagnostic tests have overall low sensitivity to rule out H1N1 infection in individual patients. Since then, the CDC has published a Morbidity and Mortality Weekly Report (MMWR) about three of the FDA approved rapid influenza diagnostic tests. Three of the largest and most distributed tests were evaluated to being 40 to 69 percent sensitive. In terms of better diagnostic tests, the Department is working with the MesoScale Diagnostics Point of Care Test, which will be used in several Influenza Incidence Sites in the U.S. to better assess age-specific infection rates and the circulation of influenza subtypes.

Dr. Jernigan closed by noting that the Influenza Reagent Resource is still available and that CDC is continuing to provide reagents.

DISCUSSION
Patricia Quinlisk, M.D., M.P.H.
Following Dr. Jernigan's update, Chair Quinlisk called for discussion.

Dr. Pavia asked for the names of the three platforms that were cleared under 510(k), and asked how the CDC will perform "rapid granular surveillance for resistance," and report the data at a faster rate than the previous year. Dr. Jernigan responded that the three platforms were Luminex RVP, Prodesse proFLU, and Verigene Respiratory Virus Nucleic Acid Test. The Biologics Surveillance Network in the U.S. consists of 95 public health laboratories that receive specimens which are tested with the H1N1 primer set. These viral specimens are then sent to the CDC where further resistance testing, including sequencing and functional testing occur. In attempt to increase the capability to detect new antiviruses through functional testing, the CDC has an initiative through the Association of Public Health Laboratories (APHL) and the Public Health Emergency Response (PHER) Grants, where states have the ability to apply for funding to improve

their antiviral resistance testing. Dr. Jernigan added that the CDC has done calculations to try to determine how many viruses are needed in order to detect a certain percentage of change. The CDC has a system where, through sampling, they could adequately detect when there is emerging resistance. Dr. Jernigan noted that a weekly report of antiviral resistance is in the FluView, distributed by e-mail and located on the CDC Web site each Friday. CDC will begin daily reporting once influenza activity increases.

Dr. Rose asked if there was a formal consideration of using the antiviral stockpile for post-exposure prophylaxis. Dr. Gellin responded that the CDC is in the process of revising antiviral guidelines, and that there is going to be a potential period in which vaccine will not be available and antivirals might. CAPT Fiore concurred and added that major emphasis will be on identifying ways people at high risk for complications or the severely ill can have more ready access to treatment. Dr. Robinson said that the Modeling of Infectious Disease Agent Study (MIDAS) group, along with several others in CDC and in BARDA has been looking at different scenarios and different amounts of vaccine being available.

Chair Patty Quinlisk asked if there has been any modeling done on risk benefits, and how does the Department make the decision on how to use the vaccine that becomes available. Dr. Robinson said that the CDC and MIDAS groups are looking at that question regarding schools.

In response to a concern raised by Dr. James regarding supply versus demand of N95s, Dr. Robinson said that members of the staff at BARDA and CDC are working on this topic and that manufacturers are working at full capacity. Dr. Gellin added that the Institute of Medicine (IOM) has been holding a workshop on personal protective equipment for healthcare workers. The group has a report due out in September. Dr. Pavia said that the Healthcare Infection Control Practices Advisory Committee (HICPAC) has recommended modification of the guidelines for personal protective equipment that, if adopted, would lead to a decreased demand for N95s. The IOM discussions are moving in the same direction. Chair Quinlisk asked CAPT Sawyer to forward the IOM report to the NBSB when it becomes available.

ADIVSORY COMMITTEE UPDATES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE (VRBPAC)
Norman Baylor, Ph.D., Director, Office of Vaccines Research and Review, Food and Drug Administration, U.S. Department of Health and Human Services
Dr. Baylor reported that the purpose of the VRBPAC meeting on July 23 was for FDA to present the pathway for licensure of the 2009 H1N1 vaccine. FDA's determination was that the monovalent vaccine against pandemic H1N1 2009 could be licensed as a strain-change supplement. The VRBPAC agreed with the FDA recommendation to license the 2009 H1N1 monovalent vaccine, absent a strain-change supplement, and they also agreed that pregnant women should be immunized with these vaccines. Dr. Baylor said that FDA did not discuss adjuvants in detail at the VRBPAC meeting. No data on adjuvants were presented at the meeting.

