



CHICAGO AREA
IMMUNIZATION
CAMPAIGN

THE UPSHOT

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FDA Commissioner's Letter to Healthcare Professionals: Safety of 2009 H1N1 Vaccines:

On November 10th 2009, Dr. Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration, sent a letter to America's healthcare professionals thanking them for their efforts during the 2009 H1N1 influenza outbreak and providing information on the safety of the 2009 H1N1 vaccines. Below is the body of the letter.

Dear Healthcare Professional,

I am writing first to thank you for your extraordinary efforts during the 2009 H1N1 influenza outbreak.

As this new infectious disease sweeps through communities across the country, you must juggle your usual patient care responsibilities with a special role in influenza response. Delays in vaccine delivery and the persistence of myths about vaccination have not made your job any easier. Thank you for rising to this public health challenge. I am also writing to provide information that can be helpful as you talk to patients about the 2009 H1N1 influenza vaccines – the best tools we have to prevent severe illness and death caused by the virus.

As the Commissioner of the U.S. Food and Drug Administration (FDA), I am pleased to have this opportunity to communicate with you directly at this key moment in time. The Department of Health and Human Services is working with influenza vaccine manufacturers and state and local public health officials to make these vaccines widely available. So far, more than 41 million doses of the 2009 H1N1 vaccine have been allocated to the states for distribution across the country, and more is becoming available every day.

Some of your patients may be asking how the FDA, the manufacturers, and the scientific community can have confidence in vaccines that were available just six months after the 2009 H1N1 virus emerged. Understanding more about the manufacturing and approval process for these vaccines should help you to answer their questions.

Every year, FDA and vaccine manufacturers follow a series of steps to make a new influenza vaccine targeted to the three main circulating strains of influenza. These steps have produced effective and very safe vaccines time and again, adding up to hundreds of millions of doses administered in the United States alone.

We followed this same path for the 2009 H1N1 vaccines.

CHICAGO AREA IMMUNIZATION CAMPAIGN

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CDPH Responds to H1N1 Outbreak with Vaccine Clinics and Outreach

Services:

In response to the latest wave of H1N1 in Chicago, as well as the availability of H1N1 vaccine, in November 2009, The Chicago Department of Public Health (CDPH) opened H1N1 Flu Clinics at seven City College locations: Daley, Kennedy King, Olive Harvey, Truman, West Side Tech, Wright and Malcolm X. The clinics ran three days a week until November 21st and then began a Saturday-only schedule until December 19th 2009. The majority of the clinic sites averaged administering 1,200-1,700 dosages per day. As of November 21st 2009, CDPH clinics had administered 85,000 total doses. Two of the clinics located in predominantly African-American communities performed somewhat lower, although, they still quadrupled the number of vaccines that were given at the same sites for seasonal influenza immunization.

Outreach:

CDPH contracted with the Chicago Area Immunization Campaign, Asian Health Coalition, Chicago Hispanic Health Coalition and African American Healthcare Council to educate the communities surrounding the H1N1 clinic sites about H1N1 influenza, the H1N1 vaccine, the availability of the H1N1 vaccine and the priority groups for receiving the vaccine. Community Health Workers canvassed local businesses, social service organizations, churches and community "hot spots" to conduct their outreach.

More Education is Needed:

As stated above, the two H1N1 clinic sites with the lowest demand are located in predominately African American communities. According to the Community Health Workers serving these areas, while some residents were happy to hear about the availability of free H1N1 vaccines, several others expressed concerns such as "more time is needed to make sure the vaccine is safe" or "flu shots give you the flu." The workers heard stories of how people knew of someone getting sick after being vaccinated with the seasonal flu shot. The outreach grants from CDPH assisted in getting the *correct* information surrounding the H1N1 disease and vaccine to community residents. Several residents in areas throughout the city expressed appreciation for receiving the information from community health workers from their communities. Several stated that they would even consider getting the vaccine, after receiving the information.

