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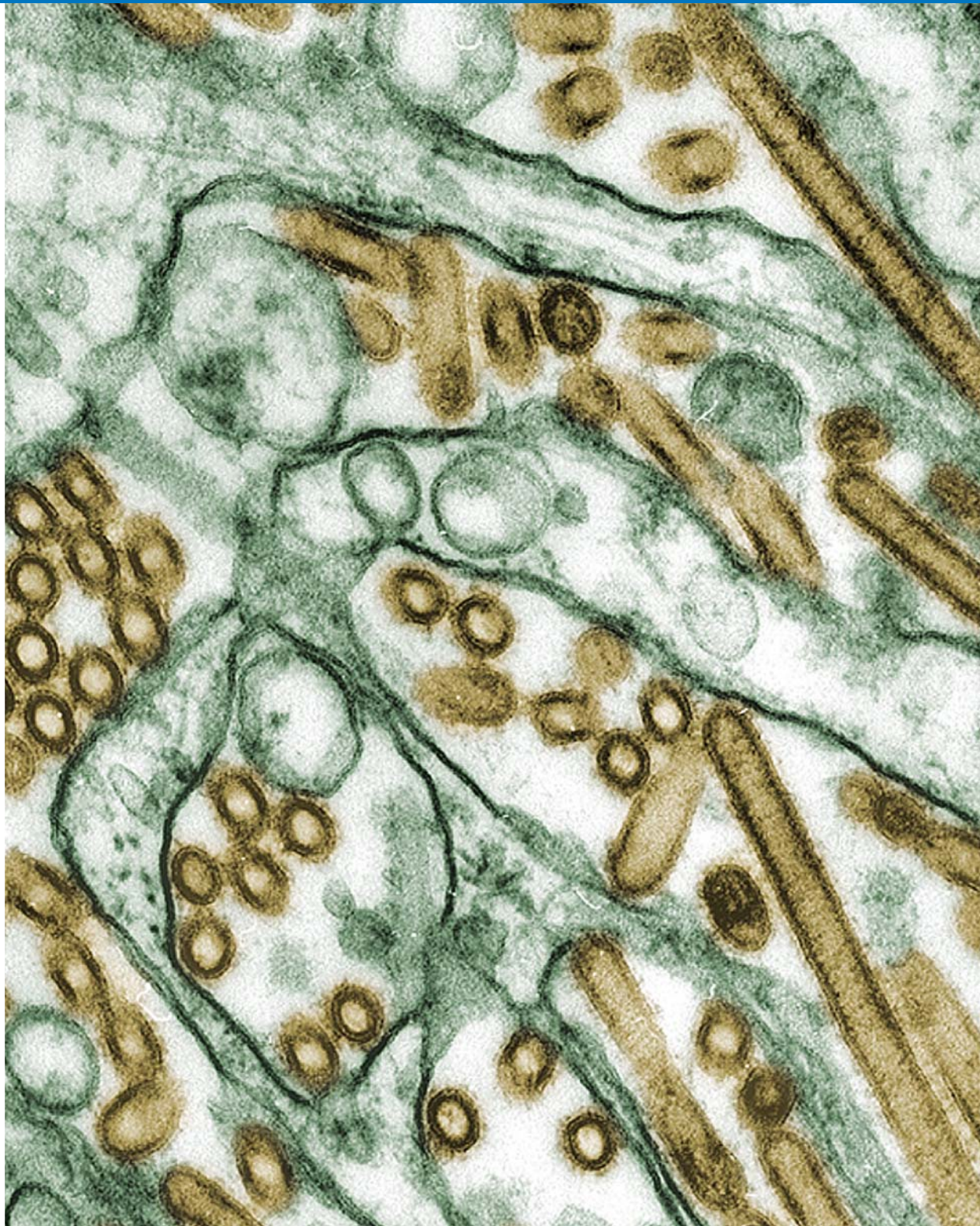
Pandemic and Seasonal Influenza Principles for U.S. Action

JANUARY 2007

THE INFECTIOUS DISEASES SOCIETY OF AMERICA IS AN ORGANIZATION OF PHYSICIANS, SCIENTISTS, AND OTHER HEALTH CARE PROFESSIONALS DEDICATED TO PROMOTING HUMAN HEALTH THROUGH EXCELLENCE IN INFECTIOUS DISEASES RESEARCH, EDUCATION, PREVENTION, AND PATIENT CARE.

