

FINAL – September 18, 2007

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Economics Club of Memphis
September 20, 2007**

Thank you all for attending today, and thank you David for that kind introduction.

I would also like to thank Nick Clark of the Economic Club of Memphis for inviting me to speak tonight.

I realize that pandemic planning is an unpleasant, even scary topic, which most of us don't consider as the best dinner conversation. Several of you have privately acknowledged that little is being done in your organizations to plan for a potential pandemic – you've got other priorities. Nevertheless, I am compelled to educate you on the facts.

The single most important fact is....

Global health authorities warn that another global influenza pandemic is inevitable...and actually overdue.

I will share more facts about a pandemic with you in a moment but first, allow me to spend a couple of minutes suggesting what exactly this fact means to you.

As many of you are business and community leaders, I urge you to consider pandemic planning as important to upholding your responsibilities – to shareholders, employees, customers and the community.

Right here in Memphis and the surrounding area, many of you come from industries that could be devastated should a pandemic strike – tourism, retail and financial services are likely to suffer the most, although technology companies would face unprecedented challenges as well. For manufacturers, supply chains would likely be the chief concern.

Beyond shareholders and customers, pandemic planning is essential to protecting employees and the communities in which your company operates. Many of your employees would likely self-impose isolation to safeguard their families. People will be afraid to come to work. Your management team may be stricken with the illness and your succession plans may no longer be sufficient.

At this point, some of you may be thinking, “Hey, I'm glad we have a business continuity plan or a crisis management plan that addresses issues like this.” Well, (pause) unfortunately, unless it distinctly covers pandemic planning, you're not safe to sit back and enjoy your dinner just yet.

Let me point out another misperception to you.

One common myth I've heard is that employees could just work from home if a pandemic struck. This is unlikely to be the case. According to the National Communications System, home-based workers could experience problems in the "first mile/last mile" connections. Internet access may be intermittent at best.

Another little known fact is, as with the great Spanish Influenza of 1918, a pandemic flu would mainly impact young and middle-aged healthy individuals far more than the normal seasonal flu. This is due to the severity of the inflammation, or cytokine storm that the pandemic induces in healthy young lungs. Being a healthy individual would not offer you safe harbor from the virus. Now, hopefully I've convinced you that pandemic planning is a critical responsibility. The remainder of my speech will focus on the facts -- why the risk of a pandemic is real and what you can do about it.

I believe an influenza pandemic is one of the most important health concerns facing this country and the world. And I'm not the only person who thinks so.

This past May, Margaret Chan, Director-General of the World Health Organization, or W.H.O., said a flu pandemic is the greatest threat to global health in the 21st century. Many other experts share this view.

But of course, at this moment, there is no global pandemic.

In the four years since the first human death from the H5N1 strain of influenza virus, about 195 people have died from the bird flu out of 319 known cases.

H5N1 is a deadly disease with almost 60% of untreated infected humans succumbing to death.

Geographically, the deaths have been diverse, occurring from Asia to Africa to the Middle East.

But almost all victims had one thing in common: close daily contact with infected birds.

H5N1 currently has great difficulty moving from the digestive tract of an infected bird to the respiratory tract of a human being. Over 200 million birds have died, either from contracting the H5N1 virus, or, far more likely, from the attempts to eliminate the virus before it can mutate into a strain that easily passes from the respiratory tract of one human being to another.

My company, Roche, is a research-based pharmaceutical company with global headquarters in Basel, Switzerland. I lead our North American Pharmaceutical business.

Roche's sole mission is to discover, develop, manufacture and market innovative medicines.

We're the world leader in cancer medicines. We've created pharmaceutical products that make

transplantation possible and therapies which have brought advances to the treatment of hepatitis B and C, osteoporosis, and HIV/AIDS.

Yet these days, with all of the media attention on avian flu, the Roche product that gets the most attention is Tamiflu, an antiviral that's one of the few available defensive treatments -- and prevention options -- against influenza.

Many companies are working on avian flu vaccines, which, unlike antivirals, must be specifically tailored to individual strains of flu virus.