CDPH has said that they will evaluate the need for future H1N1 clinics at the end of 2009. ■

Sheila Sanders, Project Coordinator, Chicago Area Immunization Campaign

NIS Reports on Teen Immunizations

According to National Immunization Survey -Teen (NIS-Teen) data released in August 2009, immunization coverage rates among teens nationally, are on the rise. In fact, 13-15 year olds nationwide attained the *Healthy People 2010* objective of 90% coverage for two childhood administered vaccines (MMR and Hepatitis B), as well as 90% with a history of varicella disease or receipt of one or more doses of varicella vaccine. Older adolescents, 16 to 18 year olds, attained 90% immune coverage against varicella and more than 80% coverage for the hepatitis B and MMR vaccines. Both Chicago and Illinois exceeded the *Healthy People 2010* goal of 90% for both the varicella and hepatitis B vaccinations and reached more than 80% for the MMR.

Immunization rates for routinely recommended *adolescent* vaccines (Td/Tdap, MCV4/Meningococcal, and HPV4/Human Papillomavirus) slightly increased or remained steady since the last NIS-Teen release. However, the September 18th *MMWR* stated that while vaccine coverage levels "continue to increase nationally, there is substantial variation between state and local areas." Chicago, for example, had the lowest coverage rates on all of the recommended adolescent immunizations when compared to other urban areas. Slightly more than 70% of Chicago adolescents have received either Td or Tdap and less than half of the adolescents in Chicago have received the MCV4. Even worse, only a quarter of adolescent girls in Chicago have received one dose of HPV vaccine. Illinois, as a whole, ranked in the top half for each of the routinely recommended adolescent vaccinations with the exception of the HPV vaccine, in which Illinois ranked among the bottom ten states.

These survey results highlight the importance of the Chicago Area Immunization Campaign's (CAIC) HPV Project, funded through a grant provided by the Otho S.A. Sprague Memorial Institute. Through this program, CAIC disseminates the HPV vaccine to several clinics in Chicago along with providing education on HPV, cervical cancer and cervical cancer prevention. Seven out of the nine clinics in this program substantially exceed the national HPV series completion rates. The Campaign is pleased to report that while funding for this program from the Sprague Institute will be depleted at the end of 2009, the Chicago Department of Public Health (CDPH) has agreed to fund this program through 2010.

The results from the NIS-Teen survey indicate that there is room for improvement concerning adolescent immunizations; especially in regard to the number of adolescent girls immunized against HPV. The Campaign is committed to continuing its efforts in this area and encourages its members to do the same.

The NIS is sponsored by the National Center for Immunizations and Respiratory Diseases (NCIRD) and conducted jointly by NCIRD and the National Center for Health Statistics (NCHS), and Centers for Disease Control and Prevention. The NIS is a list-assisted random-digit-dialing telephone survey followed by a mailed survey to children's immunization providers that began data collection in April 1994 to monitor childhood immunization coverage. ■

Lolita Lopez, MPH, Research Director, Illinois Maternal and Child Health Coalition

Upcoming CAIC Meetings

(Notice will be given if there are any changes.)

Registry Workgroup

Date: Friday, January 29, 2010
Friday, March 26, 2010

Time: 9:30 – 11:30am

Location: Illinois Maternal & Child Health Coalition
1256 W. Chicago Ave.
Chicago, IL

Public Awareness Committee

Date: Tuesday, January 19, 2010
Tuesday, February 16, 2010
Tuesday, March 16, 2010

Time: 10:00 – 11:30am

Location: Illinois Maternal & Child Health Coalition
1256 W. Chicago Ave.
Chicago, IL

CAIC MISSION STATEMENT

The Chicago Area Immunization Campaign is a diverse, community-focused coalition of more than 100 Chicago-Area public and private partners working together to increase immunization rates and prevent disease by promoting the delivery of safe, effective and timely immunizations.

Objectives:

- Identifying and removing barriers to immunization services;
- Identifying strategies to eliminate racial disparities;
- Educating families, health care providers and community members about the importance of timely immunizations and changes in the immunization schedule.
- Raising awareness among policymakers and fostering effective public policies; and
- Coordinating services and sharing information among CAIC members.

FDA Approves New Indication for Gardasil to Prevent Genital Warts in Men and Boys

On October 16th 2009, The U.S. Food and Drug Administration (FDA) approved use of the vaccine Gardasil for the prevention of genital warts due to human papillomavirus (HPV) types 6 and 11 in boys and men, ages 9 through 26.