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Infectious Diseases Society of America

PANDEMIC AND SEASONAL INFLUENZA

PRINCIPLES FOR U. S. ACTION

January 2007

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The Society wishes to express its appreciation to the members of IDSA's Pandemic Influenza Task Force for their tremendous expertise, commitment, and efforts in developing this important document.

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Executive Summary

THE NEXT PANDEMIC

Experts believe that another influenza pandemic is inevitable. The key questions that remain are when it will occur, which influenza virus will cause the pandemic, how severe it will be, and whether the world will be ready.

There are three types of influenza viruses, classified as A, B, or C, based on their protein composition. Public health experts are most concerned with type A influenza virus. Type A viruses are subdivided into groups based on two surface proteins: hemagglutinin (HA) and neuraminidase (NA), which are represented as H1 through H16 and N1 through N9.

Pandemic influenza typically is a virulent new strain of human influenza that causes a global outbreak of serious illness. Three influenza pandemics have occurred during the 20th century: the 1918-19 “Spanish flu,” the 1957-58 “Asian flu,” and the 1968-69 pandemic or “Hong Kong flu.” Scientists currently are watching the H5N1 virus as a potential pandemic strain. To date, human-to-human transmission of H5N1 has not been efficient or sustained, but the threat remains. However, it is important to recognize that a pandemic may arise from another novel influenza A virus. If a pandemic similar in virulence to the 1918 influenza strain were to occur, 2 million Americans could die and roughly 90 million would likely become ill. Furthermore, a recent study published in *Lancet* has indicated that between 51 and 81 million people could die worldwide.

RECENT PREPAREDNESS AND RESPONSE EFFORTS

Between 2005 and 2007, the U.S. federal government and state governments, private industry, and other U.S. and international stakeholders have made great strides to develop new systems, advance technologies, and build infrastructure to plan and prepare for an influenza pandemic. New domestic and international partnerships have been formed and solid progress made. The U.S. Congress, the White House’s Homeland Security Council, the Department of Health and Human Services (HHS), and its agencies have shown strong leadership as well as an acute understanding of the potential devastation to be caused by an influenza pandemic. More than \$6 billion has been committed to U.S. pandemic preparedness to date. Unfortunately, these funds have come in the form of one time supplement emergency funding bills and do not achieve the sustainability needed for long-term national, state, and local efforts.

In December 2006, the United States took a significant step to further strengthen U.S. pandemic preparedness by enacting the Pandemic and All-Hazards Preparedness Act. IDSA applauds Congress and the Administration for providing the valuable tools contained in the new law. The Act places responsibility for overall U.S. public health emergency preparedness and response within HHS and creates the new position of Assistant Secretary for Preparedness and Response to advise the Secretary. The Act authorizes significant new funding for activities that will support the public health system’s readiness to address emergencies. Other provisions will:

- identify minimum essential public health security capabilities for national and state investments
- establish a state matching funds requirement to ensure a shared financial burden

- improve the capacity of medical facilities to respond to public health emergencies
- require an evaluation of how federal assets can support local surge capacity
- authorize new funding to expand and train the public health workforce

Significant and sustainable congressional appropriations are necessary to implement the new law, if the U.S. is to sufficiently prepare and respond to an influenza pandemic.

A critical asset of the Act is its establishment of the Biomedical Advanced Research and Development Authority (BARDA) within HHS. BARDA will enhance and accelerate the research, development, and procurement of promising new medical countermeasures (therapeutics, vaccines, diagnostics) that otherwise would not be realized due to financial disincentives unique to infectious diseases products' discovery and development. BARDA will provide targeted funding at critical stages in a product's testing and development. A National Biodefense Science Board will advise the Secretary on threats, challenges, and opportunities presented by advances in biological and life sciences. Of note, BARDA-qualified countermeasures will include infectious diseases that may cause a public health emergency affecting national security, such as an influenza pandemic.

