THE CITY OF NEW YORK
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg
Mayor

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Commissioner

nyc.gov/health

Testimony

Of

Dr. Isaac Weisfuse
Deputy Commissioner for the Division of Disease Control
New York City Department of Health and Mental Hygiene

before the

New York City Council
Committee on Health

On

Avian Flu Preparedness

February 28, 2008

250 Broadway
New York City

Good morning Chairman Rivera and members of the Health Committee. I am Dr. Isaac Weisfuse, Deputy Commissioner for Disease Control at the New York City Department of Health and Mental Hygiene. I last testified on the topic of Avian and Pandemic Flu before the Council on November 17, 2005, and I am here today to update you on our preparations for the possibility of a pandemic flu outbreak.

Let me begin by reminding you that there is a difference between a pandemic flu and annual seasonal flu. A pandemic is a global disease outbreak, that occurs when a new influenza virus emerges for which people have little or no immunity, and has the ability to be easily transmitted from person to person. In a flu pandemic, disease spreads quickly between humans and causes serious illness.

There has been a great deal of publicity about avian or bird flu, also known as the H5N1 virus, which has spread widely among poultry. Nonetheless, there have been relatively few humans infected, though the mortality rate for those infected is extraordinarily high: since 2003, there have been 359 human cases of avian influenza and 226 deaths. None of these cases were in the United States and almost all people infected had been in close contact with poultry. The World Health Organization is monitoring the situation closely and there has been no evidence of any efficient and sustained human-to-human transmission of the virus.

We don't know if avian flu will lead to a pandemic and, as I mentioned, we can't predict whether or when a pandemic will occur. Against this backdrop of uncertainty, we are planning for this possible public health emergency. Some of the highlights of the Department's progress in pandemic preparedness include:

Surveillance: The City has a well tested system for year-round influenza surveillance. Information about the number of cases, who is dying from the flu and how it is being transmitted, will be critical to decision-makers during an emergency. We have enhanced our surveillance system to enable us to better detect should a pandemic arrive in New York. These enhancements include plans to monitor pandemic influenza-related hospitalizations and deaths, and in 2005 adding "novel influenza strain with pandemic potential" to the reportable disease list in our Health Code. In addition, the Department has improved our surveillance for identifying and responding to animal mortality events.

Laboratory Capability: Since I last testified on this topic, the Department has established influenza rapid testing capabilities in our public health laboratories. We bought new equipment and supplies, cross-trained personnel and worked with hospitals on protocols for sample submission. In the past the public health laboratory did not offer influenza testing and had to forward suspect samples to the New York State Wadsworth Laboratory.

Community Mitigation: We've developed materials to inform the public about how to care for sick loved ones at home and we are developing systems to coordinate subsistence support for those in need. We've reached out to businesses to raise awareness of the need for pandemic flu planning and to educate them

about absenteeism challenges they may face. We are also working with the Department of Education to ensure that critical school services continue if schools are closed due to a pandemic, and we are analyzing ways to keep children learning even if they are not in school.

Capacity: Since 2003 we've been working with hospitals on bio-emergency plans, including ensuring the ability of hospitals to expand their capacity to care for large numbers of patients. This work has included DOHMH educating hospital emergency department staff about pandemic response and conducting an influenza drill. In addition, we have been working with EMS, community health centers and nursing homes to strengthen the health care network for pandemic response to address gaps identified through careful data analysis, including building stockpiles of personal protective equipment and ventilators. We have also developed a mass fatality management plan with the Office of the Chief Medical Examiner, which is responsible for that crucial planning.

Antiviral Medication: The use of antiviral drugs can decrease severe complications of influenza and reduce hospitalizations if used early in the course of illness; they can also be used to prevent influenza. The Department has worked closely with the State and federal government to manage and plan for receipt, storage, distribution and use of antiviral drugs for treatment of ill persons. We understand that capacity for production of antiviral drugs is increasing and there is an ongoing, national discussion about the best way to use and distribute the drugs for prevention.

Vaccine Distribution: With current technology, antiviral vaccine will likely not be available until six to nine months after a pandemic is detected. The Department has identified over 300 potential vaccination locations (or Points of Distribution) throughout the City, and we used the influenza vaccine shortages of the 2004-05 and 2005-06 seasons as opportunities to test our plans to distribute vaccine and conduct mass vaccination clinics. Furthermore, we've enhanced our Citywide Immunization Registry computer system, expanding its ability to record pandemic vaccine administration and adverse events.

Mental Health: Throughout our planning, we are also preparing to address the tremendous psychosocial consequences of a pandemic. Our mental health emergency response will use pre-designated community-based and professional agencies to help.

Public Communication: Recognizing the importance of delivering consistent, frequent and dependable communication to the public, the Department's pandemic public communication plan takes advantage of television, radio, internet and the City's 311 system. We invest considerable time and effort to maintain current contact information for the full range of media in New York so that we can utilize every avenue in the case of a pandemic to reach the public and give them information about how to access medical care and other services.

My description of our work is not exhaustive, but it should give you a sense of the breadth of our activities. Many of these projects will serve New Yorkers well in a variety of emergency situations, not just in the event of a pandemic.

A current hot button issue in pandemic response is the use of antiviral drugs. There is ongoing discussion about whether antiviral drugs will only be used for treatment or whether they will be used for prevention as well. Moreover, there is no guarantee that any specific antiviral medication will be the most effective one against the emergent pandemic strain.

The federal government decided to stockpile Tamiflu, an antiviral drug, as well as another drug called Relenza; New York City's share of the federal stockpile will be distributed through the Strategic National Stockpile. In addition, the federal government negotiated an agreement with Roche Pharmaceuticals to make additional Tamiflu available for purchase by state and local governments at a discount rate for the sole purpose of stockpiling for a future pandemic. New York State purchased the New York City allocation of Tamiflu with State funds, and New York City and New York State are in total agreement that those antivirals are to be used by New York City residents and will be stored locally.

Roche Pharmaceuticals, the drug company that manufactures Tamiflu, has been actively promoting the stockpiling of its product by government and the private sector. In fact, the Department met with representatives from the company, who suggested that the City would be politically vulnerable if it did not purchase additional Tamiflu, and implying that we could not trust New York State to provide the City with the drugs they purchased for us. They are marketing aggressively, as is their right, but their interests are not identical with those of public health. Antivirals are just one aspect of pandemic flu preparedness and there is no guarantee that Tamiflu will be the best drug to protect New Yorkers in the event of a pandemic.

The Centers for Disease Control (CDC) reviewed the Department's plans for the health sector and told us that we have no major gaps. This is the highest rating available. Our Strategic National Stockpile plan, which would be the vehicle for antiviral drug distribution, received a score of 97 (out of 100), and the reviewers indicated that our communications and community containment plan have been recommended as a model for other jurisdictions.

Despite this positive feedback from the CDC, we know there is much more to do, and we recently learned that we will have to do it with less. Since 2005, the CDC provided us with a separate stream of pandemic flu funding; we've received a total of $12.7 million over the past three years. The CDC will not be allocating pandemic flu funding to states and localities in 2008, so it will be our challenge to continue to move this work forward without it.

Two and a half years ago, I told you that there is much to learn about pandemic flu and that our plans would have to be flexible. We have learned a great deal in that time, have developed a solid plan, and will continue to refine it. I am happy to answer any questions that you may have at this time.

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STATEMENT OF
NEW YORK STATE ASSEMBLY MEMBER AMY R. PAULIN
TO
THE HEALTH COMMITTEE OF THE COUNCIL OF THE CITY OF NEW YORK
HEARING ON RESOLUTION CALLING UPON THE STATE LEGISLATURE
TO ENACT A.2140/S.1312
February 28, 2008

For the last several years I have sponsored legislation (A.2140/S.1312) to allow licensed pharmacists to administer flu and pneumonia vaccines to adults in New York State. We are one of only ~~four~~ 3 states in the country that does not allow trained pharmacists to administer these vaccines.

Not surprisingly, we have one of the lowest immunization rates in the country and we know that each year between 5,000 and 7,000 New Yorkers die from vaccine-preventable diseases and more than 75,000 New Yorkers are admitted to hospitals due to flu-like symptoms. Yet studies show that when states allow pharmacists to administer vaccines, adult immunization rates improve dramatically and without incident.

Allowing pharmacists to give adults flu and pneumonia vaccines will enable us to increase public awareness of the need for an annual flu shot and expand access to life-saving health care for all New Yorkers, particularly for our most vulnerable such as the elderly and the poor.

Pharmacists are a useful resource in communities, especially for those trying to find a medical home or where, for example, in rural communities and inner city neighborhoods, there may be no physician available. As pharmacies are widely distributed throughout traditionally underserved areas of the State, arming pharmacists with the vaccines may help us reduce the racial and ethnic disparities in immunization rates. Pharmacists will therefore serve as "physician extenders" to provide vaccines to those who may otherwise go without the immunization due to cost, inconvenience or lack of a medical home.

Ensuring access becomes even more critical in the event of a mass emergency such as a flu pandemic. Public health officials have been reported to be urging local and state governments to prepare for such an event because it can result in a large number of people becoming ill at the same time and resulting in the deaths of thousands or even millions. State Health Commissioner Dr. Richard Daines has acknowledged that caring for a large number of patients during a severe pandemic would seriously overburden hospitals throughout the state. According to The Journal News, during a severe Category 5 pandemic, computer models predict that the number of hospital admissions for treatment of influenza would be 770,000 over a six-week period, whereas during an average flu season the number of hospital admissions is approximately 228,000.

In such a health crisis, community pharmacists can play an invaluable role, serving as reliable sources of public health information and advice to the public and supporting other health care providers. Pharmacies are located in urban, suburban and rural settings throughout the state, near population centers of diverse size, and many with extended operating hours. Pharmacies

can also act as a vast storage resource since they are equipped to store refrigerated medications. And because they are staffed by licensed professionals, pharmacies can be used to transmit data from field workers and receive instructions from public health authorities.

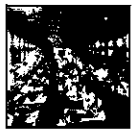
Improving the state's ability to provide preventative care and to meet the health care needs of the 21st century remains one of my top priorities and this bill is an important step toward ensuring the public's health.

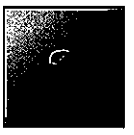
I am pleased that the City Council has come here today to consider a resolution that calls on my colleagues in the Assembly and the Senate to enact my bill. Your formal support will be a forceful voice in Albany and will demonstrate both your recognition of the necessity of providing access to these life-saving vaccines and your commitment to preventative health care to ensure that we keep all New Yorkers healthy and safe.

Overview of Potential Medical Intervention Strategies to Reduce the Impact of the Next Influenza Pandemic

Overview of Pandemic Influenza and H5N1

Influenza Pandemics: 20th Century



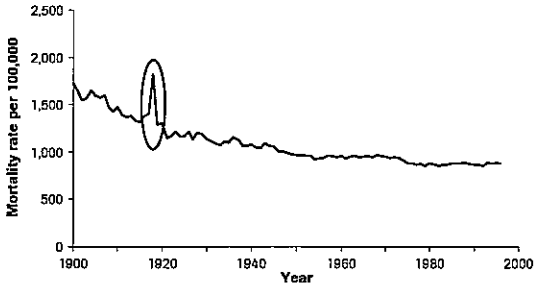



1918 "Spanish Flu"	1957 "Asian Flu"	1968 "Hong Kong Flu"	When? The Next Pandemic
A(H1N1)	A(H2N2)	A(H3N2)	A(H5N1)??
At least 550,000 US deaths	~70,000 US deaths	~34,000 US deaths	?

