

July 7, 2008

Via E-Mail: panflucomments3@hhs.gov
Department of Health and Human Services
Room 434E
200 Independence Avenue, SE
Washington, DC 20201
Attn: Pandemic Influenza Employer Antiviral Comments

**Re: Proposed Considerations for Antiviral Drug Stockpiling by
Employers in Preparation for an Influenza Pandemic**

Dear Sir or Madam:

The Securities Industry and Financial Markets Association ("SIFMA")¹ appreciates the opportunity to comment on the U.S. Department of Health and Human Services ("HHS") Draft Guidance to Assist in the Preparation for an Influenza Pandemic, particularly the *Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic*.² SIFMA appreciates the efforts of HHS and the Center for Disease Control ("CDC") to develop strategies to prepare and protect the American people in the event of a pandemic flu outbreak. SIFMA continues to take great interest in these issues in light of the long-term effects such an outbreak could have on the financial markets.

SIFMA agrees that as a part of the country's critical infrastructure, securities firms must plan for a pandemic as part of overall business continuity planning. As noted in the proposed guidance, it is impossible to determine in advance when a pandemic will begin, where a pandemic will start, and how virulent it will be. The question of how virulent the pandemic will be makes the strategy for procurement

¹ The Securities Industry and Financial Markets Association brings together the shared interests of more than 650 securities firms, banks and asset managers. SIFMA's mission is to promote policies and practices that work to expand and perfect markets, foster the development of new products and services and create efficiencies for member firms, while preserving and enhancing the public's trust and confidence in the markets and the industry. SIFMA works to represent its members' interests locally and globally. It has offices in New York, Washington D.C., and London and its associated firm, the Asia Securities Industry and Financial Markets Association, is based in Hong Kong.

² See 73 FR 31,690 (June 3, 2008) and <http://aspe.hhs.gov/panflu/stockpiling.pdf>.

and stockpiling of antiviral medications such as Tamiflu and Relenza difficult to determine. In addition, the effectiveness of these antivirals in a pandemic flu has not been thoroughly tested or proven. For these reasons and others discussed below, SIFMA urges HHS and the CDC to emphasize that the decision to stockpile antiviral medications should be at the sole discretion of the employer based on its respective risk profile. Companies which are not in the medical or emergency response industries should be given substantial leeway in determining whether or not they should stockpile antiviral medications. In addition, SIFMA is concerned that not stockpiling such medication could become an issue in future examinations by securities regulators if it is deemed necessary as part of a pandemic preparedness plan.

SIFMA is also concerned with the liabilities surrounding employer stockpiling. Antiviral medications are currently only available by prescription, which raises issues of how employers should properly dispense such medications. Many securities firms do not have medical staff on-site, and even those that do have medical staff only have such staff in their largest offices. Moreover, such staff are often nursing staff, and not medical doctors who could properly evaluate whether an antiviral should be administered to a particular staff member. As a result, administering antiviral medications could raise liability issues related to side effects, as well as HIPAA concerns.

Firms without medical staff on-site would have to undertake significant efforts and costs to retain a third party service provider to administer the antiviral medication to staff members. In the event of a pandemic outbreak, such service providers would be in very high demand and may not be available to administer the stockpiled antivirals in a timely manner.

In addition, there are some additional practical implications of stockpiling and administering the antiviral medications. Employers which do not acquire enough antivirals for every staff member, either by choice or due to a shortage, would have to determine which staff members are “critical” and then provide those staff members with the antivirals. Based on this guidance, it is difficult to determine which staff members would meet these criteria, and raises issues of equitable treatment of staff members. Putting firms in the position of having to select which staff members to treat is potential prejudicial.

Furthermore, if an employer provides antivirals to its staff members but not to the staff members’ families, then the effectiveness of the antiviral is severely diminished. Such staff members will likely not come into the office where they could receive the antiviral medication, if their families are left at home unprotected.

Finally, SIFMA also has concerns with the on-going costs of stockpiling antiviral medications. Firms may have difficulty acquiring the necessary amount of antiviral medication, and would have to ensure the proper storage of such antivirals which increases the costs. In addition, Tamiflu currently has a shelf-life of five years (which could possibly be extended to seven years by the FDA). The additional costs of replacing the full reserves of antiviral medications every five (or seven) years could potentially outweigh the benefits of stockpiling such medications.

Instead of urging employer stockpiling beyond medical and emergency response industries, SIFMA urges HHS and the CDC to consider the following possible solutions. Tamiflu should be made an “over-the-counter” medication, either now, or immediately upon outbreak of a pandemic flu. Another possible solution is to permit critical infrastructure staff members to obtain Tamiflu or another antiviral without a prescription. In addition, because of the limited availability of antivirals and the costs of replacing expired antivirals, private sector firms should be able to participate in the Shelf Life Extension Program (SLEP) in order to extend the expiration date of currently stored antivirals if they meet the program criteria. Finally, the federal government should increase its own stockpiles of antiviral drugs to cover a larger portion of the population.

* * *

If you have any questions in this regard, please contact Howard Sprow, Staff Adviser to the SIFMA Business Continuity Planning Committee, at 212-313-1248.

Sincerely,

John Panchery
Managing Director, Operations

cc: Julie Schafer, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services