IDSAs PRINCIPLES FOR U.S. ACTION

To complement the efforts highlighted above, IDSA has developed a set of Pandemic and Seasonal Influenza Principles for U.S. Action. We strongly believe that much of the work needed to adequately prepare for an influenza pandemic remains ahead of us, and we have just begun our journey. IDSA intends these principles to be informative and instructive to the Secretary of HHS and the new Assistant Secretary for Preparedness and Response as they move forward. IDSA's principles support many of the concepts addressed by the Pandemic and All-Hazards Preparedness Act, but provide some additional direction and level of specificity not contained in the law. IDSA's principles also stress the absolute interrelatedness of responses to seasonal influenza and pandemic preparedness.

Finally, IDSA also offers several new recommendations that will require additional legislative action by Congress.

A list of IDSA's general principles follows. Subsequent sections of this document include each principle along with detailed, action-oriented recommendations and the status of current activities.

IDSA Pandemic and Seasonal Influenza Principles for U.S. Action

1 Strengthen Pandemic Vaccine Efforts by Establishing a Multinational Pandemic Influenza Vaccine Master Program

The widespread use of a pandemic vaccine should be the central strategy for protection of human health during a pandemic event. IDSA supports the establishment of a Multinational Pandemic Influenza Vaccine Master Program. The federal government should lead this effort by working with public and private partners and engaging the international community to outline a comprehensive approach that will systematize, coordinate, and strengthen vaccine research and development (R&D), increase production capacity, accelerate licensure, guarantee equitable global distribution, and monitor vaccine performance and safety. The new Biomedical Advanced Research and Development Authority (BARDA) will be an important component of the Master Program, but, in and of itself, does not address the scope of the effort needed to systematize and coordinate the development of a vaccine. An effort on the scale of the Apollo space project is required. The U.S. should make a multi-billion dollar investment in fiscal years (FY) 2007 to 2011 to initiate the Master Program and to serve as a catalyst for additional financial support from international partners. A minimum U.S. investment of \$2.8 billion should be allocated for this purpose in FY 2007.

2 Strengthen Anti-Infective Pharmaceutical Research and Development and Stockpiling Efforts

Continued and strengthened R&D on new antiviral and antibacterial drugs is essential. Antiviral

drugs and other therapeutics likely will be the only medical countermeasures available to initially respond to a pandemic in the foreseeable future. Based on past pandemic history, many people will be susceptible to life-threatening secondary bacterial infections in addition to morbidity and mortality caused by the influenza virus itself. For this reason, both antiviral and antibacterial drugs must be treated as priorities within BARDA's scope. Moreover, the U.S. should stockpile enough antiviral drugs and antibacterial agents to effectively respond to a pandemic. Ideally, the antiviral stockpile should be large enough to allow for extended prophylaxis for health care workers and other essential public safety personnel for the duration of an outbreak.

3 Improve Quality and Availability of Diagnostic Tools for Influenza

Rapid and improved diagnostic tools are needed to quickly and accurately diagnose pandemic influenza strains in the laboratory as well as at the point of care. These tests must be suitable and available not only to medical facilities with sophisticated laboratories, but to any inpatient or outpatient health center, including those with limited resources and in remote areas.

4 Accelerate Development of Countermeasures to Prevent, Treat, and Diagnose Pandemic Influenza Through Additional Legislative Action and Continue to Streamline Regulatory Approval Processes

BARDA clearly will play an important role in advancing the research, development, and production of new pandemic countermeasures, such as vaccines, drugs, and

diagnostic tools. However, the money promised for BARDA will need to be appropriately allocated. Additional incentives such as strong tax credits for R&D and manufacturing and enhanced intellectual property rights will further spur the development of countermeasures and expand U.S.-based production. Moreover, the U.S. must continue to standardize and streamline the regulatory approval process for pandemic countermeasures to ensure their availability when needed. The U.S. should work with its international partners to establish similar streamlined regulatory processes.

5 Update U.S. Plans for Countermeasure Distribution and Prioritization of Use

National guidelines for the prioritization of pandemic influenza vaccines and antiviral treatment and prophylaxis should be revised with input from key stakeholders and technical experts, including experts in biomedical ethics. More detailed antiviral and vaccine distribution templates should be provided by the federal government and distributed for each state and locality to adapt. Countermeasure prioritization and distribution plans should be re-visited and updated according to the prevailing pandemic situation and as antiviral production capacity increases. A comprehensive real-time countermeasure tracking system should be developed to measure distribution, uptake, and efficacy at the federal, regional, and local levels.