The challenge in coming up with an effective vaccine is that pandemics begin when a virus mutates. That means we won't know much about the virus that causes the next pandemic until it's already well-established in the human population. That makes the antivirals, including Roche's Tamiflu, the first line of defense, and an important treatment even after an effective vaccine is available.

Another pharmaceutical company, Sanofi-Aventis, recently developed a vaccine which, at its highest dose, protects only 45% of adults from the current H5N1 strain. And that's good news. The fact that the Food and Drug Administration approved the vaccine -- with only a 45% efficacy rate -- and the fact that the U.S. is now stockpiling it... is a telling indication of how seriously the potential for pandemic is being taken at the highest levels of government.

Over the last four years, I've spent a lot of time on pandemic planning.

I've worked with Mike Leavitt, the Secretary of Health and Human Services. I've spoken with members of the President's Domestic Policy Council. I've testified before both houses of Congress. And the vocabulary that swirls around this issue is loaded. Words like "unstoppable" and "inevitable." Words like "devastating" and "catastrophic." What has to be the worst word of all is... "unthinkable."

Because right now is the time we need to be thinking about how to handle a pandemic.

As part of its "Global Influenza Pandemic Preparedness Plan," the World Health Organization has developed a six-phase sequence of events leading to a full-blown global pandemic.

It includes one phase to cover the period when a global influenza pandemic is underway... and five phases that lead up to that point... five true warning phases, each based on specific criteria... each associated with specific national and international public health actions... each focused on elimination or mitigation of the threat.

Warning phases -- that sounds familiar.

Remember the Y2K warnings? These were the polar opposite of avian flu, because we knew precisely when, but we didn't know precisely what.

How about Homeland Security Advisory System warnings, currently at "yellow," or "elevated," the exact same level the system started at, five years ago? We've raised the national advisory level five times - never for more than a month - and we've lowered it five times.

Do you remember SARS, the virus that made the jump from animals to humans and infected over 8,000 people between late 2002 and mid-2003? According to The New York Times, SARS "...brought dire predictions of recurring and deadly plague."

Warned about Y2K... no Y2K. Warned about additional acts of terror on U.S. soil... thus far, no subsequent incidents. Warned about SARS... and then SARS seemed to disappear.

Net result? We've all learned to ignore warnings, including becoming somewhat conditioned to hearing the serious warnings from Homeland Security.

Today, on September 20, 2007, with hindsight can we say that these warnings were blown out of proportion? Well...maybe.

Yes, maybe, except when it comes to SARS.

When the W.H.O. issued its definitions for pandemic phases, focusing on pre-pandemic warnings, they stated that "...early disease recognition...rapid implementation of global and national actions... high-level political support... and transparent communication [were responsible for] the successful control of severe acute respiratory syndrome or SARS in 2003."

In other words, warnings, preparedness and planning worked in the case of SARS. And based on the SARS experience, the W.H.O. now has what it calls "a promising new paradigm for the management of epidemics."

Learning from SARS, right now, it's vital that we take pre-emptive action to control the threat of a pandemic influenza outbreak...in other words, now is the time to plan.

Again, the threat of a global pandemic is very real.

On September 18 of last year, Richard Nesbitt of the W.H.O. told reporters that the risk of a bird flu pandemic continues unabated. He added, "After three years now, I'm sure many journalists and the public are starting to get tired of the same message" – that a global outbreak could strike any time – "but we have an obligation to keep giving this message."

And as Bruce Gellin, Director of the National Vaccine Program Office within HHS, says, “The ball could drop any second. You want to do as much as you can before that happens, because when that happens, the world will change.”

Many American businesses are doing their part, but more needs to be done – 73% of companies recently surveyed by Deloitte say they believe a pandemic is a real threat, but barely half feel they’ve planned adequately.

After several years of hard work, we do have a plan at Roche... but what about all of the companies we rely upon, the vendors and suppliers we depend on for the goods and services Roche needs to continue our operations?

That’s why I’m here today...my company has more to offer the business community than our products. In developing a comprehensive pandemic plan for our own business, we have covered much of the ground all businesses need to cover, as specified in the Federal Government’s National Strategy for Pandemic Influenza, introduced in November 2005.