Each year, about 2 out of every 1,000 men in the United States are newly diagnosed with genital warts.

Gardasil currently is approved for use in girls and women ages 9 through 26 for the prevention of cervical, vulvar and vaginal cancer caused by HPV types 16 and 18; precancerous lesions caused by types 6, 11, 16, and 18; and genital warts caused by types 6 and 11.

HPV is the most common sexually transmitted infection in the United States and most genital warts are caused by HPV infection.

"This vaccine is the first preventive therapy against genital warts in boys and men ages 9 through 26, and, as a result, fewer men will need to undergo treatment for genital warts," said Karen Midthun, M.D., acting director of the FDA's Center for Biologics Evaluation and Research.

Gardasil's effectiveness was studied in a randomized trial of 4,055 males ages 16 through 26 years old. The results showed that in men who were not infected by HPV types 6 and 11 at the start of the study, Gardasil was nearly 90 percent effective in preventing genital warts caused by infection with HPV types 6 and 11.

Studies were conducted to measure the immune response to the vaccine in boys ages 9 through 15. The results showed that the immune response was as good as that found in the 16 through 26 years age group, indicating that the vaccine should have similar effectiveness. The manufacturer will conduct postmarketing studies to obtain additional information on the safety and effectiveness of Gardasil in boys and men.

Gardasil is given as three injections over a 6-month period. Headache, fever and pain at the injection site, itching, redness, swelling and bruising, were the most common side effects observed.

Gardasil is manufactured by Merck and Company Inc. of Whitehouse Station, N.J. ■

For more Gardasil product information go to: www.fda.gov/cber/products/gardasil.htm

Excerpt from an FDA Press Release

FDA Approves New Vaccine for Prevention of Cervical Cancer

On October 16th 2009, the U.S. Food and Drug Administration (FDA) approved Cervarix, a new vaccine to prevent cervical cancer and precancerous lesions caused by human papillomavirus (HPV) types 16 and 18. The vaccine is approved for use in girls and women ages 10 years through 25 years.

Genital HPV infections are the most common sexually-transmitted diseases in the United States, and HPV types 16 and 18 are the cause of about 70 percent of cervical cancers worldwide. There will be an estimated 11,270 new cases and 4,070 deaths from cervical cancer in the United States during 2009, according to the National Cancer Institute at the National Institutes of Health.

"The licensure of Cervarix adds another option in the prevention of cervical cancer" said Karen Midthun, M.D., acting director of the FDA's Center for Biologics Evaluation and Research. "It has the potential to save lives from cervical cancer as well as reduce the need for biopsies and invasive procedures associated with the necessary follow-up from abnormal Pap tests."

The primary clinical study for Cervarix included more than 18,000 women ages 15 years through 25 years in the United States and 11 other countries. Of these women, about 9,000 received Cervarix and 9,000 received Havrix, a licensed hepatitis A virus vaccine, as a control.

The results showed that among women who had not already been infected by HPV types 16 and/or 18 before the start of the study, Cervarix was about 93 percent effective in preventing precancerous cervical lesions caused by these HPV types. Among all Cervarix vaccinees, which included those who tested negative for HPV 16 and/or 18, and those who tested positive at the start of the study, Cervarix was approximately 53 percent effective in preventing precancerous cervical lesions.

Studies also were performed to measure the immune response to Cervarix in girls ages 10 years through 14 years. Their immune response was similar to that of women ages 15 years through 25 years, indicating that the vaccine should have similar effectiveness in the 10 through 14 year age group.

The current data show that Cervarix provides protection for about 6.4 years, but additional information on the length of protection is forthcoming.

No vaccine is 100 percent effective, and Cervarix does not protect against HPV infections that an individual may already have at the time of vaccination, nor does Cervarix necessarily protect against those HPV types not in the vaccine. Therefore, regular Pap tests continue to be recommended for all women who receive Cervarix. Pap screening remains critically important to detect precancerous changes, which would allow treatment before cancer develops.

Cervarix contains the adjuvant ASO4. ASO4 is a combination of aluminum hydroxide and monophosphoryl lipid A (MPL) and is the first vaccine licensed by the FDA that includes MPL as an adjuvant. An adjuvant is a substance incorporated into a vaccine that enhances or directs the immune response of the vaccinated individual.

