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## **Preparing For Pandemic Flu: A Call To Action**

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**An Interim Report by  
The Blue Ribbon Commission on Mega-Catastrophes of  
The Financial Services Roundtable**

**November 1, 2006**

**THE FINANCIAL SERVICES ROUNDTABLE**

*Impacting Policy. Impacting People.*



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## Message from Steve Bartlett

A mega-catastrophe is a natural or man-made event that has *significant* adverse *national* impacts on economic activity, property or human life.

The Blue Ribbon Commission on Mega-Catastrophes was formed to develop a comprehensive report regarding the particular challenges resulting from mega-catastrophes, and specifically to ensure the devastation and human suffering they cause is mitigated to the greatest possible extent, to:

- Identify the unique challenges of mega-catastrophes and catalogue the current system of responding to such mega-catastrophes.
- Propose prevention and mitigation policies for mega-catastrophes.
- Recommend improvements to the response system to help people cope with the results of mega-catastrophes.
- Recommend policy changes in public and private sectors to pay for the consequences of mega-catastrophes.

By their very nature, mega-catastrophes affect virtually every individual on the planet – either directly or in some ancillary way. We all watched in horror as events unfolded in the wake of the tsunami disaster in Indonesia and Hurricane Katrina in the United States, and millions of individuals around the world rushed to heal the breaches these disasters uncovered.

Events such as these cannot merely be unfortunate incidents in our collective histories – we must learn lessons and understand that the key to containment and minimization of consequences when mega-catastrophes strike is straightforward: preparation, preparation, preparation. Events never unfold as we suspect they will, but having no plan is – as is well-documented – merely a plan for failure.

For the survival of ourselves and those whom we love, a plan for failure must not be allowed to stand.

This Commission has coordinated with a variety of experts in the respective fields of insurance, medicine, science, and economics. Because of their unflinching generosity, we have been able to compile a three-part comprehensive plan that will address issues arising as a result of mega-catastrophes.

The first interim report was *Accelerating the Katrina Recovery*. That report is a crucial component of the overall effort, as Hurricane Katrina was the result of both

a natural phenomenon *and lack of appropriate planning*, which led, in turn, to a “domino” effect of relief coming far later than it ought, and set the stage for recovery arriving in a piecemeal fashion (despite the best efforts of everyone on the local, state, and federal level). Recovery, as we have learned, is absolutely critical to for any plan on how to meet the consequences of mega-catastrophes, and in the Hurricane Katrina situation we have a real-time case study from which to draw conclusions.

The report you are reviewing now, *Preparing for Pandemic Flu: A Call To Action*, addresses what needs to be done urgently to prepare for a pandemic; specifically, the pandemic flu. A flu becomes a pandemic through the mutation of an especially lethal virus that becomes easily and rapidly transmissible between humans.

In spring of 2007, we will re-present the Katrina and Pandemic reports along with reports that address other mega-catastrophes – hurricanes, floods, earthquakes and terrorism. Collectively, these reports will serve as one “mega-report” on policies relating to the prevention and mitigation of and compensation for loss for all types of mega-catastrophes. That report will provide the nation – and the world – with a roadmap we so desperately need to meet the coming challenges posed by these events.

We look forward to your questions and comments on these reports.

With best wishes,



Steve Bartlett  
President and CEO  
The Financial Services Roundtable

## Acknowledgements

The Financial Services Roundtable is a unique trade association, limited to 100 of the largest financial services companies in the United States. Built on the legislative foundation created in the Gramm-Leach-Bliley Act of 1999, The Roundtable believes that a competitive marketplace is the best system for financing the American economy. Regulatory structures should ensure safety and soundness, and consumer protection, and *not* stifle the competitive market system.

The Roundtable is committed to uniform national standards, a strong economy, and actively promoting American strength in the global economy.

In the wake of recent disasters like the Indonesian tsunami and Hurricanes Katrina and Rita, a consortium of Roundtable member company CEOs undertook an enormous task: to identify gathering threats to business continuity via natural or other disasters, and then address these threats comprehensively with concrete plans on how to contain these unfortunate events when they occur, and save as many individuals as possible from pain and suffering.

The Roundtable is grateful to the following for their leadership in this unprecedented effort:

Without the dedicated leadership, persistence, and probing questions by Mr. Ed Rust, State Farm Insurance, Chairman, and Mr. Kerry Killinger, Washington Mutual, Inc., Vice Chairman, this report would not have been possible.

The 41 additional extraordinary individuals who constitute the Commission (listed on page 63 of this report) continue to spend hours on research and debate with unfailing commitment to the common good. We also commend the companies with whom these members are associated for supporting this effort by making the members available and providing the internal resources that have added the depth and knowledge required “to get it right.

We also wish to recognize Dr. J. David Cummins, Dr. Howard Kunreuther, and Dr. Erwann O. Michael-Kerjan who took the time to thoughtfully address specific issues in their areas of expertise:

The excellent professional staff at The Financial Services Roundtable, the Housing Policy Council, and BITS has provided extensive expertise and constant review to assure thoroughness and accuracy. We gratefully acknowledge the outstanding leadership provided to the Commission by Mr. William A. Longbrake, the Anthony T. Cluff Senior Policy Advisor for the Financial Services Roundtable.

We further thank the physicians, scientists, economists, insurance experts, inside and outside the organizations represented on the Commission who have shared their research, concerns, and suggestions with us so that our report can reflect the best array of approaches to cope with a Pandemic.

In addition, the Roundtable thanks Robert Litan, Vice President of Research and Policy at the Kauffman Foundation and Senior Fellow in the Economic Studies Program of the Brookings Institution, for his overall coordination of this enormous task and for his expertise and guidance every step along the way.

Finally, the Roundtable thanks the Cluff Fund and the member organizations of the Blue Ribbon Commission, which provided the financial support for this effort.

## Executive Summary: Preparing for Pandemic Flu: A Call To Action

The risk of a deadly, pandemic flu sweeping around the world is very real. For this reason, this report takes a global view of this danger. Though many of the recommendations are performance specific to U.S. preparations, the Task Force urges the U.S. Government and other non-governmental entities to work together for a comprehensive plan in order to meet this very real gathering threat.

No one is ready if the pandemic occurs within the next several years. Further, the risks to human life are great and especially so in developing countries.

When a virulent and easily transmissible strain of the flu emerges it will take as long as six months to develop and produce a vaccine. First the virus must be isolated and identified, then an appropriate vaccine found and tested, and finally the vaccine must be produced in sufficient quantities to inoculate every American. But, during this six-month period *the pandemic will be well advanced with devastating consequences.*

Taking limited vaccine production capacity in the United States and elsewhere into account, the U.S. federal government plans to be able inoculate all Americans within six months of an outbreak -- by 2011. In other words, not only will it take six months after the outbreak of a pandemic to produce sufficient vaccine, this isn't scheduled to be possible for another five years. This is not a workable plan -- a pandemic could occur at any time.

In addition, anti-viral medications that could slow the progression of the disease - and possibly save some lives -- are in limited supply. The medical systems here and elsewhere in the world are ill-equipped to handle even a mild outbreak of a pandemic virus; these systems would be overwhelmed with one that is more serious.

We must be better prepared. This report recommends a series of steps that the federal government should take, many in concert with governments of other countries, to reduce the threat to lives and the global economy.

We believe a comprehensive plan would cost roughly \$10 billion more than the \$7 billion the U.S. Government has committed to spending already. This additional sum is less than 1/10<sup>th</sup> the amount the federal government has devoted to relief and recovery from Hurricane Katrina. Additionally, it is a tiny fraction of the more than \$500 billion in lost output in the United States alone that a pandemic could cause.

Broadly, our recommendations fall into the following categories:

- Vaccine and technology: additional investment in developing new vaccine production technologies and the construction of production plants once those technologies are proven safe and effective.
- Licenses for maximum dissemination: the U.S. and other governments license all technologies that promise to accelerate production of a vaccine.
- Encourage more individuals to get annual flu shots: business and the government should work together to encourage every American to get a flu shot; businesses should pay for seasonal flu vaccinations of their employees, and the federal government and state officials should engage in an annual campaign to encourage every American to be inoculated.
- Medical equipment and personnel to treat the afflicted: the U.S. government should spend more to develop other medications which can treat symptoms of the flu, should purchase additional ventilators, and adopt a training program for more medical personnel to operate ventilators.
- Continuity in the delivery of services: all firms and organizations which make up this nation's "critical infrastructure" should implement and regularly simulate pandemic preparedness plans; the federal government should monitor and report on their readiness.
- Work globally to ensure maximum sustained coverage: because a future pandemic almost certainly will be global, the U.S. government should provide global leadership and work with other developed countries (and foundations) to support construction of vaccine production facilities in less developed countries, which have fewer resources to combat a pandemic.
- Even with the best of preparations, however, it is an unfortunate fact that many people will die if a pandemic flu breaks out. Aggressive proactive policy actions taken now can reduce the extent of human tragedy and economic disruption associated with a pandemic. This report is a clarion call to action.

In the words of Winston Churchill during World War II: "It is no use saying, 'We are doing our best.' You have got to succeed in doing what is *necessary*."

## Recommendations

*The Commission urges action on twenty-two specific recommendations.*

### ***To Expedite Vaccine Production:***

There is a real risk that a pandemic, one with potentially staggering consequences – in deaths, infections, and in loss of economic output – could strike the United States and other parts of the world as early as this flu season, in subsequent years, or perhaps never. Vaccine cannot be developed in the U.S. or elsewhere until a pandemic actually occurs. And, even then, it will take considerable time, using current “egg-based” production technologies, to produce enough vaccine for much of the U.S. population. The federal government’s pandemic plan calls for enough pandemic vaccine to be available for all Americans within six months by 2011. Given all that is at stake, this target is not sufficiently ambitious.

1. Because a pandemic could occur in the next several years, the federal government should commit to ensuring that all Americans have access to a pandemic-specific vaccine *well before* 2011. Indeed, given the possibility that a pandemic could occur at any time, achieving this objective should be one of the nation’s highest priorities.
2. The U.S. and other developed country governments should fund research and development of other vaccine production technologies and not rely solely on cell-based technologies as the only alternative to egg-based production. This research should include dose-sparing vaccine formulations (adjuvants) and immunization techniques.
3. The governments of the U.S. and other developed countries should be prepared to fund the construction of vaccine production plants.
4. The Health and Human Services Department (HHS) should regularly evaluate its vaccination priority plans to ensure that the spread of a future pandemic is slowed in the most effective manner.
5. Business and the government should work together to encourage every American to get a flu shot. Businesses should pay for seasonal flu vaccinations of their employees, and the federal government and state officials should engage in an annual public campaign to encourage every American to get a flu shot.
6. The U.S. and other governments should explore ways to license the use of adjuvants and other related technologies that will significantly increase

vaccine production capacity. Licenses should compensate developers with appropriate royalties, and technologies should be made widely available to manufacturers everywhere.

***To Enhance Medical Treatment:***

The medical establishment of no country, the United States included, is ready to handle the masses of people who will need medical care if a pandemic breaks out over the next few years (or even later). While it may be extremely expensive to pay for enough “surge capacity” – in beds, medical equipment and supplies and trained personnel – to deal fully with a worst case, there are concrete additional measures that should be taken by policy makers in this country to improve medical readiness.

7. The federal government should bear costs for meeting its anti-viral stockpile goal, which would protect 25 percent of the U.S. population.
8. The federal government should augment its support of testing and research and development (R&D) for developing other anti-viral medications.
9. HHS should purchase additional ventilators.
10. The Public Health Service should implement a program for training and certifying medical professionals (including retirees) to operate ventilators. States should waive restrictions on licensed medical professional from other states in the event of a pandemic.
11. The federal government should more aggressively educate individuals and their families in how to safely care for themselves and others at home.

***To Minimize Disruptions in Operations:***

A significant fraction – perhaps as many as 40 percent of the working population – will stay at home for extended periods of time in the event of a future pandemic, because their employers will tell them to, because they are caring for a sick relative, or because they will be too fearful to venture out in public. Schools and a host of public facilities in affected areas likely also will be closed to prevent the spread of the disease. Given this likely reaction, it is essential that private and public bodies that are critical to the functioning of a modern economy – electricity, water, telecommunications, key public services, financial services, food supply, among others – continue to function. Although some steps have been undertaken to prepare for significant disruptions in these activities, additional measures should be taken.

12. The Department of Homeland Security (DHS) should adopt a system for monitoring the adoption and systematic simulations of pandemic preparedness plans in the public and private sectors and should regularly report the status of readiness.
13. Every organization, public and private, should have a pandemic plan in place, and should simulate the plan at regular intervals to identify and remedy vulnerabilities. It is imperative for those industries that are part of the nation's critical infrastructure to do so.
14. Regulators should provide greater clarity to private financial institutions about the nature and extent of regulatory relief in the event of a pandemic so that the private sector can better prepare.
15. It is urgent that private sector organizations representing different segments of the nation's critical infrastructure intensify efforts to collaborate with each other to improve readiness. DHS, along with the Treasury Department as the lead agency for the banking and financial sector, should facilitate these efforts and work in partnership with the Financial Services Sector Coordinating Council for Critical Infrastructure Protection (FSSCC) and other critical infrastructure sector coordinating councils, especially for telecommunications and electricity.
16. Private sector firms in the financial and other critical industries should develop, along with regulators, common assumptions about what events will trigger the implementation of pandemic response plans. The FSSCC should play a critical role in this process.
17. Private and public sector organizations that are part of the nation's critical infrastructure should have both external and internal communication plans for disseminating what they plan to do in the event of a pandemic. Existing bodies, such as the FSSCC, should facilitate this activity.
18. The Federal Reserve should make liberal use of its "lender of last resort" lending authority through financial institutions to provide the liquidity that many firms and organizations in the economy will require to keep functioning.
19. Congress should promptly undertake a study of the impact of a pandemic, including a worst case analysis, on the capacity of the life insurance industry, and examine options for addressing any significant problems.

