



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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STATEMENT OF

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Joshua M. Sharfstein, Principal Deputy Commissioner and Acting Commissioner at the U.S. Food and Drug Administration (FDA or the Agency). Among its other responsibilities, FDA protects the public health by facilitating access to safe and effective human and animal drugs, human biological products, and devices. Recognizing the global nature of public health issues, we collaborate with foreign counterpart regulatory agencies and international organizations to carry out our mission. FDA plays a vital role in the Nation's preparedness for, and response to, challenges such as the one presented today by the 2009-H1N1 Flu Virus.

FDA is part of a team led by the Department of Health and Human Services (HHS or the Department). Since the beginning of the 2009-H1N1 Flu Virus outbreak last Thursday, FDA has worked closely with the Department, our sister HHS agencies, other U.S. government agencies, the World Health Organization (WHO), and foreign governments.

I appreciate the opportunity to discuss the Agency's response, including our approval of several emergency use authorizations earlier this week, and the efforts of several internal FDA teams.

Emergency Use Authorizations

Section 564 of the Federal Food, Drug, and Cosmetic Act, which was added by the Project BioShield Act of 2004 (Public Law 108-276), permits the FDA Commissioner to issue an

Emergency Use Authorization following a determination and declaration of a public health emergency, provided certain statutory criteria are met. An Emergency Use Authorization allows the use of an unapproved product or an approved product for an unapproved use, in a declared emergency. To authorize the emergency use of a product, FDA must generally find that the agent (in this case, the 2009-H1N1 Flu Virus) can cause a serious or life-threatening disease or condition; that based on the totality of the scientific evidence available it is reasonable to believe that the product may be effective against the disease or condition; that the known and potential benefits of the product's use outweigh the known and potential risks; and that there is no adequate, approved, and available alternative.

Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act provides that, before an Emergency Use Authorization may be issued, the Secretary of HHS must declare a public health emergency justifying the authorization based on one of three grounds, including “a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.”

This past Sunday, April 26, 2009, the Acting HHS Secretary issued a nationwide public health emergency declaration in response to recent human infections from a newly discovered influenza A virus, the 2009-H1N1 Flu Virus. On April 26 and April 27, the Acting Secretary issued declarations justifying emergency use of certain antivirals, in vitro diagnostics, and personal respiratory protection devices.

On April 27, 2009, FDA issued four Emergency Use Authorizations in response to requests from the Centers for Disease Control and Prevention (CDC). Three of these Emergency Use Authorizations make available to public health and medical personnel for emergency use two FDA-approved drugs, Relenza and Tamiflu, for the treatment and prevention of the 2009-H1N1 Flu Virus, and an rRT-PCR test for diagnosing infection with the virus. The fourth authorizes the emergency use of certain personal respiratory protection devices, specifically disposable respirators certified by CDC's National Institute for Occupational Safety and Health, known as N95 respirators.

These authorizations expire by statute in one year unless previously revoked by the Agency, but they can be renewed if the conditions giving rise to the determination and declaration continue to exist.

Currently, Tamiflu is approved for the treatment of uncomplicated illness due to influenza and prevention of influenza in patients 1 year and older. Relenza is approved to treat acute uncomplicated illnesses due to influenza in adults and children 7 years and older who have been symptomatic for less than two days, and for the prevention of influenza in adults and children 5 years and older.

One of the emergency use authorizations allows for Tamiflu also to be used to treat and prevent influenza in children under one year. In addition, under the authorizations, both medications may be distributed with information pertaining to emergency use to large

segments of the population without complying with the label requirements otherwise applicable to dispensed drugs. They may also be distributed by a broader range of health care workers, including some public health officials and volunteers, in accordance with applicable state and local laws or public health emergency responses.

The Emergency Use Authorization for the rRT-PCR 2009-H1N1 Flu Panel diagnostic test allows the CDC to distribute the 2009-H1N1 Flu Panel test to public health and other qualified laboratories that have the needed equipment and the personnel who are trained to perform and interpret the results.

The test amplifies the viral genetic material from a human sample. A positive result indicates that the patient is presumptively infected with the 2009-H1N1 Flu Virus, but it doesn't identify the stage of infection. A negative result does not, by itself, exclude the possibility of 2009-H1N1 Flu Virus infection.

The Emergency Use Authorization for certain disposable respirators permits HHS to deploy these products from the Strategic National Stockpile for use to help reduce exposure to airborne germs. These products, when used properly and in accordance with information that is provided, may help reduce the chances of getting sick. They do not eliminate the risk of illness or death. They should always be used in conjunction with other infection control measures, such as frequent hand washing, and other measures recommended by CDC and state and local public health authorities.

