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SANOFI PASTEUR

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REGARDING

INFLUENZA PANDEMIC PLANNING

WRITTEN TESTIMONY

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On behalf of sanofi pasteur, thank you for the opportunity to testify today before the Energy and Commerce Subcommittee on Health. Sanofi pasteur is committed to working with the federal government to develop a safe and effective vaccine to protect the American public in the event of an influenza pandemic. Our common goal is to provide sufficient vaccine for 300 million Americans within the first 12- to 18-month period of a pandemic, and we welcome the chance to provide the committee with our perspective on this important public health issue.

Sanofi pasteur, the world's largest influenza vaccine manufacturer, also manufactures vaccines against more than 20 different diseases. Worldwide, we produce almost 1 billion doses of vaccines annually. The company, which employs more than 9,000 employees worldwide, is headquartered in Lyon, France. Sanofi pasteur's US operations are located in the Pocono Mountains in Swiftwater, Pa., at a site where vaccine has been produced for more than 100 years. Influenza vaccine has been produced in this facility for more than 30 years and 95% of this vaccine is used exclusively to supply the United States. Sanofi pasteur also has an influenza vaccine production facility in France that supplies other markets.

During the past decade, sanofi pasteur has reliably and consistently increased production of influenza vaccine in the US. Last year, we produced 58 million doses for the US market. We continue to expand our vaccine manufacturing capacity in Pennsylvania and have embarked on the largest infrastructure investment in the company's history, spending almost \$80 million to build a new formulation and filling facility. We are also in the final design phases of our influenza vaccine facility expansion, which will significantly increase our US production capabilities.

Pandemic Overview

An influenza pandemic is a global epidemic that has the potential for severe morbidity and mortality.

Three influenza pandemics occurred during the 20th century: the 1918-1919 Spanish flu pandemic, the 1957 Asian flu pandemic and the 1968 Hong Kong flu pandemic. The Spanish flu pandemic was the most severe, causing over 500,000 deaths in the US and an estimated 20 to 40 million deaths worldwide.

The prospect of a pandemic is taking on increasing urgency because of the emergence of an H5N1 avian influenza strain in Southeast Asia 17 months ago. It continues to circulate and has the potential to mutate and become a human pandemic strain. To date, it has infected at least 97 people and killed more than half of its victims.¹ This is a completely new strain and epidemiologists believe the American population would be at risk if it spreads between humans.

Many experts believe that if this H5N1 virus sparks the next pandemic, it would most closely resemble the 1918 pandemic in terms of morbidity and mortality.²

According to the World Health Organization (WHO), the next pandemic is likely to result in 1 to 2.3 million hospitalizations and 280,000 to 650,000 deaths in industrialized nations alone. The US Centers for Disease Control and Prevention (CDC) estimated that as many as 207,000 Americans could die and up to

¹Remarks to the 58th World Health Assembly Plenary Session, Mike Leavitt. U.S. Department of Health and Human Services. Numbers updated on 5/23/05.

Accessed May 17, 2005 at: <http://www.hhs.gov/news/speech/2005/050516.html>

² Osterholm MT. Preparing for the next pandemic. *N Engl J Med*. 2005 May 5;352(18):1839-42

734,000 could be hospitalized during the next pandemic. Other estimates are even higher. Studies have estimated the costs of an influenza pandemic in the US between \$71 billion and \$166.5 billion. These estimates include only direct costs of medical care and indirect costs of lost productivity and mortality rates. Some experts have predicted that a major pandemic could bring the global economy to a halt.³

Sanofi pasteur recognizes the urgency of adequate preparation for a pandemic event and is taking steps to be ready.

Progress to Date

We believe the expertise of vaccine manufacturers, particularly those with a track record in influenza vaccine production and distribution, should be utilized early in the planning process. Vaccines, by their very nature, are challenging to develop, produce and distribute. Manufacturers have a unique understanding of these challenges and can provide valuable process and policy input. Our knowledge and experience with the complexities of vaccine supply make industry an essential partner in pandemic planning and policy formulation.

The enormous public health threat posed by a potential pandemic prompted sanofi pasteur to re-examine our internal pandemic planning process. We have taken specific and deliberate steps toward a comprehensive pandemic strategy. We formed a global working group to examine preparedness, development, communications and legal issues. In the US, we have worked in cooperation with the US

³ Osterholm MT. Preparing for the next pandemic. *N Engl J Med*. 2005 May 5;352(18):1839-42

Department of Health and Human Services (HHS) to exchange ideas on how best to prepare for and respond to a pandemic influenza outbreak, and have provided significant input into the initial draft of its pandemic plan.

We have moved forward with clinical research and vaccine production because of important funding provided by Congress and the Administration. In May 2004, sanofi pasteur entered into the first of four pandemic agreements with the US government. The National Institute of Allergy and Infectious Diseases (NIAID) contracted with us to produce an investigational influenza vaccine based on the currently circulating H5N1 avian influenza virus strain. On March 10, 2005, in accordance with that agreement, sanofi pasteur delivered more than 8,000 investigational doses, which currently are being used in NIH-conducted clinical trials.

In September 2004, the company was awarded a second contract by HHS to produce two million bulk doses of an attenuated version of the same H5N1 avian influenza virus strain of vaccine. This contract represents an important step in gaining experience producing pandemic influenza vaccine on a large scale. This is critical because scale-up presents unique challenges in vaccine production. Part of our agreement is to determine the stability of this vaccine, which is important for understanding our ability to establish an H5N1 reserve.

