

THE ROLE OF ANTIVIRAL AGENT STOCKPILING IN BUSINESS SURVIVAL AND RECOVERY FROM PANDEMIC INFLUENZA

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Abstract

Survival and recovery of businesses from Pandemic Influenza will depend primarily on their planning efforts and ability to continue operations during the disaster. One suggested method of optimizing employee wellness and continued participation at work is through use of Tamiflu and other antivirals to maintain the workforce.

In recent months, there has been an increased emphasis by businesses to stockpile certain pharmaceutical items and personal protective equipment (PPE). One of the most contentious areas of stockpiling is the specter, and growing reality, of hoarding Tamiflu. Many large international corporations have spent millions of dollars stockpiling antiviral agents in the hope of maintaining their workforce and aiding in recovery following Pandemic Influenza. Preliminary data has indicated that over 40% of larger corporations are stockpiling Tamiflu for their employees. This raises issues of antiviral effectiveness, availability (and ethics of prescription patterns), cost, misuse, safety, and product liability.

Our paper will address three areas of concern: Potential effect of antiviral stockpiling on survival and recovery of the business sector, ethical issues in stockpiling of drugs by various sectors, and the potential effectiveness of antiviral agents as compared to social distancing procedures. Concrete suggestions and guidelines will be provided in how to best address the issues of stockpiling in the face of an Influenza Pandemic.

Introduction

The specter of Pandemic Influenza continues to place all sectors of our society in confusion as related to issues of stockpiling potentially needed supplies, and how to handle rationing of care and medicines/vaccines should the worst materialize. Visions of the 1918-1919 pandemic that wiped out hundreds of thousands of Americans, and millions of our young and vigorous populations worldwide haunt us. These decisions directly impact the ability of businesses to recover following a major disaster of this type. All those in Emergency Management are being forced to face these issues, along with shortages in workforce, continuity of operations planning, quarantine and isolation, protection of our medical facilities and other critical infrastructure issues. It is estimated that 20% of companies will suffer fire,

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flood, power failures, terrorism, or hardware/software disasters. Of businesses suffering a disaster, 43% will never recover sufficiently to reopen their business, and of those that do open, only 29% are still open 2 years later (Deloitte Center for Health Solutions, 2006). This is, in large part, because of their lack of planning and preparation. This purpose of this paper is to specifically address the issues surrounding potential stockpiling of antiviral agents by the business sector as a mechanism of maintaining business continuity and minimizing recovery time following Pandemic Influenza.

Background and Thesis

Great controversy still rages concerning the appropriate steps to be taken by businesses in preparation for the dreaded Pandemic Influenza. Avian Influenza is continuing its march across the globe, although it has yet to be definitively identified as reaching the United States. Great effort and extensive resources have been spent in preparing ourselves for this likelihood. Much has been learned from observing how other nations, especially the United Kingdom, have dealt with this reality in recent weeks (Grey, 2007; Revill, 2007; Shaikh, 2007; Elliott, 2007). Whether or not the H5N1 strain transforms into the pandemic form remains to be seen. However, as long as this particular virus continues to infect hundreds of thousands of domestic birds, as well as the wild bird populations, potential for pandemic still exists and continues to grow.

We have all been inundated by health education and mailings from public health professionals in our nation focusing on the need to become prepared for Pandemic Influenza. The amount of information pertaining to how to prepare ourselves has been overwhelming until many residents are no longer interested in listening. Home preparedness kits are marketed and sold, and bogus remedies continue to be sold over the internet as we try to become better prepared. We are all becoming more aware of what types of actions may be necessary to help our families and loved ones survive. We look to the government and our employers to provide guidance, education, protection, and a safe workplace in which to thrive.

There has been great emphasis on our governmental and public health structures to stockpile antiviral agents, specifically Tamiflu, in order to treat members of our critical infrastructure and first responders should the pandemic occur. Their interest is in the continuation of our critical services in order to provide viability of our medical system and the security necessary should the social underpinnings of our society be disturbed. Stockpiling of antivirals for protection of our residents is, in fact, government's responsibility and would seem to be an appropriate use of funds. However, it must be noted that these stockpiles are only for treatment, not prophylaxis or protection of others who are uninfected.

Prevention is a separate, and much more daunting, consideration. Antiviral agents are not vaccines, any more than antibiotics are. Antiviral medications can theoretically help prevent one from acquiring the infection, but only for the duration of time that the medicine is actually taken. One course of Tamiflu is 5 days long, a very short period indeed when one considers that each wave of Pandemic Influenza would likely be months in duration, and that there may be many waves. Some more recent recommendations call for prophylaxis for up to eight weeks.