***Meeting the Global Challenge:***

A future pandemic almost certainly will affect the entire world. Developed countries that have the resources to minimize the consequences will be in a far better position to handle this kind of crisis than developing countries. Because a pandemic, by definition, is a global health problem, it is in the clear national interest of developed economies to help developing countries combat the disease and reduce its transmissibility. This will save lives and minimize economic disruption in all economies.

20. Any government of a country in which vaccine production method breakthroughs occur should take all possible steps to license those technologies for use in other countries, especially in less developed countries.
21. The U.S. government should immediately join with other countries – developed and less developed – to formulate a plan for assisting the funding of vaccine plant construction and production for residents of less developed economies. Private foundations with interests in health can play a constructive role in this effort.

***Funding:***

Given the consequences of even a mild pandemic, let alone a severe one along the lines of the one experienced during 1918-19, it should be straightforward that the necessary funding to minimize the spread of the disease should be forthcoming. Although more precise cost estimates will need to be developed by the appropriate experts, we believe that significant progress toward minimizing the impact of a future pandemic could be achieved if the U.S. government were to spend something on the order of  $1/10^{\text{th}}$  of what it has just spent for relief and recovery efforts after Hurricane Katrina.

22. We urge the Administration and Congress to adequately fund all of the recommendations in this report, in addition to amounts that already may be planned.

## Introduction

It is now widely recognized that the United States and the entire world face a risk of pandemic flu that, in a worst case, could have devastating consequences to people around the world. According to official estimates, anywhere from 200,000 to 2 million Americans could die in successive waves of such a flu. In addition, U.S. economic output could fall by more than 4 percent in one year and many fear that financial markets could face significant disruption as a result of a pandemic. Globally, deaths could range between 175 million and 350 million.

The wide range in estimates is due to the uncertainties surrounding both the probability of a pandemic outbreak and its lethality if it occurs. There is no medical or scientific consensus on either of these issues, although the weight of the evidence appears to be that another pandemic is inevitable. The uncertainty in the timing and severity of the possible disease outbreak, however, complicates efforts to prepare for the eventuality.

One fact is certain: if the pandemic flu arrives, the steps that governments and private businesses and individuals take collectively to limit its transmission will determine how many will die or suffer, and how disruptive its impact will be to the global economy and society. Our purpose in this report is to outline measures that, in combination, have a reasonable chance of keeping the human and economic toll of any future pandemic to a minimum.

A pandemic is far different from the seasonal flu that infects millions every year and causes roughly 36,000 deaths annually in this country alone. Three times in the past century, the “flu” has been far more deadly: a strain of the virus that has spread quickly around the world and killed many more. The worst such pandemic was in 1918-19 and had consequences difficult to imagine. Over half a million Americans died during three waves of this pandemic (when the population was one-third as large as it is today). By some estimates, as many as 50-100 million died around the world.

The latest concern about the possibility of future pandemic stems from the H5N1 avian flu, one of the most virulent and deadly forms of influenza ever identified. Since 1997, over 200 individuals, almost all in Asia, have been infected with the H5N1, and approximately half have died. The numbers of reported human infections have been increasing each year and if past patterns continue, an upsurge in cases in late 2006 or early 2007 is possible, if not likely. The great, albeit unknown, fear is that this particular strain of influenza (or a close variation) – which currently is transmissible from birds to human beings – will mutate into a form that is easily transmissible between humans. If that should occur, the new strain could become the next great pandemic.

The U.S. government, the World Health Organization (WHO), and other governments already have taken some measures to contain the spread of any new and deadly flu virus. In particular, various governments have worked closely with the WHO to destroy flocks of birds in which the H5N1 virus has been discovered. Additionally, much work has gone into planning for a pandemic by the U.S. federal government, which has issued useful guidance to other levels of government and to the private sector. The Administration requested \$7.1 billion over fiscal years 2006-08 and has received to date \$6 billion in appropriations from Congress to fund research and development on new vaccine technologies, to stockpile some vaccine and antiviral medications, and to support pandemic preparedness.

As important as these steps are, more should be done, and as rapidly as possible as the next flu season is imminent. This call to action is an *Interim Report of the Blue Ribbon Commission on Mega-Catastrophes of The Financial Services Roundtable*, a group formed for the specific purpose of examining public and private sector policies relating to various mega-catastrophes.<sup>1</sup> The Roundtable consists of 100 of the largest integrated financial services companies in the United States. The Commission consists of executives from 35 Roundtable member companies, plus a number of other organizations active in the financial arena (See Appendix for a list of members). This report reflects what is known from publicly available information, as well as the expertise within the member organizations represented on the Commission. We have also consulted with various experts in the scientific and medical communities and elsewhere in the private sector. In addition, the report reflects the past guidance and current input from the Financial Services Sector Coordinating Council for Critical Infrastructure Protection (FSSCC), the Department of Homeland Security (DHS), and BITS (all described more fully below), on behalf of the Roundtable.

Our Commission, the Roundtable, and, indeed, all institutions active in the financial sector of our economy have a deep interest in and concern about the threat posed by a possible future pandemic. We care because the organizations active in financial activities employ over 10 million people in the United States who could be affected. We also care because our institutions perform services that are at the nerve center of our economy – processing payments; providing credit; and storing the wealth of individuals, businesses, and non-profit institutions. It is not just our financial well-being, but the financial health of the American – and indeed the global – economy that would be at stake in the event of a severe pandemic. That is why the federal government regards the financial services

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<sup>1</sup>The Commission has also released another interim report on “Accelerating the Katrina Recovery.” The Commission anticipates issuing a full report in the spring of 2007 on policies relating to the prevention and mitigation of and compensation for loss for all types of mega-catastrophes.

industry as an integral part of the Nation's critical infrastructure, along with certain other industries, such as telecommunications, electricity and transportation.

## Findings

Based on the best information we have been able to compile, largely from public sources but also from our own analysis and experience, we reach the following principal findings:

- 1) Despite the efforts that have been made thus far, the United States and the rest of the world currently, and for the next several years, are ill equipped to deal on a number of fronts with a severe pandemic. Using current technologies, it will take at least six months or longer to produce enough vaccine perfectly matching a particular pandemic strain to protect everyone in the United States. In the meantime, existing vaccines and antiviral medications may prevent some infections and mitigate the suffering of some patients. But our medical systems – hospitals, medical supplies, and trained personnel – are not equipped to handle a large surge in patients. For that reason, many who get sick are likely to stay home, a course of action that will, indeed, be the best option for those who will not need ventilators or other medical equipment to recover.
- 2) In late July 2006, GlaxoSmithKline (GSK), a British pharmaceutical company and a leader in vaccine development, announced that it had developed and tested a vaccine that appears to be the most effective vaccine to date to immunize individuals against the H5N1 virus, and at doses far smaller than in previous H5N1 vaccines. Although this announcement is welcome news, medical experts we have consulted urge the governments of all countries to remain vigilant against a possible pandemic. At the same time, if an important part of the formula for producing the GSK vaccine or any other vaccine proves effective, we encourage the U.S. and other governments to do what they can to license the technology and make it widely available to other manufacturers, with the goal of expanding vaccine production capacity to rapidly manufacture a vaccine aimed at the specific pandemic flu strain.
- 3) Over the longer term, our assessment of the pandemic risk is more favorable, especially if one or more new vaccine production technologies prove to be effective, if other vaccine research and development (R&D) efforts now underway bear fruit, and if prompt actions are taken to enhance vaccine production capacity now and in the immediate future. More time will also allow for higher production rates of antiviral medications and for the purchase of additional medical supplies. In addition, businesses and

governments will have more time to prepare, provided – and this is an important caveat – that they do not let down their guard and become complacent.

Given the complexity of dealing with the pandemic threat, this report does not attempt to cover all the actions that should be undertaken to address the issues raised by our findings. Instead, we focus on those steps we believe have the highest potential payoff and which, given our own collective expertise, we feel most comfortable recommending. These steps include measures to:

- ✓ Prevent spread of disease, if an outbreak occurs
- ✓ Enhance medical care for the sick
- ✓ Minimize impact on the operations of public and private sector establishment
- ✓ Cushion the human, economic, and social impact of a pandemic in other countries, especially less developed economies with limited economic resources to address a potential crisis of significant magnitude

Although we concentrate primarily in this report on those measures the public and private sectors can and should take to protect the health and economic well-being of American citizens, we are acutely aware that any pandemic almost certainly would be global in scope, and, for that reason, the members of our Commission urge that this threat be addressed in a global fashion. The pandemic threat should be treated first and foremost as a *global public health problem*. In an age where people and businesses increasingly are interconnected by human travel across borders, any pandemic by definition will not be limited to any one part of the globe, but rather will affect the entire world. For this reason alone, the United States must be prepared to prevent the spread of any pandemic originating from outside this country.

Specific recommendations are summarized in the accompanying table and elaborated more fully in the text that follows. All told, we believe that these recommendations would entail additional federal expenditures beyond those already envisioned in federal plans to prepare for a future pandemic in the range of \$10 billion over several years, with the precise cost depending largely on the degree of the U.S. commitment in supporting a global effort to provide a pandemic-specific vaccine when it is ready. Given the potentially devastating human and economic costs of a severe pandemic (even one of moderate or mild severity) we believe that such an amount – about 10% of the cost of the federal disaster relief and recovery effort after Katrina – would be money well spent. If necessary due to budgeting reasons, Congress and the President could treat this expenditure as an emergency, in much the same way it has treated disaster relief.

## I. The Pandemic Threat

Every year, millions of Americans catch a seasonal flu, a respiratory illness often transmitted from person to person that kills roughly 36,000 – primarily the very young and the elderly – annually.<sup>2</sup> Vaccines are manufactured in advance of every flu season and generally successfully immunize most individuals.<sup>3</sup>

Avian (or bird) flu is a virus that occurs naturally among wild birds. Although there are many strains or types of avian flu, the H5N1 variant is especially deadly to birds and other animals, as well as to any humans who may catch it from birds. Since 1997 when this virus first appeared, over 200 individuals around the world have caught H5N1 from birds and approximately half of them have died. Unlike the seasonal flu, the avian flu has struck most heavily amongst prime-age individuals, or those between the ages of 20 and 40 (a fact that is relevant to the priority for vaccination, as we discuss later).

So far, with some rare exceptions, the H5N1 virus has not been consistently transmitted between humans. For this virus, or one comparable to it in potential lethality, to pass directly from person to person would require some mutation from current strains. If this occurs and human-to-human transmission is not readily contained (which for reasons to be noted will be very difficult), the possibility exists for a global pandemic, or the outbreak of a virulent and lethal form of influenza that may or may not be similar to the H5N1 strain. Three pandemics occurred in the 20<sup>th</sup> century: the worst – the Spanish Flu – in 1918-19, another in 1957, and a third in 1968.

There is a wide range of opinion within the medical and scientific communities regarding the likelihood of a pandemic, when one might occur, or how lethal it might be. A pandemic could come as early as this flu season, in subsequent years, or perhaps never.

There are also varying views about pandemic mortality rates. The mortality rate during the 1918 pandemic, which killed at least 500,000 in the United States and perhaps as many as 50-100 million worldwide, was 2 percent of those infected. The mortality rate for the small number of identified avian flu cases has been something on the order of 50 percent. There seems to be some consensus, however, that a variation of H5N1 or a similar virus that is easily transmissible among humans would not be nearly as lethal. In the event of pandemic a mortality rate of 2 percent in the United States and the rest of the world would have

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<sup>2</sup> An estimated 1-1.5 million die worldwide each year because of the seasonal flu or complications [Osterholm, 2006].

<sup>3</sup> Sources for the statistics noted in this section include [www.pandemicflu.org](http://www.pandemicflu.org); [www.who.org](http://www.who.org); National Governors Association, 2006, and Barry, 2004.

unprecedented human consequences. And there is no assurance that the mortality rate could be kept below 2 percent.

The potential severity of a pandemic is one reason – perhaps the most important one – why pandemic risk both should be and is being taken very seriously by public health authorities and governments around the world. These parties are right to be concerned.

There are other reasons for concern. One worrisome factor is the rapid spread and further mutation of the H5N1 strain (there have already been multiple variations). Second, all influenza strains mutate and adapt to their hosts. That is why the 1918-19 pandemic occurred in three separate waves, and why experts expect another possible pandemic to follow a similar pattern. Some draw comfort, if not optimism, from the fact that the H5N1 virus has not in almost a decade yet mutated into a form easily transmitted between humans. This optimism may be justified. It is wiser to be prudent and safer in our view, however, to assume that a mutation will occur at some point.

### **A. Potential Mortality Impact**

In announcing its pandemic preparedness plans, the federal government has used assumptions largely drawn from the 1918-19 pandemic experience. These assumptions are displayed in the accompanying box.

Based on these assumptions, if, as was true in 1918-19, 2 percent of those infected die of the flu or related complications, then approximately 1.8 million Americans would die.<sup>4</sup> The federal government has projected an upper range slightly higher at 2 million and a lower end estimate of 200,000 [Homeland Security Council, p. 6]. The Congressional Budget Office (CBO) has projected a similar range, from 100,000 to 2 million deaths.

The worldwide consequences, obviously, would be far greater. With a global population of approximately 6 billion – roughly three times as many people living as there were in 1918 – a 1918-like pandemic could kill 175-350 million worldwide. Such a tragic outcome, in sheer numbers alone, would be unprecedented in human history. This number is “100 times more people than were swept away by the 2004 tsunamis. It is more than the number of people killed in all wars and by the most murderous governments throughout the 20<sup>th</sup> century. These people would die not in 100 years, but in 1 or 2.” [Fedson, 2006, p. 38].