The safety of the vaccine was evaluated in about 24,000 girls and women, with about 13,000 of these receiving Cervarix. The most commonly reported adverse reactions in the Cervarix group included pain, redness, and swelling at the injection site, fatigue, headache, muscle and joint aches, and gastrointestinal distress.

Although Cervarix is not indicated for pregnant women, the FDA is requiring the manufacturer, GlaxoSmithKline Biologicals to conduct a postmarketing study to assess the safety of Cervarix in pregnant women following vaccination prior to identification of pregnancy. Women who are pregnant, or think that they may be pregnant, or plan to become pregnant during the vaccination course, should not use Cervarix.

Cervarix is administered in three separate shots, with the initial dose being followed by two additional shots at one and six months.

Cervarix is manufactured by GlaxoSmithKline Biologicals, based in the United Kingdom. ■

Excerpt from FDA Press Release

9th National Conference on Immunization and Health Coalitions

**9th National Conference
on Immunization and
Health Coalitions
Strengthening Our Connections
May 26-28, 2010
Chicago, Illinois**

We are pleased to announce that the Chicago Area Immunization Campaign (CAIC) has been chosen to host the 9th National Conference on Immunization and Health Coalitions (NCIHC). The conference will be held at the Westin River North in Chicago from **May 26-28, 2010**. The NCIHC is intended to advance educational and networking opportunities for members of health coalitions and the public health community. The conference brings together doctors, nurses, volunteers, public health, academic, business and non-profit professionals, policy makers, community advocates, students, and health educators. The conference will be an excellent opportunity to facilitate the sharing of successful strategies by coalitions that address immunization and other health issues in order to strengthen their efforts and thereby, improve the health status of our communities.

Confirmed Plenary Speaker

Ari Brown, M.D., FAAP, is a pediatrician, book author, child health advocate, and a mom. Dr. Brown completed a bachelor's degree in child development from the University of Texas at Austin and her general pediatric residency at Harvard Medical School/Boston Children's Hospital. Dr. Brown is Board Certified and is a Fellow of the American Academy of Pediatrics. She works full-time in a private practice in Austin, TX.

Dr. Brown's passion to educate families about children's health led her to co-author the best-selling "411" parenting book series. *Baby 411: Clear Answers and Smart Advice for Your Baby's First Year* and *Toddler 411: Clear Answers and Smart Advice for your Toddler* have sold over 300,000 copies.

She is the pediatric health expert for WebMD and serves on the advisory board for Parents Magazine. She is also a spokeswoman for the American Academy of Pediatrics and has appeared on numerous national news and talk shows including NBC's Today Show, CNN, Dr. Phil, and Rachael Ray.

Registration for NCIHC is now open! Go to <http://www.ilmaternal.org/ncihc2010.html>. Early registration ends on February 12th! For more information please Contact Lilah Handler at 312-491-8161 ext 21 or email her at lhandler@ilmaternal.org.

Sponsorship Opportunities:

Interested in sponsoring or exhibiting at the National Immunization and Health Coalition Conference? Contact Lilah Handler at 312-491-8161 ext 21 or email her at lhandler@ilmaternal.org for more information.



Ari Brown, M.D., FAAP

Call for Abstracts

This conference is intended to advance educational and networking opportunities for members of health coalitions and the public health community at large. NCIHC 2010 will showcase successful ways in which health coalitions can improve immunization protection, prevent disease, improve access to care and health outcomes for underserved populations, reduce racial, ethnic, and geographic health disparities, educate new populations, and build community health infrastructures.