The Dark Side of Pandemic Influenza for Businesses

It is anticipated that Pandemic Influenza would hit in several waves of from 2 – 12 weeks in duration. The peak of each wave could last for 4 weeks, with up to 50% absenteeism of employees at all levels. Both supply chains and customers would also be affected, disrupting the entire business operation. Existence of a Continuity of Operations Plan is essential for survival, and must identify succession of operational leadership, business critical staff, business critical suppliers, and detailed recovery instructions.

Both the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) continue to closely monitor the movement of H5N1 Avian Influenza, as well as the human cases and corresponding threat of an influenza pandemic. Numbers released from the WHO indicated that there have now been 274 cases of Influenza A/(H5N1) reported and a total of 167 deaths. This corresponds to mortality rate of 61%. Recent events in the United Kingdom have demonstrated the continued movement of avian influenza, where bird flu was reported February 3, 2007 at the Bernard Matthews turkey farm and plant in Suffolk (Shaikh, 2007). Ultimately, over 160,000 turkeys were destroyed (Smith, 2007). The social disruption such an event is capable of causing is immense. Since the infection was identified, there have been issues of “virus cover-ups”, hygiene lapses at the turkey farm, possible prosecution of the owner of the turkey plant, connections to bird flu discovered at a goose farm in the eastern Csongrad region of Hungary in January, concern over the response of Department for Environment, Food, and Rural Affairs (DEFRA), and concerns over preparedness of the nation, including stockpiling of antivirals and vaccines. Although it would be easy to say that such situations could never happen in the United States, the stark reality is that they can, and have in the past with other infectious agents.

It is apparent that although avian influenza and the potential for pandemic influenza have moved to the back pages in the popular press, those in public health and emergency response continue their relentless preparation for this and other potential infectious disease menaces.

Sources of Information and Findings

Effectiveness of Stockpiling Tamiflu in Survival and Recovery of Businesses to Pandemic Influenza.

Obviously there is no “correct” answer to this question, since we have never faced this situation in the past. Issues of societal preparedness continue to be subjects of discussion and disagreement. One area of controversy has been the place of antiviral agents in our regimen of weapons against the potential devastation of pandemic influenza. There are those who believe that with massive, rapid administration of antivirals to local areas with Pan Flu outbreaks, the Pandemic could be averted, or at least significantly diminished (Germann et al., 2006). Longini et al (2004) used a modeling system to demonstrate that if 80% of exposed persons maintained prophylaxis for 8 weeks, the epidemic could be maintained. One has to keep in mind that the normal dose pack of Tamiflu covers only a five day time period, although some regimens exist calling for up to 8 weeks of antiviral use. Others believe that this is too optimistic and that pandemics of this sort cannot be stopped, only slowed (Mackenzie, 2005). Of the basic four antiviral agents for use in this disease, there is significant resistance to two, leaving only Relenza and Tamiflu as antiviral candidates. At present, only Tamiflu is produced in tablet form. In 2005, the FDA extended its prophylaxis protocol for Tamiflu to include children between 1 and 12 years of age. It should be noted that there is no information concerning how effective this agent might be as a preventive agent, and some early information indicates that large doses might be necessary for treatment of the H5N1 strain. Antiviral agents are one of a number of measures that must be included in any business continuity of operations plan. No one aspect of the plan will guarantee

business survival. It is logical to believe that with an effective prophylactic antiviral agent that is effective against the particular infecting virus, and available to all in a short period of time, there would be significant reduction in mortality, and less business disruption. However, there are many issues to be considered when deciding what is the right course of action for any business. This is the classic risk vs benefit ratio when considering any course of action. As with any treatment or preventive therapy, decisions regarding use must be made on an individual risk versus benefit ratio, as well as placement of this modality in contrast to all of the measures being taken as part of your Continuity of Operations plan. Potential benefits and risks are:

Potential Benefits

- Protection of the workforce, or at least those identified as business critical, so that business can continue (and survive) during a pandemic
- Creation of a caring community where staff will be safe when coming to work
- Access to the drug if needed
- Perception of safety in the work environment

Potential Issues/Problems

- Distribution – who would you give it to and when?
- Cost and availability – social equality issues?
- Hoarding of supplies when there may be ill people who need treatment.
- Who has the authority to actually dispense the medications
- Would all employees (and family members) receive the medication or only those selected by a Continuity of Operations Plan as critical staff?
- Who would create a prioritization scheme for who gets the medication and how would they do it?
- Reports of possible serious mental health side effects involving children.
- What is the shelf life of the drug? How often would you have to rotate stock and who would have that responsibility?
- Protection only for the 5 days the drug is taken.
- How would you protect your supplies?
- Does anyone have the right to commandeer business stockpiles in the face of a national emergency?
- Would it be used for those infected, or as a prophylactic measure?