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<sup>4</sup> This figure is calculated by multiplying approximately 300 million in total population times a 30 percent infection rate times a 2 percent mortality rate.

There are reasons why a future pandemic could be either worse or, on the other hand, be possibly less severe than the deadly 1918-19 outbreak. On the positive side, medical treatments have advanced considerably since the early years of the 20<sup>th</sup> century, especially the development of antibiotics that, while not useful for viral infections, can effectively treat the bacterial infections that are sometimes a serious complication of the flu. On the negative side, increased populations in urban areas and airplane travel that vastly increases the speed of transmission might lead to even more catastrophic results than the 1918-19 outbreaks.

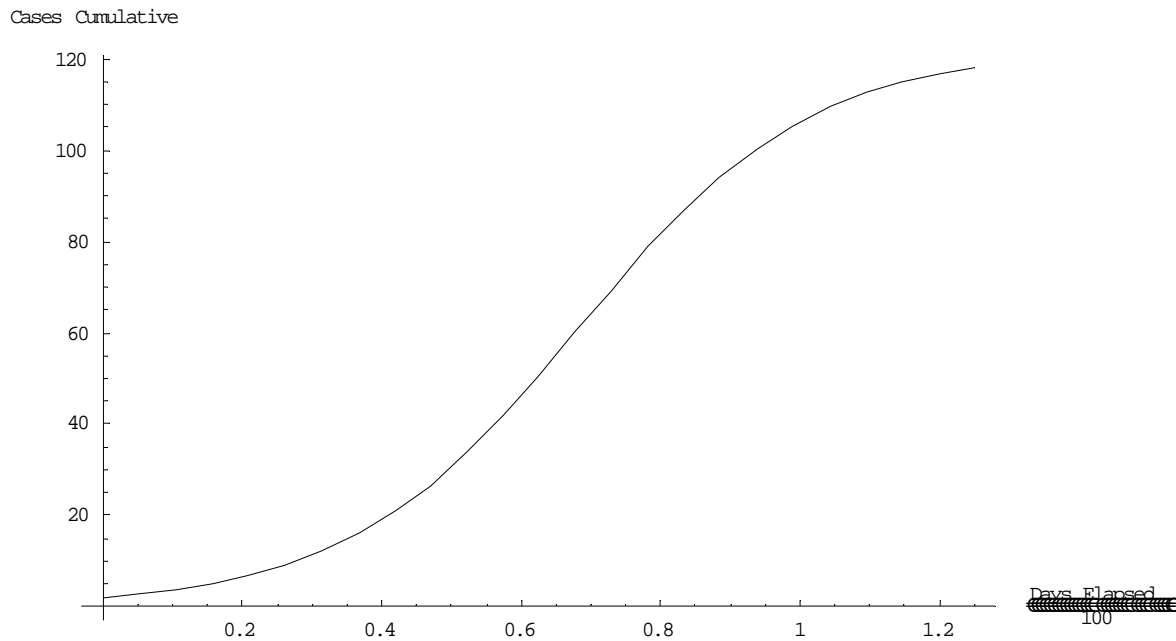
Chart 1 illustrates the rapid way in which a pandemic virus could spread in the United States, once arriving here from outside the country. Theoretically, even one individual can infect everyone else on a single plane, each of whom, in turn, might travel to multiple other communities. As this chart chillingly illustrates, by the 120 day mark, roughly 120 million Americans would be infected.

#### **Key Pandemic Flu Planning Assumptions of the U.S. Government**

1. On average, 30 percent of the population would be infected. Illness rates would be highest among school-aged children (approximately 40 percent), and decline with age. The infection rate among working adults would be 20 percent.
2. Although the number of infected individuals who would seek medical care cannot be predicted, in previous pandemics about half of those who become sick sought treatment. This proportion may be higher in the next pandemic if sufficient antiviral medications are available.
3. Rates of serious illness, hospitalizations and deaths depend on the virulence of the flu strain, which cannot be predicted in advance, although separately, the Homeland Security Council projects possible U.S. deaths ranging from 200,000 to 2 million.
4. Rates of absenteeism also depend on the severity of the pandemic. In a severe scenario, absenteeism could peak at 40 percent of local workforces due to illness, the need to take care of family members, and fear of infection.
5. The typical incubation period (the time between infection and symptoms) is two days. Individuals who become ill can transmit infection for one-half to a full day before the onset of symptoms; on average, sick individuals will infect two additional people. The risk of transmission is greatest during the first two days of infection. Children play a major role in transmission and are likely to experience higher illness rates than other age groups.
6. Epidemics are likely to last 6 to 8 weeks in affected communities. The illness is likely to mutate and, thus, affect the country in multiple waves, each lasting two to three months (as outbreaks spread across the country). Although historically the largest waves have occurred in the fall and winter, the seasonality of a pandemic cannot be predicted with certainty.

Source: Homeland Security Council (2006), p. 25.

**Chart 1. Pandemic Infection Rate (Total Number of US Cases, in Millions)**



Source. Estimated from Germann, T (2006)

## **B. Potential Economic Impact**

A pandemic would reduce economic activity in all countries, whether their populations are infected or not, since economies are linked to one another through trade and capital flows. A pandemic would reduce the demand for goods from countries suffering outbreaks, and thus dampen exports from other countries. In addition, a pandemic could cause stock and other asset prices to decline in all countries, but especially in countries directly affected [IMF, 2005]. Lower stock prices, in turn, would limit consumption and investment, and therefore economic output.

Several respected studies have been conducted to estimate the economic impact in the United States if the disease were to affect the U.S. population. The Congressional Budget Office has estimated that a pandemic similar in severity and scope to the 1918-19 pandemic would reduce Gross Domestic Product (GDP) by about 4.25 percent during the year of the pandemic [CBO, 2005 and 2006]. The CBO reports similar estimates by McKibben and Sidorenko [2006] and Cooper [2006]. All studies project that economic activity would quickly rebound once the pandemic has passed.

To put these percentages in perspective, it is useful to keep in mind that the current annual output of the U.S. economy is roughly \$13 trillion. A 4.25 percent drop in output, therefore, would translate into an annual output reduction of approximately \$550 billion, a loss, according to the CBO, comparable to the average post-War recession. In a milder pandemic – one that would cause 100,000 deaths – the CBO projects an output loss of about 1 percent [CBO, 2005].

The global losses are even more staggering in aggregate terms. In mid-September, a senior World Bank official estimated that in a worst case, a pandemic outbreak would reduce world output by as much as \$2 trillion (or 3 percent of world GDP).

There is one study, however, that is more optimistic about the economic impact. Two economists at the Canadian Finance Department have estimated that a severe pandemic on the scale of the 1918-19 event would cut the Canadian GDP (and by implication U.S. GDP) by only 0.3-1.1 percent [James and Sargent, 2006]. This projection draws on economic impacts estimated from earlier pandemics, including the 1918-19 episodes and the SARs outbreak, both of which hit Canada. According to this study, despite its highly lethal nature, the 1918-19 pandemic caused only a 0.5 percent decline in GDP in the United States and had no discernible impact either on financial markets or trade flows. The study found similar small effects from the SARS outbreak.

We draw little comfort, however, from any study based on extrapolations from past pandemic outbreaks, especially the 1918-19 flu. As already noted, the U.S. economy is vastly more interconnected than it was nearly a century ago. Just-in-time delivery systems are now commonplace throughout the economy – here and elsewhere. Major disruptions in parts of the economy are, therefore, more likely to ripple through the rest of the economy and at faster rates than in earlier times. We find it difficult to believe that an event today causing the deaths of roughly 2 million people in a relatively short span of time would not significantly depress consumer demand and, in turn, the willingness (or capabilities) of businesses to make investments in new plants and equipment. For all these reasons, even though economists differ on the projected impacts, we believe it more prudent for policymakers and firms to presume that a severe pandemic would cause a decline in output closer to the estimates of the majority of studies – estimating GDP losses in the neighborhood of 4-5 percent.

Whatever the overall economic consequences of a pandemic might be, they will differ significantly across different industries and areas of the country. Certain industries in which revenues are largely derived from in-person transactions – travel, retail establishments, restaurants, and other service providers, for example – would be more adversely affected than industries or activities in which business can be conducted without personal contact. Although some business would be

transferred to the Internet, the magnitude of this offsetting impact could be muted by the impact of the pandemic on the Internet itself. As we discuss in Section II (D), the surge in Internet traffic that might result from an increase in telecommuting would slow upload and download times, perhaps to the point at which the network could not function effectively. This would dampen use of the Internet for commercial purposes.

One financial sector in particular – the life insurance industry – obviously could suffer significant adverse impacts as a result of the unexpected increase in the numbers of death claims. The Institute for Insurance Information (III) projects that a mild pandemic would cause relatively few life insurers to become insolvent, but the Institute is not so sanguine about the impact of a severe pandemic in which total capital losses could reach as high as \$133 billion. Although the III report does not project the number of insolvencies in a severe pandemic scenario, it indicates that “five to eight of the 30 leading group life insurers might struggle to pay their group life claims, particularly, if other lines of business, as well as their asset values, are also under stress.” The report also suggests that individual and group life insurers “might have to go into the capital markets to raise additional funds for claims payments,” which implicitly suggests that they might be rendered insolvent without the additional capital [III, 2006, pp. 9-13]. We offer a specific recommendation relating to the life insurance industry in Section IV (D) of this report.

## **II. Addressing The Pandemic Threat**

Addressing the pandemic risk requires attention to the actions of both the public and private sectors on five broad fronts: monitoring, containment, medical response, avoiding/mitigating business interruption, and assisting other countries in prevention and treatment. We discuss under each of these topics the current and projected state of affairs based on what we know about existing public and private sector plans, our assessment of these plans, and our recommendations for further urgent actions to reduce the human and economic impact of a pandemic.

### **A. Monitoring**

The first step in containing a pandemic – since preventing one is likely to be impossible – is to monitor its presence, and, specifically, to detect as early as possible the first cases of human-to-human transmission. While critical, it is important to understand that this is not an easy task because each pandemic virus is different and its unique signature must be isolated and identified through blood tests from an infected individual or individuals. Further, it is to be expected that individuals who come down with the disease may not recognize its special character until it is too late for them or until after they have infected many others.

The best that can be done on the monitoring front is already being done, from what we are able to determine. The course of any virus strains that *may* develop into a pandemic – currently, the H5N1 virus is a leading candidate – must be closely monitored on an international basis since a pandemic, by definition, is a global phenomenon. Fortunately, the World Health Organization is an international body that is already performing this function well. U.S. officials, medical specialists, and scientists are working closely with the WHO.

So far, it is only through the efforts of the WHO that we know the H5N1 virus has been detected in roughly 230 individuals. As a result of the WHO's efforts, the destruction of poultry in the affected regions have thus far contained the spread of H5N1, making it less likely that this particular strain will mutate. We have nothing further to recommend in this regard and encourage the U.S. government to continue its active support of and cooperation with the WHO.<sup>5</sup>

### **B. Containment**

The best way to contain the spread of pandemic flu is to vaccinate as many individuals as possible around the world, ideally with a vaccine that “perfectly matches” the specific virus. Should this prove impossible, individuals should be vaccinated with flu vaccines that are currently available. A second containment method is to provide individuals in affected regions with anti-viral medications, as well as additional medications now used for other purposes that may also be useful in treating those who become infected. A third step is to adopt “social distancing,” by closing certain facilities and events otherwise open to the public and encouraging individuals at home and at work to avoid close contact with others.

In the following sections, we review the current status of containment efforts, and offer recommendations for additional measures.

### **C. Perfect Match Vaccines and Related Concerns**

A vaccine cannot be perfectly matched to a particular pandemic virus – and thus immunize virtually all who receive it – until human beings become infected and vaccine manufacturers have time to isolate the virus and mass produce a dead form of it to inject into other humans. Manufacturers must have sufficient capacity to produce the vaccine to inoculate a vast population – not just U.S. citizens (300 million), but ideally, everyone in the world.

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<sup>5</sup> For daily up-to-date information about the status of H5N1 or other possible pandemic influenza strains, see [www.who.org](http://www.who.org).

The Administration's pandemic flu plan calls for sufficient capacity to inoculate all Americans within six months of an outbreak by 2011 [Homeland Security Council, 2006, p. 120]. In an effort to achieve this goal, Congress approved \$531 million in funding in fiscal year 2006 to expand current egg-based vaccine production capacity and roughly another \$1.2 billion to develop alternative vaccine production technologies. In December 2005 Congress also granted vaccine manufacturers and other parties liability protection, without which research and development of vaccines could have been discouraged.<sup>6</sup>

Currently, all flu vaccines are manufactured using chicken eggs as part of the process. However, these egg-based methods have limits, including the critical fact that the eggs must be specially prepared and treated, thereby eliminating the possibility of quickly expanding production capacity in the event of an emergency. Further, the current production of eggs in the United States, 100 million annually, would have to increase to roughly 2 billion to permit the production of enough vaccine for the population of the entire country, during a time when there also may be pressure to destroy chickens to prevent bird-to-human transmissions.<sup>7</sup>

For all these reasons, HHS is counting on egg-based production methods to meet only 20 percent of the "perfect match" vaccine required by 2011.<sup>8</sup> Even that amount would represent a seven-fold increase from the current U.S. capacity, a goal that is not attainable without the construction of the additional egg-based capacity that HHS is apparently hoping to fund with the \$531 million appropriated in FY 2006, unless the government is able to find a way to license a new adjuvant to boost vaccine effectiveness with lower doses, such as the one reportedly pioneered by GlaxoSmithKline (as discussed below).<sup>9</sup> For the remaining 80 percent, HHS has extended approximately \$1 billion in contracts to six separate companies to develop production technologies to produce vaccines in cells that, in principle, should be ready and able to meet demand in a pandemic emergency. The key advantages of cell-based methods for providing the environment for growing the vaccine (assuming the technologies can be perfected) are that cells can be

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<sup>6</sup> The Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006 prohibits federal and state lawsuits against manufacturers of medical products and health care providers for injuries caused by treatment for pandemic influenza, other epidemics, and diseases caused by acts of terrorism. Liability protection exists only during the period that the Secretary of HHS declares a public health emergency (and protection does not extend to willful misconduct).