Sanofi pasteur subsequently entered into a third agreement with HHS to establish and maintain flocks of egg-laying hens and to maintain other essential supplies. The goal is to ensure our ability to manufacture pandemic influenza vaccine at current full capacity levels on a year-round basis. Until now, egg availability has existed only on a seasonal basis to support normal influenza vaccine production. The agreement also

calls for sanofi pasteur to manufacture, on an annual basis, investigational influenza vaccine of a candidate pandemic-like strain. Each year, HHS will identify the strain to be used in the investigational lot and will provide the reference virus on which each investigational lot will be based. This will enable us to gain experience working with various viral strains that might be similar to the next pandemic strain.

Finally, in April 2005, sanofi pasteur was awarded a fourth contract from HHS. This was to speed the development process for new cell culture influenza vaccines in the US and to design a US-based cell culture influenza vaccine manufacturing facility.

Required Action:

We are encouraged by the increased attention pandemic planning is receiving from the US government, industry, international agencies and key stakeholders. However, unresolved critical issues remain. The failure to address these challenges could adversely affect our country's ability to respond to a pandemic event.

I would like to briefly outline steps that should be taken to help the country better prepare for a pandemic and minimize the effects should one occur.

A first step is to steadily increase interpandemic influenza immunization rates. Manufacturers will respond to increased and predictable demand by producing additional vaccine to fulfill this demand.

This is important because our ability to produce and administer large quantities of influenza vaccine during interpandemic periods will enable a more rapid response during a pandemic. Increasing capacity in dedicated influenza vaccine production facilities and establishing an infrastructure that can deliver vaccine

and immunize large numbers of people in a short period of time is a key component of pandemic preparedness.

To that end, Congress, industry and stakeholders need to work together to encourage higher influenza immunization rates in accordance with HHS' Healthy People 2010 immunization goals. The objective is to immunize approximately 180 million Americans. However, as a nation, we have never immunized more than 85 million people in any given year. This is unacceptable. A steady and sustained increase in interpandemic demand would give current manufacturers the confidence to continue expansion plans and new companies the incentive to enter the market.

Second, we need to ensure a proper combination of private and public sector distribution of vaccine in the event of a pandemic. We believe that while it will be important to establish mechanisms for mass immunizations and clinics, the private physicians' offices will continue to play a vital role as well. During a typical influenza season, the private sector distributes more than 85% of the nation's influenza supply. The private market provides maximum flexibility in vaccine distribution and allows us to reach large segments of the US population in their "medical homes." This includes the elderly, who should not stand in long lines and may be more comfortable with their personal physicians.

Last year's influenza vaccine shortage illustrated sanofi pasteur's unique expertise in processing and shipping product to virtually any location in the United States within 24-48 hours. We shipped vaccines to end-users in accordance with the CDC's recommendations and distribution plan. Further, the unprecedented degree of collaboration between sanofi pasteur and the CDC underscores our willingness to work with public agencies to protect America's public health. This year, sanofi pasteur has modified our ordering process to

provide that, in the event of another shortage, available vaccine reaches high-risk people first. All of our “pre-book” customers are being asked to estimate what percentage of the vaccine they are requesting will be used for priority patients. The systems utilized to collect these data and the ability to easily identify priority recipients, as specified by federal, state and local governments, will be key in protecting the public health in the event of a pandemic. We also believe that there should be greater funding for coordinating communications between federal and state agencies and the private sector regarding vaccine allocation issues.

A third challenge is to continue to build pediatric stockpiles of all routinely recommended pediatric vaccines. When pandemic influenza strikes the United States, sanofi pasteur will have to slow down routine production, filling, and packaging for all other vaccines. We would have to shift personnel and other resources to optimize production and release of a monovalent pandemic influenza vaccine. Thus, it is essential that we resolve problems associated with the pediatric vaccine stockpile. HHS has appropriated funds but they have not been spent.

You may have read *The Washington Post* article on April 17, 2005 entitled “Pediatric Vaccine Stockpile at Risk.” It pointed out that only 13 million of the requested 41 million doses of pediatric vaccine have been stockpiled due to a Securities and Exchange Commission rule that clarified standard accounting practices for a bill and hold sale. As a result, what had been a 20-year routine practice of stockpiling vaccines is no longer an option for sanofi pasteur. Over the last two years, we have been actively engaged in discussions with the CDC to address the issue. We encourage the Committee to help resolve the issues that surround the establishment of routine pediatric stockpiles in advance of a pandemic.

Pandemic influenza vaccine liability protection is another critical issue in pandemic preparedness. A special compensation and liability protection program will need to be established similar to the 1976 swine flu and 2002 smallpox model. Liability protection for companies is essential to ensure that manufacturers are able to fully participate in the development and licensure of a pandemic vaccine. This is of paramount importance. The new program should be completely distinct and separate from the existing Vaccine Injury Compensation Program (VICP). It should focus exclusively on liability protection for a monovalent influenza pandemic vaccine, precisely the type of vaccine that will be produced in a pandemic event. The failure to offer liability protection on a timely basis could have profound implications for the actual testing and development of large-scale production of vaccine, leaving the nation unprepared. It is important to address liability issues before a health emergency arises. This ensures that pandemic vaccines will be developed, economic costs will be mitigated, and the potential for needless and costly litigation will be curtailed.

We strongly urge Congress to consider -- and establish -- liability protections that are as strong as those afforded providers of smallpox vaccine under the Homeland Security Act of 2002. Vaccine liability provisions ensure that we can bring a pandemic influenza vaccine to market as quickly as possible.

Sanofi pasteur is committed to protecting America's public health in the fight against influenza through vaccinations. We want to commend Congress and the Administration for dedicating time and resources to this critical area. Thank you for giving us the opportunity to express our views on this important issue.