Shay DK. US Dept of Health & Human Services. NVPO National Vaccine Advisory Committee (NVAC) Pandemic Influenza Working Group. Presentation: Influenza Pandemics of the 20th Century. Washington, DC: April 19, 2005. Available at: http://www.hhs.gov/nvpo/meetings/agenda42005019.html. Accessed October 24, 2006.

Photo credit: US National Museum of Health and Medicine, Washington, DC

20th-Century Influenza Mortality Rates in the US



Adapted from Shay, 2005.

Shay DK. US Dept of Health & Human Services. NVPO National Vaccine Advisory Committee (NVAC) Pandemic Influenza Working Group. Presentation: Influenza Pandemics of the 20th Century. Washington, DC: April 19, 2005. Available at: http://www.hhs.gov/nvpo/meetings/agenda20050419.html. Accessed October 24, 2006.

What Is the Likelihood of Another Influenza Pandemic Occurring?

- Health records indicate at least 10 influenza pandemics over the past 300 years[a]
- The evolution of flu viruses cannot be readily predicted[a]
- WHO asserts that once a virus allows for efficient human-to-human transmission, a pandemic can occur[b]

a. Osterholm MT. Preparing for the next pandemic. *N Engl J Med*. 2005;352:1839-1842.
b. Osterholm MT. Preparing for the next pandemic. *Foreign Affairs*. 2005;84(4). Available at: http://www.foreignaffairs.org/20050701faessay84402/michael-t-osterholm/preparing-for-the-next-pandemic.html. Accessed October 20, 2006.

How Might a Future Flu Pandemic Impact Mortality?

Characteristic	Moderate (1958/68-like)	Severe (1918-like)
Illness	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9,900,000
ICU care	128,750	1,485,000
Mechanical ventilation	64,975	742,500
Deaths	209,000	1,903,000

- Even in a best-case scenario, tens of thousands of people in the US could die and hundreds of thousands would require medical attention
- Extrapolations are problematic because the world of today is a different place from the world of 1918

Osterholm MT. Understanding pandemic influenza in the modern world. Paper presented at: Business Planning for Pandemic Influenza: A National Summit. Center for Infectious Disease Research & Policy (CIDRAP). February 14, 2006. Minneapolis, MN.

Estimated Loss to GDP by State During a Severe Pandemic

State	Percent GDP Loss	Year Based on [illegible] Dollars
Nevada	[illegible]	[illegible]
Hawaii	[illegible]	[illegible]
Alaska	[illegible]	[illegible]
Wyoming	[illegible]	[illegible]
Nebraska	[illegible]	[illegible]
Louisiana	[illegible]	[illegible]
Mississippi	[illegible]	[illegible]
Tennessee	[illegible]	[illegible]
Iowa	[illegible]	[illegible]
Indiana	[illegible]	[illegible]
Kentucky	[illegible]	[illegible]
Montana	[illegible]	[illegible]
Arkansas	[illegible]	[illegible]
Florida	[illegible]	[illegible]
Missouri	[illegible]	[illegible]
North Dakota	[illegible]	[illegible]
South Dakota	[illegible]	[illegible]
West Virginia	[illegible]	[illegible]
Vermont	[illegible]	[illegible]
South Carolina	[illegible]	[illegible]
Illinois	[illegible]	[illegible]
Kansas	[illegible]	[illegible]
Texas	[illegible]	[illegible]
Wisconsin	[illegible]	[illegible]
Oklahoma	[illegible]	[illegible]
Ohio	[illegible]	[illegible]
Arizona	[illegible]	[illegible]
Pennsylvania	[illegible]	[illegible]
Utah	[illegible]	[illegible]
North Carolina	[illegible]	[illegible]
Georgia	[illegible]	[illegible]
Oregon	[illegible]	[illegible]
Alabama	[illegible]	[illegible]
Minnesota	[illegible]	[illegible]
Idaho	[illegible]	[illegible]
New Jersey	[illegible]	[illegible]
New Mexico	[illegible]	[illegible]
Colorado	[illegible]	[illegible]
Michigan	[illegible]	[illegible]
Maine	[illegible]	[illegible]
California	[illegible]	[illegible]
Washington	[illegible]	[illegible]
Delaware	[illegible]	[illegible]
New Hampshire	[illegible]	[illegible]
Rhode Island	[illegible]	[illegible]
Connecticut	[illegible]	[illegible]
Massachusetts	[illegible]	[illegible]
New York	[illegible]	[illegible]
Virginia	[illegible]	[illegible]
Maryland	[illegible]	[illegible]
District of Columbia	[illegible]	[illegible]

Trust for America's Health. Pandemic flu and the potential for US economic recession. Available at http://healthyamericans.org/reports/flurecession/FluRecession.pdf. Accessed March 26, 2007.

CDC Assessment of the Current Status of H5N1

- If H5N1 viruses become efficient and sustained in human transmission, an influenza pandemic could result, with potentially high rates of illness and death
- Little natural immunity to H5N1 pre-exists in humans
- Efforts to produce H5N1 vaccines are underway; however, today's strains are not the pandemic strain
- Once a strain is identified, it will likely require many months before such vaccines could be mass-produced and made widely available

Centers for Disease Control and Prevention. Avian influenza: current situation. Available at: http://www.cdc.gov/flu/avian/outbreaks/current.htm. Accessed October 20, 2006.

Potential Medical Interventions

Vaccinations Are Critical

- The best method of preventing and reducing the impact of the flu on the population is the timely development, distribution and administration of influenza vaccine[a]
- Key target groups include persons at increased risk for complications[b]:
  - Healthcare workers
  - People 50-64 YO
  - Children 6-23 MO
  - Pregnant women
- There is currently no commercially available vaccine to protect humans against the H5N1 avian influenza[c]

a. National Vaccine Program Office. Ongoing influenza defense tactics. US Dept of Health and Human Services Web site. Available at: http://www.hhs.gov/nvpo/pandemics/flua.htm. Accessed October 16, 2006

b. Centers for Disease Control and Prevention. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2005;54(RR-8):1-42.

c. US Dept of Health and Human Services. General information. DHHS Web site. Available at: http://www.pandemicflu.gov/general. Accessed April 13, 2006.

Antivirals Are Recommended as an Important Adjunct to Vaccine

- Neuraminidase inhibitors: TAMIFLU® (oseltamivir); Relenza® (zanamivir)[a]
  - Stop virus proliferation, which decreases duration of illness
  - Effective against influenza A and B
  - Treatment should begin within 48 hrs of onset
- M2 protein / ion channel blockers (amantadine, rimantadine)[b]
  - Acts against hemagglutinin protein in type A virus only[b]
  - Decreases symptoms when begun within 48 hrs of onset[b]
  - Not currently recommended for use (for seasonal influenza) by ACIP* as drug-resistant strains have been found in up to 1/3 of patients[a]

* CDC's Advisory Committee on Immunization Practices.

a. Centers for Disease Control and Prevention. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2006;55(RR-10):1-42.

b. *Physicians' Desk Reference*® 61st ed. Montvale, NJ: Thomson PDR; 2007:1135-1136; 1183-1184.

Strategies for Mitigating a Flu Pandemic through Use of an Antiviral Drug Stockpile

	No intervention	Treatment*	Treatment* + PEP of household contacts	Treatment* + PEP of ALL contacts
Antiviral stockpile required (% of total population)	0	29%	57%	102%
Clinical attack rate (cumulative)	34% US: 102m Ill EU: 204m Ill	32% 96m 192m	22% 66m 132m	13% 39m 78m
Death rate (per 1'000)	6.8	3.2	2.2	1.3
Predicted deaths US EU	693'600 1.38m	307'200 614'400	145'200 290'400	60'700 101'400

Analyses done by Ferguson and Gani

Significant reduction of illness & death (>80%)

* within one day after onset of symptoms

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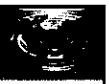
TAMIFLU Activity Against Avian Flu in Animals



- Clinical studies in humans have not been conducted; in vitro and animal data do not necessarily demonstrate clinical activity
- One study in ferrets showed that TAMIFLU administered 4 hours after inoculation prevented viral replication in the upper respiratory tract and effectively treated all infected ferrets with no deaths. All ferrets in the control group died[a]
- One in vivo study in mice tested oseltamivir for protection against avian strains H5N1 and H9N2. The results showed that oseltamivir provided complete protection against the H5N1 virus starting at a dose of 0.1 mg/kg/day and against the H9N2 virus starting at a dose of 1.0 mg/kg/day[b] (Human adult weight ~75kg)

a. New data confirm efficacy of TAMIFLU given early against the current H5N1 avian virus [press release]. Basel, Switzerland: Hoffmann-La Roche Inc.; January 20, 2006. Available at: http:www.roche.com/med-div-2006-01-20.htm. Accessed April 26, 2006.
b. Govorkova EA, Leneva IA, Goloubeva OG, Bush K, Webster RG. Comparison of efficacies of RWJ-270201, zanamivir, and oseltamivir against H5N1, H9N2, and other avian influenza viruses. *Antimicrob Agents Chemother.* 2001;45:2723-2732.

Clinical Experience with Oseltamivir in the Treatment of People Infected with H5N1

- Limited number of confirmed cases; geographically dispersed[a]
- In cases where oseltamivir was administered, vast majority received the drug late[b,c,d]
- Benefit appears greatest when oseltamivir is given early[c,e]
- Survival may correlate with rapid reduction in virus titer[e,f]
- Clinical studies evaluating the efficacy of oseltamivir in the treatment of people infected with H5N1 have not been conducted

a. Center for Infectious Disease Research & Policy (CIDRAP). Laboratory-confirmed human cases of H5N1 avian influenza, December 2003 to present. CIDRAP. Available at: http://www.cidrap.umn.edu/cidrap/content/influenza/avianflu/case-count/avflucount.html. Accessed November 6, 2006.
b. Tran TH, Nguyen TL, Nguyen TD, et al. Avian influenza A (H5N1) in 10 patients in Vietnam. *N Engl J Med.* 2004;350:1179-1188.
c. Chotpitayasunondh T, Ungchusak K, Hanshaoworakul W, et al. Human disease from influenza A (H5N1), Thailand, 2004. *Emerg Infect Dis.* 2005;11:201-209.
d. WHO. Avian influenza A (H5N1) infection in humans. *N Engl J Med.* 2005;353:1374-85.
e. de Jong MD, Tran TT, Truong HK, et al. Oseltamivir resistance during treatment of influenza A (H5N1) infection. *N Engl J Med.* 2005;353:2667-2672.
f. de Jong MD, Simmons CP, Thanh TT, et al. Fatal outcome of human influenza A (H5N1) is associated with high viral load and hypercytokinemia. *Nat Med.* 2006;12:1203-1207.

The Resistance Profile of TAMIFLU

- The majority of patient data for seasonal flu indicate that the incidence of resistant virus is low[a,b]
  - In clinical studies, 1.3% (4/301) of adults and adolescents and 8.4% (9/105) of pediatric patients showed emergence of resistant virus[b]
- As with any antiviral, the theoretical potential exists for an influenza virus to emerge with decreased sensitivity to the drug
- The probability of resistance can be minimized by taking the prescribed dose for the full treatment duration
- Resistance cannot develop unless there is influenza virus present in the individual

a. Roberts NA. Treatment of influenza with neuraminidase inhibitors: virological implications. *Phil Trans R Soc Lond.* 2001;356:1895-1897.
b. Yen H-L, Herlocher LM, Hoffman E, et al. Neuraminidase inhibitor-resistant influenza may differ substantially in fitness and transmissibility. *Antimicrob Agents Chemother.* 2005;49:4075-4084.