This plan outlines the important roles to be played not only by the Federal Government, but also by state and local governments, private industry, international partners and individual citizens.”

The National Strategy delineates roles and responsibilities for each of these groups. Here’s what the strategy has to say about private industry:

“While a pandemic will not damage power lines, banks, or computer networks, it will ultimately threaten all critical infrastructures by removing essential personnel from the workplace for weeks or months.”

“The private sector represents an essential pillar of our society, because of the essential goods and services that it provides. Moreover, it touches the majority of our population on a daily basis, through an employer-employee or vendor-customer relationship. For these reasons, it is essential that the U.S. private sector be engaged in all preparedness and response activities for a pandemic.”

So, the World Health Organization has a plan; the Federal Government has a plan; OSHA has just introduced a plan; The Tennessee Department of Health has a plan; and the Memphis and Shelby County Health Department has a plan.

The best business pandemic plans work exactly the same way.

Now, back to the W.H.O.’s six-phase sequence leading to a pandemic.

At this moment, according to the W.H.O., the world is at Phase Three. In Phase Three, there are "...human infections with a new [influenza] subtype, but no human-to-human spread, or at most, rare instances of spread to a close contact."

Additionally, in Phase Three the virus has mutated – moving beyond fowl to infect mammals, including cats, leopards, tigers, and pigs.

The next phase, Phase Four, is the tipping point, characterized by "...[highly localized] small clusters with limited human-to-human transmission..."

When we hit Phase Four... which could literally happen tomorrow... the opportunity for individual businesses to develop pandemic plans will effectively be over. Business continuity experts consider Phase Three the "planning phase." When the W.H.O. announces Phase Four, we move into the implementation phase.

And that's alarming because the announcement of human-to-human transmission may well be what finally pushes some corporations -- the ones former Secretary of HHS Tommy Thompson said are viewing a potential pandemic "... like a deer in the headlights..." -- to begin thinking about their options. And believe me, they won't have many options at Phase Four if they are only beginning to plan. Alternatively, there are some corporations, my own included, that are poised to implement specific actions on the day human-to-human transmission is announced.

The Federal Government has made it clear that it will do everything within its power to ensure preparedness and communication and provide continuous surveillance and detection in order to be ready to respond and contain a future outbreak.

At the same time, the Federal Government explicitly stated in its National Strategy for Pandemic Influenza that, "...preparing for, and responding to a pandemic cannot be viewed as a purely federal responsibility."

At a 2006 summit on corporate pandemic preparations, HHS Secretary Leavitt made this point in blunt language when he stated that "Avian flu... will severely test the best-laid plans... and many companies are not making any plans at all. Those expecting the Federal Government to ride in and come to their rescue [will] be sorely disappointed."

In 2003, when the H5N1 strain roared back into life in Asia and the very first human infections were reported... teams from Roche met with teams from HHS and the CDC.

At that time, the WH.O. and other authorities recommended that governments start stockpiling antivirals and other essential supplies in preparation for pandemic influenza. Suddenly, all eyes focused on Tamiflu, which appeared to work against the H5N1 strain.

Then, as now, it was recognized that the development of a strain-specific vaccine was the ultimate goal. Then, as now, developing such a vaccine requires knowledge and samples of the actual mutated pandemic influenza strain capable of human-to-human transmission. And then, as now, that strain would clearly only become available... once the pandemic was underway. In late April 2007, W.H.O. reiterated its guidance on treatment of patients infected with H5N1, in which Tamiflu is the only antiviral given a “strong recommendation” for both prophylaxis and treatment. The updated guidelines note, "Experience with early Tamiflu treatment suggests its usefulness in reducing H5N1-associated mortality. In addition, evidence of prolonged H5N1 virus replication indicates that treatment is warranted even when treatment is started late in the course of the disease."

So antivirals were, and are, the first line of defense until the right vaccine can be produced in sufficient quantities to inoculate the population.

Stockpiling of Tamiflu is necessary because the manufacturing cycle takes from six to nine months - sometimes upwards of 12 months - from beginning to end. To stockpile enough to treat 25% of the U.S. population, the Federal Government’s ultimate goal, about 80 million courses of therapy would be needed, and that represented a phenomenal increase over usual demand.