NATIONAL VACCINE ADVISORY COMMITTEE (NVAC)
Bruce Gellin, M.D. (Financing), Director, National Vaccine Program Office, Office of Public Health and Science, U.S. Department of Health and Human Services
Dr. Gellin reported that since the Federal government is going to be purchasing all of the doses, the issue of financing revolves around the administration fee. In order to save time, Dr. Gellin suggested that members of the NBSB read the recommendations as they were forwarded to the Assistant Secretary for Health (ASH). Dr. Gellin asked the Board members to keep in mind that the NVAC recommendations were works in progress.

Andrew Pavia, M.D. (Safety Monitoring), Chair, Subcommittee on Safety, NVAC
Dr. Pavia followed Dr. Gellin's report with a brief overview of the NVAC vaccine safety recommendations, which have been forwarded to the ASH and shared with the Secretary as well The first recommendation was to recognize the need for developing, in writing, a comprehensive and detailed plan that outlines agency-wide and government-wide the plan for vaccine safety monitoring. The second recommendation was to strengthen existing systems and to look toward novel systems to be able to evaluate potential vaccine risk. The final recommendation was to consider the development of something resembling the Data Safety and Monitoring Board (DSMB) that would provide a second look at vaccine safety data. This proposed board would provide the epidemiologic, statistical, and vaccine expertise to provide a secondary perspective with an unbiased view of the data.

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Larry K. Pickering, M.D., FAAP
Executive Secretary, Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Dr. Pickering reported that an emergency meeting of the ACIP was held on July 29. The four goals for the meeting were: 1) to review the epidemiology and virology of H1N1, 2) to use scientific data to support guidance on which groups should be focused on the initial vaccine efforts, 3) to provide recommendations on which groups should be prioritized for vaccination, and 4) to provide recommendations that would allow the overall vaccine program to be the most successful.

Anthony Fiore, M.D., M.P.H., CAPT USPHS, Medical Epidemiologist, Influenza Division, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
Following Dr. Pickering's update, CAPT Fiore reviewed the ACIP vaccine priority recommendations. The intent of the ACIP recommendations was to develop a large target-group that exceeded the initial vaccine supply to try to get the vaccine programs up and running. The ACIP took into consideration an experience in 2004 where there was a projected vaccine shortage, and vaccine doses were still being disposed of due to over-prioritizing. The initial large priority groups (~160 million) the ACIP chose included: pregnant women, households that have contact with children less than six months of age, healthcare and emergency personnel, persons aged six months through 24 years, and persons aged 25 to 64 with medical conditions that confer a higher risk of complications.

Since demand and distribution factors are hard to predict, the ACIP developed a narrower focus group in situations where the vaccine supply may be initially very tight; however, if all goes as planned, the smaller prioritization group (~42 million) may never need to be utilized. The final set of recommendations will be published as early as next week.

Lastly, the ACIP is assuming that two doses for the H1N1 vaccine are going to be needed; and did not want vaccinators to keep in reserve the second dose once the first dose was administered per person. They also want to emphasize the use of seasonal vaccine for all the people for whom seasonal vaccine is recommended.

DISCUSSION

Dr. Scannon asked if there were any recommendations relative to the timing of seasonal vaccine versus H1N1. CAPT Fiore said that the recommendations state to administer both vaccines simultaneously. In response to a concern raised by Chair Quinlisk, Dr. Pavia said that there is no intention of making vaccination mandatory for any group.

