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Influenza Outbreak
A Call to Action

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Two of the three named authors on this report (Stephen G. Brozak and Lawrence F. Jindra) hold significant ownership in a company focused on the development of an anti-inflammatory therapeutic that seeks to control, among other conditions, cytokine storm resulting from influenza infection. Mr. Brozak is the Chairman and Chief Executive Officer of the company and Dr. Jindra is a shareholder. (Further information can be found in the Disclosure Statement on page 9.)

Thus far, the current Type A (H5N1) Swine Flu outbreak is serving more as a warning than a threat to life in the U.S. As of Sunday morning, there were 226 confirmed cases in 30 states with only one death. The Centers for Disease Control (CDC) had announced that 25 percent of the supplies in the Strategic National Stockpile (SNS) were scheduled to be delivered to all states in the continental United States. In addition, the Federal Government and manufacturers have begun the process of developing a vaccine against the H1N1 virus and expect to have both H1N1 vaccine and seasonal flu vaccine available by this Autumn.

In our opinion, the world will react to this pandemic flu warning much as it did to the H5N1 Avian Flu threat. There will be immediate alarm. Numerous Web sites will pop up that advise people how to survive in their homes and provide home remedies for treating flu victims. There will be a spike in sales of emergency supplies like batteries, bottled water and candles. Internationally, governments will create new agencies, write new plans and set aside money for marginally effective remedies. After a few weeks, attention will be directed to another news story and people will take for-granted the presence of what could have become a deadly threat in our midst.

Though it sounds glib, the only thing we know for sure is that the current threat will get worse, stay the same or get better. With a 66% chance that the world will have more time to prepare, it would be prudent to advance preparations for a deadly pandemic that could come at any time.

All Pigs Are Equal (Are Some More Equal Than Others)?

The influenza threat level increased two days ago, when Canadian health officials announced that a swine herd in the province of Alberta had been infected with the H1N1 virus by a carpenter who recently traveled to Mexico. Though we don't know the protocols used in this pig herd, we do know that pigs in North America are treated very differently than pigs in other parts of the world.

Pork is big business. In 2007, the pork industry had sales of $97 billion. U.S. pork producers operate 67,000 farms, and most domestic operations are large-scale. On these large farms, great care is often taken to avoid human-to-animal or animal-to-animal contamination.

In parts of the world outside North America, large-scale agriculture is growing, but backyard farms where a few pigs are raised in rural and in urban areas are common. In these backyard operations, pigs and humans can live in close proximity to one another and with other animals such as chickens and ducks.

Victoria Brazil

Southeast Asia

Source: Food and Agriculture Organization, United Nations

The opportunity to exchange diseases between species is great in these small, multiple species farms. The situation is exacerbated when people bring their animals to local markets for sale.

With multiple pandemic influenza strains circulating among several species, the opportunity for resortment (genetic reassortment), where multiple species merge, increases. If such a resortment were to occur in humans or swine, and be transmitted between species, a deadly virus could emerge.

Our Vulnerable Medical Delivery System

The world is at the mercy of a virus, among one of the simplest organisms on the planet. Our current defenses and our medical delivery system are incapable of combating a severe influenza threat. We have at our disposal neither a universal flu vaccine, a fast vaccine manufacturing capability, nor an effective, universal therapy for flu patients,

There is a dirty little secret about what could happen in the event of a severe flu epidemic. It is comparable to the financial meltdown that began on March 14, 2008.

On March 13, few people doubted the fundamental soundness of the U.S. and world financial systems. The next day, the Federal Reserve and JP Morgan Chase & Company (JPM) provided Bear Stearns with emergency funding following a depletion in Bear Stearns cash reserves. By March 16, JPM agreed to acquire Bear Stearns for the equivalent of $2 per share. Then, on September 15, Lehman Brothers Holdings, Inc. filed the largest bankruptcy in history and Bank of America (BAC) agreed to acquire Merrill Lynch for about $50 billion.

These events shook the foundation of the world financial system. After the fact, we learned that a small coterie of people knew how vulnerable the financial system had become, but it was not publicly discussed, for fear of creating panic and accelerating disaster.

A similar rude awakening about the vulnerability of the medical delivery system could arise suddenly in the face of a deadly influenza pandemic. Medical delivery is based on regularity, predictability and minimal variability in rates of disease. A predictable number of people per thousand will get infections, have automobile accidents, suffer heart attacks or come down with diseases. The number of doctors, nurses and hospital beds is derived from this statistical certainty. Even the likelihood of natural disasters like fires, floods and hurricanes is more or less predictable.