6 Expand Vaccine Uptake, Stabilize Vaccine Manufacture, and Test and Evaluate Vaccine Distribution Plans During Annual Influenza Seasons

The U.S. should adopt policies to increase the public's uptake of seasonal influenza vaccinations and to determine the most effective vaccination strategies for the population. Such policies will help to

reduce the morbidity and mortality of annual influenza and help stabilize vaccine manufacturing capacity. Strengthened policies should include mandatory annual influenza vaccination among health care workers (with an allowance for a written declination to permit health care workers to object for religious or philosophical reasons, or if medically contraindicated). Annual influenza vaccine distribution should be used as an opportunity to test vaccine protocols and distribution plans.

7 Protect the Health Care Workforce During a Pandemic

The U.S. must preserve medical readiness by ensuring that health care workers, including physicians, nurses, pharmacists, allied health personnel, first responders, and others, are able to perform their duties during an influenza pandemic. By its very nature, their work puts these individuals at higher risk during a pandemic. To this end, the U.S. should ensure the availability of influenza vaccinations, antiviral treatment (and ideally prophylaxis), a guaranteed, pre-defined injury compensation plan, and liability protection to eliminate barriers to health care workers' participation during an influenza pandemic.

8 Build National, Regional, and Local Health Care Systems Capable of Responding to Mass Casualty Events

The federal government should act now to establish a national strategy to ensure a coordinated continuum of care during a pandemic. This involves building national, regional, and local health care systems capable of responding to a mass casualty event by establishing the protocols necessary to develop and sustain medical surge capacity; providing training, education, and credentialing to public health and medical personnel; and developing detailed, evidence-based guidance.

9 Develop and Test Community Mitigation Measures

National guidance on community mitigation measures such as social distancing, school closures, and isolation should be developed in collaboration with key stakeholders and technical experts and should articulate a standardized, scientifically rigorous and locally adaptable approach to community containment. The scientific basis and public health rationale for the prescribed measures should be clearly communicated to stakeholders responsible for implementing the strategies and to the public. The discussion should encompass limitations, assumptions, and potential social and economic consequences of such measures on local communities.

10 Improve and Coordinate Influenza Surveillance

Surveillance is a critical component in identifying the emergence of a novel influenza A virus and its subsequent spread within a population. A sustainable level of funding support is critical to maintain and enhance surveillance systems at the international, national, state, and local levels and to monitor in a timely manner seasonal virus strains as well as novel influenza A subtypes. Traditional influenza surveillance systems should be enhanced and strengthened with a renewed emphasis on linking data with clinical laboratory and reference laboratory reports, existing electronic health data, and new systems for influenza-like illness syndromic surveillance in an effort to improve the consistent measurement of the burden of severe disease. Excess reliance on any one system, especially an untested new system, should be avoided. Establishing effective surveillance systems for influenza viruses with pandemic potential will foster cooperative networks between U.S. health care, public health, and animal health sectors as well as between the U.S. and other countries. Strengthening

surveillance will support refinement of mathematical and epidemiologic models of disease transmission.

11 Continue to Strengthen Leadership, International Collaboration, and Communication

The Pandemic and All-Hazards Preparedness Act has strengthened U.S. pandemic preparedness efforts by identifying the Secretary of HHS as the lead federal official for public health emergency preparedness and response, consistent with the National Response Plan. However, the HHS Secretary and the federal government as a whole must continue to strengthen leadership capacity for pandemic influenza response by regularly clarifying lines of authority and key responsibilities, holding table top and other exercises, involving technical experts and stakeholders, and issuing and updating national standards and guidance for planning based on the latest science and ethical guidelines. The U.S. also must continue to be a leader in fostering international collaborative efforts related to pandemic preparedness and in developing and issuing responsible messages to the public and health sectors.

12 Allocate Significant and Sustainable Funding for Long-Term Planning and Action

The Pandemic and All-Hazards Preparedness Act authorizes several critical activities as well as significant, new funding that will result in improved U.S. readiness. However, federal, state, and local pandemic preparedness and response goals cannot be achieved without increased, long-term sustainable funding. Many of the activities being requested of state and local health agencies, hospitals, and other local institutions require certainty that ongoing funding is assured. Long-term investments in this area will have collateral benefits in defending against other biological agents.