So we at Roche went into overdrive and ramped up Tamiflu production. We doubled our production capacity in 2004 and doubled it again in 2005. In addition, we built a dedicated U.S.-specific supply chain.

We’ve also granted licenses to manufacturers in India and China for supplies to these countries only and have donated 5 million courses of therapy to the W.H.O. for their use. In short, supply of Tamiflu is not an issue.

I believe wholeheartedly that efforts made within the private sector to plan for continued business operations during a pandemic are essential. I take my cue from the Federal Government’s National Strategy for Pandemic Influenza, which states that “...the private sector should play an integral role in preparedness before a pandemic begins, and should be part of the national response.”

Allow me to tell you why that’s a good idea, not only for the businesses that create pandemic plans, but for the entire country.

Right now, you and I are close to the emergency room at Methodist University Hospital. If the Methodist emergency room was busy and backlogged, we could go instead to one of the 15 Memphis-area hospitals. Technically, we could still go to Methodist because federal and state

law mandates that an emergency room cannot turn a patient away for any reason. But it would be pretty foolish to go there if the EMTs were told that the Methodist emergency room was closed. Emergency rooms effectively close when crowding conditions become unmanageable. They divert incoming ambulances to other facilities.

That's a big issue here in Tennessee, where 11 hospitals have closed permanently in the past four years.

Two years ago, the UCLA School of Public Affairs did a study on emergency room diversion. They found that nationally, two out of three hospitals "go on diversion" at least once per year. A study conducted by the Tennessee Hospital Association found that emergency room visits in the state had increased 31% over three years, twice the national rate.

Last year, Governor Bredesen (BRED - uh - sen) signed a planning resolution in which he agreed to prepare the state for the possibility of pandemic influenza. The governor agreed to assure that the state's operational plan for pandemic influenza response is an integral element of the overall state and local emergency response plan. In addition, Tennessee has already established a Pandemic Preparedness Coordinating Committee.

But what happens to healthcare services that are already stretched to the limit during a pandemic? Influenza pandemics are not static events like a hurricane or tornado, nor confined to a specific area. Pandemics come in multiple waves, each one affecting a given area from four-to-twelve weeks. During the first wave, officials expect 20 to 30% of people will become ill. Here in Memphis, that's 135 to 200 thousand people who will get very sick in a very short period of time, inundating emergency rooms already strained to near capacity.

People without symptoms will be struck suddenly, and within hours, be too weak and sick to walk. Many people will die within days.

All of this leads to the conclusion that a pandemic will effectively shut down the healthcare system. Even with a plan that includes the use of National Guard armories and indoor basketball stadiums as emergency rooms – and indoor ice rinks as temporary morgues – the system will simply be overwhelmed. There will be shortages not only of space, but also of supplies, including beds and ventilators. And if 20 to 30% of people are sickened in the first wave, 20 to 30% of doctors, nurses, and other essential healthcare personnel will be missing from their jobs.

As you may know, pandemic influenza did sweep across this country, and the world, in 1918 – the so-called 'Spanish Flu.' Now, that was a long time ago. Therefore, it's of limited value to cite facts and figures from 1918, let alone draw conclusions about what might happen tomorrow based on what did happen nearly ninety years ago.

But, we have some positive things in our favor. For example, we have the capability for advanced warnings through vastly improved international communication, our better understanding of how influenza works and how it kills. We have antivirals we can use immediately and vaccines in development we can fine-tune once the pandemic virus has been identified.

On the other hand, people living in -- or escaping from -- outbreak areas on the other side of the world are now only hours away from any city in the world.

In the United States, during the Spanish Flu Pandemic, about 28% of the population came down with flu, and somewhere between 500,000 and 700,000 died. Even in areas where mortality was low, the numbers of those incapacitated by the illness were often so great as to bring much of everyday life to a complete stop.

Here in Memphis, in the fall of 1918, "two suspicious cases" were reported. Four days later, that number jumped up to 95 cases. By the middle of the month, Memphis alone was fighting more than 6,000 cases of the flu, and it was spreading from urban to rural areas.