WHO Recommendations

Where neuraminidase inhibitors are available

- In May 2006, the WHO published recommendations for the treatment of patients with confirmed or strongly suspected human infection with the H5N1 virus in the current pre-pandemic situation[a]

Treatment

- ✓ TAMIFLU® treatment (strong recommendation)
- ✓ Relenza® as an alternative (weak recommendation)

- Applies to adults (including pregnant women) and children
- Dosage regimen same as for seasonal influenza

a. World Health Organization. WHO Rapid Advice Guidelines on pharmacological management of humans infected with avian influenza A (H5N1) virus. Available at: http://www.who.int/entity/medicines/publications/WHO_PSM_PAR_2006.6.pdf. Accessed November 21, 2006.

WHO Recommendations

Where neuraminidase inhibitors are available

Chemoprophylaxis[a]

- ✓ In high-risk exposure groups, oseltamivir / zanamir (alternative) should be administered (strong recommendation)
- ✓ In moderate-risk exposure groups, oseltamivir / zanamavir might be administered (weak recommendation)

- Continuing for 7–10 days after the last known exposure
- Dosing regimen for H5N1 is as recommended for seasonal influenza

a. World Health Organization. WHO Rapid Advice Guidelines on pharmacological management of humans infected with avian influenza A (H5N1) virus. Available at: http://www.who.int/entity/medicines/publications/WHO_PSM_PAR_2006.6.pdf. Accessed November 21, 2006.

Antiviral Stockpiling

Benefits of Antiviral Stockpiles for Pandemic Preparation

Treatment with antivirals may reduce hospitalizations and deaths

- The WHO has advised that in the absence of vaccines, antiviral drugs will be the only medical intervention for providing both protection against the pandemic strain and therapeutic benefit in people who become infected[a]
- Mathematical modeling work suggests that antiviral stockpiles sufficient to "treat" 20–25% of the population could provide:
  - a 50% - 77% reduction in hospitalizations
  - a 53% reduction in deaths[b]

a. World Health Organization. Avian influenza: assessing the pandemic threat. Available at: http://www.who.int/csr/disease/influenza/H5N1-9redult.pdf. Accessed November 21, 2006.
b. Gani R, et al. Potential impact of antiviral drug use during influenza pandemic. *Emerg Infect Dis.* 2005;11:1355–1362.

Surge Production of Antiviral Agents Is Not an Option for Pandemic Response

- Manufacturing of antiviral agents generally geared towards significantly lower seasonal demand for these products
- Responding to a pandemic with surge production is not an option due to
  - Long timelines for scale up,
  - Sourcing of raw materials and
  - Manufacturing cycle-times
- Contingency planning needs to be in place to cope with the demands of a pandemic
- The WHO has advised that "stockpiling drugs in advance is presently the only way to ensure that sufficient supplies are available at the time of a pandemic"[a]

a. World Health Organization. Avian influenza: assessing the pandemic threat. Available at: http://www.who.int/csr/disease/influenza/H5N1-9redult.pdf. Accessed November 21, 2006.

Roche's Organizational Commitment to Global Pandemic Planning

- Company has been taking steps to prepare for pandemic since 1997
- Multiple donations of antivirals (5.1 million treatment courses) to WHO for regional & rapid use
- Roche is committed partner to US & global health authorities; meeting with US & other governments around the world
- Ramped up production more than 10-fold since '04
- Established multiple supply-chain relationships, sublicenses to improve supply & production

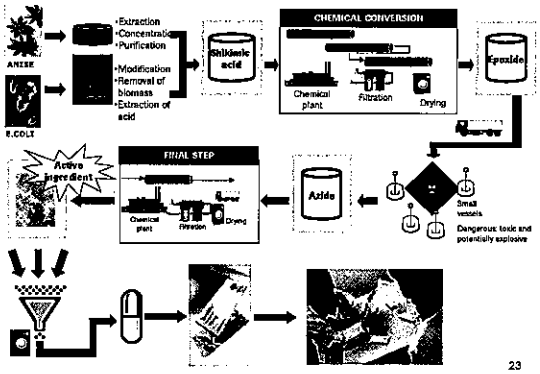
Conference Board Webcast. Pandemic readiness planning at Roche: how a company in the public eye prepares. September 2006. Available at: http://www.conference-board.org/Webcasts/describe_wc.cfm?ID=1218.

TAMIFLU Supply

- Roche achieved the capacity to produce 400 million treatment courses annually at the end of 2006[a]
- Roche has a dedicated supply chain in the US that can produce 80 million treatment courses[a]
- Federal pandemic flu plan calls for the delivery of 81 million doses of antiviral medication by the end of 2008[b]
- Roche prioritizes product in the following order: seasonal influenza demand, government orders, non-governmental orders
- Roche presently has supply to fill state government orders on a first-come, first-served basis

a. TAMIFLU readily available for 2006/2007 influenza season. [press release] Basel, October 2, 2006. Available at: http://www.roche.com/med-cor-2006-10-02. Accessed October 10, 2006.
b. US Dept of Health and Human Services. Pandemic planning update: a report from Secretary Michael O. Leavitt. (March 2006). Available at: http://www.pandemicflu.gov/plan/pdf/panflu20060313.pdf. Accessed October 10, 2006.

The Making of Tamiflu



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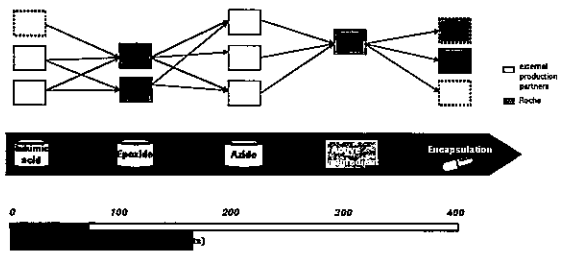
Tamiflu Supply Chain: September 2005 (baseline)



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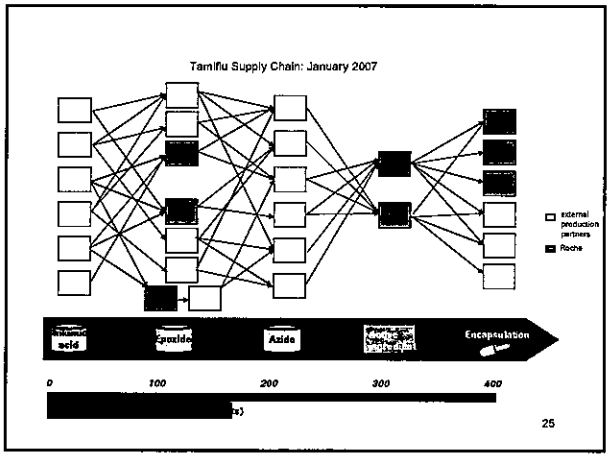

Efficacy and Safety of TAMIFLU

Overview of TAMIFLU

- TAMIFLU is the only prescription antiviral pill indicated to prevent and treat type A and type B influenza in patients one year and older. FDA approval[a]:
  - October 1999 for the treatment of uncomplicated acute illness due to influenza infection in adults[b]
  - November 2000 for the prevention of influenza in adults and adolescents 13 years and older[c]
  - December 2005 the extension of the indication of TAMIFLU to include the prevention of influenza types A and B in children aged 1 through 12 years following close contact with an infected individual[d]
- About 40 million people worldwide have been treated with TAMIFLU*[e]
  - TAMIFLU is approved in more than 80 countries[e]

a. US Food and Drug Administration extends prophylaxis indication for TAMIFLU to children between one to 12 years of age. (press release). December 22, 2005; Basel, Switzerland. Hoffmann-La Roche Inc. Available at: http://www.roche.com/med-cor-2005-12-22b. Accessed October 10, 2006.

b. FDA, Center for Biologics Evaluation and Research Web site. TAMIFLU information page. Available at: http://www.fda.gov/cder/drug/infopage/tamiflu/default.htm. Accessed October 10, 2006.

c. FDA Web site. *FDA Talk Paper*. FDA approves TAMIFLU for another indication—prevention of influenza. Available at: http://www.fda.gov/bbs/topics/ANSWERS/ANS01056.html. Accessed October 10, 2006.

d. FDA Web site. *FDA News*. FDA approves TAMIFLU for prevention of influenza in children under age 12. December 22, 2005. Available at: http://www.fda.gov/bbs/topics/news/2005/NEW01285.html. Accessed October 10, 2006.

e. Roche Pharmaceuticals Web site. Factsheet TAMIFLU (November 2006) Available at: http://www.roche.com/med_mbfstamiflu.pdf. Accessed December 18, 2006.

Indications for TAMIFLU

- Treatment of influenza
  - TAMIFLU is indicated for the treatment of uncomplicated influenza caused by virus types A and B in patients 1 year and older who have had symptoms for no more than 2 days
- Prophylaxis of influenza
  - TAMIFLU is also indicated for the prophylaxis of influenza in patients 1 year and older
  - TAMIFLU is not a substitute for early and annual vaccination as recommended by the CDC's Advisory Committee on Immunization Practices (ACIP)

TAMIFLU® (oseltamivir phosphate) package insert. Nutley, NJ: Roche Laboratories Inc.; November 2006.

TAMIFLU – Treatment

- TAMIFLU significantly reduces duration of influenza[a,b]
- When initiated within 48 hours, TAMIFLU significantly reduced flu duration by 1.3 days (30%) versus placebo ($P<0.001$)[a]
- Symptom relief was defined as the first 24-hour period in which all influenza symptoms were described as mild or none[a]

a. TAMIFLU® (oseltamivir phosphate) package insert. Nutley, NJ: Roche Laboratories Inc.; November 2006.
b. Nicholson KG, Aoki FY, Osterhaus ADME, et al. Efficacy and safety of oseltamivir in treatment of acute influenza: a randomised controlled trial. *Lancet* 2000; 355:1845–1850.

TAMIFLU – Treatment

- Indicated for children and adults (≥1 years of age)
- Treatment should begin within 2 days of symptom onset
- Oral dosing – Adults (≥13 years of age): 75 mg capsule twice daily for 5 days
  - Dose reductions recommended for patients with renal impairment
- Oral dosing – Children (<13 years of age): 30/45/60 or 75 mg (based on weight) twice daily for 5 days
  - Each bottle of oral suspension is supplied with a bottle adapter and oral dispenser

TAMIFLU® (oseltamivir phosphate) package insert. Nutley, NJ: Roche Laboratories Inc.; November 2006.

TAMIFLU – Prophylaxis in Adults

- For postexposure prophylaxis:
  - 75 mg capsule once daily for 10 days
  - Administration should begin within 2 days of exposure to an infected close contact during a seasonal outbreak
- For seasonal prophylaxis:
  - 75 mg capsule once daily during a seasonal outbreak for up to 6 weeks
  - Adverse events were qualitatively very similar to those seen in the treatment studies, despite a longer duration of dosing
  - Duration of protection lasts for as long as dosing is continued

TAMIFLU® (oseltamivir phosphate) package insert. Nutley, NJ: Roche Laboratories Inc.; November 2006.