Drug delivery for specific diseases operates on a just-in-time principle that takes into account the predictability of demand. Inventories are kept to a minimum to conserve capital and extend shelf life. Manufacturing and delivery chains are created based upon predictable expectations of need.

If a sudden, vicious, new disease, like a highly dangerous flu pandemic were to strike, the system would be overwhelmed. Doctors, nurses, medical technicians and even hospital clean-up crews would be overworked. Only drugs that were stockpiled would be available in the quantities needed to meet the sudden new demand. If those drugs were ineffective, or if there were insufficient quantities to meet the need, there would be little chance of survival.

This is a difficult scenario that few government leaders discuss in public. It is why the flaws of our current flu defenses are a potential mortal threat.

Five Flawed Flu Defenses

Donald Rumsfeld, former Secretary of Defense, is famous for having said "You go to war with the army you've got." What holds true for a military threat also holds true for a medical threat. You meet the threat with the defenses at your disposal. Unfortunately, after six years since the appearance of the deadly H5N1 Avian Flu, little progress has been made in building new defenses to meet a severe flu threat.

Following are the five primary defenses currently available to combat a flu surge. Each of them has serious flaws.

> **Vaccine** – Vaccines work well when they are available. Each year a newly formulated batch of vaccine must be created and manufactured to meet a changing flu threat. According to the Department of Health and Human Services (HHS), two companies currently have influenza vaccine production facilities in the United States. They are Sanofi Pasteur, the vaccine division of Sanofi-Aventis SA (SNY) and MedImmune, the biologics business unit of AstraZeneca International (AZN), although only SNY's entire production process is based in this country.
>
> There is no universal influenza vaccine. A single vaccine formula stops all smallpox, whooping cough, plague and a wide variety of other, once-deadly diseases. Flu vaccine must be modified to meet the differing characteristics of each flu strain.

It takes up to six or eight months to create enough vaccine to meet a new flu threat. The technology now used for flu vaccine production is close to 60 years-old. It uses eggs to germinate the disease from which the vaccine will be made. There may not be sufficient manufacturing capacity to produce pandemic vaccine without delaying seasonal flu vaccine production, and seasonal flu kills, on average, 36,000 people in the U.S. every year.

There are several serious disadvantages to the current vaccine production process in the face of a deadly pandemic flu.

- 900 million eggs and several months are required to produce 300 million doses of vaccine.

- Egg-producing flocks could decline if the flu were Avian based, jeopardizing vaccine production capabilities.

- Eggs cannot be stored. They must be used when they are fresh.

- The virus must be manipulated so it can adapt to grow in eggs.

- People who are allergic to chicken eggs cannot receive vaccines produced from them.

New vaccine technology that will speed the manufacturing process has been under development for a number of years, but is advancing slowly. This “cell-based manufacturing” uses mammal kidney cells to grow the vaccine. The virus is injected into the cells where it multiplies. The cells' outer walls are removed, harvested, purified, and inactivated. Polio vaccine is currently produced using the cell-based method.

There are several advantages to the cell-based vaccine process that make it superior to egg-based manufacturing

- No eggs are required, so there is no threat to the growing medium in the event of an Avian Flu, no adaptation of the virus is required for the virus to survive in the egg medium and people who are allergic to eggs can receive the vaccine.

- Cell lines can be safely kept frozen indefinitely, increasing the capability to rapidly produce vaccines if an influenza pandemic were to occur.

In March 2005, HHS issued a five-year contract to Sanofi-Pasteur for $97.1 million to develop cell-based influenza vaccine technology and conduct clinical trials, with the goal of obtaining an FDA license for this vaccine. Under this advanced development contract, the company has committed to develop a plan to establish a U.S. cell-based influenza vaccine manufacturing facility, capable of producing at least 300 million doses of a pandemic influenza vaccine over a one-year period.

In May 2006, HHS awarded five contracts totaling more than $1 billion to accelerate development and production of new technologies for influenza vaccines within the U.S. Thus far, little progress has been reported.

- **Social Distancing** – This practice calls for avoiding crowds and limiting large gatherings of people. But it is vulnerable. One sick person in a crowd would threaten to infect anyone nearby. In the event of a threat, where voluntary social distancing was imposed, public transportation would be curtailed, schools would be closed and public events canceled.