<sup>7</sup> See CBO, 2006.

<sup>8</sup> Leavitt, 2005.

<sup>9</sup> CBO (2006) explains that even with Sanofi's groundbreaking in 2006 of a vaccine-production plant in Pennsylvania that should double domestic capacity to produce H5N1 vaccine, that company still would be only to provide only 16-20 million courses of treatment (at two shots per person), enough for just 5-7 percent of the U.S. population.

frozen in advance and that large numbers of them can be grown quickly.<sup>10</sup> HHS plans to make additional funding awards in 2007 and 2008 to those companies documenting some initial success in their cell-based R&D efforts.

Still, potentially significant uncertainties remain regarding the efforts to ensure sufficient capacity to produce “perfectly matched” vaccines by 2011.

### Concerns

- *It is not certain to what extent a perfect match vaccine developed for the first wave of a pandemic would protect populations against successive waves, a pattern the federal government expects if a pandemic outbreak occurs.* The flu virus constantly mutates and the second or third version of a pandemic virus could react significantly differently to a vaccine produced for the first wave. Further, given the rapid speed of transmission of the flu due to modern transportation, it is possible, if not likely, that the first wave will be over by the time the perfect match vaccine is developed. For all these reasons, therefore, it would be a mistake to assume that a perfect match vaccine is a panacea, although the experts we have consulted believe it will provide far better protection against subsequent waves than any existing vaccine.
- *There is no guarantee that any of the cell-based techniques the HHS has funded so far will work, in the sense that they will be able to mass-produce the perfect match vaccine in the six-month time frame the HHS has announced as a goal – and that they will be able to do so by 2011, the other HHS-announced vaccination goal.* Moreover, even if a cell technology is demonstrated to be effective, some experts believe it would take four years to build the necessary plants and qualify for FDA approval. Again, according to the CBO, HHS believes that the timeline could be expedited by performing a number of the steps required – design and construction of the plants and clinical trials, for instance – in parallel time frames. But this HHS strategy is still a bet – a reasonable one, in our view – but not a sure thing.

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<sup>10</sup> CBO (2006) also notes that there are competing views about the additional value or disadvantage of cell versus egg-based technologies. The uncontested advantage is that cell-generated vaccines could be used by individuals who are allergic to eggs. The debate centers on whether cell technologies provide added or less security than egg-based methods. Egg-based methods are subject to contamination by poultry-based diseases, however, and even the Administration has acknowledged that cells could be subject to contamination [Home Security Council, 2006, p. 105, fn. 16].

- *It likely will be necessary in the future for the federal government to fund the construction of additional vaccine production plants. As noted, HHS already has plans to do this for egg-based technologies, but since cell-based methods have not yet been proven, funding for construction of those facilities will not be required until one or more such methods has been demonstrated to be effective. But, because much of that capacity may not be needed for the production of non-pandemic related vaccines, the government should be prepared in subsequent years to fund vaccine plant construction, although the amounts required will depend on the successful development of safe and efficacious dose-sparing adjuvants, as discussed below.*
- *Ironically, early success in developing cell-based vaccine production technologies that can be used to produce current vaccines for seasonal flu or pre-pandemic vaccines may discourage private sector efforts to develop other technologies for vaccine production. Accordingly, if the federal government wants – as it should – to maximize the chances of success in having sufficient surge capacity to produce a perfect match vaccine, then the government should fund research into the development of other methods of vaccine production.*

On the following pages, we outline several specific suggestions related to vaccine development and production that, in combination with other measures, can reduce the severity of the pandemic threat to the United States – and indeed, to the rest of the world.

## Preparing for Pandemic Flu: A Call to Action

### 1. Successful Vaccination Delivery Must be Earlier

Despite the uncertainty clouding the effectiveness of a perfect match vaccine for subsequent waves of any pandemic virus, having the capacity to quickly produce mass quantities of the first perfect match vaccine should make it easier to produce vaccine for subsequent waves. In addition, it is possible that the perfect match for the first wave could immunize a substantial portion of the U.S. and other populations against successive waves.

2011 as a goal is simply too far away for comfort. The government should do all it can to accelerate its ability to meet the universal U.S. vaccination target for a perfect match vaccine as soon as possible.

The pandemic threat should be treated with the same degree of seriousness and intensity as any other threat to our national security, because, in fact, it is. A virus that can kill as many as 2 million of our citizens is every bit as much of an external danger as a military attack and should be treated accordingly.

**Recommendation 1: Because a pandemic could occur in the next several years, the federal government should commit to ensuring that all Americans have access to a pandemic-specific vaccine *well before* 2011. Indeed, given the possibility that a pandemic could occur at any time, achieving this objective should be one of the nation's highest priorities.**

### 2. Vaccine: Other Technologies

Cell-based methods are not the only alternatives to egg-based vaccine production methods. Further research should be conducted into ways to stretch the amounts of vaccine required for effective immunization through dose-sparing adjuvants, as well as research relating to different methods of immunization.

HHS rejected proposals from companies in its first round of vaccine funding that would have used recombinant genetic techniques to manufacture vaccines, but according to the latest CBO report (2006), HHS has changed its position and is now preparing to issue requests for similar proposals. Other technologies have also been suggested, including the development of a universal vaccine to immunize individuals against all flu strains, and it is quite likely that more ideas will surface if HHS offers to fund research. Given that roughly \$1 billion has been spent on the six initial cell-based research grants, it is not unreasonable for the government to

spend at least half that much (\$500 million) for R&D contracts, prizes, or other reward-based compensation systems to induce the development of other vaccine production technologies.

One potentially promising, though untested, concept is the possible use of current bioreactors, or vessels that use organisms such as cells to carry out chemical processes. There are multiple bioreactors in the United States and other countries currently used for other purposes that may be suitable for vaccine production, ideally with a dose-sparing adjuvant that could considerably expand effective vaccine production capacity.<sup>11</sup> At least in principle, this process might be capable of producing several billion doses of perfect match vaccine in several months, well in advance of the six-month target for inoculating all Americans. We urge HHS to give this concept especially serious consideration.

Other developed country governments should increase funding of vaccine research and production. Four of the leading companies in vaccine and pandemic-related research and production – Chiron, GSK, Roche, and Sanofi – are non-U.S. firms. Governments in the countries in which these firms are headquartered or have research and manufacturing facilities should join with the United States in funding as many research efforts as possible that offer reasonable promise for quickly expanding the world's ability to rapidly produce a perfect match vaccine.

**Recommendation 2: The U.S. and other developed country governments should fund research and development of other vaccine production technologies and not rely solely on cell-based technologies as the only alternative to egg-based production. This research should include dose-sparing vaccine formulations (adjuvants) and immunization techniques.**

### 3. Vaccine: Production Possibilities

Because of what might be termed the surge nature of any pandemic vaccination program, much of the production capacity to vaccinate the U.S. population (including peoples in other countries, a subject discussed later in this report) is unlikely to be needed for private sector use later. In addition, the Congress Budget Office has pointed to several other reasons why private firms do not invest the socially optimal amount in vaccine production capacity, including the fact that individuals do not take into account the benefits they confer on others when they get a shot, that flu vaccine cannot be stored after one season, and that the manufacturing process is subject to contamination which could result in vaccines

<sup>11</sup> Currently, the best bet for such an adjuvant is the one that appears to have been developed but not yet thoroughly tested by GlaxoSmithKline discussed later in this report. It is possible that other adjuvants might be developed in the future that would be equally, if not more, effective.

being withheld from the market.<sup>12</sup> For all these reasons, only government funding support can assure the requisite surge capacity.

The Administration's pandemic implementation plan calls for HHS to purchase and maintain stockpiles of 20 million courses of vaccine against each flu virus deemed to have pandemic potential. Even if these vaccines are no more effective than the seasonal flu vaccine discussed next in this report, the purchases would stimulate the building of additional plant capacity that could be called on in the event that a pandemic occurs and surge capacity is needed to manufacture a perfect match vaccine.

In other circumstances in which a vaccine is well known but in which demand is not great enough to encourage sufficient investment in production capacity, government purchase agreements can provide sufficient demand-side incentives to make up for any market-related shortfalls.<sup>13</sup> However, demand-side incentives may not be well suited to encouraging expansion of production capacity when vaccine manufacturers do not know when the purchases actually will be made. A perfect match vaccine in particular cannot be manufactured until after a pandemic virus has already spread and can be isolated. For this reason, the federal government is more likely to encourage expansion in vaccine production capacity if it provides assistance directly for construction itself, either in the form of grants, tax incentives, loans, or loan guarantees.

At this point, we are not in a position to recommend a specific dollar figure for government financial assistance in any form because the best production technique – whether cell-based or some other technology – has not yet been proven. Indeed, it is conceivable that relatively little government financial support would be necessary if something like the bioreactor/adjuvant approach (or other technologies even more promising) turns out to be the best way to quickly ramp up production of a perfect match vaccine. However, if more expensive and complex technologies prove to be necessary, we urge the federal government to provide the construction aid that promises the most rapid buildup of vaccine capacity.

Should research into the alternative production technologies that we hope the United States and other developed countries will support ultimately bear fruit, we urge these countries to commit to assisting the construction of additional plant capacity to serve the needs not only of their own citizens, but others around the world.

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<sup>12</sup> CBO (2006), p. 25.

<sup>13</sup> See, e.g. Kremer and Glennerster (2004).

**Recommendation 3: The governments of the U.S. and other developed countries should be prepared to fund the construction of vaccine production plants.**

#### **4. Vaccination Prioritization**

The HHS has developed a near-term priority plan for allocating scarce supplies of any vaccines that are closely matched to the particular pandemic virus: first to medical workers and then to the elderly and individuals with chronic conditions making them highly susceptible to hospitalization and death. This may be the right priority system, but it may not be.

If a future pandemic bears significant similarities to the 1918-19 pandemic, for example, then younger, healthier individuals (those between the ages of 18 and 40 in particular) are likely to be at greater risk. These individuals are also more mobile, making them more likely to spread the disease.

Accordingly, it is necessary for the HHS to regularly evaluate its vaccination priority plan in light of what is actually known about the nature of the specific virus that may represent a pandemic.

**Recommendation 4: HHS should regularly evaluate its vaccination priority plans to ensure that the spread of a future pandemic is slowed in the most effective manner.**

#### **5. Flu Shots for Everyone**

Until a perfect match vaccine is developed, a conventional seasonal flu shot offers the best protection against a pandemic, however imperfect such protection is likely to be. The more people who get the seasonal vaccine, the greater will be the surge vaccine production capacity in the event of a pandemic. In addition, higher seasonal flu shot penetration should reduce the likelihood that seasonal flu symptoms will be confused with pandemic flu in the event a pandemic occurs during the regular flu season.

As of early September, the Food and Drug Administration had approved four companies to supply flu vaccine for the coming season; these companies collectively have indicated they will deliver 100 million doses of seasonal flu vaccine, up from 85 million doses in 2005. To help ensure that this will happen, both the public and private sectors should stimulate demand for the vaccine. Federal officials can and should do this, especially since a system is now in place to compensate individuals harmed by vaccine side effects without manufacturers

having to fear large liability awards. Businesses can also stimulate demand by not only encouraging employees and employees of any contractors visiting their premises to be vaccinated, but also by paying the costs of shots their employees choose to take.

**Recommendation 5: Business and the government should work together to encourage every American to get a flu shot. Businesses should pay for seasonal flu vaccinations of their employees, and the federal government and state officials should engage in an annual public campaign to encourage every American to get a flu shot.**

## 6. Paying for the Research

The U.S. government already is funding research into how to make dose-sparing vaccines using adjuvants to reduce the amount of vaccine required to effectively immunize individuals. In late July 2006, GlaxoSmithKline, a leading British pharmaceutical company, announced that it had developed a pre-pandemic vaccine, based on the H5N1 virus that is also dose-sparing [Grady, 2006]. GSK said that it had tested its vaccine on 400 healthy individuals in Belgium and will be seeking approval from food and drug agencies in the United States and other countries. A spokesman for the company said it could make 60-70 million doses annually once the vaccine is approved, equal to the company's seasonal flu production capacity, and that it expects production capacity for the new vaccine to rise to 150 million doses annually by 2008.

The news from GSK is clearly promising, but in our view it is premature at this time for the U.S. government to undertake a large-scale purchase of the GSK vaccine until its protective value is more clearly ascertained. Indeed, even if additional tests document its value, the U.S. government may be at disadvantage in completing a large-scale purchase since GSK is a British company and may allocate any limited supply to British citizens first.

Nonetheless, the most important breakthrough that GSK may have accomplished is not so much the specific vaccine it has announced, but the *adjuvant* that the company apparently has discovered for making *any* vaccine more effective and dose-sparing. Adjuvants function as additives to help stimulate the immune system, thereby reducing the dose required to achieve a given level of immunity. Adjuvants may also provide protection against multiple flu strains.

If the GSK adjuvant proves to be as effective as initially claimed, then it could greatly add to the effective vaccine production capacity worldwide by stretching quantities of vaccine over a broader population and speeding up the time required to immunize the entire U.S. population – or the population of any other country for

that matter – with a perfect match vaccine. This may be especially true if the concept of using the adjuvant with bioreactor technology proves promising.

