

JULY 2008

An Analysis of Recent Developments & TrendsLITTLER MENDELSON, P.C.
THE NATIONAL EMPLOYMENT & LABOR LAW FIRM®**Antiviral Drug Stockpiling for Pandemic Planning**

by: Donald W. Benson

Summary: CDC issues "Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic." Employers who decide to buy antiviral drugs must: (1) decide whether to stockpile for outbreak prophylaxis, exposure prophylaxis, or treatment; (2) develop an appropriate level of stockpiling, (3) select the mechanics for maintaining and distributing the stockpile, and (4) develop procedures in light of the employment law issues surrounding the allocation and distribution of limited resources.

Avian flu has not been in the news as much lately. Even if there is certain amount of "flu fatigue" because the anticipated pandemic has not yet developed, employers and federal, state and local governments are actively engaged in a wide range of planning activities. The Centers for Disease Control and Prevention recently issued "Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic."¹

While the CDC urges every employer to plan for a pandemic to protect employees' health and safety and anticipates that employers will play a large role in limiting the pandemic's impact on health, the economy and society, the CDC does not suggest that every employer stockpile antiviral influenza drugs but recognizes that antivirals can be important part to a layered approach to pandemic mitigation.

Employers who decide to buy antiviral drugs must (1) decide whether to stockpile for outbreak prophylaxis, exposure prophylaxis, or treatment; (2) develop an appropriate level of stockpiling; (3) select the mechanics for maintaining and distributing the stockpile; and (4) develop procedures in light of the employment law issues surrounding the allocation and distribution of limited resources.

Vaccine Development and the Need for Antivirals

The principle strategies for fighting a pandemic outbreak are: (1) providing vaccination; (2) isolating ill persons and quarantines of well household members and others exposed; (3) closing child care facilities and schools; (4) decreasing close contact among people through social distancing efforts; (5) using antiviral drugs to treat and prevent illness; and (6) improving hand and respiratory hygiene and using

protective equipment such as face masks or N-95 respirators in infection control settings to reduce the chance of becoming infected when in close contact with an infected person.

With current technologies, it will take at least 20 weeks before the first doses of a pandemic vaccine are available. In contrast, antiviral drugs can be stockpiled in advance of the development of the pandemic influenza.

The Food and Drug Administration has approved four antiviral drugs for the treatment and/or prevention of influenza: amantadine, rimantadine, zanamivir, and oseltamivir. The CDC is currently purchasing two agents for the Strategic National Stockpile: oseltamivir (Tamiflu®) and zanamivir (Relenza®). Oseltamivir and zanamivir have been shown to reduce the duration of symptoms in patients with seasonal influenza illness by 1 to 1½ days when begun within the first 48 hours of illness. One Canadian study indicated reduction of 3 to 4 days when started within 12 hours of illness onset. Several studies reported that treatment with these antivirals decreased respiratory complications of pneumonia and bronchitis and decreased hospitalization rates.

State and federal governments have set a target stockpile of 81 million courses of antivirals, which the CDC estimates would be sufficient for "treatment of those who are ill with pandemic disease and who may benefit from therapy based on assessment of medical need." There is currently no decision to expand the state and federal stockpile sufficiently to extend the use of the antivirals in prophylaxis for healthcare and emergency services personnel and key employees in business providing essential community services as is recommended in the Guideline.

continued...

continued from cover

Which Employers Are Considering Stockpiles?

Employers who provide frontline emergency and healthcare services must plan to protect their employees who will likely be exposed to ill persons during a pandemic. The CDC Guideline recommends antiviral prophylaxis (i.e. antiviral use to prevent infection in persons either before or after they are exposed to pandemic influenza) be provided to these high risk employees for the duration of a community pandemic outbreak. Businesses that provide goods and services essential to community health, safety or well-being (e.g., utilities, public transportation, communications, financial systems, and food delivery chains) also need to plan for continued operations in the event of a pandemic. A comprehensive pandemic preparedness plan would identify those essential employees who are critical for continued operations and provide them with antiviral prophylaxis.

Current government plans recommend using up to 6 million courses of the federal stockpile as part of a comprehensive public health response to contain the initial outbreak, wherever it occurs in the world, to reduce transmission when cases first appear in the United States, and to use the majority of the stockpiled drugs to treat persons who have pandemic illness and may benefit from therapy. The CDC Guidelines recommend expanding the use of antiviral drugs to include prophylaxis in healthcare and emergency services occupations, for people whose immunity is compromised by an underlying medical condition or treatment, and for people living in group settings (e.g. nursing homes) if an outbreak of pandemic disease occurs at the facility.

Employers may purchase antiviral drugs for stockpiling for several reasons: (1) to provide prophylaxis for front-line healthcare and emergency services workers whose occupations are both essential and whose jobs put them at high risk of exposure to the illness; (2) to provide prophylaxis for key

employees critical to essential operations in critical infrastructure businesses to sustain essential community services; (3) to assure early treatment to employees who become ill, (4) to protect overseas employees and operations where the U.S. effort will not reach and employees who must travel for business necessity.

Planning an Employer Antiviral Stockpile

States are currently developing plans for allocating, distributing and dispensing antiviral medications during a pandemic. Employers should consult with state and local authorities in developing their own pandemic preparedness plans including the decision and methods of stockpiling. Employers are encouraged to ask health providers and healthcare facilities that are dispensing antivirals on their behalf to report cases of pandemic illness to state and local health facilities. During a pandemic, the CDC and state and local health officials will provide specific guidance to healthcare providers for reporting cases and the timing and appropriate use of antiviral medications.