Dr. Dretchen asked if there was going to be data coming out of the clinical trials that would help elucidate if the second priority group, of those aged 25 to 64, would change, given the wide disparity of the age factor and that those individuals may just need a single dose. CAPT Fiore noted that the CDC is hoping that it will have data available about whether two doses are really needed.

PSYCHOLOGICAL IMPACT OF H1N1

Dan Dodgen, Ph.D., Executive Director, Disaster Mental Health Subcommittee, U.S. Department of Health and Human Services

Dr. Betty Pfefferbaum, Chair of the Disaster Mental Health Subcommittee, spoke about the psychological impact of H1N1. Dr. Pfefferbaum said that when people are exposed to more frequent information about H1N1 in the fall, there will be an increase in anxiety and stress. In the event that flu results in a significant increase in serious illness stress and grief reactions will be widespread and will require psychological and bereavement support. Professionals and caregivers need to prepare now to educate and reassure children and their families on how best to remain healthy and cope if they or their friends become ill.

After Dr. Pfefferbaum's update, Dr. Dodgen spoke about the recent efforts of Disaster Mental Health Subcommittee. In May, the Subcommittee hosted a behavioral health symposium for ASPR staff on disaster mental health strategies to assist both respondents and civilians with coping and remaining resilient in the face of emergency events. Dr. Dodgen said that the Subcommittee has been having conference calls, doing outreach strategies related to migrant workers and immigrant populations, and looking at the specific needs of at-risk populations.

Dr. Flynn from the Subcommittee spoke briefly about risk communication issues. The Subcommittee divided its work on communication into three categories: intervention, education and training, and communications and messaging. The two recommendations that came before the NBSB from the Subcommittee were, 1) to develop a disaster mental

health and behavioral health strategy that talked about the development of mass communication messages to deliver psycho-education, and develop education and training programs regarding the integration of behavioral health and mental health and social principles and risk communication, and 2) the development of an Internet-based toolkit. With respect to special concerns and priorities, Dr. Dodgen emphasized the impact of language, the role of leadership, integration of messaging policy and planning with stakeholders, and addressing specific communications issues for vulnerable populations.

Dr. James recommended that the NBSB work with Dr. Dodgen and the Subcommittee to get some specific material to the Board to provide further guidance to the Disaster Mental Health Subcommittee.

PUBLIC COMMENT AND DISCUSSION

CAPT Sawyer provided the public and the NBSB with a sample of the information that the Department received in advance of the meeting as public comment. CAPT Sawyer said that all of the public comments will be made available to the public as part of the meeting summary.

Gabe Hoffman from Accipiter asked what the procedures were for accessing additional funds for the direct federal stockpile. Mr. Hoffman also asked if when HHS looks at doing EUAs for use as an agent and thinking about antivirals, is it a factor that plays into the Department's decision-making whether it's a different formulation of an already approved agent such as an IV zanamivir versus an IV peramivir which is not currently in production. Chair Quinlisk indicated that the NBSB would need to get back to Mr. Hoffman with an answer.

Martin Shkreli from Elea Capital Management said that he was having a hard time understanding the rationale for stockpiling an investigational intravenous agent or a neuraminidase inhibitor when there are 90 million oral doses stockpiled. Dr. Pavia responded that there are patients with severe illnesses for whom it is difficult to administer oral drugs. Also, people with more severe illnesses need to get higher doses.

Michael Murphy from New World Investor asked why it was taking so long to get through the emergency use authorization process when schools are about to open. Chair Quinlisk indicated that NBSB would need to get back to Mr. Murphy with an answer.

William Rodriguez from the FDA asked if there have been any vaccine studies started with children and when will the public find out if there needs to be a second dose if it's adjuvanted. Dr. Baylor responded that clinical trials will be starting shortly in pediatrics, and that information about a second dose will not be available until 21 days after the first dose.

Bob Koch from the public commented that he has seen very little neighborhood planning as to how neighbors can help neighbors if the worst case scenario should unfold. Mr.