  This is an extremely disruptive and expensive intervention. When schools close, parents must stay home to take care of children. Parents of toddlers will miss work because day care will be closed along with the schools. Public libraries, movies and other places where people gather could be closed. Airlines, trains, subways, sporting events and plays will suffer economically. But people will need to go to public places to buy food, seek medical care, or escape the tedium and monotony of days confined at home.

- **Quarantine and/or Isolation** – This intervention requires you to stay home if you are sick. If someone in your family were sick, that person would be required to stay home and you would too. Maintaining quarantine will require tremendous logistical support. People will soon run out of food and medicine. How and by whom they will be resupplied has not been addressed. National Guard units, the historic resource for states during domestic emergencies, are either depleted or deployed. Prisons, nursing homes and other group living facilities will be in dire straits very quickly, and if infection enters one of those institutions, it will run through it like wildfire.

- **Personal Hygiene** – This intervention calls for washing your hands, covering your mouth when you cough or sneeze and keeping well rested. It includes the use of personal protection devices, such as masks, gowns, gloves and goggles. Among the U.S. manufacturers of medical masks and gloves are: Johnson & Johnson (JNJ), Becton Dickinson Company (BDX), 3M Company (MMM), Kimberly-Clark Corporation (KMB), Cardinal Health, Inc (CAH) and Lakeland Industries, Inc. (LAKE)

  This intervention is very difficult to universally enforce and universal adherence is necessary to have an impact. Cruise ships have hand sanitizer stations throughout, yet gastrointestinal and respiratory diseases remain a constant threat.

- **Antivirals** – Effectiveness of antivirals is flawed, neurological side effects could be fatal and the manufacturing process is complex, limiting production capacity.

  The U.S. government, state governments, and governments around the world have invested millions of dollars to purchase Relenza from GlaxoSmithKline (GSK) and Tamiflu from Roche Holdings, AG (RHHVF). Gilead Sciences, Inc. (GILD) is the developer of Tamiflu and receives a royalty for sales of the drug by RHHVF. Both of these drugs appear to be effective against the H1N1 Flu but have limited effectiveness against the more deadly H5N1 Flu. Amantadine and Rimantadine,

members of an older generation of antiviral drugs, appear to have some effectiveness against H5N1 but to be to be ineffective against H1N1.

One of the shortcomings of Tamiflu is availability of its basic ingredient, shikimic acid. The primary natural source of shikimic acid is the Star anise fruit, which is used in Chinese Five-Spice Powder. Star Anise is grown in four provinces in China and harvested between March and May. (Japanese star anise, which is virtually indistinguishable from Chinese star anise, is highly poisonous.) In 2006, RHHVF purchased 90 percent of the world's production of star anise. RHHVF has developed a synthetic process to produce shikimic acid but it is expensive and complex.

By 2007, Roche was producing 400 million doses of Tamiflu a year (33 million per month) worldwide and was in the midst of expanding its production plant in Florence, South Carolina, to a capacity of 80 million doses per year (6 million per month). The expansion was expected to go online in early 2009.

The Tamiflu Suicide Risk

There are some disturbing side effects that have been reported, especially among children taking Tamiflu. As the drug is used more widely, it is likely we will see additional instances of these side effects.

Reports of self-injury, suicide and delirium, caused the FDA to add a warning to the Tamiflu label in 2008. The warning includes the following. "There have been post-marketing reports (mostly from Japan) of delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes, in patients with influenza who were receiving Tamiflu. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution." None of the cases had any reported psychological or neurological problems before taking the medication.

The Need for a Mitigant

In addition to the lack of a universal vaccine that can be manufactured and distributed quickly when a flu threat emerges, there is no drug available to mitigate the effects of flu on the human body.

Death from flu can be triggered by our body's over-reaction to the virus. This over-reaction is called hypercytokinemia or "Cytokine Storm" and is a primary cause of death from more virulent forms of influenza infections.

When our bodies detect these deadly viruses, T-Cells are dispatched to our lungs, which are the sites of the infection. As more and more T-Cells accumulate in the lungs, they cause a form of pneumonia that can suffocate patients.

Theoretically, Cytokine Storm can be mitigated by reducing the cytokine cascade. But the cytokine cascade is a complex process that is not full understood. There are hundreds of cytokines, some up-regulate inflammation and some down-regulate inflammation. Knowing how

each cytokine works individually, and in combination with others, is crucial to creating an effective drug.

Why Flu is Tough to Stop

Some people say that the flu virus is clever. It is not. It is a very simple biological entity, not even considered a living thing.