Abstracts are being sought in the following topic areas:

- Coalition roles with state registries; discussion of mandates
- Coalition marketing and media relations: from low-tech to high tech
- Coalition fundraising in lean times
- Provider trainings on your specific health issue
- Government agencies and coalitions: roles, conflicts of interest, opportunities
- Legislative and administrative advocacy campaigns
- Strategic Planning, programmatic efforts and evaluation
- Membership Development
- Non-traditional partnerships/Working with pharmaceutical companies, insurance companies and other business communities: How to create win-win relationships and avoid problems
- Strategies to reach the hard-to reach populations
- How to use volunteers: AmeriCorps, area schools and other resources
- Working with schools
- Working with faith communities
- Using technology (specific programs)
- H1N1 Update
- Risk Communication: Addressing safety issues with the public; how to successfully use science
- Starting a Coalition
- Technology/"E-Tools": Facebook, web pages, blogging, etc.
- An overview of current climate for health care/Prospects for health care reform/New health legislation and what it means/Funding for services and research/Federal Electronic Information System (EIS) Initiatives
- Social marketing of issues
- Collaboration between health coalitions: working together, sharing agendas, non-duplication of efforts
- Addressing racial/ethnic disparities in health outcomes
- Maintaining and nurturing partnership relationships
- Public engagement and coalitions' roles with the general public

Abstracts are welcome from all disciplines such as physicians, nurses, health educators, coalition staff, community-based providers, social workers, program staff, government and non-government agencies, media organizations and anyone with coalition experience.

Abstract applications must be received electronically, no later than February 1, 2010. Please limit to 3 pages and email to: lkritz@ilmaternal.org. For more information, contact Lisa Kritz (312) 491-8161 or lkritz@ilmaternal.org

AMA, AAFP, ACOG and CDC Encourage H1N1 Vaccination for Pregnant Women

The following is a reprint of a November, 2009 "Dear Colleague letter" regarding the importance of immunizing pregnant women against H1N1 from The American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), the American Medical Association (AMA), and the Centers for Disease Control and Prevention (CDC):

The American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), the American Medical Association (AMA), and the Centers for Disease Control and Prevention (CDC) are asking for your help in urging your pregnant patients to get vaccinated against 2009 H1N1 and seasonal influenza.

Increased risk of morbidity and mortality due to 2009 H1N1 and seasonal influenza:

- Pregnant women represent 6% of confirmed 2009 H1N1 influenza deaths in the United States, while only about 1% of the general population is pregnant.
- As of August 21, 2009, 28 pregnant women have died from 2009 H1N1 influenza.
- Pregnant women are also more likely than the general population to become severely ill from seasonal influenza.

Why pregnant women should receive 2009 H1N1 monovalent and seasonal influenza vaccines:

- A study of seasonal influenza vaccine showed that vaccination during pregnancy reduced febrile respiratory illness both in the mothers and infants and reduced lab-confirmed influenza in the infants. There is every reason to believe that the 2009 H1N1 monovalent vaccine will have the same benefits.
- Caregivers of newborns are potential sources of transmission of H1N1 influenza. Women who were not vaccinated during pregnancy should receive the vaccine postpartum to prevent the mothers from getting influenza and then passing it to their infants. Vaccinating everyone who lives with or cares for infants <6 months of age (who are too young to receive the vaccine themselves) is the best way to prevent these children from getting influenza.
- The Advisory Committee on Immunization Practices (ACIP) has recommended that pregnant women receive 2009 H1N1 monovalent and seasonal influenza vaccines.

Safety of 2009 H1N1 monovalent influenza vaccine:

- The safety of the 2009 H1N1 monovalent vaccine is expected to be similar to seasonal influenza vaccine, which has been given to millions of pregnant women.
- 2009 H1N1 monovalent and seasonal influenza vaccines can be given to pregnant women in any trimester and can be given at the same time but in different injection sites.
- Pregnant women should receive inactivated vaccine (flu shot) but should NOT receive the live attenuated vaccine (nasal spray).
- Postpartum women, even if they are breastfeeding, can receive either inactivated vaccine or live attenuated vaccine (nasal spray).
- Although there is no evidence that thimerosal (a mercury containing preservative added to multidose vials to prevent contamination) causes harm, in order to accommodate patient preferences, there will be vaccine available in single-dose preservative-free units. CDC recommends that pregnant women receive influenza vaccine with or without thimerosal.

- As healthcare providers, physicians and their healthcare staff are also a target group designated by the ACIP to receive 2009 H1N1 monovalent and seasonal influenza vaccines to protect themselves as well as their pregnant patients.