The challenge is that this particular adjuvant is a trade secret and entirely within the power of GSK to license – or not license – as it chooses. Nonetheless, if further tests confirm GSK's claims about the cost-effectiveness of its new vaccine, we urge the U.S. government, ideally in combination with other governments (and the British government is a natural partner given that GSK is a U.K. company), to seek a license and pay appropriate royalties to use and make widely available to other manufacturers the GSK adjuvant and any related technology.

More broadly, we urge the U.S. and other governments to license *any* adjuvant or technology discovered or developed in the future that would safely expand effective vaccine production capacity and to which governments might not otherwise already have rights. We presume, for example, that since the U.S. government is funding the development of alternative cell-based production technologies, it owns the rights to license any of those technologies that might prove to be effective and safe.

We underscore the importance of paying royalties to the developer of any adjuvant or capacity-expanding technology because it is vital that private sector firms continue to have an incentive to develop potentially life-saving innovations.

#### Other Vaccines

Until a pandemic breaks out, no perfect match vaccines will be available. In the meantime, the U.S. government has funded the stockpiling of 8 million doses of pre-pandemic vaccines – specifically those derived from the H5N1 avian virus that may be close to a future pandemic virus, but are unlikely to be a perfect match – as well as the development of other dose-sparing vaccines that provide immunity at lower doses than otherwise required. The 8 million stockpiled doses would cover only 4 million people, however, since an effective treatment course consists of two doses per person. As noted above, GSK has recently announced the development of a dose-sparing, pre-pandemic vaccine that, according to the company, could be the most cost-effective vaccine developed to date.

Regardless of what is done to gain access to any potentially path-breaking adjuvant and to related technology for expanding vaccine production capacity, the most promising course now, in the absence of a perfect match vaccine, is to vaccinate as many people as possible with the regular or seasonal flu vaccine. Although the seasonal vaccine will not be matched to the particular pandemic strain, the consensus among the experts appears to be that it could, nonetheless, reduce the chance that H5N1 or another strain of similar pandemic potential could

reassort with a human flu virus to produce a pandemic. Accordingly, the seasonal vaccine should slow the rate of transmission. In addition, even if the seasonal vaccine offered none of these health benefits, its purchase in mass quantities would build up the capacity to produce the perfect match vaccine if and when it is needed.

Accordingly, we simply reemphasize here the importance of having the federal government and all private businesses encourage as many individuals to get a seasonal flu shot annually and that private firms pay for shots for their employees.

### Anti-Viral Medications

Two anti-viral medications – Tamiflu taken orally and Relenza administered by inhaler – have been developed to reduce the intensity and duration of the seasonal flu. It is widely believed in the medical community that these medications could also perform the same function for those who may be infected during a pandemic or, at the very least, help reduce the ease of transmission of the virus, although neither effect is known with certainty.

The federal government has recognized the value in having some anti-viral medications stockpiled and ready for use in case of a pandemic outbreak. Congress appropriated over \$700 million in Fiscal Year 2006 for further anti-viral research and for federal and state purchase initiatives. HHS is using the money to stockpile 25 million regimens (each anti-viral medication must be taken for several days) by the first quarter of 2007, assuming the medications are delivered on time. Ultimately, the federal government plans to stockpile 50 million regimens by the end of 2008.

In addition, the federal appropriation subsidizes 75 percent of the cost of the medications purchased by the states. If all states took advantage of the offer, this would add another 31 million regimens to the national stockpile, bringing the total stockpile eventually to 81 million regimens, or enough to treat 25 percent of the population, the target set by the American College of Physicians and the WHO.<sup>14</sup>

Ideally, we would like to see that goal met sooner rather than later – in the best of all worlds, by the beginning of this flu season. However, given capacity constraints in the production of anti-virals to be discussed shortly in more detail, this does not seem possible.

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<sup>14</sup> See American College of Physicians (2006). The ACP report recommends, understandably, that anti-virals be used on a prophylactic basis by medical workers in an area affected by a pandemic, with scarce remaining supplies reserved for treatment of infected individuals.

**Recommendation 6: The U.S. and other governments should explore ways to license the use of adjuvants and other related technologies that will significantly increase vaccine production capacity. Licenses should compensate developers with appropriate royalties, and technologies should be made widely available to manufacturers everywhere.**

## 7. Meeting the Costs

One measure that could help achieve the goal of having sufficient stockpiles to treat 25 percent of the population: change the federal funding formula for state purchases of anti-virals. As of the August 1, 2006 deadline for states to announce their purchase plans to HHS, at least five states had indicated they were unlikely to take their full allotment (when final notice is required on December 31, 2006). According to published reports, these states either questioned the efficacy of the medications or preferred to devote their limited tax revenues to other purposes.<sup>15</sup>

In our view, states should not have been required to share the cost of the anti-viral medications in the first place. A pandemic, by definition, is a national – indeed global – problem. If the virus shows up in one state, it is virtually certain to show up in others. Likewise, when one or more states administer anti-viral medications to their citizens, this can benefit other states as well, by slowing the rate of transmission or perhaps even reducing the severity of the pandemic in other states.

This recommendation implies not only that the federal government should pay the 25 percent share for the states deciding not to fully participate in the state portion of the anti-viral program, but also, in the interest of fairness, the share of other states as well.

**Recommendation 7: The federal government should bear costs for meeting its anti-viral stockpile goal, which would protect 25 percent of the U.S. population.**

## 8. Research and Development: Exploring Additional Options

It is natural also to consider whether the federal government should purchase more anti-viral medications – specifically Tamiflu and Relenza – once the stockpile has reached the 25 percent-of-population target recommended by the ACP. This is a difficult issue since the medical consensus is that current anti-virals will confer some benefits in treatment and in prevention, but this will not be known with certainty unless and until a pandemic occurs. If unlimited capacity to produce more anti-virals existed, it might be easy to err on the side of caution and continue

<sup>15</sup> See, e.g. Schmit, 2006a and 2006b.

to purchase more of these medications. However, although Roche, the patent holder and principal manufacturer of Tamiflu, has entered into contracts with suppliers and sub-licensed the manufacturing rights to companies outside the United States that could produce an additional 400 million regimens during 2007, there are many other countries that also want the drug. Even if the United States could purchase as much of this additional production as it wanted – which is not within our control – there is a question of global fairness to consider: is it appropriate for the United States to dominate the purchase of a limited amount of Tamiflu when other countries want it as well? This question, too, might be easier to answer if the patent holder were a U.S. company, but this is not the case. The same is true for GSK, the manufacturer of Relenza.

Taking all these considerations into account, we believe the federal government should wait before adding more to the stockpile until there is further evidence of the efficacy of the two existing anti-viral medications and/or if both of the other two courses of action we now lay out prove inadequate.

First, while the federal stockpile should be viewed as an emergency backstop, private individuals will still be able to purchase both Tamiflu and Relenza on a prescription basis on the open market, if not in 2006 then certainly by 2007. According to the CBO, Roche is currently producing 80 million regimens of Tamiflu a year in U.S. facilities. Although it is unclear how much of this will be directed to the federal government in 2006, once the government's current purchase plans are satisfied, production at this annual rate should be available mostly, if not entirely, to supply the private market in 2007. In addition, GSK has also increased this year's production of Relenza from 1 million to 15 million regimens worldwide, but not yet in the United States. GSK has announced, however, that it will begin production of the medication in North Carolina in 2007.<sup>16</sup>

Second, given the uncertainties surrounding the effectiveness of both *current* anti-virals, the federal government should more aggressively support research into any other anti-virals or their equivalents holding the promise of reducing the severity and/or transmissibility of a future pandemic.

The federal government has already recognized the need to develop other medications or therapies for treating and reducing the transmissibility of both pandemic and seasonal influenza. HHS plans to spend \$200 million for this purpose. However, given the gravity and urgency of this objective, we urge the government to do more.

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<sup>16</sup> CBO, 2006, p. 14.

Specifically, HHS should continue to spend annually at least at the level that it is spending now (approximately \$200 million) for research and development of other anti-virals. However, this funding should also cover testing of the use of medications that have already been suggested might be effective in moderating the symptoms of influenza.

In particular, the appropriate agencies of the federal government should immediately test the efficacy of statin drugs, now widely used for lowering blood cholesterol levels that may also be potentially useful in reducing the inflammations typically associated with influenza.<sup>17</sup> Statins are already widely used on a regular basis by many Americans and others around the world, and should be both more readily available and more easily stockpiled than either of the current anti-virals. Their effectiveness for treating influenza symptoms should be promptly tested.

**Recommendation 8: The federal government should augment its support of testing and R&D for developing other anti-viral medications.**

## 9. Acquisition and Deployment of Medical Equipment

We have already discussed the need for more testing and research into medications to minimize the suffering and possibly save the lives of individuals who may become infected with pandemic flu. But there are more immediate challenges to be addressed.

In particular, there is broad consensus that most local health care systems – hospitals in particular – do not have the excess capacity of beds, equipment, and trained personnel to handle a large influx of patients seeking medical care in a moderate to severe pandemic.<sup>18</sup> In principle, however, the shortage of hospital beds is the easiest problem to solve. Assuming treatment were available, patients could be housed in local schools or hotels, as many state plans envision.

The more difficult challenges are the shortages of medical equipment and trained personnel to operate it – ventilators in particular. The CBO report indicates that only 1.2 million N95 respirators (used in Canada by medical personnel during the SARS outbreak) are currently held in the national stockpile, with an additional 104 million to be delivered by September 2007. Current appropriations are funding the purchase of only 4,000 ventilators, when an additional 650,000 would be needed in a severe pandemic, according to the planning assumptions of HHS.

<sup>17</sup> Institute of Medicine, 2005, pp. 194-96 and Fedson, 2006b.

<sup>18</sup> See the conclusions and various citations in CBO, 2006, pp. 16-18.

One important question is whether additional spending for ventilators and other supplies, as well as for training individuals to operate ventilators, is justified in light of the unknown likelihood of a future pandemic. The CBO cites one estimate that an additional \$5 billion would be required to provide the supplies alone to meet the challenge of a severe pandemic.<sup>19</sup> The true figure could be much higher if, as has been publicly reported, ventilators could each cost \$30,000. Based on this assumption, another 650,000 ventilators would require an investment of approximately \$20 billion.

We have wrestled with the difficult decision whether to recommend the expenditure of either of these amounts for the additional ventilators. At this time, however, we recommend a more limited approach –namely that HHS purchase some additional ventilators, consistent with production capacity constraints -- for several reasons. One issue is the fact that there is currently a significant shortage of personnel trained in the use of the equipment, although we suggest later in this report one way to address this problem. There is also a shortage of the oxygen suitable for use with ventilators and the fact that we do not know how quickly additional ventilators can be produced. And, finally, the uncertainty of the pandemic itself is an important consideration. In light of all these factors, we conclude that if the federal government were to spend as much as \$5-20 billion on pandemic related investments, the money could be better spent on vaccine research and capacity expansion, coupled with additional investment in anti-virals and other medications.

**Recommendation 9: HHS should purchase additional ventilators.**

## **10. Deployment of Medical Personnel**

The Public Health Service is ideally suited to oversee the implementation of a national program to train and certify medical professionals – most likely current nurses and paramedics and retired or former medical personnel – who are not already certified to operate ventilators so that more personnel would be available to carry out this function in a pandemic emergency. The training could be commenced very quickly through local hospitals and health care organizations. We believe that many health care professionals would volunteer to help in this fashion in a pandemic, if also provided with appropriate protections against infection in the form of anti-viral medications and respirators.

One concern in a pandemic is that states may refuse to recognize the licenses of medical professionals from other states, not only for ventilator operation but also for more general care. States should waive these limitations in the event of a

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<sup>19</sup> CBO, 2006, p. 17.

pandemic emergency and allow licensed medical professionals from all other states to provide care in a pandemic emergency.

**Recommendation 10: The Public Health Service should implement a program for training and certifying medical professionals (including retirees) to operate ventilators. States should waive restrictions on licensed medical professionals from other states in the event of a pandemic.**

## 11. Care of the Stricken

Realizing the shortage of formal health care facilities, coupled with the fear of becoming infected or developing further complications as a result of being hospitalized, many – and perhaps most – ill individuals are likely to stay at home rather than be taken to a hospital or equivalent public facility. This underscores the need for individuals to know how to care for themselves and for family members contracting the pandemic virus, as well as how to avoid getting sick in houses where others are ill.

The federal government has posted such information on the official pandemic website ([www.pandemicflu.org](http://www.pandemicflu.org)) and various local and national television shows have provided some information. We believe that more needs to be done, through newspaper inserts (as has been done already in some areas) and regular public service announcements (PSAs) on television and radio directing individuals to the federal website and to other places where this information is available. Indeed, the PSAs can and should cover the basic measures that are likely, although not all proven, to be at least somewhat effective in preventing transmission, including social distancing, frequent hand-washing, and the wearing of masks (coupled with other self-help measures such as stockpiling some food, necessary medications, and having an emergency kit on hand).

### Social Distancing

Virtually all of the personal and business pandemic planning guides we have reviewed recommend that individuals and organizations for which they work practice “social distancing” to minimize their chances of contracting the flu, either in its seasonal form, or in a pandemic.

Social distancing is universally recommended, although the way in which it is carried out will differ from locality to locality. Some social distancing is likely to be mandated: non-essential workers would be asked, if not ordered, to stay home. The consequences of this issue are discussed later in connection with business continuation.