TAMIFLU – Pediatric Postexposure Prophylaxis

- Oral dosing: 30/45/60/or 75 mg (based on weight) once daily for 10 days
- The safety and efficacy of TAMIFLU for prophylaxis of influenza in pediatric patients younger than 1 year of age has not been established
- Prophylaxis in patients 1 to 12 years of age has not been evaluated longer than 10 days' duration
- Prophylaxis therapy should begin within 2 days of exposure

TAMIFLU® (oseltamivir phosphate) package insert. Nutley, NJ: Roche Laboratories Inc.; November 2006.

TAMIFLU Shelf Life and Storage

- Product shelf life is 5 years[a]
- TAMIFLU capsules are supplied for state government pandemic stockpiles in bottles of 10 (NDC 0004-0800-06)[b]
  - They are 75 mg grey/light yellow hard gelatin capsules. "Roche" is printed in blue ink on the grey body, and "75 mg" is printed in blue ink on the light yellow cap[b]
- TAMIFLU capsules must be stored at 25° Celsius (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)[b]
- Storage of TAMIFLU must adhere to storage guidelines of United States Pharmacopeia (USP)[b]

a. The Threat of and Planning for Pandemic Flu: Hearings Before the Subcommittee on Health of the House Committee on Energy and Commerce, 109th Cong. 1st Sess. (2005) (statement of Dominick A. Iacuzio, Ph.D. Medical Director, Hoffmann-La Roche Inc.)
b. TAMIFLU® (oseltamivir phosphate) package insert. Nutley, NJ: Roche Laboratories Inc.; November 2006.

Important Safety Information for TAMIFLU® (oseltamivir phosphate)

- Treatment
  - Adult patients: (≥1%): nausea, vomiting and other events (bronchitis, insomnia and vertigo) reported more frequently compared with placebo
  - Pediatric patients (1-12 yo): (≥1%): vomiting and other events (abdominal pain, epistaxis, ear disorder, conjunctivitis)
  - Self-injury and delirium reported, mostly from Japan, and primarily among pediatric patients
    - TAMIFLU's contribution to these events is unknown
    - Patients should be monitored throughout treatment period
- Prophylaxis
  - Adult patients: (≥1%): nausea, vomiting, diarrhea, abdominal pain, dizziness, headache, insomnia. AEs similar to treatment
  - Pediatric patients (1-12 yo): (≥1%): AEs consistent with treatment studies; GI most frequent

Refer to the complete Prescribing Information for these products before prescribing.

TAMIFLU® (oseltamivir phosphate) package insert. Nutley, NJ: Roche Laboratories Inc.; November 2006.

Important Safety Information for TAMIFLU® (oseltamivir phosphate), cont'd

- No evidence for efficacy of TAMIFLU in any other illness than influenza A and B
- Patients should be 1 year and older; symptomatic for no more than 2 days
- TAMIFLU is not a substitute for vaccination; early, annual vaccination is recommended
- Treatment efficacy in high-risk patients not established (chronic cardiac, respiratory disease)
  - No differences in incidence of complications between treatment and placebo groups in this population
- Safety and efficacy of repeated treatment of prophylaxis courses not studied
- Rare cases of anaphylaxis and serious skin reactions, including toxic epidermal necrolysis, Stevens-Johnson syndrome and erythema multiforme, have been reported post-marketing
- Concurrent use of TAMIFLU with live attenuated influenza vaccine (LAIV) intranasal has not been evaluated
  - LAIV should not be administered 2 weeks prior or 48 hours after TAMIFLU administration
  - Trivalent inactivated influenza vaccine can be administered any time relative to the use of TAMIFLU

Refer to the complete Prescribing Information for these products before prescribing.

TAMIFLU® (oseltamivir phosphate) package insert. Nutley, NJ: Roche Laboratories Inc.; November 2006.

Roche

AMERICAN LUNG ASSOCIATION®
of the City of New York, Inc.

Testimony of
American Lung Association of the City of New York
Regarding
Res. No. 1231 regarding Enactment of A.2140 / S.1312 Pharmacists as Immunizers

February 28, 2008

Good afternoon. My name is Sheetal Bhatia, Program Manager for the American Lung Association of the City of New York.

For more than 100 years, the American Lung Association of the City of New York has worked to prevent lung disease and promote lung health among the residents of the five boroughs. In that regard, on behalf of the organization, I am pleased to provide the following testimony in support of Res. No. 1231, a resolution calling upon the State Legislature to enact A.2140 / S.1312, an act to amend the education law in relation to allowing immunizing agents to be administered to adults by pharmacists.

Influenza, more commonly known as "the flu," is a serious infectious disease that spreads easily from person to person, primarily when an infected individual coughs or sneezes. Influenza can be transmitted even before symptoms appear and for many days after the symptoms begin. Typical influenza symptoms include abrupt onset of high fever, muscle and joint pain, chills, a dry cough, headache, runny nose, and a sore throat. Often, in early stages, these symptoms are confused with that of a cold, and the severity of the illness is underestimated.

Each year, an estimated 2.6 million New Yorkers get the flu, causing illness and even death in certain high-risk populations, such as adults and children with heart, kidney and lung conditions, including asthma. The impact cannot be overstated. Annually, the flu causes 192 million days spent in bed, 70 million lost working days and 346 million days of restricted activity. Nationally, an average of 36,000 people die from the flu and its complications. Here in NYC, flu and pneumonia are the third leading cause of death.

The truth is, the majority of these deaths are preventable. The best tool against getting the flu is the flu shot. A yearly influenza vaccination is up to 92 percent effective in preventing influenza and reducing the severity of the influenza. Even in years when the vaccine does not cover the specific influenza strain circulating among the population, it offers cross-protection to other strains of the flu, thereby reducing severity and burden of illness. Although mild side effects including soreness at injection site are possible, a person cannot get influenza from the vaccine.

However, despite longstanding immunization recommendations for people with chronic lung diseases like asthma, only 40 percent of these adults and 10 percent of these children are actually immunized. This leaves the vast majority of people with asthma at increased risk for serious complications and illness from influenza infection.

~ more ~

We applaud the Council for keeping pressure on our New York State legislators to pass legislation, which would give pharmacists the ability to provide flu and pneumonia immunizations. Allowing pharmacists to immunize is quickly becoming the standard of care in this country, but sadly New York lags behind as one of only three states nationwide that do not allow pharmacists to administer vaccinations.

Allowing pharmacists to vaccinate results in higher influenza vaccination rates: 18 to 64 year olds are 27% more likely to be vaccinated and those over 65 are 22% more likely to be vaccinated for flu in states that allowed pharmacists to provide vaccinations than in states where pharmacists were not allowed to vaccinate. Influenza vaccination rates among those over age 65 also grew at triple the rate in states that passed legislation that allowed pharmacists to provide vaccinations (10.7% increase) compared with states that did not (3.5% increase).

Pharmacists offer a natural entry point for targeting those who are at high-risk for influenza and its complications. People at elevated risk – for example, those with chronic conditions– regularly see their pharmacist to refill their prescriptions, providing an opportunity for flu vaccination. Further, pharmacists are now required to receive doctoral level training, which includes course work in physiology, pharmacology, drug administration, drug interactions, and patient management. These critical skills make them strong candidates for providing immunizations. In addition, considering the growing international concern of widespread flu disease, pharmacists' ability to administer vaccine would be vital additional resource in the event of a health emergency, such as a pandemic influenza outbreak.

As a safe and cost-effective way to prevent illness and save lives, vaccinations must be as widely available as possible. Enabling pharmacists to administer flu and pneumonia immunizations is an effective way to prevent these respiratory diseases and drastically increase the amount of people who receive influenza immunizations. Resolution Number 1231, calling on the State Legislature to enact A.2140 / S.1312 is a common-sense solution to increased immunization rates and a healthier New York City and New York State.

The American Lung Association of the City of New York is pleased to work with the New York City Council, and our elected leadership to ensure that we increase immunizations, decrease the incidence of influenza and allow New York City residents to breathe easier.

Thank you.

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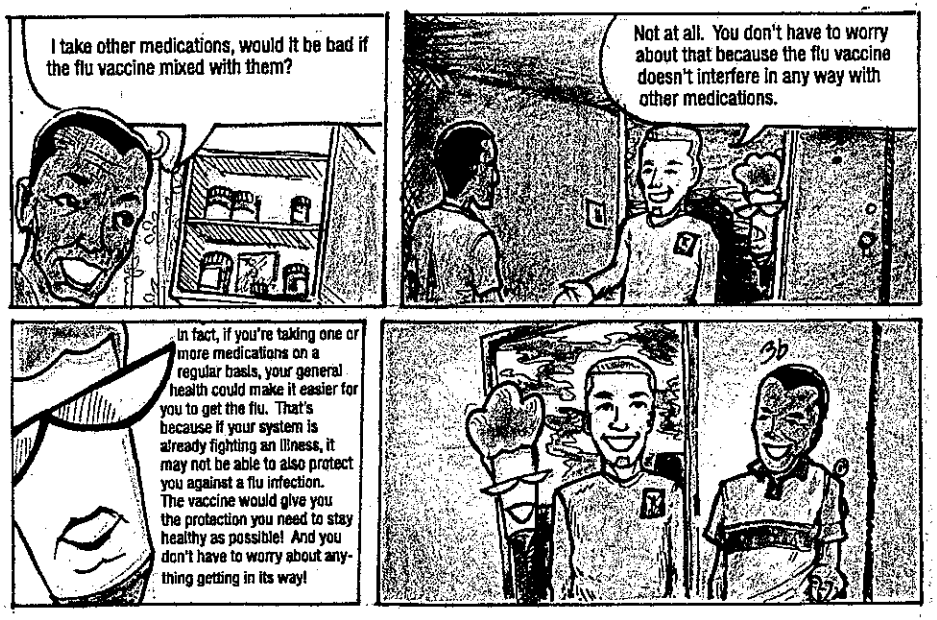
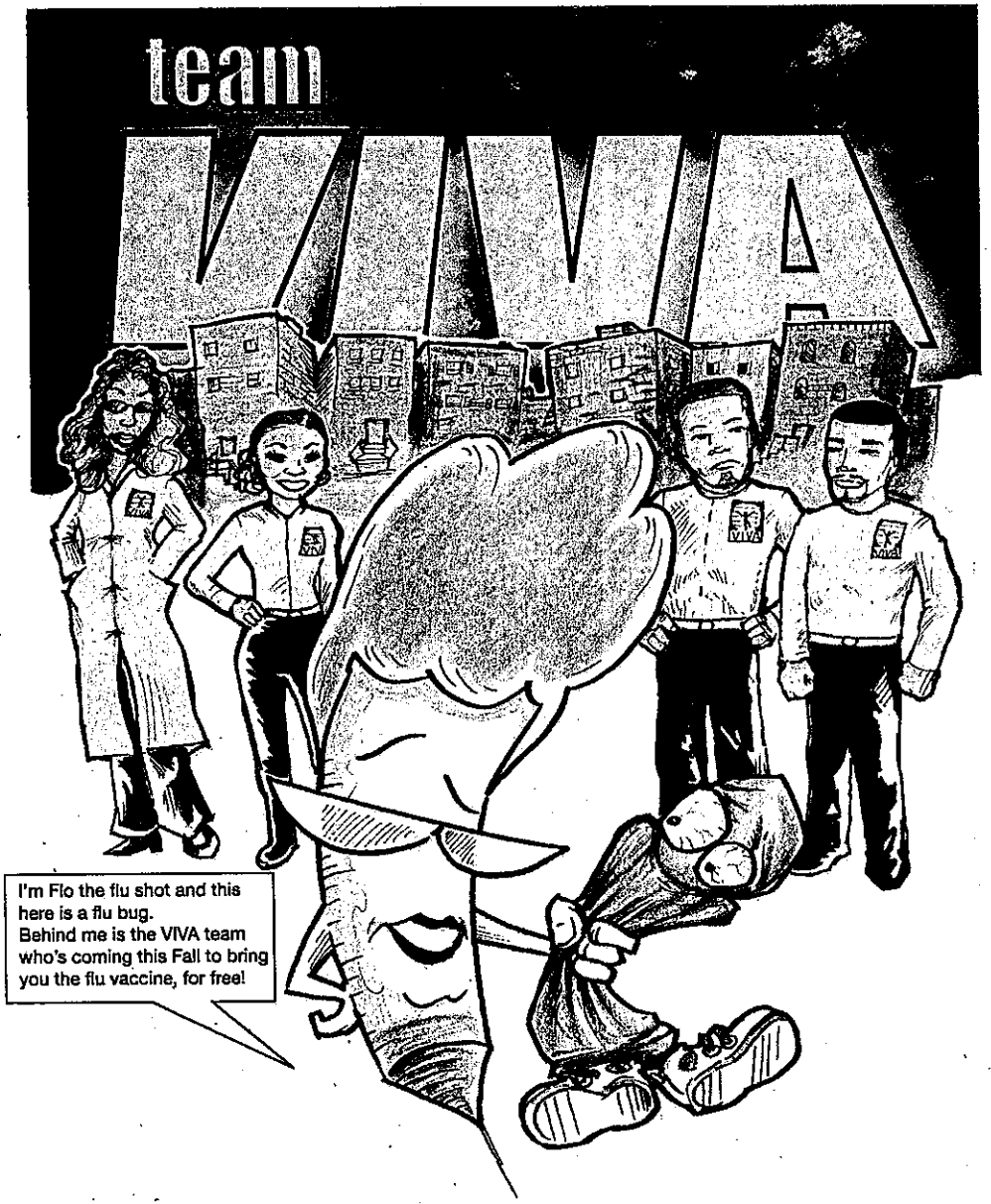