Koch would like to see more activism on the part of government to raise awareness and to assist in neighborhood planning.

Frederick Hayden from the University of Virginia asked what lessons were learned from the late presentation for care and initiation of therapy in terms of the deployment side on the antivirals and treatment of individuals. Regarding timely susceptibility, Mr. Hayden asked what the plans were to try to increase the capacity to make informed decisions in hospitalized patients. Chair Quinlisk said that NBSB would need to get back to Mr. Hayden with answers to his questions.

Deborah Robinson from Robinson Consulting asked if the current teleconference and past teleconferences will be archived so that the public can access them. CAPT Sawyer referred Ms. Robinson to the NBSB's Web site, www.hhs.gov/aspr/omsph/nbsb, and to flu.gov. Flu.gov links to various federal advisory committees providing guidance on H1N1 and other issues dealing with flu.

WRAP UP AND ADJOURN

Chair Quinlisk noted that she would like to solicit comments or suggestions for the Disaster Mental Health Subcommittee and that she and CAPT Sawyer will get back to Dr. Lurie to see if the NBSB can provide specific advice going forward regarding H1N1 and population subgroups.

CAPT Sawyer reminded everyone that there will be a full-day public meeting of the NBSB on September 25 in the D.C. area.

Chair Quinlisk thanked the members of the Board, speakers, and members of the public for their participation. She adjourned the teleconference at 2:03 p.m.

Enclosures—Public comments

-----Original Message-----
From: Jim Cappuccio [mailto:jjcappuccio@yahoo.com]
Sent: Wednesday, August 12, 2009 11:50 AM
To: OS NBSB; Robinson, Robin (HHS/ASPR/BARDA)
Subject: NBSB Public Comment - Emergency Use Authorization for Peramivir

TO: National Biodefense Science Board

RE: Emergency Use Authorization for Peramivir

Dear Members of the Board:

I would like to express my ongoing concern about the H1N1 flu pandemic and what our nation is doing to protect its citizens. As the parent of two young children living near a large city, I remain very concerned about the limited number treatments available to my family.

During the last flu season, my wife was administered Tamiflu as soon as flu symptoms presented in an effort to minimize exposure to our young children. Unfortunately, she was not able to complete the course due to the vomiting side effect and was only able to take the initial dose and a follow up dose. I feel we were very lucky that the strain did not infect my children and we successfully dodged a bullet. However, as the H1N1 pandemic continues to spread, and given there are no assurances the vaccines will be effective (we will get vaccinated regardless), I am very concerned we won't be as lucky this season.

In an effort to make myself aware of all treatment options, from vaccination for prevention to antivirals when symptoms present, I have reviewed the transcript from your June 17, 2009 meeting. I found Dr. Robinson's comments of particular interest, especially as they relate to Tamiflu resistance, lack of any real IV formulations and production limitations:

"And you should know that there is a consideration on the table right now, it's being recommended to the Secretary that we go forward with it, and purchase more Zanamivir, and more pediatric formulations of Tamiflu. The amount of pediatric dosages going forward would give us about 20 percent of the entire federal stockpile would be for children, which would then have us in accord with the population for those ages. And the reason we went with Zanamivir was the previous acknowledgment that the virus had already started to change for H1N1, and then we started to see isolated incidents of resistance to Oseltamivir with these 2009 H1N1 viruses. So, ultimately, we wanted to move from an 80-20 split to a 50-50, and so the next procurement we have will be moving toward that. We will not get there this year, because there's not

enough capacity in production to allow that to happen. So, basically, again we're buying what we'll be able to produce in the United States at this time.

And there's one other thing, there's the consideration for emergency use authorization of at least one drug that's been tested in humans through Phase II clinical trials for severely ill influenza patients. This is a drug called Peramivir. There are clinical studies that will go on for intravenous uses for Phase III of that drug. Also is under consideration whether we should have some of that product available for individuals that are in desperate need. IV forms of Tamiflu and Relenza will be undergoing further Phase I clinical studies, and it's probably unlikely that they will be available at all until late in the season, or maybe even next year, so that's where we are with the antivirals."