The FDA's Efforts on 2009-H1N1 Flu Virus

As soon as we became aware of the 2009-H1N1 Flu Virus outbreak, I asked Dr. Jesse Goodman, FDA's Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs, to coordinate and lead FDA's efforts on the 2009-H1N1 Flu Virus. Dr. Goodman previously directed FDA's Center for Biologics Evaluation and Research and is a world-recognized infectious disease expert with extensive experience in issues related to influenza vaccine development and evaluation.

Dr. Goodman leads an incident management approach that now includes seven substantive teams, which are cross-cutting and include staff from across the FDA as needed. All of FDA's Centers are engaged in this important work.

These teams work with the Department, CDC, other agencies, national and international partners. The teams include: Vaccine Team, Antiviral Team, In Vitro Diagnostics Team, Personal Protection Team, Blood Team, Shortage Team, and the Consumer Protection Team.

The incident management structure also includes an operations section, a logistics section, and a communications section that coordinates external relations, including media, stakeholders, international, legislative, and Web site development. It includes FDA senior-level health, international, and legal advisers.

Below is a brief summary of the focus of each team. This management approach is flexible and likely to change over time.

Vaccine Team

Surveillance for novel strains of influenza is ongoing. If epidemiological data suggest the emergence of a novel human influenza virus, we have the infrastructure to begin work in the event that a vaccine needs to be manufactured for the novel strain. The Vaccine Team is working to facilitate the availability of a safe and effective vaccine to protect the public from the 2009-H1N1 Flu Virus as soon as possible.

Part of the team is growing and genetically engineering the 2009-H1N1 Flu Virus in the laboratory for possible use in a vaccine. FDA is also beginning to prepare reagents that will be needed to help manufacturers produce and test the vaccine. The Vaccine Team also is working with CDC and other WHO centers on laboratory studies that may help us understand how well the seasonal flu vaccine might protect against the 2009-H1N1 Flu Virus.

At the policy level, the vaccine team is also fully engaged in discussions with the Biomedical Advanced Research and Development Authority (BARDA), a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in HHS, the National Institutes of Health (NIH), and manufacturers regarding the initiation of clinical trials to evaluate the immune response to vaccines derived from this 2009-H1N1 Flu Virus and in considering options for production. FDA is a WHO/Pan American Health Organization collaborating center and is already working closely with WHO on vaccine issues, including testing and development of seed strains in preparation for vaccine development. FDA is also fully engaged with sister regulatory agencies throughout the world.

Antiviral Team

The goal of the Antiviral Team is to identify and evaluate antiviral drugs that can be used to prevent and treat illness caused by the 2009-H1N1 Flu Virus and to facilitate access to these medications. This team led the Agency's efforts to issue the April 27, 2009, Emergency Use Authorizations for Relenza and Tamiflu. In addition, the team is in communication with manufacturers to explore potential investigational options for treatment of the 2009-H1N1 Flu Virus. Like the Vaccine team, the Antiviral Team is working closely with sister regulatory agencies throughout the world.

In Vitro Diagnostics Team

The In Vitro Diagnostics Team's goal is to identify and evaluate in vitro diagnostics that can help test for the 2009-H1N1 Flu Virus. This team led the Agency's efforts to issue the April 27, 2009, Emergency Use Authorization for the rRT-PCR test developed by CDC. This team is in communication with the Biomedical Advanced Research and Development Authority at HHS and manufacturers regarding potential shortages with the FDA-approved rapid influenza A test.

Personal Protective Equipment Team

This team works to facilitate the availability of personal protective equipment that may help reduce the risks from exposure to the 2009-H1N1 Flu Virus. This team led the efforts to issue the April 27, 2009, Emergency Use Authorization for disposable N95 respirators. The team is in communication with manufacturers regarding current demand and ability to increase

production to meet expected demand. The team is working with CDC on public communications about usage of various forms of respiratory protection.

Blood Team

The Blood Team is dedicated to the safety and availability of blood and blood products needed for transfusion by the American public during this influenza outbreak. Though we have no evidence to date that the 2009-H1N1 Flu Virus has affected our blood supply, we are monitoring the situation for developments, and working closely with HHS, our sister agencies, blood banks, and other experts.

Shortage Team

The Shortage Team works to facilitate the availability of antiviral drugs to the American public. The team participates in daily calls with HHS' Biomedical Advanced Research and Development Authority and manufacturers to assess current needs and availability of these products. FDA will be referring private individuals, including health care providers, to their state and local health departments to obtain information about product availability in their locale.

Consumer Protection Team

This team has the goal of protecting consumers from fraudulent and potentially dangerous medical products. FDA is monitoring the internet for sites selling products that claim to prevent, treat, or cure the 2009-H1N1 Flu Virus, among other activities to protect consumers.

CONCLUSION

FDA is fully committed and engaged in protecting the public's health during this difficult time. Among us are laboratory scientists, medical reviewers, epidemiologists, product experts and field inspectors. We will bring every skill and resource we have to this critical mission.

Thank you very much for the opportunity to testify today. I welcome your ideas and your questions.