PROJECT VIVA

How can you get more information or give us feedback?

If you want more information about Project VIVA or about our other projects, please contact Micaela Coady, Project VIVA Project Director at NYAM's Center for Urban Epidemiologic Studies, 212-822-7277, or at mcoady@nyam.org.




I see you got your flu shot last year. That's really great! Have you gotten one this year?
Oh I sure hope so! You know, you have to get a new shot every year.
That tricky Flu Bug changes from year to year.
So I have to be sure to change costumes each year to outsmart the different bugs.
...or else the protection you received from the flu vaccine last year may not protect against the virus that's causing the flu this year.
Ooooh, I don't think I can get a flu vaccine. I'm scared of needles.
I understand, and you're definitely not alone. Most people don't like getting a shot, but you'll like the flu even less.
Most needles only cause a little pinch for just a second. The flu can make you sick and knock you off your feet for a week, or even more! You won't be able to work or take care of your house or family.
Or worse, you could end up in the hospital! You know, about 114,000 people are admitted into the hospital every year because of the flu.
So it might be worth it to get a little pinch from a shot than have to be sick in bed for a while.


I don't want a flu shot because I think it made me sick!
No, it can't be, the vaccine can't make you sick! See, the material in the flu vaccine isn't active—so it can't give you the flu...HOWEVER—it can take up to two weeks for your body to build antibodies to fight off the flu and for the vaccine to really work. If you're exposed to the flu before the two weeks, you could have some of the symptoms: you start out being tired, having a headache or a stomach ache, or just wanting to be in bed. EVEN SO, because you've had the flu shot, you won't get as sick as you would have if you hadn't gotten the vaccine.
103°
keep myself strong and healthy, I don't get sick. I can beat out any illness, even the flu!
...but I can make you STRONGER!
It's great that you take care of yourself—keep up the good work! But did you know that, if you are exposed to the flu virus, you can pass it on to someone else? The flu can really catch you off-guard. If you take the flu shot, you can be sure to protect yourself from getting sick, and at the same time protect friends and family from possibly getting the flu from you!

THE NEW YORK ACADEMY OF MEDICINE

Testimony of Dr. Danielle Ompad, Associate Director of the Center for Urban Epidemiological Studies at The New York Academy of Medicine

New York City Council Committee on Health
Oversight Hearing the City's Preparedness for the Avian Flu

February 28, 2008
New York City

Thank you for the opportunity to discuss City Council Resolution 2131 calling upon the State Legislature to enact A.2140/S.1312 thereby amending the education law to allow pharmacists to immunize adults for influenza and pneumonia. On behalf of The New York Academy of Medicine, we appreciate the City Council Health Committee's interest in this issue, which has been the subject of important research at the Academy and has led the Academy to directly engage our local community to increase immunization rates. Our research has also led us to fully support City Council Resolution 1231 and the enactment of A.2140/S.1312 because we believe it will increase rates of immunization, particularly among hard to reach populations who may not be connected to traditional health care.

The New York Academy of Medicine, founded in 1847, is an independent non-profit which uses research, education, community engagement and evidence-based advocacy to improve the health of people living in cities, especially disadvantaged and vulnerable populations. The impact of these initiatives reaches into neighborhoods in New York City, across the nation, and around the world. We look forward to working with the City Council on this and many other issues of mutual importance.

Every year, 10% to 20% of the American population falls ill with influenza, and on average, 36,000 persons die from influenza-related complications. Immunization reduces the illness and death that results from influenza and respiratory tract infections that result from the underlying influenza. Influenza immunization rates among the elderly, the population that accounts for 90% of influenza-related deaths, rose steadily for a number of years, but have now leveled off at between 60 and 70%. In New York City, the City Health Department reports a city-wide rate of immunization of 60% for adults aged 65 and over.

Efforts to increase vaccination rates have historically targeted individuals at high-risk for complications due to influenza, including the elderly and those with certain chronic health conditions. Despite recommendations from the Advisory Committee on Immunization Practices (ACIP), vaccination coverage among high-risk populations has been generally low. We systematically reviewed 56 studies, published between 1990 and 2006, evaluating programs in different settings, from within medical settings to venue-based and community-based approaches, in an effort to identify programs that successfully increased immunization rates. In the US, the Healthy People 2010 (HP2010) goals included 90 percent vaccination coverage for adults aged ≥65 years and 60 percent for high-risk adults aged 18-64 years. Only a handful of the studies we reviewed managed to meet those goals.

Of the 56 studies we examined, more than half of the studies occurred in primary care settings, one in four were large-scale regional programs (i.e., Medicaid, etc.), 7% were in tertiary care facilities or hospitals, 3% were targeted to nursing homes or long term care facilities, and 3% included active community engagement. Thus, most studies examined vaccination within the context of primary care settings or large-scale regional programs. In short, these programs targeted people already connected to the health care system. An important limitation of these types of approaches is their inability to reach those people who are not engaged in the health care system.

Two studies in our review examined the effectiveness of pharmacy-based vaccination programs in the US. One compared urban chain pharmacies in Washington, where pharmacists could legally administer influenza vaccines, to similar pharmacies in Oregon, where pharmacists could

not vaccinate. Vaccination coverage in Oregon remained stable and increased by 4.7 percent in Washington between 1997 and 1998. The other study compared vaccination coverage in eight states where pharmacists could administer vaccine to eight states where they could not. Between 1995 and 1999, vaccine coverage increased by 10.7 percent in states where pharmacists could administer vaccine and 3.5 percent in states where they could not.

Data from several sources, including the National Health Interview Study, suggest that immunization rates are lower in racial/ethnic minority groups than Whites, a disparity that exists for all age groups, including elderly persons covered by Medicare and populations specifically targeted by public health interventions. Of particular concern is what is known as "hard-to-reach" (HTR) populations. While no uniform definition of HTR population exists, HTR populations have typically been defined from the perspective of the absence of regular linkage with the health care system. Although data are limited, hard-to-reach (HTR) groups such as the housebound elderly, disenfranchised groups, people living in disadvantaged urban communities, undocumented immigrants, and substance users may be less likely than individuals receiving routine health care services to receive influenza immunization.

While failure to be immunized is related to lack of health insurance and to having a regular provider, other barriers to accessing care may include: culturally derived attitudes and belief systems; negative experiences with past treatment; language and other barriers in patient-provider relationships; and, legal status (e.g., undocumented immigrants). Some groups harbor substantial myths about and distrust of the medical system; previous research has shown that their attitudes appear to be strong predictors of being immunized.

Members of HTR groups may also be at increased risk of morbidity and mortality secondary to influenza because of increased incidence and prevalence of medical conditions for which influenza vaccine is recommended (e.g., asthma, diabetes), and reduced immune system activity due to lifestyle factors.

As noted above, a number of interventions have been shown to be effective for increasing vaccination coverage among the general population, including provider-based interventions,

interventions aimed at increasing community demand, and, importantly, enhancing access to immunization services. Studies on how best to immunize HTR populations are sparse, however. Existing research suggests, however, that most interventions are strengthened by multiple approaches, particularly those that are community-based.

In light of the limited data available addressing vaccine access among HTR populations, we at the New York Academy of Medicine sought to fill this gap. We assessed the barriers to influenza vaccination in disadvantaged areas of East Harlem and the Bronx. Of 760 total respondents, 62% had received influenza vaccination at some point in their life. Having access to routine medical care, receipt of health or social services, having tested positive for HIV, and current interest in receiving influenza vaccination were significantly associated with having received influenza vaccination in the previous year. Of participants surveyed, 80% were interested in receiving an influenza vaccination at the time of survey. Among participants who had never previously received influenza vaccination in the past, 73% were interested in being vaccinated. In summary, we found that participants who are unconnected to health or social services or government health insurance are less likely to have been vaccinated in the past, although these persons are willing to receive vaccine if it were available.

Because HTR populations experience significant barriers to vaccination, especially the lack of access to primary health care, we worked to increase interest in receiving influenza vaccination in a non-traditional urban setting. The Harlem Community and Academic Partnership, a network of community-based organizations and health leaders affiliated with The Academy, carried out Project VIVA (Venue Intensive Vaccines for Adults). Project VIVA included a set of intervention activities aimed at increasing acceptance of influenza vaccination among HTR populations in East Harlem and the Bronx. Following Project VIVA activities, individuals living in intervention neighborhoods were more interested in receiving influenza vaccine than before the intervention. Specifically, members of HRT populations, persons reporting a prior influenza vaccine, and persons medically indicated to receive vaccine were more likely to be interested in receiving vaccine.

The Academy has also conducted studies focused on increasing the role of pharmacists in providing syringes, information, and referrals to injection drug users. These studies suggest that

pharmacists are willing and able to take on new roles and that HTR populations will seek services and care from pharmacists when it is made available. We believe this research demonstrates both the demand for and the feasibility of delivering vaccine to members of HTR populations in non-traditional urban settings, like pharmacies.