How to vaccinate pregnant women:

- Providers interested in obtaining 2009 H1N1 monovalent vaccine should contact their local or state health department. If providers are not offering vaccine, they should be aware of locations in their area where 2009 H1N1 monovalent vaccine will be provided and make this information available to their pregnant patients. Contact information can be found at: <http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm>.
- The U.S. Food and Drug Administration (FDA) has approved the use of a single dose of vaccine for persons >10 years of age.

Please help to protect your pregnant patients against influenza by encouraging them to get the 2009 H1N1 monovalent and seasonal influenza vaccines and addressing their concerns. You are playing a crucial role in helping to prevent influenza in your patients, which can save their lives. More information can be found at: <http://www.cdc.gov/h1n1flu/pregnancy/>.

Sincerely,

Thomas R. Frieden, M.D., M.P.H., Director: Centers for Disease Control and Prevention

Lori J. Heim, M.D., President: American Academy of Family Physicians

Gerald F. Joseph, Jr., M.D., President: American College of Obstetricians and Gynecology

J. James Rohack, M.D., President: American Medical Association ■

FDA Commissioner's Letter (Continued)

Continued from page 1

Making the 2009 H1N1 Vaccine

First, scientists at laboratories in the United States and elsewhere modified the 2009 H1N1 virus into a version suitable to be used as the “seed” for the development of vaccines. The process that was followed is similar in every respect to that which is employed every year for the preparation of seasonal influenza vaccines, as slightly different strains appear regularly each year. For the 2009 H1N1 virus, modified strains suitable for vaccine manufacturing were created and provided to influenza vaccine manufacturers by late May.

Next, companies began manufacturing the 2009 H1N1 vaccines in the same factories where they are licensed to manufacture seasonal influenza vaccines – using the same equipment and the same testing procedures. FDA inspects these plants at least once a year to assure that quality controls are followed at every step in the production process. FDA's oversight covers both those facilities that make the inactivated vaccines (the “flu shot”) and those that make live attenuated viral vaccine (the “nasal spray”).

A critical part of influenza vaccine production is the growth of the vaccine strain in specially produced eggs. After inoculation of the eggs, the virus replicates, creating hundreds of thousands of copies of itself. It is the efficiency of this growth that determines how much vaccine can be produced and how quickly. The material harvested from these eggs is then further processed into the vaccines that you administer to your patients.

As recently as a few years ago, egg shortages would have prevented summertime and fall production of a vaccine against a new strain of influenza. Fortunately, this year, manufacturers could tap into a reserve supply of eggs made by additional flocks of chickens. These flocks were available under contracts put in place for just this purpose – to respond to a possible pandemic.

At the end of July, FDA sought public input. We convened a public meeting of FDA's expert vaccine advisory committee to review the agency's approach to approval of the 2009 H1N1 vaccines. This committee includes scientists, physicians, public health officials and a consumer representative. The committee supported making the vaccines according to the same approach used every year for the seasonal influenza vaccines.

The next step was to develop a tool to accurately measure the amount of vaccine antigen that was being produced. Scientists from the United States, United Kingdom, Australia, Japan, and other nations, working together as part of the World Health Organization, developed the reagents needed to assure the proper amount of antigen goes into each dose of vaccine.

On September 15, after reviewing applications from manufacturers similar to those submitted each year for licensed seasonal vaccine, FDA licensed four vaccines against the 2009 H1N1 influenza virus.

The agency found that all of the appropriate documentation had been submitted, and all of the standards had been met. In fact, had this new virus emerged a few months earlier, it could have been included as one of the three strains in the 2009 seasonal vaccine. In this key respect, although the strain of the 2009 H1N1 virus is new, the 2009 H1N1 influenza vaccines are not.

Over the summer, the National Institutes of Health and vaccine manufacturers initiated clinical trials to determine the dose and number of doses needed to induce an optimal immune response. The good news is that just as for seasonal vaccine, one dose of H1N1 vaccine will likely be protective for healthy adults, the elderly, and older children. For children ages nine and younger, two doses of the H1N1 vaccine will likely be optimal, also similar to seasonal vaccine. No serious adverse events attributable to the vaccine have emerged during the clinical trials, which have so far included over 3600 patients at NIH-supported institutions alone.