A virus is a submicroscopic parasite. It can only live and reproduce within a living cell of a human or other animal. It is composed of a core of RNA, surrounded by a protein coat, a capsid, or outer shell, and a protein coating. A single virion (an individual virus) can create and release thousands of progeny in a 10-12 hour life cycle.

The huge numbers of offspring and speed of reproduction accelerate the mutation process, called antigenic drift, in viruses. The simple structure of viruses enables them to blend with one another to create a new viral strain in a process called antigenic shift.

Virus genes are composed of eight separate pieces of ribonucleic acid (RNA). Each piece of RNA specifies the amino acid sequence of one and sometimes two of the virus's proteins. The segmented nature of the RNA allows different flu viruses to easily "mate" with each other to form hybrid strains of virus with bits of RNA from each parent. That is how the H1N1 virus evolved as a combination of a Swine, Avian and Human strain.

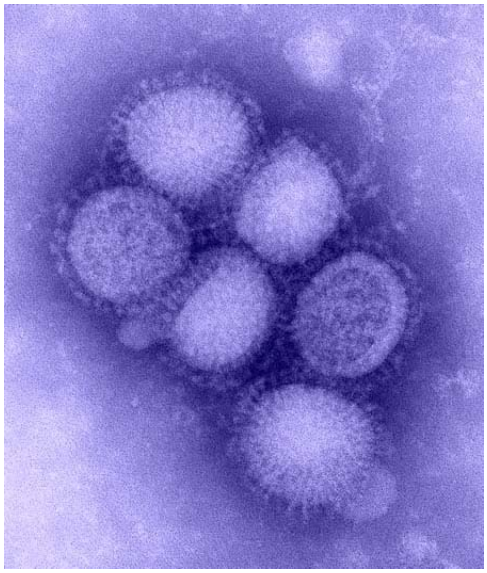
Spikes on the surface of viruses are crucial to viral reproductive capability. Viruses have two kinds of probes sticking out from their shells.

- One spike is hemagglutinin and the other neuraminidase. (You can see them in the photo of H1N1 viruses below.) The flu virus uses a hemagglutinin spike to latch on to the surface of a cell in the lungs and punch a hole in it. Then, RNA is released into the host cell where it reproduces new virions.

- The Neuraminidase spike contains a sialic acid molecule on its end that dissolves the outer wall of the host cell so the new virions can escape. Tamiflu inhibits the action of the neuraminidase on the flu virus cells, causing the new virions to be trapped inside the host cell where they eventually die.

There are 16 different hemagglutinin types and 9 neuraminidase types. Virus strains are identified by the version of hemagglutinin and neuraminidase types they contain. Other genetic variations within the RNA create sub-types of virus strains, called clades. Different vaccines must be produced for each hemagglutinin and neuraminidase combination and for variations within those combinations.

H1N1 Virus



Source: CDC

For Further Information

We list the following for further information on pandemic influenza. WBB Reports are available on Thompson First Call.

WBB What You Should Know About Avian Flu - October 12, 2005

WBB Avian Flu Maginot Line - October 19, 2005

WBB Avian Flu Not Business as Usual - February 2, 2006

WBB Avian Flu Coming To America - March 2, 2006

WBB Flu Scare Investors Beware - March 27, 2006

WBB A Report on the White House Avian Flu Plan - May 4, 2006

WBB H5N1 State of Denial (Update on Highly Pathogenic Avian Influenza) April 23, 2007

WBB Preparing to Fight the Last Flu War (Update on Highly Pathogenic Avian Influenza) January 24, 2008

WBB A Primer on Avian Influenza September 3, 2008

WBB the Last Straw (Report on the Threat of an Influenza Pandemic) April 27, 2009

WBB Flu – A Call to Action April 30, 2009

Potential Influenza Effects on Military Populations, Institute for Defense Analysis – December 2003

A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues, Congressional Budget Office – December 8, 2005

National Strategy for Pandemic Influenza: Implementation Plan, Homeland Security Council – May 2006

Fatal outcome of human influenza type A (H5N1) is associated with high viral load and hyhpercytokenemia, Nature Medicine – September 10, 2006

Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States, Department of Health and Human Services, Centers for Disease Control – February 2007

Disclosure Statement

The company previously stated is StormBio, Inc., a Delaware corporation. It is a development-stage biopharmaceutical firm that is developing innovative anti-inflammatory therapies to treat a wide range of medical conditions. The first application for StormBio's technology is treatment of life-threatening influenza. Subsequent applications include other severe acute inflammatory conditions and eventually chronic inflammatory conditions.

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