New York City has taken important steps to increase vaccination rates, and we applaud the New York City Department of Health and Mental Hygiene's efforts to track flu vaccination rates, increase provider awareness, and undertake public education. Efforts to expand immunizations amongst hard-to-reach populations will require creative and intensive efforts and must include community-based efforts to promote vaccination in non-traditional settings and at times convenient to HTR populations. Current strategies for vaccination all-too-often miss the hard-to-reach population. This population cannot be ignored, and the strategies we implement today, and the lessons we learn, will be vital if, and when, we face a pandemic influenza. We urge, therefore, the passage of City Council Resolution 1231 and S.1312/A.2140, creating another venue for adult immunization and to increase rates of immunization, particularly among those most vulnerable.

Thank you for the opportunity to testify, and I look forward to any questions you might have.

JPAC *for OLDER ADULTS*

Joint Public Affairs Committee / 132 West 31st Street – 10th Floor / NY, NY 10001 / 212-273-5262
Sponsored by Jewish Association for Services for the Aged (JASA)

Public Hearing: "Pharmacists as Immunizers"
February 28, 2008

Remarks by Cameron Gelisse
Brooklyn Borough Coordinator
Joint Public Affairs Committee for Older Adults (JPAC)

Chairperson and Members of the Committee,

I am Cameron Gelisse and I am the Brooklyn Borough Coordinator for the Joint Public Affairs Committee for Older Adults (JPAC). JPAC is a non-partisan interdenominational, multicultural social action coalition of older adult representatives from senior centers, community groups, coalitions and independent individuals from throughout Metropolitan New York. For 30 years JPAC and its members have been fighting for programs and protections that benefit the lives of older adults in the New York City area.

JPAC supports any legislation that increases the accessibility of flu shots to senior citizens. JPAC, is therefore supporting City Council Resolution Number 1231, which calls upon the State Legislature to enact Assembly bill A.2140 and State Senate bill S.1312, which amend the education law to allowing immunizing agents to be administered to adults by CDC approved and certified pharmacists.

Seniors are the most vulnerable population when it comes to influenza and pneumonia. It is reported that 90% of the more than 3000 influenza deaths annually in New York City occur in adults over the age of 65 and that 80% of these deaths could be prevented by vaccination.

It is certainly not JPAC's intent to replace doctors providing this service, but rather to reach out to seniors who cannot easily access the vaccine through their doctors and provide an extra army of immunizers in the case of an emergency such as an outbreak of the avian flu. Similar legislation in 44 other states has shown a huge increase in immunizations to seniors across the board. An average of 22% of seniors were more likely to be vaccinated for the flu in states that allow pharmacists to administer vaccinations than those that do not. For seniors who rely on Medicare, there is frequently difficulty in accessing conveniently located doctors. Having the opportunity to go to properly trained neighborhood pharmacists who are able to provide these vaccinations, will likely increase the number of vaccinated older adults, saving lives and enhancing the quality of life for older adults in New York.

Representing JPAC here today, again I urge you to pass Resolution number 1231 calling upon the state legislature to adopt this legislation as specified in the New York State Senate S.1312 and New York State Assembly A.2140. Not only will the passage of this legislation help scores of seniors and other New Yorkers to obtain vaccinations which save lives, but also helps to prepare the city in the event of a preventable outbreak and save countless health care dollars by decreasing emergency room visits and hospitalizations for influenza and pneumococcal pneumonia.

Thank you.

Testimony of Macary Weck Marciniak, Pharm.D., BCPS
New York City Council Committee on Health
Pharmacists as Immunizers
February 28, 2008

Chairman Rivera, distinguished Members of the Committee on Health and guests, thank you for the opportunity to speak today regarding the critical issue of pharmacists and immunizations. My name is Macary Marciniak and I am an Associate Professor at Albany College of Pharmacy (ACP) and a Clinical Pharmacy Specialist with Price Chopper Pharmacy. I am a pharmacist and a member of the American Pharmacists Association (APhA) and the Pharmacists Society of the State of New York (PSSNY). It is an honor and a privilege to speak on behalf of PSSNY and share my knowledge and experience regarding pharmacist-provision of immunizations.

Pharmacists are health care professionals whose education and training make them well-qualified to address the immunization needs of patients. Today's pharmacist is a graduate of a six-year Doctor of Pharmacy (Pharm.D.) program. The Pharm.D. curriculum integrates anatomy and physiology, disease processes, pharmacology and pharmacotherapy. Communication and counseling skills are critical and are emphasized throughout the curriculum. Pharmacists are trained to take medical and medication histories and to identify and resolve medication therapy problems. Vaccines are drugs and, as such, pharmacists are educated about immunizations and take responsibility for ensuring that the medication (vaccine) needs of their patients are addressed. Indeed, pharmacy school curricula include the requisite knowledge and skills for pharmacists to identify patients in need of immunizations, initiate conversation and educate patients about these medications, and provide these vaccines, if needed.

Nationwide, pharmacist administration of immunizations is the standard of care. As of today, 47 states permit pharmacists to administer vaccines to patients. New York, along with Maine and West Virginia, are the outliers. Since 1997, APhA has offered a national curriculum to train pharmacists in immunization advocacy, facilitation and delivery. APhA's *Pharmacy-Based Immunization Delivery* certificate training program has been developed by an advisory panel that includes physicians and pharmacists and is recognized by the Centers for Disease Control and Prevention (CDC). Over 30,000 pharmacists have been trained to date with about 3 million vaccine doses administered by pharmacists. Recently, PSSNY licensed this training program from APhA and last month we launched our Train-the-Trainer program. PSSNY has trained 30 pharmacists who will serve as regional trainers throughout New York State. Through PSSNY, these pharmacists will travel across the state to train more and more pharmacists to immunize. Our goal is to build a network of pharmacists who are ready, willing and able to immunize once this legislation passes.

In addition to the 47 states where pharmacists can immunize, 28 states permit trained student pharmacists to immunize (underneath the supervision of a trained pharmacist). At ACP, I developed, coordinate and teach a course entitled *Immunizations and Emergency Preparedness.* This course is based on the APhA *Pharmacy-Based Immunization Delivery* training program. Upon successful completion of the class, students receive the same certificate of achievement as a pharmacist. Many of the other schools and colleges of pharmacy nationwide and in New York

State utilize this same training program. In this way, our graduates will be ready to immunize patients as soon as they enter practice.

In fact, our student pharmacists in Albany are already serving as immunization advocates and facilitators. I serve as an Advisor for the ACP chapter of the APhA-Academy of Student Pharmacists (APhA-ASP), the student branch of our national professional organization. In 1997, APhA-ASP created *Operation Immunization*, the largest service project in the history of student organizations. Through *Operation Immunization*, student pharmacists work in cooperation with local pharmacist practitioners and other health care providers to educate the community about immunizations. In the history of the program, over 538,000 people have been immunized and thousands more educated about immunizations through the work of student pharmacists. The APhA-ASP chapter at ACP has won the regional award for *Operation Immunization* for the past four years in a row. The innovative projects the students have undertaken include presentations on human papillomavirus (HPV) and the new vaccine Gardasil® to local high school students, presentations on shingles and the new vaccine Zostavax® to local senior citizens, volunteering at immunization clinics in the Capital District and distributing immunization information and record cards to local pharmacies as well as to patients at American Diabetes Association and American Lung Association events. They have even worked with a travel agency to promote immunizations to their clients. Through our students' efforts, we have reached thousands of patients in the Capital District alone and their work is a model for other student pharmacists and pharmacists in our state.

It is clear that pharmacists, student pharmacists, and pharmacies offer numerous advantages in the provision of immunization services. The equivalent of the United States population visits a pharmacy each week. Every day, pharmacists have regular contact with patients in need of immunizations; in fact, these individuals can be identified through prescription records. Pharmacies already serve as sites for immunization clinics. Each fall, we host nurses to come into our pharmacies and administer immunizations to our patients. When pharmacists are able to immunize, we will have another trusted and trained healthcare professional "on the front lines" who is able to immunize New Yorkers. Additionally, pharmacy access is unparalleled. Pharmacies are on just about every street corner and offer the added convenience of evening, weekend and holiday hours, times when many other health care providers are unavailable. And, patients listen to their pharmacists. 50%–94% of people respond to a pharmacist's recommendation to be vaccinated and people are 74% more likely to be vaccinated if prompted by their pharmacist than if not prompted.

I applaud the New York City Council Committee on Health for their resolution to support A.2140/S.1312, which would allow pharmacists to administer influenza and pneumococcal immunizations to adults in New York State. This bill has significant potential to improve the health of the people in this state. It is a travesty that the legislature has waited so long to take action on this vital issue, for it is truly our citizens who are at a loss. This legislation is absolutely needed and, in fact, is long overdue. It is time for New York State to allow trained pharmacists to administer immunizations to patients. Thank you for allowing me the opportunity to speak with you today. I appreciate your time and consideration regarding this important matter.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Testimony of the National Association of Chain Drug Stores (NACDS)

Before the Committee on Health

On Proposed New York City Resolution Number 1231

Thursday, February 28, 2008

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On behalf of the chain pharmacies operating in New York City, the National Association of Chain Drug Stores (NACDS) thanks the Committee for consideration of these comments on Resolution Number 1231, a resolution calling upon the State Legislature to enact A2140/S1312, an act to amend the education law in relation to allowing immunizing agents to be administered to adults by pharmacists

The National Association of Chain Drug Stores (NACDS) and its members supports legislation (S.1312/ A.2140) to permit licensed pharmacists to administer influenza and pneumococcal vaccinations to adults, based on non-patient specific orders prescribed by licensed physicians or certified nurse practitioners.

Further, we support the bill provisions which require licensed pharmacists who choose to become immunizers to complete training in techniques for screening, obtaining informed consent, techniques for administration, contraindications in the use of agents, recordkeeping and handling emergencies in order to become certified to provide immunizations.

New York's more than 4,000 chain and independent pharmacies are conveniently located in urban and rural areas, small towns and city neighborhoods and underserved and low-income communities throughout the state. By allowing licensed pharmacists who are trained and certified to provide recommended immunizations to adult patients, the state could significantly increase flu and pneumonia vaccination rates, particularly among those with serious and chronic conditions or who are elderly and cannot easily access a physician's office or clinic. As a result, lives will be saved through a marked reduction in flu and pneumonia rates and the dangerous complications that result, while also saving considerable health care dollars.

Enabling pharmacists to provide adult immunizations has become the standard of care throughout the United States, with 47 states currently allowing pharmacists to administer vaccinations. We strongly urge the Legislature to act now to pass this life saving legislation and make New York number 48.

TESTIMONY ON BEHALF OF THE
MEDICAL SOCIETY OF THE STATE OF NEW YORK
PRESENTED BY BARBARA ELLMAN
BEFORE THE NEW YORK CITY COMMITTEE ON HEALTH
February 28, 2008
New York, New York

My name is Barbara Ellman. I am the Associate Director for Policy for the Division of Governmental Affairs for the Medical Society of the State of New York. On behalf of the Medical Society and of the twenty-five thousand physicians that it represents, I want to thank you for inviting MSSNY here today to discuss legislation (A.2140,Paulin)/S.1312,Fuschillo) which would amend the scope of practice of a licensed pharmacist to permit pharmacists to administer vaccines for flu and pneumococcal disease to adults. First, let me state for the record that the Medical Society unequivocally supports the goal of increasing vaccination rates among adults and the Medical Society is committed to work with all interested parties to move us to that goal. However, the approach reflected in this measure is not the preferred means by which New York City and, indeed, the State of New York should accomplish this objective. Consequently, for the reasons which I will elaborate upon below, the Medical Society of the State of New York is strongly opposed to this measure.