All across the state, businesses deemed nonessential were told to close. Schools and churches were shut down and public gatherings were to be avoided whenever possible. The Nashville Street Railway and Light Company was instructed to run their cars with the windows open to allow the cars to air out. And some communities placed armed guards at their borders to quarantine or turn back travelers. One U.S. town outlawed shaking hands.

And nothing much helped. Books about life and death during the 1918 pandemic read pretty much like Stephen King novels. People had to deal with "the unthinkable" every day.

There have been two pandemics since 1918 – the Asian Flu in 1957 and the Hong Kong Flu in 1968. Death tolls were significantly lower, possibly due to advances in healthcare, disease surveillance, and available treatments... possibly due to less virulent strains of flu... or perhaps both.

Experts concur that another pandemic is inevitable, and some of the predictions being made about the next pandemic are disturbing, to say the least.

Even if closings are not mandated by the local or federal government, people will avoid public places like shopping malls. They'll have to go to the grocery store, but they won't like it. If half of the check-out clerks are sick at home, and a significant portion of the other half are afraid to show up at work, fearing infection, the lines will be long...that is if there is any food to purchase at all. If 40% of the truck drivers who transport goods to the store are sick, there won't be much on the shelves. And if members of the police force find themselves too sick to work, it won't be a pretty picture.

And there will be a drop in demand for products and services. There will be a decline in discretionary income, as businesses are forced to halt operations.

The Trust for America's Health is a nonpartisan, nonprofit organization that recently released a report titled, "Pandemic Flu and the Potential for U.S. Economic Recession." This study predicts the loss to Tennessee's GDP would be nearly \$14 billion as a result of a major pandemic.

Industry sectors such as agriculture, manufacturing, transportation and warehousing, food services and hospitality would be among the hardest hit.

So, that's why we need to plan. That's why we have to think in ways we've never thought before about protecting our employees and keeping the critical components of our businesses running. Who comes to work? Who can work from home? Which positions are essential to keep the core part of the business running? Who gets cross-training as an 'understudy,' ready to take over a critical task that absenteeism leaves empty? How will you service customers? How will you get raw ingredients? How will you run your factories and ship your products?

At Roche, we've been thinking about these questions for our own business continuity plan for many years. We don't have all the answers, and what's right for our business may not be what's right for yours, but we can offer advice and do have suggestions that can help you create or update your pandemic response plan. We've put this information on the web at pandemictoolkit.com.

And as part of the Roche plan, we developed a brochure for all of our employees. It's called, ***What to do in case of a flu pandemic***, and it provides our employees with useful information on such things as influenza, the risk of a flu pandemic, and how to prepare for a flu pandemic. We have copies for all of you to pick up on your way out of the room.

This planning is not easy by any means. It takes time and effort.

And when you leave this meeting, there are some specific things that you can do.

Number one: put pandemic planning on the agenda for your next board meeting or senior staff discussion. Find out what your company is doing to prepare for a pandemic.

Second: ask the hard questions and don't settle for the brush off. Make it your business to ensure that your company is indeed adequately prepared for a pandemic. Think about the unthinkable. Dust off your succession plan. Consider the worst-case scenarios. Conduct your own research to validate your company's plan. Remember that a general business continuity plan typically will not suffice.

Finally, leave this item on the agenda of your board or senior staff meetings until you are confident that indeed, you have fulfilled your responsibility to all of the stakeholders of your company.

The only alternative to effective planning now is hope.

We certainly can hope that it never becomes necessary to implement the federal, state and local pandemic plans. We can hope that when H5N1 mutates and becomes transmissible between humans, it loses some of its power in the process, which is certainly possible. We can hope that if and when we are threatened by some other virus that realizes its pandemic potential, the results resemble 1968 or 1957 more than they do 1918.

But if all you have is hope, you are not going to be ready. Remember, the W.H.O. says phase three...the phase that we're in now...is the time to plan. When we hit phase four, it's too late to plan.

When H5N1, or another strain, mutates, allowing easy human-to-human transmission, and an infected passenger arrives at Memphis International Airport, it will be time to implement your plan. It will be impossible to effectively begin planning in stage four as pandemic panic begins to spread across America.

Thank you and I'll be happy to answer your questions.