### Minimizing Disruptions In Operations

It is inevitable that in the event of a pandemic, some operations of private businesses and governmental organizations will be disrupted in affected regions and, indeed, beyond: in areas supplying goods and services to areas and regions where the illness has occurred and threatens to spread. In particular, individuals who become ill, those who need to care for sick family members, and/or people who fear venturing from their residences are likely not to come to work for some period of time. As noted, the U.S. government's pandemic planning document assumes absentee rates as high as 40 percent in affected regions for some significant period of time – perhaps for the expected 6 to 8 week duration of any outbreak in a given area or even, conceivably, much longer.<sup>20</sup> The possibility that public and private establishments may be required to operate for extended periods with high levels of absenteeism in many different parts of the country and at differing times makes a pandemic much different – and potentially much worse – in character than other possible catastrophes, whether natural or man-made, that are typically isolated to limited geographic areas.

#### **Preparing for a Pandemic Illustrative Steps All Organizations Should Take**

Maintain “social distancing” at work and at home (telecommuting, separation of workers on site).

Make available disinfectants at multiple locations throughout buildings (especially near hard surfaces).

Train employees on how to prevent spread of infection (use disinfectants, washing hands, covering their faces when coughing, maintaining distance from other individuals when speaking).

Be prepared to function with only some essential workers on-site, and others working from home.

Shed non-essential work (such as plans for further expansion), and focus on core missions. This is especially important for firms and organizations designated by Homeland Security Presidential Directive 7 to be part of the nation's critical infrastructure, including banking and finance, drinking water, energy, telecommunications, food, health care, among others.<sup>1</sup>

Make certain you will have the ability to communicate with managers and employers by telephone (home and cell, if available).

Have “succession” plans in place, so that management knows which individuals are designated to step up in case others cannot perform their duties (due to illness, or in a worst case, death).

*Sources: Compiled from various federal, state and private sector pandemic planning documents. For complete lists, see Hender, 2006 and FSSCC, 2006, as well as, the sources compiled in the next box.*

<sup>20</sup> The National Governors Association, for example, projected in July 2006 the possibility that state and local governments could experience this level of absenteeism for up to 14 months (National Governors Association, 2006). This clearly is a worst-case outcome and one that presumably covers multiple waves of the disease.

Accordingly, a central challenge facing all communities, states, regions, and nations is to *prepare in advance* for the pandemic threat in order to minimize its economic and social impact. The federal government has issued several reports urging precisely this, but putting most of the emphasis on planning by private sector organizations, presumably reflecting the dominance of private sector output in overall economic activity. At the same time, it has also issued guidance to all federal departments and agencies, and offered suggestions for state and local governments. Similar plans have been developed by individual states or by organizations representing them and by the private sector. (See the accompanying boxes).

We applaud those at all levels of governments who have taken these initiatives. We further welcome the continuing efforts by HHS and its Secretary, Michael Leavitt, in holding planning summits for state and local government officials. All states have submitted preparedness plans to the Centers for Disease Control and many states have extended their planning to the regional and community levels. This fall HHS is planning to hold risk communications training sessions and already has simulated or conducted “tabletop exercises” for state and local public health professionals and community leaders in each of the ten HHS regions.<sup>21</sup>

We believe, however, that additional measures are necessary and should be adopted as rapidly as possible. On the following pages we outline recommendations relating broadly to all state and local governments and private businesses, as well as advancing recommendations relating specifically to the

#### **Preparing for Pandemic Flu: A Guide to the “Guides”**

There have been numerous planning documents issued to assist public and private sector organizations to continue operating in event of a pandemic. What follows is an illustrative guide to some of them. For further information, see [www.pandemicflu.gov](http://www.pandemicflu.gov) and [www.ready.gov](http://www.ready.gov).

#### **Federal Government**

Department of Homeland Security, 2006. *National Infrastructure Plan (NIPP)*, July (see <http://www.dhs.gov/dhspublic/display?content=512>).

Department of Homeland Security, 2006. *Pandemic Influenza: Preparedness, Response and Recovery, Guide for Critical Infrastructure and Key Resources*, June 21

U.S. Office of Personnel Management, 2006. *Human Capital Planning for Pandemic Influenza*, 2d Installment, 2006

#### **State and Local Government**

ChicagoFIRST (see [www.bitsinfo.org/downloads/Publications/percent20Page/chicagofirstbk.pdf](http://www.bitsinfo.org/downloads/Publications/percent20Page/chicagofirstbk.pdf)).

Department of Health and Human Services, 2005. *State and Local Pandemic Influenza Planning Checklist*, December 2 (available at <http://www.pandemicflu.gov/plan/pdf/Checklist.pdf>)

National Governors Association, 2006. *Preparing for a Pandemic Influenza* New York City Department of Health and Mental Hygiene, 2006. *Pandemic Influenza: Preparedness and Response Plan* (available at [www.nyc.gov/hoh/downloads/pdf/cd-planflu-plan.pdf](http://www.nyc.gov/hoh/downloads/pdf/cd-planflu-plan.pdf))

#### **Private Sector**

Aon, 2005. *Pandemic Influenza: Managing the Risks of an Invisible Threat*, October ([www.aon.com/about/publications/pdf/issues/wp\\_2005\\_10\\_pandemic\\_influenza\\_managing561.pdf](http://www.aon.com/about/publications/pdf/issues/wp_2005_10_pandemic_influenza_managing561.pdf))

Financial Services Sector Coordinating Council for Critical Infrastructure Protection and Homeland Security (FSSC), 2006, January 23 ([www.sia.com/business\\_continuity/pdf/FSSCCAvianflu\\_statement.pdf](http://www.sia.com/business_continuity/pdf/FSSCCAvianflu_statement.pdf)) HHS and CDC, *Business Pandemic Influenza Planning Checklist* (available at <http://www.pandemicflu.gov/plan/pdf/businesschecklist.pdf>)

North American Electricity Reliability Council (NERC), *Electricity Sector Influenza Pandemic: Planning, Preparation, and Response Reference Guide*

<sup>21</sup> HHS, 2006, p. 11.

financial sector with which the members of our Commission and their organizations have the greatest expertise. Indeed, because the continued operation of financial institutions and markets in a pandemic (as in any emergency) will be central to the functioning of our economy and society, measures minimizing business interruption in the financial arena have broader economic and social benefits.

### Continuity of General Operations

Having a pandemic readiness plan – including the possibility that many employees may not be able or willing to come to work and third parties that you depend upon not able or willing to fulfill their obligations – is only a first step in preparing for an outbreak. State and local governments, as well as private business establishments, must take steps to ensure that their organizations are ready at any time to *implement* those plans. This is not just an immediate challenge – one looming large as the 2006-07 flu season approaches – but, perhaps, even more difficult, it will remain a challenge in future years, at least until the medical and scientific communities can provide strong assurance to the global community that the threat has passed.

Indeed, maintaining vigilance and convincing public officials and citizens that the threat remains (if, in fact, it does) and that readiness plans should be maintained over the longer term may be more difficult if a virulent flu outbreak does *not* occur in the next several years. In that event, it may be tempting for officials and the public to relax their guard. One constructive way to keep all authorities and the public engaged is to stress that many, if not most, pandemic preparedness measures are similar to those that are useful in *any* emergency, natural catastrophe, or act of terrorism. In short, readiness for these unfortunate, but inevitable, events is essential to function – and perhaps even to stay alive – in our modern society.

**Recommendation 11: The federal government should more aggressively educate individuals and their families in how to safely care for themselves and others at home.**

## **12. and 13. Simulations and Monitoring of Pandemic Preparedness Plans**

### The Federal Government's Role

To our knowledge, there is no system in place in the federal government to systematically track the extent to which private and public organizations are responding to the government's urgings to not only have adequate contingency plans in place to deal with a pandemic, but also to systematically simulate those plans to ensure their feasibility and that individuals are aware of the measures they

need to take. Both the plans and their continued simulations are vital because the resiliency of every organization, and, indeed, every individual, is dependent on the adequate preparation of all others in society. It is no understatement to say that we are all in this together, and the fate of each of us – as organizations and as individuals – is bound up with the fate of others.

Of course, plans alone do not ensure that a community or a firm is ready to meet a pandemic crisis. For example, when asked as recently as this summer if their city was prepared to meet a crisis on its own without federal assistance, only 30 percent of 183 Mayors' offices responded affirmatively. This was the case even though 70 percent of the offices said that they had been contacted by federal officials to discuss preparedness for such an event.<sup>22</sup>

Because a pandemic threatens the entire nation, the federal government has an essential role to play in actively encouraging organizations to be prepared. One critical way to accomplish this goal is to monitor compliance with the government's preparedness recommendations and to regularly report on the status of readiness in different parts of the country.

We are *not* calling upon the federal government to act as "Big Brother." We are acutely aware that government cannot control everyone's lives in the event of a pandemic; forcing all workers not essential to operating the nation's critical infrastructure to stay home, for example, while compelling all others to show up for work at the risk of being infected would be inappropriate. Nonetheless, by collecting preparedness data and regularly reporting compliance data by geographic region and by industry (most efficiently, on a government website), the government can arm the public with this important information. Once individuals and organizations know the state of readiness in their areas, they will be able to bring to bear peer pressure, media attention, and the simple power of an informed citizenry to press employers, local and state governments, and other organizations to ensure that they have pandemic preparedness plans in place and are ready to act on them. Information, after all, is power.

### *Private Industry's Role*

In addition to having plans in place, organizations – especially those that are part of the nation's designated critical infrastructure – must take steps to make sure that they work. The most-effective way of doing so is to conduct simulations – exercises that convene key managers and employers to demonstrate their familiarity with the plans, to discuss what they would do in their own areas of responsibility, and become familiar with what is being done throughout their

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<sup>22</sup> The United States Conference of Mayors (2006), p. 6.

organizations. These simulations also should identify planning assumptions or the many ways each organization is dependent on the continuing operations of others, as well as what can be cost effectively done to reduce this dependence to manageable levels in recognition of the fact that no entity, public or private, is an island in our modern economy. Beyond the simulations, organizations should have plans in place to respond to a potential pandemic emergency.

In the case of financial institutions in particular, federal financial regulators have already issued very specific advice for disaster response in general, which is equally applicable to preparing for pandemic risk. As the Federal Financial Institutions Examination Council has observed:

“These periodic tests are more effective when they simulate realistic disasters and require the processing of a sufficient volume of all types of transactions to ensure adequate capacity and capability at all recovery sites. The tests should also consider all critical functions and applications, use only off-site data and supplies, and include some level of improvisation to meet unexpected events.

For example, you may want employees to practice using *manual back-up procedures (e.g. debit and credit tickets) to process transactions until electronic systems are restored*. Or, a disaster drill could simulate situations that involve the restoration of damaged loan files or documents, and how to protect employees from potentially harmful exposure to contaminated bank records, cash, or contents in safe deposit boxes.”<sup>23</sup>

Nonetheless, as important as simulations are, they are not real world exercises and have their limitations. Moreover, organizations depend on each other since, for example, virtually all organizations rely on the continued functioning of the telecommunications and electricity networks.

Of particular interest to the financial industry (which is part of the critical infrastructure) is whether the telecommunications and electricity networks would continue to function, since in, the event of a pandemic, many workers would attempt to telecommute from home by using the Internet. Accordingly, we urge the DHS (via the National Communications System) to work with telecommunications companies to assess the capacity of their networks to function assuming that 20-40 percent of employees in any area work from home, while

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<sup>23</sup> FFIEC, p. 4

school-age individuals who are at home due to school closures also access the Internet. The FSSCC (with participation of BITS staff) and the Finance and Business Informational Industry Committee (FBIIC) have convened several meetings to discuss pandemic planning issues. During these meetings, the FSSCC and FBIIC have asked the National Communications Systems (NCS), a division of DHS, to engage the telecommunications providers in analyzing telecommunications capacity.

Furthermore, the electricity grid would be essential for the telecommunications network, as well as for virtually all other establishments. Additionally, although portions of the financial industry – the banking industry in particular – have generators to power their key functions in the event of a wide range of emergencies, the ability of even this sector to function on generators for the six to eight week period of any one pandemic wave is untested. Therefore, we urge the DHS to work with the FERC and the electricity sector to assess the banking sector's ability to function with up to 40 percent of its employees absent and to address any vulnerability as expeditiously as possible.

A live test could be quite costly to a particular locality. Nonetheless, if it were possible for the electricity and telecommunications providers in a test locality to arrange for emergency backup intervention, the risks inherent in running a test might justify the value. We urge the DHS to consider ways that such live tests might be undertaken.

However, until a live test can be conducted, DHS should explore ways to urge all establishments belonging to the DHS-defined critical infrastructure sectors to regularly simulate their pandemic plans. Ideally, these simulations should be conducted as quickly as possible. Simulations should continue on a regular basis (which could be defined by DHS) so that the establishments forming our critical infrastructure remain prepared as long as the risk of pandemic lasts.

DHS, as well as the federal financial regulatory agencies and other possible entities, should also give serious consideration to conducting an exercise similar to the one that began on October 13, 2006 in the United Kingdom. Specifically, the Financial Supervisory Agency (FSA), the entity supervising all U.K. financial institutions, has organized a rolling six-week simulation of a pandemic involving 60 organizations, during which participating institutions will attempt to react to continuously evolving events. Much should be learned from this exercise. We believe U.S. authorities could profit not only by observing the FSA's exercise, but also by organizing similar and, perhaps, expanded exercises involving organizations in differing sectors of this nation's critical infrastructure.