IDSA's Pandemic and Seasonal Influenza Principles for U.S. Action

(With Specific Recommendations and Current Status of Preparedness Efforts)

1 Strengthen Pandemic Vaccine Efforts by Establishing a Multinational Pandemic Influenza Vaccine Master Program

CURRENT STATUS: Progress has been made in vaccine research and development (R&D) in areas such as cell-based technologies and antigen-sparing regimens (i.e., each dose of vaccine would contain a smaller amount of the antigen that evokes an immune response so that supplies of vaccine could be stretched). The Department of Health and Human Services (HHS) invested more than \$1 billion in the advanced development of cell-based vaccine technologies. HHS has stockpiled roughly 8 million doses of vaccine against a clade I H5N1 virus strain isolated from Vietnam in early 2004. To increase production capacity in the U.S., HHS issued requests for proposals (RFPs) for the construction of new facilities and/or the expansion or retrofitting of existing facilities. HHS also has awarded three contracts, totaling \$132.5 million, for advanced development of antigen-sparing vaccines. The federal government plans to announce contracts to adapt existing egg-based vaccine facilities for pandemic vaccine production. While broad in focus, current R&D efforts may not produce rapid progress owing to a lack of coordination, rapid sharing of results, and transparency. In October 2006, the World Health Organization (WHO) released the "Global Pandemic Influenza Action Plan," which focuses on furthering vaccine R&D and increasing vaccine production capacity. The WHO projects \$3 billion-10 billion in U.S. dollars will be needed over the next 5-10 years to implement this plan.

PRINCIPLE:

The widespread use of a pandemic vaccine should be the central strategy for protection of human health during a pandemic event. IDSA supports the establishment of a Multinational Pandemic Influenza Vaccine Master Program. The federal government should lead this effort by working with public and private partners and engaging the international community to outline a comprehensive approach that will systematize, coordinate, and strengthen vaccine R&D, increase production capacity, accelerate licensure, guarantee equitable global distribution, and monitor vaccine performance and safety. The new Biomedical Advanced Research and Development Authority (BARDA) will be an important component of the master program, but, in and of itself, does not address the scope of the effort needed to systematize and coordinate the development of a vaccine. An effort on the scale of the Apollo space project is required. The U.S. should make a multi-billion dollar investment in fiscal years (FY) 2007 to 2011 to initiate the Master Program and to serve as a catalyst for additional financial support from international partners. A minimum U.S. investment of \$2.8 billion should be allocated for this purpose in FY 2007.

To achieve these goals, IDSA offers the following specific recommendations:

THE ADMINISTRATION, SUPPORTED BY THE WORK OF THE U.S. CONGRESS, SHOULD WORK IN CONCERT WITH THE WORLD HEALTH ORGANIZATION, VACCINE MANUFACTURERS, AND OTHER PUBLIC AND PRIVATE INTERNATIONAL PARTNERS TO:

- Establish the "Multinational Pandemic Influenza Vaccine Master Program" taking into con-

sideration the objectives and strategies outlined in the WHO's Global Pandemic Influenza Action Plan.

- Develop the formulation of pre-pandemic vaccines, prepare for the development, production, and distribution of a global supply of suitable pandemic vaccines, harmonize regulations, strengthen global capacity to provide broad and equitable access to a vaccine, and monitor vaccine performance and safety.

- Increase openness and transparency to rapidly provide critical data to government experts, industry, and academics from around the world.
- Support, through BARDA and other mechanisms, the development of new vaccines with improved immunogenicity, efficacy, and breadth of protection.
- Continue to support research on the molecular pathophysiology of influenza.
- Support, through BARDA and other mechanisms, the development of new or more effective vaccines to prevent secondary bacterial lung infections that may lead to many deaths during an influenza pandemic. Vaccines are particularly needed for *Streptococcus pneumoniae*, *Staphylococcus aureus*, and *Haemophilus influenzae*, which cause substantial morbidity and mortality with concurrent influenza infection.