Employer purchasing and stockpiling must comply with federal and state laws and regulations that set standards for the storage, handling, distribution, securing, and dispensing of prescription drugs. Because states heavily regulate the medical and pharmacy practice and the wholesale distribution and dispensing of drugs, employers should consult with their state pharmacy boards and review state laws with the guidance of legal counsel, health insurance and other insurance carriers. Planning should ensure appropriate receipt and storage procedures. An employer should not directly distribute a prescription drug to its employees without a prescription or outside lawful dispensing process established under state law.

Decisions about the strategy for using antivirals and the amount to purchase cannot be made in a vacuum. Employers need to assess the likely efficacy of non-pharma-

ceutical measures such as educational steps to promote personal hygiene and social engineering steps to minimize close contact in the workplace including increasing the physical distance between workers, promoting flexible schedules and telecommuting, encouraging sick employees to stay home, etc.

Employers can only judge how many courses to buy after deciding whether the antiviral will be used only for: (1) outbreak prophylaxis (preventive use of antiviral drugs for the duration of a local pandemic influenza outbreak estimated at potentially up to 12 weeks); (2) post-exposure prophylaxis (preventive use of antivirals within 48 hours of close contact with someone who has pandemic illness); and/or (3) treatment. Post-exposure prophylaxis could distinguish between workplace exposures and exposures that include those in the home or community.

The CDC identifies several models that employers could use for stockpiling and dispensing antivirals. Employers could: use existing healthcare or pharmacy facilities, and contract with a wholesale drug distributor for on-site stockpiling by employers and pre-pandemic dispensing. Employers should select the model appropriate for their concerns, size, facilities and economic constraints. Whichever model is selected, employers need to confirm the appropriate environmental conditions for stockpiling, tracking the expiration dates of drugs, stockpile security and developing educational information for employees and families when antivirals are dispensed, and adopting procedures for the recording of who has received antivirals and monitoring the reporting of any adverse reactions.

Manufacturers of antivirals are beginning to develop programs to help employers overcome some of the logistic hurdles of stockpiling. Roche, the manufacturer of Tamiflu®, announced on June 26, 2008, a program to encourage businesses to stock-

continued from page 2

pile the drug. For an annual fee, Roche will store, secure and rotate a supply designated for that company with a guaranty that the stockpile will be delivered at the company's direction within 48 hours of a request. This program promises to rotate the supply within its 5-year expiration date and assesses a fee of \$6 per 10-tablet treatment course, about one-sixth the full wholesale purchase cost, which would be payable when a company requests its order be distributed.²

Legal and Ethical Decisions

Employers who decide to stockpile antivirals and identify who is to receive the medicine face a range of legal and ethical decisions. A key consideration on for employers when picking who receives antivirals is the risk of occupational exposure of workers defined by the Occupational Safety and Health Administration's risk pyramid.³

In addition to the confidentiality issues and HIPAA protections for employee information that might be gathered and assessed in deciding who might benefit from the prophylaxis use of antivirals, healthcare providers will also be checking medical histories to make sure that a candidate would not be harmed by the antiviral and obtaining informed consent. Like any other group selection process, such as a layoff, employers will need to avoid an accusation of discrimination and start from the beginning to build a defense that explains how the selection of certain jobs was based on scientific and business reasons unrelated to a discriminatory motive.

Conclusion

The CDC's Proposed Guidelines for Employers suggests a re-consideration of the stockpiling decision by employers in formulating their pandemic response plans.

Many employers may have initially rejected the idea of stockpiling antiviral medications due to the uncertain science regarding their possible benefits in shortening a pandemic, rather than just for treatment, and what appeared on first consideration to be intractably complicated issues of predicting the costs and logistics involved in stockpiling. With the Proposed Guidelines, new manufacturer initiatives, and the recent experiences of other employers, many of those initial problems and risks can now be better quantified and more practical solutions developed. It is time to reassess whether stockpiling of antiviral medications makes sense for your layered approach to pandemic preparation so as to minimize the spread of the pandemic and to promote as quick a resumption of operations as possible from a pandemic that the CDC and the World Health Organization still say could spread world-wide at pandemic levels in as little as three months once the H5N1 influenza virus mutates to be more easily communicable in human to human transmissions.⁴

Donald W. Benson is a Shareholder in Littler Mendelson's Atlanta office. If you would like further information, please contact your Littler attorney at 1.888.Littler, info@littler.com, or Mr. Benson at dbenson@littler.com.

¹ <http://aspe.hhs.gov/panflu/stockpiling.html>

² Center For Infectious Disease Research & Policy, Academic Health Center, University of Minnesota. <http://www.cidrap.umn.edu/cidrap/content/influenza/biz-plan/news/jun2608-tamiflu.html>

³ http://www.osha.gov/Publications/OSHA3327_pandemic.pdf or http://www.osha.gov/Publications/influenza_pandemic.html#classifying_exposure

⁴ "Pandemic- Is Your Workplace Prepared for a Disaster?" by Donald Benson and Julie Adams, The North Carolina State Bar Journal, June 2008; "Don't Just Wing It," by Donald Benson and Gina Cook, The Tennessee Bar Journal, February 2008; "Pandemic Preparation In The Workplace," by Donald Benson, The Georgia Bar Journal, October 2006.