Monitoring Vaccine Safety

We are now in a position never before experienced in the history of influenza. Just as a new and serious virus is spreading widely around the country, causing hospitalizations and deaths, a vaccine is becoming available to help prevent infection and protect the public. This accomplishment is the result of the efforts of hundreds of scientists across the world in the private and public sectors. Although a gap still remains between the demand for the vaccine and the currently available supply, this is the first time in history that any vaccine has been available at the time that an influenza pandemic has struck.

We are not cutting any corners. Just as for seasonal influenza vaccine, no lot of the 2009 H1N1 vaccine can be used until it has been carefully evaluated and released as sterile and potent by both the manufacturer and by the FDA.

In addition, the FDA and other agencies are looking for any unexpected, rare, serious adverse events and are quickly investigating concerns. We are also collaborating with our global counterparts to share information and experience. Should any safety concerns arise, we will evaluate them thoroughly and bring them to the public's attention quickly.

I encourage you to report any adverse effects that you believe are linked to any vaccine, including the 2009 H1N1 influenza vaccine, to the Vaccine Adverse Event Reporting System (<http://vaers.hhs.gov/index>). Other resources for 2009 H1N1 influenza, including a detailed description of vaccine safety efforts, are online at www.flu.gov.

It is likely that most families in the United States will be touched by H1N1 influenza this year. Fortunately, many will experience mild illness. Others will endure unspeakable tragedy. The benefits of preventing serious consequences from infection with the 2009 H1N1 influenza virus far outweigh the risks associated with vaccination. All Americans, and especially pregnant women and others at high risk of severe influenza infection, should seriously consider the recommendation for vaccination to help protect themselves and their loved ones.

Thank you for your critical work during this challenging time.

Sincerely,

Margaret A. Hamburg, M.D., Commissioner of Food and Drugs ■

Merck Announced Decision Not To Resume Production of its Monovalent Measles, Mumps and Rubella Vaccines

On October 21st 2009, Merck issued a letter to healthcare providers stating that on the counsel of the Advisory Committee on Immunization Practices (ACIP) and other advisors, the company has decided not to resume production of its monovalent measles, mumps, and rubella vaccines. The combination MMR vaccine is recommended by the ACIP, AAP, and the American Academy of Family Physicians (AAFP), and is preferred over the monovalent vaccines because it eliminates the need for three separate injections and reduces the chance of delays in helping to protect against any of these potentially serious diseases. There is no medical reason to administer the measles, mumps, and rubella antigens separately, and ACIP guidelines do not support this administration. The Centers for Disease Control and Prevention (CDC) has posted more information on this topic on its Vaccines Shortages & Delays website. ■

Information from November, 2009 ICAAP-lets

Support the Illinois Maternal and Child Health Coalition

The Chicago Area Immunization Campaign is a project of the Illinois Maternal and Child Health Coalition (IMCHC). This year, IMCHC celebrates its 21st anniversary of improving the health and well being of Illinois women, children and families.

Please consider the Coalition during its 21st anniversary with a donation to IMCHC. Visit www.ilmaternal.org and click on "Donate Now" to make a secure donation online. You can also contact Kathy Chan at 312-491-8161x24 to inquire about other giving opportunities.

Thank you for supporting a healthier society for women, children and families.



CHICAGO AREA IMMUNIZATION CAMPAIGN

Illinois Maternal & Child Health Coalition

Chicago Area Immunization Campaign
1256 West Chicago Avenue
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Keep Vaccinating Against Seasonal Influenza!

Remember: The 2009 H1N1 influenza vaccine will not protect people against seasonal influenza, and the seasonal influenza vaccine will not protect against H1N1 influenza. If you are wondering if you should continue to vaccinate patients against seasonal influenza despite the release of the H1N1 influenza vaccine, the answer is YES.

The Influenza Vaccine Availability Tracking System (IVATS) provides information about vaccine manufacturers and distributors with vaccine available for purchase. Providers seeking seasonal influenza vaccine that is still available for purchase can access an Excel spreadsheet containing this information at http://www.preventinfluenza.org/ivats/ivats_09_10.xls. ■

Annie Claggett, Project Associate, Chicago Area Immunization Campaign