**Recommendation 12: The Department of Homeland Security should adopt a system for monitoring the adoption and systematic simulations of pandemic preparedness plans in the public and private sectors and should regularly report the status of readiness.**

**Recommendation 13: Every organization, public and private, should have a pandemic plan in place, and should simulate the plan at regular intervals to identify and remedy vulnerabilities. It is imperative for those industries that are part of the nation's critical infrastructure to do so.**

## 14 and 15. Collaboration for Critical Infrastructure Cohesiveness

### *The Federal Government's Role*

Ordinarily, regulators and policymakers worry about creating a moral hazard if they announce specific regulatory plans for addressing future crises, whether it be lending by the Federal Reserve (or the Treasury) to specific enterprises or to the economy in general. The moral hazard danger arises since private actors may then relax their guard, knowing that policymakers or institutions will “rescue” them in some fashion if they run into trouble. This is a legitimate concern and one that should not be questioned in normal times and even for what might be termed routine emergencies.

The pandemic threat, however, is fundamentally different in the potential magnitude and length of its impact. Fortunately, in recent times the United States – and the world – has never experienced anything like the 1918-19 pandemic. But any disease outbreak in the future raises questions, uncertainties, and fears that go well beyond anything that has happened in this country before. And if all actors are to be as prepared as they can reasonably be expected to be for a future pandemic, some significant degree of comfort about what the federal government – federal regulators in particular – plans to do in that event is required so that institutions can adjust their plans *now*. A potential moral hazard is not a central concern in this circumstance, with one important exception relating to lending to specific enterprises that will be discussed shortly. Instead, government policymakers should be interested in having firms and other governmental entities avoid having to prepare and spend for contingencies that need not arise if regulators could remove the uncertainties beforehand.

Thus, financial institutions and exchanges in particular could benefit from having regulators clarify now what regulatory requirements – such as those relating to lending to private parties in temporary distress, to filing requisite forms, and to various other modes of regulated operations – will be modified or relaxed in the

event of a pandemic. Indeed, this is a suggestion that regulators in other arenas – public utilities, transportation companies, and the like – should consider as well. It would benefit all of our firms, as well as others facing similar regulatory oversight, if they knew certain activities could be deemed non-essential ahead of time, allowing these firms to make plans accordingly rather than waiting to find out on an ad hoc after-the-fact basis.

Fortunately, there is a body of experience to draw on: the financial sector and its regulators worked closely both during and after 9/11 and Katrina to keep operations running. Financial firms have taken away important lessons from these episodes and we are confident that regulators have done the same. We urge them to apply any and all lessons learned in developing and announcing their plans for regulatory relief in the event of a pandemic.

We want to be clear. We are not advocating across-the-board regulatory forbearance. There will continue to be a need for many regulations, to protect worker and consumer safety and the environment, among other worthy social objectives. But the *temporary* relaxation or modification of certain rules would facilitate *continuity of operations* in a crisis. Knowing what these changes might be as soon as feasible would both accelerate the preparation for a pandemic and minimize the costs of planning for the possibility.

Fortunately, there is an existing federal body, the Finance and Banking Information Industry Committee (FBIIC) that is an ideal position to take the lead on this set of issues, at least in the financial sector. As for other regulatory agencies, the federal government might find it useful to coordinate executive regulatory agency responses through the Office of Information and Regulatory Affairs (OIRA) within the Office of the Management and Budget. Independent federal agencies such as the SEC, the CFTC, the FCC, and the FERC should announce

#### **Financial Services Coordinating Mechanisms: The FSSCC and FBIIC**

The Financial Services Sector Coordinating Council (FSSCC) was formed at the request of the U.S. Department of the Treasury in response to Homeland Security Presidential Directive 7 requiring various federal agencies to identify, prioritize, and protect the critical infrastructure and key resources of the U.S. The FSSCC, nonetheless, is a private sector body that includes organizations representing the full range of financial services in the United States. The work of the FSSCC is conducted by member associations, including BITS, SIA, ABA, and the organization that chairs the FSSCC.

The FSSCC's mission is to facilitate the coordination of activities and initiatives in the financial sector in order to better able the sector to withstand and recover from a wide range of significant disasters, both natural and man-made. A guide to the FSSCC, its members, and its activities can be found at [www.fsscc.org](http://www.fsscc.org).

The federal government has established a federal agency counterpart to the private sector FSSCC, the Finance and Banking Information Infrastructure Committee (FBIIC). The two bodies work together to coordinate responses in the event of major national emergencies.

The FBIIC is chaired by the Treasury Department and consists of all federal financial regulatory agencies and their state counterparts, such as the national bodies for banking, insurance, and securities regulation. The FBIIC is chartered under the President's Working Group on Financial Markets.

regulatory relief measures on their own since OIRA does not have oversight authority over agencies outside the executive branch.

### Private Industry's Role

From what we know, many if not most of the private sectors making up the nation's critical infrastructure have organizations that are or have been collaborating in preparation for a pandemic and other emergencies. In the financial sector, we have been vigorously engaged in such efforts through the BITS Crisis Management Coordination Working Group and the FSSCC, as described in the accompanying box. We urge all sectors that have not already initiated comparable efforts to do so promptly and encourage all others to intensify their efforts, especially with another flu season approaching. DHS and the Treasury Department, as the lead agencies responsible for different parts of the nation's critical infrastructure, should facilitate these efforts and work with the councils.

Given the linkages among sectors, it is equally important for sector-specific organizations to *cooperate and collaborate with each other*. The FSSCC has recently formed an Infectious Disease Forum to collaborate with its counterpart in the telecommunications industry. A similar effort should be quickly mounted for collaborations with the electricity sector, as well as with other possible sectors. Each of these efforts will benefit from the continued collaboration with government regulators and, ideally, from leadership by the federal government.<sup>24</sup>

The financial services industry, like virtually all others, will be heavily dependent on both the telecommunications and electricity sectors in the event of a pandemic when many of our workers will be telecommuting from home. Indeed, firms in the financial services, telecommunications, and other industries have already dispersed their workforces in the wake of 9/11. But the decentralization that makes sense in the context of some, if not most, national emergencies, is critically dependent on parts of the nation's critical infrastructure – electricity and other sources of energy in particular – continuing their operations. Of particular interest and importance to us is that the mutual assistance agreements electricity and telecommunications firms have in place to assist each other in a crisis (and which were instrumental in the wake of Katrina). These agreements must be honored in

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<sup>24</sup> For example, we understand that both of these sectors work closely with the National Infrastructure Advisory Council, a body composed of up to 30 senior leaders from private industry, academia, and state and local government. The Council provides the President with advice on the security of the critical infrastructure sectors and their information systems. In addition, the North American Energy Reliability Council (NERC) is a corresponding body created to facilitate the necessary collaboration amongst the multiple segments of the electricity industry – generation, transmission, and distribution – if electricity is to reach all customers in affected regions. We are hopeful that the Federal Energy Regulatory Task Force will work closely with NERC to ensure that all possible steps will be taken to assure this outcome in the event a pandemic occurs.

any future pandemic when large numbers of even essential workers may not be able or willing to come to work on site when needed.

### *The Role of the Financial Sector*

As already noted, the financial services sector is integral to the continued performance of our economy, and, indeed, our modern society, to an even greater extent than in 1918-19 when financial institutions and markets were neither as central nor as inter-connected with other types of businesses.

Banks are essential for providing cash, operating the payments system, and providing liquidity in the form of loans to those who need and have the means of repaying them.

Securities firms, mutual funds, and the stock, commodities, and futures exchanges are essential not only to finance or hedge against various risks for much of American business, but also to provide individuals and businesses access to funds they may need in the event of a crisis through the sale of securities. (The latter, of course, raises the prospect of a resulting significant downward pressure on the prices of equities, bonds, and other financial instruments.)

Insurance companies are essential to quickly make payments on claims on policies purchased precisely to provide financial protection to individuals, families, and businesses for catastrophic events, of which pandemic flu is only one type.

Regulators require financial institutions to develop and maintain business continuity plans. In recent years, financial regulators and self-regulatory organizations have focused greater attention on business continuity planning, requiring written business continuity plans and tested procedures for responding to emergencies or significant business disruptions.<sup>25</sup>

The financial community became seriously engaged with emergency and contingency planning to assure continuation of operations in advance of Y2K and has intensified planning efforts since then, especially after 9/11. In addition to causing the deaths of nearly 3,000 people, the terrorist attacks destroyed the essential telecommunications facilities upon which the financial institutions there depend – including the New York and American stock exchanges. Fortunately, many institutions were prepared for this event, having already dispersed some of

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<sup>25</sup> See, for example, the “Interagency Paper on Sound Practices to Strengthen the Resilience of the U.S. Financial System,” issued by the Federal Reserve Board, Office of the Comptroller of the Currency and the Securities and Exchange Task Force, April 2003 (<http://www.occ.treas.gov/ftp/bulletin/2003-14a.pdf>) and the FFIEC’s *Business Continuity Planning* booklet ([http://www.ffiec.gov/ffiecinfobase/html\\_pages/bep\\_book\\_frame.htm](http://www.ffiec.gov/ffiecinfobase/html_pages/bep_book_frame.htm)).

their operations to other locations and backing up their computer and information systems. Others worked in Herculean fashion to resume operations quickly after the attack by setting up operations in other places.

Some skeptics may dismiss parallels with Y2K, noting that the many warnings of business interruption did not occur. By implication, some may be tempted to dismiss warnings to be prepared for a pandemic.

This would be a serious mistake for all concerned for two reasons. There was a definite end date in the case of Y2K, after which any danger clearly had passed. This is not true in the case of a pandemic where the threat is widely expected by the medical and scientific community to persist for years, if it does not, in fact, arrive sooner. More importantly, Y2K proved to be a non-event *only because business and governments spent billions of dollars and man-hours in preparing for the event and took measures to prevent the dire warnings about its impact from coming true*. Only a similar, and, indeed, even more intense and ambitious effort can minimize the impact of a possible pandemic.

The FSSCC has recommended that all financial firms follow the same measures it has recommended for all other organizations in the event of a pandemic and which are summarized in this report. However, because the financial sector is so heavily dependent on other parts of the critical infrastructure, the FSSCC and BITS have paid special attention to ensuring that the electricity and telecommunications networks are working in the event of a future pandemic, or, at the very least, that certain back-up measures are in place.<sup>26</sup>

While the members of our industry have made much progress through the work of BITS, FSSCC, and the FBIIC to insure our preparedness for a wide range of contingencies, the sheer magnitude of the number, complexity, and severity of potential business continuity problems in the event of a pandemic in the financial sector, along with the rest of the economy, calls for yet additional measures. We recommend them here.

In 2006 DHS and HHS requested the National Infrastructure Assurance Council (NIAC) Working Group to engage in a number of efforts in preparation for a

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<sup>26</sup> It is important that financial institutions maintain back-up electricity generators in the event of power outages (*BITS Guide to Business-Critical Enterprise Power*, available at [www.bits.com](http://www.bits.com)). In addition, institutions should plan for resiliency in telecommunications networks through appropriate contracting, testing, and monitoring of key telecommunications services (*BITS Guide to Business-Critical Telecommunications Services*, available at <http://www.bitsinfo.org/downloads/Misc/bitstelecommguide.pdf>). For overviews of the financial sector's preparedness efforts, see Hender, 2006 and Allen, 2005.

pandemic.<sup>27</sup> The FSSCC is representing the banking and finance sector in this working group and has also formed a working group of its own to examine retail payments, electronic benefits transfer, and any other critical financial services outside the scope of services covered in the *Interagency Paper on Sound Practices to Strengthen the Resilience of the U.S. Financial System* (known hereafter as the *Sound Practices Paper*). The FSSCC is also collaborating with the Treasury Department on the critical financial services provided by the firms covered in the *Sound Practices Paper*.<sup>28</sup> The Commission believes that the Roundtable should continue to leverage the work of BITS as the Roundtable's principle representative in the FSSCC, including that organization's involvement in the NIAC and other CEO-level advisory councils.

We also applaud the efforts of BITS and Roundtable members active in the BITS Crisis Management Coordination Working Group, the FSSCC, and the Financial Services Information Sharing and Analysis Center (FS/ISAC). These dedicated officials have focused on addressing all aspects of business continuity planning, including preparing for a pandemic.

In the meantime, financial institutions should be aware that the FS/ISAC has begun distributing periodic *General Disease Outbreaks* reports to the FS/ISAC members, which includes senior officials at thousands of financial institutions. The reports include information on infectious disease outbreaks within the United States and around the world from the National Biosurveillance Integration Center of the U.S. Department of Homeland Security. All financial institution members of the FS/ISAC should take advantage of this valuable source of information.

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<sup>27</sup> These include the identification and definition of critical services that must be maintained in a pandemic, establishing criteria and principles for critical service prioritization, definition of critical service priorities, identification of critical employee groups within each critical priority service, development of recommendations to build a structure for communication and dissemination of resources, and identification of principles for effective implementation by DHS and HHS.

<sup>28</sup> Both DHS and HHS have acknowledged that critical infrastructure and key resource owner-operators are best equipped to understand the activities of personnel engaged in operations and what considerations are necessary to maintain essential levels of service during a pandemic episode.

**Recommendation 14: Regulators should provide greater clarity to private financial institutions about the nature and extent of regulatory relief in the event of a pandemic so that the private sector can better prepare.**

**Recommendation 15: It is urgent that private sector organizations representing different segments of the nation's critical infrastructure intensify efforts to collaborate with each other to improve readiness. DHS, and the Treasury Department, as the lead agency for the banking and financial sector, should facilitate these efforts and work in partnership with the FSSCC and other critical infrastructure sector coordinating councils, especially for telecommunications and electricity.**

## 16. A Game Plan

Given the linkages among differing sectors of the economy (including the government), it is important that pandemic plans be coordinated to at least some degree. In particular, it is important for different sectors to know which events will trigger certain actions, such as encouraging or ordering certain employees to work from home.