The issue of vaccine immunization is more complicated than simply determining which health care professionals are capable through their education and training to

administer an immunization. Frankly, there is a sufficient supply of health care practitioners to administer influenza and pneumococcal immunizations to adults including approximately 400,000 registered physicians, nurse practitioners, physicians assistants, registered professional nurses and licensed practical nurses who are already recognized by law as having received the necessary education and training to provide such immunizations in accordance with their scope of practice in New York State.

The real reasons for low vaccination rates in New York arise out of a number of systemic and societal problems which derive from: (1) the often changing insurance status of our uninsured and underinsured populations, Medicaid, CHP and FHP populations; (2) the ability of primary care providers to obtain a supply of vaccine in quantities sufficient to inoculate their patient population and (3) patient knowledge and self awareness of the importance of obtaining regular vaccinations and responsibility to schedule an appointment to obtain a vaccination. These problems are not easily addressed and until remedied they will remain obstacles to improvement of City and State immunization rates. MSSNY continues to work with all affected parties to redress these problems with the hope that we will enhance coordinated care delivery through increased access to a reliable medical home and improve overall health outcomes for all New Yorkers.

With regard to the issue of universal coverage, we are pleased that Governor Eliot Spitzer is already taking concerted action to address the problem of the uninsured. Under his leadership, a Task Force entitled the "Partnership for Coverage" is currently exploring effective alternatives to incrementally enhance insurance coverage

opportunities for all New Yorkers. We have provided testimony on this subject and have attached a copy of it hereto for your information.

In recent years, the vaccine supply has been anything but stable. Moreover, we've experienced an absurd dynamic within the vaccine market in which large retail establishments including large chain pharmacies and big box stores are favored over individual physicians and other health care providers who, in times of limited supply, have lacked the market strength to leverage a meaningful supply of vaccines away from these large chain stores. As an aside, we note that Governor Spitzer is exploring a strategy to assure that physicians have an adequate supply of vaccine. In his proposed budget for fiscal year 2008-09, Governor Spitzer has proposed that the Commissioner of Health conduct a study on the feasibility through state market leverage of making vaccines universally available to children and adolescents up to age 19 without charge to the patient or physician. This is a good first step in assuring that physicians and other primary care providers have an adequate supply of vaccine to assure that patients can obtain vaccinations as part of their regular health care routine.

Given the current market dynamic, however, many commercial establishments will continue to advertise "flu clinics", open to all comers, where vaccinations are administered by licensed health care providers such as registered professional nurses and nurse practitioners. This practice, while sometimes affording a 'consumer' or 'customer' of such establishment, the only opportunity he or she might have to obtain a vaccination, has significant negative implications for the health care of a physician's 'patient'. Despite the focus on implementing interoperative health information technology in today's health care delivery system, we are years away from a fully

operational interoperative health care delivery system. Therefore, now and for many years to come, in almost every instance where a patient receives an immunization in a clinic offered by a pharmacy or other retail store, the patient's physician will not be notified. Consequently, the patient's medical record will not reflect this vitally important information. Some immunizations such as the pneumococcal vaccine are not given annually, but at five or more year intervals. This needs to be documented in the patient's medical record in order to ensure that the patient is being vaccinated at the recommended intervals. Immunizations at too frequent or too long an interval could have a seriously negative effect on the patient. It is well documented that separating a patient from his or her physician for segments of medical care results in poor outcomes for the patient. We believe the measure which you now consider, A.2140/S.1312, will further fragment health care delivery for immunizations and will result in a decline in the quality of care provided by our healthcare system and an increase in the overall cost of care.

Moreover, since immunization clinics are already occurring in pharmacy establishments, we also question the need for the legislation. Current law (Section 6527 of the Education Law) allows a physician to order a non-patient specific regimen to a registered professional nurse, for: (a) administering immunizations; (b) the emergency treatment of anaphylaxis; (c) administering purified protein derivative (PPD) tests.; and (d) administering tests to determine the presence of the human immunodeficiency virus. This provision enables the pharmacy to hire a nurse to administer immunizations at the clinic sponsored by the pharmacy. This measure would, therefore, provide no additional 'opportunity for vaccination' that doesn't already exist under the law now.

Moreover, Executive Law already provides the Governor with the necessary authority to declare a state of emergency, suspending current law and empowering certain individuals to provide immunizations in the event that a tragic set of circumstances exists such as an outbreak of a virulent flu such as the Avian Flu or an act of bioterrorism which necessitates massive immunization of the citizenry. This measure, therefore, is not necessary.

This bill should be viewed solely as a bill to expand the scope of practice of a particular health care profession. The Medical Society advocates strongly against such measures, particularly when there is no demonstration of need. The fact that this bill authorizes a pharmacist to receive specialized training in drug administration, drug interactions, physiology, pharmacology and patient management actually means that they haven't received such training in their years of education. This makes a pharmacist no different than any of the other non-physician title VIII providers recognized by law who are not authorized by law to administer immunizations. In our opinion, the further fragmentation of the health care delivery system and the less than optimal patient care inherent in such authorization should weigh heavily against this measure. We urge you to consider our perspective and opinion as you continue your review of this proposal.

Moreover, we would also like to explore additional and continuous efforts to educate the public/our patients as to the importance of regular immunization. To a large degree, the patient must embrace personal responsibility for scheduling an appointment on a routine basis with his or her physician or other primary care provider. At the same time, physicians must make inquiry regarding immunization status a routine part of an

annual visit. Together – government, health care providers and patients- can work toward improving the immunization rates in New York State.

Conclusion

I thank you for providing the Medical Society of the State of New York with this opportunity to present our thoughts and positions on the important issues you address today. We look forward to working with you in the future on these and other matters affecting the health care needs of all New Yorkers.

Testimony of

The Medical Society of the State of New York

Before The Partnership for Coverage

November 2, 2007

New York City

On behalf of the Medical Society of the State of New York and its almost twenty five thousand practicing physicians we represent, we would like to thank you for providing us with an opportunity to explore possible mechanisms which may be employed to address the challenge of how to increase access to medical care in New York State.

The public is worried about the state of health care in the United States today and especially about the rising cost of their own health insurance. Physicians are concerned because to them any system dominated by the managed care industry which in New York extracts conservatively over a billion dollars in profit from the healthcare system annually is broken and in need of a major overhaul.

The scope and composition of the uninsured population in New York State and the changing demographics of the insurance market demonstrate the multi-faceted, complex nature of the issues which must be considered as the state contemplates actions designed to enhance access to health insurance coverage. Specifically, data show that:

• There remain 2.8 million non-elderly uninsured (2.3 million adults and 450,000 children) in New York State.

• An estimated 1.2 million of these uninsured residents are eligible for but not enrolled in Medicaid, Family Health Plus or Child Health Plus.

• Three quarters of all uninsured children or approximately 320,000 children are eligible for Medicaid or Child Health Plus while approximately 40% of uninsured adults or 870,000 adults are eligible for public coverage.

• Another one million of uninsured residents have low to moderate incomes (below 300 percent of the federal poverty level) but are ineligible for public coverage.

• And the remaining twenty-three percent of uninsured New Yorkers (approximately 644,000 individuals) have incomes above 300 percent of the federal poverty level. In upstate New York, 35,000 of uninsured adults earn above $50,000.

• Fully 16% or approximately 1.4 million workers in New York State are uninsured. Fifty percent of those uninsured workers are self-employed or are employed by small firms with less than twenty five workers.

MSSNY will advocate for changes which will achieve universal coverage. MSSNY has created a Task Force on Health System Reform to examine alternate health system reform proposals with the objective of achieving consensus on the parameters of a cost-effective and equitable reform structure which will assure universal coverage and enhanced quality of care for all New Yorkers. The preliminary statement of the Task Force is articulated below for your consideration. We have suggested two proposals.

Universal Coverage

The goal of universal coverage must be premised upon recognition of the fact that the health care system is a partnership between patients, physicians, hospitals and the State to improve health care and its delivery. Universal health care means health care for all New Yorkers, with access to coverage for the uninsured.

If an individual or family currently has coverage and access is acceptable, then no change in coverage is necessary as long as the insurance offered is compatible with other basic principles enumerated herein.

The community physician and hospital must be recognized as the base of any health care delivery system.

The present infrastructure should be used wherever possible. Where there is a community or hospital based health clinic, these facilities should be strengthened and should continue to be a delivery site of clinically appropriate health care. Appeal should be made to the physician community at large, including medical students and residents to provide care focused on primary and preventive services in such clinics. To enhance interest in such service, service contracts between those physicians and the state should be executed which provide for tuition rebates; loan forgiveness; medical liability indemnification through the state and appropriate annual salary (See attachment B).

The community physicians and the community hospitals present difficulties with payments, forced added overhead expense and insurmountable medical liability premiums must be recognized and solved as without a buy-in by the physician and the hospital, no solution for coverage of the uninsured/underinsured will work. A long term view is necessary.

Given the demographic variables associated with the uninsured population, we embrace a multi-faceted, incremental approach to assure access to affordable insurance coverage with comprehensive benefits.

A) Enhance Enrollment of Currently Eligible Uninsured into Public Health Insurance Programs and Simplify Program Eligibility Requirements

Initially, we must identify and implement strategies to address the problem of that segment of the population (approximately 400,000 children and 870,000 adults) which remains eligible for but not enrolled in publicly-sponsored insurance programs such as Medicaid, Family Health Plus and Child Health Plus.

MSSNY supports initiatives which would serve as a catalyst to enrollment of that segment of the uninsured which is eligible for publicly sponsored health coverage. MSSNY supports simplification of the enrollment and renewal process including self-attestation of income levels; recertification every other year rather than annually; and elimination of the "face-to-face" interview. Streamlining eligibility determinations and the

recertification process for these public programs saves time, reduces waste, and most importantly, assures that eligible patients do not lose coverage as a result of unnecessary and excessive bureaucratic hassles. Moreover, MSSNY supports the exploration of expanding facilitated enrollment opportunities for other professionals and providers, including physicians who provide services in the underserved communities within which they work. Expanded usage of interface sites such as schools, emergency rooms, state offices and utility companies is necessary.

Additionally, MSSNY supports expanding eligibility for both CHPlus and FHP. We support the Governor in his request of the Bush administration to re-consider its ill-conceived policy which in effect will prevent the implementation of legislation enacted as part of the state budget for fiscal year 2007-08 which would require enrollment in the Child Health Plus program of all children in families with income up to 400 percent of the federal poverty level (approximately 70,000 children). We also support expanding FHP eligibility to 150 percent of the federal poverty level.

Moreover, MSSNY will strive to assure that there exists parity of coverage for persons living with mental illness in programs offered by New York State, including the Child Health Plus, Family Health Plus and Healthy New York programs in a manner consistent with coverage provided for other health conditions under Timothy's Law.

B) Enhance reimbursement for care provided to beneficiaries of the Medicaid program.