Much emphasis has been placed on corporate preparedness in recent months as avian influenza continues its movement toward the United States, and attitudes are changing. In the 2006 Deloitte Center for Health Solutions survey of large U.S. companies (Deloitte, 2006), 73% of those responding believed that pandemic flu represented a significant threat, up from 59% the year before. In 2006, 68% said they were very concerned, in contrast to the former 43%. Even though 73% had identified pandemic flu as a real threat, only 52% said they believed they had adequately planned. That 52% was a significant increase from the 14% who had formerly said they had adequately planned ways to protect themselves in 2005. Other experiences, however, still indicate the need for more serious interactions between Emergency Management, Public Health, and the Business sector in order to optimize interactions that will need to take place in the event of an outbreak. This relationship remains critical throughout the recovery phase as businesses seek to regain their stability, staff and customers.

There is great controversy as to the usefulness and wisdom of Tamiflu stockpiling in the United States. There is no doubt that most major agencies, including WHO and CDC, consider Tamiflu to be an important component of Pandemic Influenza Readiness. However, the WHO and the Food and Agriculture Organization of the United Nations (FAO)

recommend against using Tamiflu prophylactically because of potential loss of its effectiveness due to resistance. In June of 2006, the Deputy Assistant for Critical Infrastructure Protection and Compliance Policy for the U.S. Department the Treasury testified before the Financial Services Subcommittee on Oversight and Investigations that businesses needed to have contingency plans that including stockpiling of such items as masks, gloves, and antiviral agents (Parsons, 2006). The Hong Kong Center for Health Protection (2006a, 2006b) has urged Hong Kong businesses to stockpile antivirals, primarily because the public healthcare system will be overwhelmed. Certainly, the manufacturer of antiviral agents has also voiced strong support for stockpiling as a mechanism for businesses to survive such a devastating pandemic. Advertising campaigns and an online Pandemic Toolkit have been created surrounding this concept.

There is some evidence that large businesses have begun stockpiling of antiviral agents, although specifics are difficult to obtain. In reality, use of antivirals is but one piece of a much larger puzzle that businesses must assemble to be appropriately prepared for a Pandemic of Influenza H5N1. There are many locations, including [www. PandemicFlu.com](http://www.PandemicFlu.com) and www.who.int that can assist businesses in their efforts to become better prepared. Continuity of Operations plans must be created, with special attention paid to the Continuity of Human Capital, Customer Continuity, Supply Continuity, and IT Continuity (Deloitte Center for Health Solutions, 2006).

Ethical Issues of Stockpiling Tamiflu

One of the risks in encouraging stockpiling of an antiviral agent, whether by businesses, organizations, or individuals, is that this changes from good preparedness into a situation of hoarding a limited supply of life saving medications. Roche has been criticized (Russell, 2006; CIDRAP News, 2006). for marketing their Tamiflu to businesses, with some calling it socially irresponsible. In fact, Roche has created an online Toolkit to help businesses decide how many doses to order. Although the Department of Health and Human Services has not specifically addressed this issue with corporations, they do advise against any personal stockpiling. Some states, including California have advised their physicians not to prescribe prophylactic antiviral agents for their patients. This is, again, based on the fear that there would not be enough of the drug if needed.

Some believe that since the practice is employment based, that the unemployed or those unable to pay would be unfairly punished. Dr. Howard Markel, a medical historian at the University of Michigan, correlates the existence of a crisis with not only stockpiling, but hoarding, black marketing, and other inappropriate behaviors (Franklin, 2005). In considering the issue of stockpiling, Proctor and Gamble Corporation addressed the ethical considerations of such a move (Prystay et al., 2006). If a limited stockpile is acquired, who gets it and on what basis? If others you know you have a stockpile, do you not become a potential target? Swire Pacific Ltd.'s Cathays Pacific Airways, Ltd. has some type of stockpile, but no specific priority order. Virgin Atlantic Airlines purchased 10,000 doses for their employees (Wolk, 2005). When it's gone, it's gone. Much of the drive to acquire Tamiflu is based on anxiety levels among the population, according to Ira Cohen, an education consultant in Beijing. Myles Druckman, an employee of International SOS who advises companies about Pandemic Flu preparedness, is working on programs to manage anxiety in the work force. The irony of the stockpiling is that the virus may ultimately be resistant to the drug, making high doses necessary, or the drug ineffective. People forget that this is not an antibiotic. It is only protective for the short period it is taken, and they are again vulnerable. How good will a few days of protection be for a pandemic that could go on for months or years, or in many waves?