In researching the various treatment alternatives I was surprised and relieved to find that Peramivir very recently completed successful Phase III studies in overseas trials. Given the Board understands the great need for an IV antiviral, it would seem that an Emergency Use Authorization would be granted to this medication immediately. Other IV antivirals are barely in Phase I development and as the concern of resistance intensifies there is a great need for Peramivir. In the event of a flu-related hospitalization, and given we are in a pandemic, I simply can not see how this medication can not be made available to the public. Thankfully, my wife's symptoms resolved on their own, but in the event they did not, I would absolutely want Peramivir available.

I urge the members of this committee to have Peramivir made available and stockpiled to protect our families. If ever there was a time for an Emergency Use Authorization, this is it. What possible harm could come from having a successful Phase III drug candidate available to protect us during a pandemic?

Thank you for your consideration of this matter.

From: Jared [jsender72@yahoo.com]
Sent: Friday, August 14, 2009 8:29 AM
To: OS NBSB

Please discuss the options for parenteral antivirals. We now have phase 3 data for peramivir. Would like to know more about the eua process for this agent

Sent from my iPhone

From: Moshe Sadofsky [sadofsky@aecom.yu.edu]
Sent: Friday, 8/14/2009 10:06 AM

I hope todays meeting addresses the issue of Tamiflu resistance arising in influenza H1N1. A broader antiviral stockpile is needed in addition to a vaccine program.

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Moshe Sadofsky, Associate Prof. of Pathology Albert Einstein College of Medicine of Yeshiva University 1300 Morris Park Ave. F-514A Bronx, N.Y. 10461 Ph. 718-430-2222. Fax 718-430-8541. Sadofsky@aecom.yu.edu

From: Jim Cappuccio [jjcappuccio@yahoo.com]
Date: Fri, 14 Aug 2009 2:22 PM
To: “OS NBSB”
Subject: Re: Public comments for August 14, 2009 NBSB Teleconference

Thank you very much. Can you also please provide me with the answers to the unanswered question from the call.

Lastly, are purchases under an EUA done on a "cost plus" pricing or some other measure?

Sent from my Verizon Wireless BlackBerry

From: "OS NBSB"
Date: Fri, 14 Aug 2009 12:22:21 -0400
To: <jjcappuccio@yahoo.com>
Subject: Public comments for August 14, 2009 NBSB Teleconference
Attached are the public comment’s that have been received for today’s National Biodefense Science Board teleconference. The transcript, summary, and any recommendations from today’s meeting will be available at a later date, and I will make sure to send them to you when they become available. Thank you for your interest.

From: Dore Stein [tangentsradio@gmail.com]
Date: Fri, 14 Aug 2009 4:24 PM
To: OS NBSB
Subject: Q&A

Dear Dr. Robinson,

I greatly appreciate that the NBSB cc is made available to the public. As you may know, the public comment Q&A were mostly directly to you, but you had already left the meeting. Most questions went unanswered but the moderator said all the questioners would receive answers to their questions. I believe that the public should also be informed of the answers. I hope that the answers will be added to the transcript.

Thank-you for your essential work.

sincerely,

Dore Stein

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From: Cappuccio, James [mailto:JCappuccio@rbcpt.com]
Sent: Wednesday, August 19, 2009 1:35 PM
To: Ford-Barnes, Arwenthia (HHS/ASPR/OPSP)
Subject: Request for answers from the August 14th meeting

On the August 14th NBSB conference call, several questions were asked, but unable to be answered, as certain panel members had to leave the call early. The moderators indicated that the answers to questions would be provided to each individual at a later date. Can you please let me know if those questions have been answered, and if so, can you please forward me the answers to those questions.

Thank You,

Jim Cappuccio
t) 212-905-5724
jcappuccio@rbcpt.com