Ideally, these triggers would be coordinated *within* certain broad sectors, as well as also *across* sectors. For example, within the financial sector, securities firms will want to know if and when the organizations clearing their trades and the banks transferring their funds order certain workers to telecommute so they can better plan when they can do the same. Similar reasoning applies across industry sectors; the financial sector, for example, needs to know the triggers used by the utility networks, and so on.

DHS may be able to facilitate the process of setting common triggers or it may be possible for private organizations to work together to accomplish the same objective. Specifically, we urge the FSSCC to get the process started by providing regulators with specific suggestions.

**Recommendation 16: Private sector firms in the financial and other critical industries should develop, along with regulators, common assumptions about what events will trigger the implementation of pandemic response plans. The FSSCC should play a critical role in this process.**

## 17. Communications Plan

All organizations, public and private, that are part of the nation's critical infrastructure should have communications plans in place to inform their workers, contractors, and customers of when certain operations may be curtailed and why. The more information all parties have at all stages in a possible pandemic, the easier it will be for individuals to plan and the less fear there will be. Fear is heightened when individuals don't know what to do. Well-planned communications strategies can displace or, at the very least, reduce fear.

**Recommendation 17: Private and public sector organizations that are part of the nation's critical infrastructure should have both external and internal communication plans for disseminating what they plan to do in the event of a pandemic. Existing bodies, such as the FSSCC, should facilitate this activity.**

## 18. The Federal Reserve's Role

The Federal Reserve is the one major institution in our society that can help plug financial and economic leaks when untoward events happen. The Fed provided liquidity to the markets after the 1987 stock market crash, after the 1997 Asian financial market crisis, and again after 9/11.

The Federal Reserve very likely would be called upon to perform a similar function in the event of a pandemic, especially a worst-case scenario producing the kind of GDP loss estimates cited earlier. When individuals don't go to work or out to shop, firms can run short of cash and have difficulty repaying loans. By injecting liquidity into the financial system – creating money – the Federal Reserve can limit the damage.

We want to underscore that we are not recommending that the Fed lend *directly* to troubled non-banking or non-financial businesses, although it has the authority to do so. Instead, the Fed historically has acted as a “lender of last resort” only to the *banking system*, which acts as intermediary with the rest of the economy. If the Fed were to lend directly to affected institutions, it would have to judge the credit risk of each borrower, something the Fed is not equipped to do on a large scale. Instead, when the Fed urges financial institutions to roll over their loans to borrowers, it can have a positive effect without having to make credit judgments itself. Banks, in turn, can be more judicious, knowing that if they have a liquidity problem, they can borrow from the Fed.

Of course, it will also help if regulators inform banks ahead of time that they will not be penalized by supervisors for extending loan maturities – one of the key

reasons why we have called for greater regulatory clarity as a component of pandemic preparedness.

Admittedly, the challenge becomes greater for the Fed the longer any pandemic crisis lasts since what might begin as a temporary liquidity crisis for individual institutions and firms can eventually turn into insolvency. The Fed cannot and should not try to prevent massive insolvencies driven by underlying economic events at the risk of post-event inflation. If things become sufficiently dire, the main responsibility for stimulating the economy should fall to the federal government, acting through the Congress via some combination of tax cuts and/or additional spending.

However, if a future pandemic follows past historical patterns, it is highly unlikely to strike the entire economy at the same time, but instead will occur in rolling waves. In addition, each wave is expected to be limited in duration, although there are likely to be multiple waves and the transmission of each wave will certainly occur faster than in the 1918-19 pandemic. These characteristics of a future pandemic should represent at least some silver linings in otherwise dark economic clouds.

**Recommendation 18: The Federal Reserve should make liberal use of its “lender of last resort” lending authority through financial institutions to provide the liquidity that many firms and organizations in the economy will require to keep functioning.**

## 19. The Role of Congress

Though most life insurers would not be threatened in mild to moderate pandemics, there could be significant risks from a worst-case scenario. As we have noted, the Insurance Information Institute (III) has estimated that the total dollar value of additional death claims from the flu for both group and individual life insurers could reach \$133 billion, more than double the roughly \$50 billion in death claims paid out annually. Even in a moderate pandemic, total additional claims could be an estimated \$31 billion.<sup>29</sup>

The III report does not say so explicitly, but it indicates that in a severe scenario claims costs would not only cause many life insurers to dip into capital, but would also induce some of them to go to the capital markets to raise more funds. Higher claims costs could force some companies into insolvency, leaving policyholders unable to collect on their claims. Although state guaranty funds would be available to help cover the claims of insolvent insurers, they too have limited funds and

<sup>29</sup> See Insurance Information Institute, 2006.

limited ability to assess surviving insurers each year. As a result, policyholders of failed life insurers could wait years before collecting their full claims.

Therefore, we urge Congress to promptly undertake a study of the potential impact of a pandemic, including a worst case analysis, on the life insurance industry. Such a study should also review the options available for ensuring that policyholders can be paid and that confidence in the industry remains. Such options could include allowing life insurers to begin establishing tax-deductible pandemic loss reserves as a way of building up capital for a pandemic event, as well as federal loans to state guaranty funds in exigent circumstances.

**Recommendation 19: Congress should promptly undertake a study of the impact of a pandemic, including a worst case analysis, on the capacity of the life insurance industry, and examine options for addressing any significant problems.**

## 20. Licensing: Ensuring Maximum Coverage

By definition, the pandemic risk is global in nature. There are at least two reasons why the U.S. government, the American people, and the governments of other developed economies, have a clear interest in assisting other countries – especially those in the developing world without adequate resources – in prevention and medical treatment.

First, the outbreak of a pandemic disease that is easily transmissible among humans is likely to begin abroad, since all of the bird-to-human cases to date have originated primarily in Asia, although it is conceivable that the disease could mutate here from an individual infected abroad who traveled here before his or her symptoms appeared. Given the ease with which the disease can quickly travel the globe through just one airplane flight, let alone through the many flights that may continue before the authorities are aware that a dangerous mutation has occurred, all countries have a clear and direct interest in helping countries where the outbreak initially happens – even if, as many believe, it is unlikely that the disease could be halted at its source.

Second, even if containment efforts abroad were successful in keeping the disease from spreading to the United States, the interruption in global commerce and travel that could attend a pandemic clearly would adversely affect the U.S. economy through lower exports and increased costs of doing business. For example, it has been estimated that the SARs episode in 2004 – which would pale in significance compared to a pandemic flu – cost the Asian economy more than

\$40 billion.<sup>30</sup> As noted earlier, the 4.25 percent drop in GDP that could be expected from a worst-case pandemic would represent a much steeper output loss, or roughly \$550 billion.

Other industrialized countries with per capita incomes close to that of the United States clearly have the resources to take the best possible precautions and provide the best available treatment to residents who become infected during a pandemic. The policy challenge for the United States, as well as these other countries, is how to help the residents of poorer countries with per capita incomes far lower than the United States, Continental Europe, Japan, Canada, Australia, and, perhaps, the richer countries of Southeast Asia.

Outside the pandemic context, the governments of developed countries as well as private foundations are already providing funds to treat victims of malaria and AIDs, largely for humanitarian reasons. In the case of a pandemic, developed country governments have not only a humanitarian interest in helping residents of developing and emerging market countries, but also a clear self-interest since, unlike malaria and even AIDs, a pandemic is easily and rapidly transmissible among all humans and across all countries.

So what should be done? In one important sense, citizens of all countries, rich and poor alike, are likely to be somewhat defenseless against the first wave of a pandemic, until a perfect match or “close-to-perfect-match” vaccine is developed. Even then, the real problem is how to quickly ramp up production to meet the huge global need for the vaccine. And, of course, how and who is to pay for supplying the vaccine to countries without adequate resources to pay for it is a key issue.

On the subject of surge production capacity, residents of all countries, including the United States, must hope that the multiple R&D efforts now under way to develop alternatives to egg-based vaccine production methods – cell-based and possibly others – will bear fruit in time to be of use in the event of a future pandemic. This underscores the importance of our earlier recommendation that the U.S. government expand its R&D efforts in this area and we repeat our call on other developed country governments to do the same. The best recent news on this front is the possibility that the adjuvant developed by GSK will prove to be efficacious and safe, considerably expanding effective production capacity of even egg-based methods by reducing the amount of vaccine required for each dose.

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<sup>30</sup> Osterholm, 2006, citing a study by Jong-Wha Lee and Warwick McKibbin of Australian National University.

We have already urged the U.S. and other governments to seek a license to use and manufacture any adjuvant and related technology proving to be safe and efficacious in significantly expanding effective vaccine production capacity. If the legal systems of other countries are similar in one respect to that of the United States, then governments where any breakthroughs occur should have the ability to license these technologies on their own. If not, we urge the governments to take all appropriate steps to encourage companies in their jurisdictions to provide those licenses, with suitable royalty arrangements to assure that the companies are fairly compensated for their efforts and that other companies developing further breakthroughs will also be compensated.

Licensing vaccine production technologies for use in other countries has two important advantages. First, it enables countries to have their own facilities close to their own populations, freeing them from relying on transportation to deliver the vaccine during a pandemic when many workers may not choose or be able to work. Second, it will very likely be considerably cheaper to produce vaccines in other countries where wages and other materials costs are lower than in richer economies.

**Recommendation 20: Any government of a country in which vaccine production method breakthroughs occur should take all possible steps to license those technologies for use in other countries, especially in less developed countries.**

## 21. Production: Ensuring Maximum Coverage

We will defer to others to decide what forum is most appropriate – although the WHO seems to be a most logical candidate – for convening a consortium of countries to develop a plan, including funding commitments, to support the building of vaccine plants and the eventual production of vaccine to be used in the event of a pandemic. Given that there is no time to waste, plant construction using traditional egg-based techniques should proceed while research continues on ways to produce vaccines using cell-based technologies. The funding for actual production, if priced at cost, should be reasonable.

For example, consider the following illustrative scenario – and we stress that, it is only illustrative, since we do not have access to the precise cost and price data to offer a more definitive estimate. The typical price (and presumably cost) of regular flu vaccine in the United States is in the range of \$15 per dose. If pandemic vaccine production aimed at meeting the needs of those in developing and emerging market countries is located in those countries where manufacturing costs are lower, it is possible that the cost per dose could be reduced to \$5 or less. Using the \$5 figure, the cost to vaccinate 2 billion people in the poorest countries of the

world would be a one-time expenditure of \$10 billion. This is comparable to the \$8.6 billion already pledged to deliver medication to developing countries to combat AIDS, tuberculosis, and malaria through the Global Fund formed for this purpose in 2002.<sup>31</sup> A one-time expenditure of \$10 billion, spread across multiple developed country governments, perhaps roughly in proportion to their GDPs, and private foundations, would be a small price to pay to help developed and developing country citizens alike.

There are existing models in which the nations of the world have joined together to meet a common global challenge, with the various agreements aimed at minimizing the loss of the ozone layer covering the earth as one striking example. A more closely related example is the Global Fund just noted. We have every reason to believe that a similar effort mounted to meet the pandemic challenge would also be successful. But the effort should not be delayed until a pandemic is already here. By that time, there will be virtually no time to address the issue and, indeed, travel restrictions may even make it impossible for countries to send their representatives to any negotiations. The international effort therefore should start now.

**Recommendation 21: The U.S. government should immediately join with other countries – developed and less developed – to formulate a plan for assisting the funding of vaccine plant construction and production for residents of less developed economies. Private foundations with interests in health can play a significant role in this effort.**

## 22. Funding Recommendations

Finally, we note that some, but not all, of our recommendations will require additional federal funding, beyond the funds that have been committed to pandemic preparedness so far.

Because we do not have the expertise to provide detailed funding estimates for those proposals requiring further spending (the development of additional vaccines, monitoring, and other pandemic activities of the DHS, for example), we recommend that the Office of Management and Budget work with the relevant agencies (DHS and HHS in particular) to promptly compile a spending package. The Administration should submit an appropriate spending package for the next fiscal year, as well as future fiscal years, reflecting these and other proposals

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<sup>31</sup> The Global Fund to Fight AIDS, Tuberculosis and Malaria is a partnership of developed and developing countries, the private and non-profit sectors, and local communities. So far, this Global Fund has received pledges of \$8.6 billion, of which the United States has counted for \$2.3 billion. See Schocken for a more complete description.

holding promise for containing the human, economic, and social costs of a future pandemic.

For the United States alone, we do not envision large additional expenditures. Counting our suggestions for expanded research, possible support for U.S. vaccine production capacity, and other items, it is possible that the incremental cost would be several billion dollars spread out over several years. However, a significant commitment by the United States to any global effort to counter the pandemic – through support of vaccine production facilities, for example – could raise the total price tag to approximately \$10 billion. Given the enormous human and economic stakes involved, an expenditure of even this amount (about 10% of the cost of disaster relief and recovery spending following Katrina) would be well worth it.

**Recommendation 22: We urge the Administration and Congress to adequately fund all of the recommendations in this report, in addition to amounts that already may be planned.**

### III. Conclusions

The possibility – some believe inevitability – of a pandemic poses the greatest risk to the health of the U.S. population over a short period since the 1918-19 episode and, perhaps, in all of American history. It also poses some of the most complex challenges to government and the private sector of any set of events in our experience.

We, like all Americans and, indeed, all citizens of the world, have a vital stake in how all affected parties meet this challenge. There is no doubt in our minds that we all must be prepared for this risk, and that only preparation can minimize its consequences should a highly lethal flu virus easily transmitted among humans break out.

We have written this report in an effort to lay out some of the high priority measures we believe could significantly reduce the human toll and the economic damage of a pandemic. We cannot overstate their importance. We repeat the words of Winston Churchill, uttered during World War II: “It is no use saying, ‘We are doing our best.’ You have got to succeed in doing what is *necessary*.”

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