Comparison of Tamiflu Use to Social Distancing

There has been much discussion of the issues surrounding the concepts of isolation and quarantine. Legal questions, concerns over level of force allowed to maintain quarantine, keeping quarantined populations supplied with basic necessities, and the infringement on individual right are all being debated. Using the new *Community Strategy for Pandemic Influenza Mitigation in the United States* (CDC, 2007) and its Pandemic Influenza Severity Guide with its five levels of severity, a level five would project over 1.8 million lives lost, with a case fatality rate of 2%. Levels four and five would recommend that such things as school closure, cancellation of movies, sports events and other public gatherings, voluntary isolation and quarantine, and use of teleworking strategies be used for months at a time (McNeil, 2007). However, it is anticipated that with the level of illness and death present at that point, the public would be so fearful of large groups that these recommendations would occur naturally. These events would greatly reduce levels of exposure and the potential need for use of Tamiflu.

Findings and Discussion

As the discussion concerning Avian Influenza and the potential for Pandemic Influenza has evolved and matured, much of the hysteria and many of the reactionary positions have been tempered. Regardless of the decision made, each business should at least ask the question of whether stockpiling is a logical and ethical, as well as financially feasible given their specific circumstances. As a guideline, we suggest that you ask the following questions:

1. Have you created a Continuity of Operations Plan (COOP) to guide you in your decision-making process?
2. Have you given appropriate education to your staff and their families concerning how to best prepare for disasters such as pandemic influenza?
2. Are you in a business deemed to be “critical infrastructure” so that governmental plans may already provide various types of assistance, including antiviral agents?
3. If you decide that stockpiling is an appropriate choice for you organization, have you considered the potential issues/problems listed above?

The majority of businesses do not survive after major disasters. The decision as to whether or not to stockpile antiviral agents must be made based after consideration of the many factors presented in this paper, and is just one component of the preparedness equation. The key to the survival of your business will be on taking concrete action based on the plans you have created.

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Dr. James Hagen is Professor and Director of the Public and Non-Profit Management Program at the Graham School of Management, Saint Xavier University in Chicago. He is also Director of the Disaster Preparedness and Management Certificate Program that provides education and training for those responsible for helping their organizations prepare, respond, and recover from both manmade and natural disasters. Dr. Hagen is a Professor of Public Health and Epidemiology, and served as Deputy Executive Director of the DuPage County Health Department from 1999 to 2005. Dr. Hagen is a licensed Nursing Home Administrator, and works to prepare long term care organizations for the special needs of vulnerable populations. He is a certified Emergency Response Coordinator, a Certified Public Health Administrator, and is certified by the Department of Homeland Security as a Master Exercise Planner.

During the federal TOPOFF 2 full-scale exercise in the Chicago area during 2003, Dr. Hagen served as a public health Incident Commander. He was a presenter for the TOPOFF 3 National Biological Seminar, moderator of Advanced Distance Learning Exercise panels, and a mentor for the New Jersey Venue. He works to train hospitals in several emergency preparedness areas, including communication, isolation and quarantine, and SNS issues. In 2005, Dr. Hagen worked as consultant during the Alaska Shield/Northern Edge Military Exercise in Alaska. He also worked in post-Chernobyl, post-Soviet Union Ukraine with the health ministry to study recovery issues and to assess public health needs.

Dr. Hagen is a graduate of Michigan State University and obtained his M.S. from the University of Montana. He was trained as a research microbiologist at Loyola University Medical Center, where he earned a Ph.D. He also holds an M.P.H. from Benedictine University, and an M.B.A. from Saint Xavier University.

Ms. Beverly Parota is Emergency Response Coordinator for the DuPage County Health Department and one of the lead instructors in the Disaster Preparedness and Management Certificate Program, Saint Xavier University. She was responsible for the development and implementation of all-aspects of the DuPage County Health Department emergency preparedness response plans. These plans were tested during the TOPOFF 2 full-scale exercise in 2003. She designed and assisted in the development of PRO-NET, one of the first locally developed and utilized rapid alert, disease tracking systems. The AmbulanceLink system developed by Ms. Parota and utilized by the DuPage County Office of Homeland Security and Emergency Management, is a sentinel surveillance system that tracks and reports all ambulance calls and provides early notification to public health officials. She is a member of the State of Illinois Strategic National Stockpile Advisory Committee and numerous other state and regional emergency planning committees. She is a Certified as an Emergency Response Coordinator and as a Public Health Administrator. She is a national consultant working to better prepare long term care facilities, senior facilities, schools, and municipalities.

Ms. Parota has been employed by the DuPage County Health Department for more than twenty years, also having supervised health promotion, community education and

information, vital records, web development, media information, graphic design, and dental services. Her programs and efforts have received national acclaim. Twice she was awarded the Secretary's Award for Excellence from the United States Department of Health and Human Services. In addition she received the County Achievement Award from National Association of City and County Health Officers, awards from the American Dental Association and other agencies.

Ms. Parota is a graduate of Loyola University of Chicago. She earned a Master of Education, in Adult Instruction and Management, from Loyola University of Chicago and a Master of Business Administration from the University of Notre Dame.