For too many years, New York State, through the financing methodologies of the Medicaid program, the New York Prospective Hospital Reimbursement Methodology (NYPHRM) and the Health Care Reform Act (HCRA), furthered policies which either directly or indirectly encouraged Medicaid beneficiaries to obtain care in facilities recognized pursuant to Article twenty-eight of the Public Health Law. Treatment provided in these institutional settings, however, proved far more costly than identical services which could have been received in private physician offices. New York State must take steps to de-emphasize care delivery within institutionally based or controlled settings when such facilities are not clinically necessary and, instead, promote care delivery within the more clinically appropriate physician owned private practice environments. One way to accomplish this goal is to re-involve practicing primary care and specialist physicians in all aspects of the Medicaid program. This objective can be accomplished through reform of Medicaid reimbursement rates for physicians and improvement of antiquated and cumbersome prior approval and claims processing processes.

Since the inception of the state's Medicaid program, the nation's consumer price index has increased 659% and yet only one modest increase has been implemented (in October of 2000) to the Medicaid fee-for-service reimbursement rate for physician services. Even this increase was limited and applied only to certain physician services, primarily those related to the delivery of primary care, emergency care and anesthesia care. This increase, while welcomed and needed, was grossly inadequate to counter

the historically low fee structure – particularly when viewed in conjunction with the dramatic increases in the cost of doing business which physicians have experienced.

Importantly, the inadequacy of the Medicaid fee structure necessarily impairs the ability of New York communities, which are in desperate need of physicians, to retain or attract physicians within certain specialties. The reimbursement disparity is more apparent when the level of reimbursement for certain physician services is compared across payors or even the reimbursement rates paid by Medicaid programs of sister states. Without question, New York's Medicaid fees are substantially lower than other government payors, private plans and other states (See Attachment A). As an example, Medicaid reimburses an otolarngologist $40 for a Fiberoptic laryngoscopy which Medicare reimburses at $134.67 and Workers' Compensation reimburses at a rate of $224.46.

While reform of the Medicaid reimbursement structure will not of its own accord redress the problem of the uninsured, fair and reasonable payment enhancement for physicians under the Medicaid program is one of several components of reform which are necessary to assure a sufficient supply of physicians, to serve the needs of beneficiaries of our publicly sponsored programs including any program which will be established to cover the uninsured/underinsured of New York State.

C) Enhance Opportunity for the Purchase of Coverage

A program must be developed to enable all New Yorkers including the uninsured/underinsured to purchase affordable health coverage. In our opinion, the governance of this program should reflect as much autonomy from the political process as possible. An entity should be created which operates separately from the state but subject to rule and regulations established by the state. The program should be administered under the auspices of a stand alone organization with its own administrative staff. There must be proper oversight to guard against corruption, cost shifting, misuse of funds and overpayment to executive employees of the plans authorized to underwrite the coverage provided under this program. A limit on program administrative costs, advertising, and profit to a level more commensurate with publicly administered health plans such as Medicare or Medicaid or those in our neighbor country to the north must be obtained.

All uninsured/underinsured New Yorkers must, at least, obtain basic health coverage through this program. This should be effectuated through a mandate upon individuals to purchase insurances. This is a personal mandate as the young and healthy must be involved. Every New Yorker also should be offered the opportunity to purchase this basic health coverage. For the uninsured or underinsured, there must be income dependent subsidization up to 400-500% of the federal poverty limit. Subsidization, coupled with insurance changes to introduce affordability such as widening the base of covered persons is important. In our opinion, a widened base may produce a modest premium reduction for all.

Coverage offered through this program should be portable within the State. Insurance renewal should be guaranteed for as long as necessary. A patient should be able to slip seamlessly into the plan when necessary. There should be no administrative waste on either end with regard to issuance.

There should be disincentives for those who do not purchase health coverage. The specific mechanism for enforcement of the mandate, whether it is a tax penalty or fine, must be sufficient to assure compliance.

The members of MSSNY's Task Force on Health System Reform are opposed to an employer mandate.

Through this program, the state must explore additional coverage options to enhance the affordability of health insurance, particularly for New Yorkers who choose to not purchase or for whom employers do not provide health coverage opportunities.

Health Savings Accounts (HSAs) are one vehicle through which individuals particularly young New Yorkers may voluntarily purchase health coverage. HSAs tax-exempt trusts or custodial accounts established for the purpose of paying the beneficiary's qualified medical expenses. To be eligible to establish an HSA, an individual must be enrolled in a high deductible health plan (HDHP), must not be covered by another non-HDHP plan, must not be entitled to Medicare benefits, and may not be claimed as a dependent on another person's tax return. An HDHP is defined as a health insurance plan which has

an annual deductible of at least $1,100 and an annual out-of-pocket expense maximum of no more than $5,600 for self-coverage and an annual deductible of $2,200 and an annual out-of-pocket maximum of no more than $11,200 for family coverage. An HDHP may exempt preventive care from the deductible but may not provide benefits in any year for any non-preventive care until the deductible for that year is met. Properly structured, HSAs provide affordable protection against high medical costs and greater patient control over use of health services. HSAs are permanent and portable. Both employer and employee contributions are allowed. All contributions to the account are tax free as are all distributions from the account. Up to 100% of the health plan deductible may be saved annually or up to a maximum of $2900 for an individual policy/$5800 for a family policy, whichever is less. Additionally, individuals age 55-65 can make additional tax-free "catch-up" contributions of up to $1,000. Since their inception in 2004 there has been a seven fold increase in individuals covered by HSA products. It is now estimated that approximately 3.2 million Americans are now enrolled in an HSA. HSAs are expected to provide expanded coverage opportunities for a great number of previously uninsured individuals and families. MSSNY will work to enhance public awareness of HSAs and will work with all appropriate authorities to enhance the availability of HSAs in New York State as an alternative to conventional health insurance. On the other hand, some physicians have expressed concern with the logistical hassles involved in receiving payment under these plans. Therefore, MSSNY will also work to assure that HSA payment policies are fair and timely and that physicians do not bear additional financial exposure.

Simplicity, such as in Gap insurance for Medicare, should also be pursued as an alternative to the complexity of the current system.

At all times, New York must be ready to roll its system into any national plan which might evolve so as to take advantage of tax relief and/or credits, individual ownership, national portability and resultant attenuations of restrictive federal rules.

New York's health coverage program for the uninsured/underinsured must provide equitable coverage and benefits, similar to programs adopted in other states such as Massachusetts. Universal parameters with a single tier of insurance and one benefit package for those receiving public funds is critical so as to reduce the administrative burden. Simplicity must replace the complexity of the current system.

D) Additional Health System Reforms

Any proposal to address the problem of the uninsured must necessarily also address issues related to affordability, efficiency quality and shared responsibility. MSSNY supports the imposition of a minimum medical loss ratio (MMLR) which assures an adequate investment of payor revenue in the provision of medical care. In our opinion, we should seek to allocate at least 95% of all revenue to reimburse health care providers including physicians for patient care. Moreover, we recommend that this requirement be established in tandem with the enactment of a prior approval rate process which will assure that the rate structure implemented will afford adequate resources to support the provision of necessary medical care and treatment.

MSSNY also supports the streamlining of administrative and procedural requirements of HMO, PPO, ASO and POS products. The extent to which investor-owned companies pervade both the commercial insurance and the publicly sponsored coverage markets should concern policy-makers as it does the provider and patient community which has suffered in recent years under the weight of policies and practices imposed by the managed care industry. These practices constrain the ability of physicians and other providers to assure patient access to cost efficient, clinically sound and effective medical treatment. Importantly, insurance cards, including those for self-funded corporate plans, should be dated with the date of issue and termination and specify all coverage limitations and cost sharing requirements. For all there must be oversight of the plans to guard against corruption, cost shifting, misuse of funds and overpayment to executive employees of a plan. A limit on and reduction in plan administrative costs, advertising and profit to a level more commensurate with publicly administered health plans such as Medicare or Medicaid or those in Canada must be obtained. As we seek to redress the problem of the uninsured we must also assure that the coverage which is provided will assure access to high quality, cost effective care. Because ERISA prevents the state from regulating self-insured plans, we advocate for a two-pronged, state and federal approach which seeks administrative simplification on the state level with concomitant reform on the federal level.

Individual health responsibility for patients to avoid chronic disease is essential. While this may not save up front costs the increase in value by a program which achieves this

may be immeasurable. Obesity, hypertension, smoking, excess alcohol consumption and diseases which may be related to lifestyle improprieties must be addressed. Quality and effectiveness of medical treatment is the central consideration. Quality bench marks such as those promulgated by the physician consortium and by the AMA can be used to effectuate clinical care improvement and enhanced quality for all.

Conclusion. The number of persons without health insurance coverage in New York State will continue to grow unless action is taken to address this escalating health crisis. The Medical Society of the State of New York believes that this problem must be addressed through a multifaceted approach which would at a minimum include:

1) Enhanced Enrollment of Currently Eligible Uninsured into Public Health Insurance Programs.
2) Simplified Program Eligibility Requirements for Existing Publicly Sponsored Coverage Programs.
3) Enhanced reimbursement for care provided to beneficiaries of the Medicaid program.
4) Development of a Program to enable the uninsured/underinsured to purchase affordable health coverage.

We stand ready to assist you in your consideration of strategies to address this most important health policy issue.

Attachment A- Comparison of New York's Medicaid Fees to Other Payors and States

New York Medicaid Fees Compared to Other Payors and State Programs							
			NYS M'caid doctors' office	Medicare*	W/C**	Kentucky	Florida
Psychiatry	90801	Initial diagnostic evaluation	$ 45.00	$ 175.50	$ 218.35	$ 85.01	$ 84.13
	90807	Psychotherapy 45-50 minutes	$ 54.00	$ 120.14	$ 156.33	$ 73.50	$ 57.95
	90862	Pharmacologic management	$ 22.50	$ 59.83	$ 74.11	$ 39.02	$ 28.66
Otolaryngology	42825	Tonsillectomy	$ 60.00	$ 335.74	$ 748.96	$ 173.02	$ 152.68
	31575	Fiberoptic laryngoscopy	$ 40.00	$ 152.05	$ 224.46	$ 78.25	$ 67.51
Urology	52000	Cystoscopy	$ 17.00	$ 315.37	$ 235.91	$ 98.06	$ 152.68
	55700	Prostate Bx	$ 20.00	$ 243.26	$ 267.98	$ 89.95	$ 93.47
Pediatrics	99291	Critical care (PICU) 99293	$ 25.00	$ 247.59	$ 285.78	$ 147.84	$ 118.61
	99292	Critical care (30 min.) 99294	$ 12.50	$ 127.52	$ 142.89	$ 71.86	$ 60.86
E&M	99202	E&M, new, minor	$ 30.00	$ 76.75	$ 61.43	$ 35.29	$ 33.85
	99214	E&M, established, moderate	$ 30.00	$ 97.91	$ 71.49	$ 41.97	$ 43.20

	99215	E&M, established, high	$ 30.00	$ 142.12	$ 114.33	$ 66.39	$ 63.31
Prepared by the Division of Socio-Medical Economics			* All Medicare fees are based on Par rate for Loc. 1 w/o site of service differential				
			** All WC fees are = WC Loc. 4				

Attachment B: Suggested programs for recruiting physicians to the infrastructure.

1) Tuition rebates for medical students indicating desire to join such program.
2) State reduction of medical school debt by a formula which forgives some medical school debt for each year of service. A minimum of $30,000/per year to be applied to medical school debt is appropriate. This will bring stability to the physician work force.
3) A salary should be given which is a living wage.
4) Medical liability indemnification through the state
5) A work contract for a minimum of four years.