2 Strengthen Anti-infective Pharmaceutical R&D and Stockpiling Efforts

CURRENT STATUS: Studies currently are being conducted on a few neuraminidase inhibitors and on the impact of resistance to anti-infective drugs. HHS plans to issue \$200 million in contracts to develop additional antiviral candidates and announced a \$102.6 million contract for advanced development of an antiviral drug. Meanwhile, HHS plans to stockpile enough antiviral treatment courses to treat 25 percent of the U.S. population. HHS allocated \$782 million in 2006 for the purchase of antivirals. The Administration expects state governments to purchase 31 million courses of antiviral medications—about one-third of the stockpile. Initial reports indicate that a significant number of states lack the fiscal resources to purchase their share of antiviral drugs or have determined that state antiviral stockpiles are not a priority. In October 2006, the WHO released the document, "Rapid Advice Guidelines on pharmacological management of humans infected with avian influenza A (H5N1) virus," which includes recommendations for antiviral supply. A working group at the Centers for Disease Control and Prevention (CDC) is reassessing the proportion of licensed antiviral drugs to maintain public sector stockpiles and defining further research that would contribute to optimal antiviral drug use during a pandemic.

PRINCIPLE:

Continued and strengthened R&D on new antiviral and antibacterial drugs is essential. Antiviral drugs and other therapeutics likely will be the only medical countermeasures available to initially respond to a pandemic in the foreseeable future. Based on past pandemic history, many people will be susceptible to life-threatening secondary bacterial infections in addition to morbidity and mortality caused by the influenza virus itself. For this reason, both antiviral and antibacterial drugs must be treated as priorities within BARDA's scope. Moreover, the U.S. should stockpile enough antiviral drugs and antibacterial agents to effectively respond to a pandemic. Ideally, the antiviral stockpile should be large enough to allow for extended prophylaxis for health care workers and other essential public safety personnel for the duration of an outbreak.

To achieve these goals, IDSA offers the following specific recommendations:

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SHOULD:

- Continue support, through BARDA and other mechanisms, for R&D of new next-generation neuraminidase inhibitors and alternative therapies such as polymerase inhibitors and potential approaches such as fusion proteins.
- Provide support for further research in the use of neuraminidase inhibitors in the treatment and chemoprophylaxis of H5N1 infection, and combination therapy with M2 inhibitors and novel drugs. Support should be provided for research on and surveillance of influenza resistance to antiviral drugs.
- Accelerate the development of an adequate stockpile of antiviral drugs, including oseltamivir

(Tamiflu) and zanamivir (Relenza), to treat at a minimum 25 percent and ideally 40 percent of the U.S. population.

- Consider increasing the antiviral stockpile as antiviral production capacity increases and additional relevant information becomes available, with consideration given to:
 - Ensuring the availability of a sufficient supply of antiviral drugs to health care workers who provide direct patient care and are at high risk for exposure to the virus.
 - Expanding the availability and indications for prophylaxis to other essential community workers and high risk patients.
- Ensure equity of antiviral supply throughout the United States so all residents have equal access to antiviral drugs regardless of the state or locality in which they reside.
- Support, through BARDA and other mechanisms, the development and stockpiling of antibacterial drugs to treat secondary bacterial complications resulting from influenza infections that could lead to many deaths during a pandemic. These might include pneumonia caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and methicillin-resistant *Staphylococcus aureus*.

3 Improve Quality and Availability of Diagnostic Tools for Influenza

CURRENT STATUS: Two recent technological developments (the FluChip and the Influenza A/H5 Virus Real-Time RT-PCR Primer and Probe Set) allow for more rapid identification of pandemic strains and allow for expansion of influenza diagnostic capacity in lower-level bio-safety facilities. In 2004 and 2006, the National Institute of Allergy and Infectious Diseases (NIAID) awarded grants to develop new diagnostics for pandemic and avian influenza. In 2006, NIAID intended to commit \$10 million to support research projects focused on developing rapid throughput assays that are suitable for screening and development of influenza therapeutics. CDC has revised guidelines for avian influenza A (H5N1) virus testing and lab work and awarded \$11.4 million to four companies for the development of new diagnostic tests. However, these are incremental first steps to improving diagnostics. Rapid and type-specific clinical diagnosis is currently not adequate for managing a pandemic.

PRINCIPLE:

Rapid and improved diagnostic tools are needed to quickly and accurately diagnose pandemic influenza strains in the laboratory as well as at the point of care. These tests must be suitable and available not only to medical facilities with sophisticated laboratories, but to any inpatient or outpatient health center, including those with limited resources and in remote areas.

To achieve these goals, IDSA offers the following specific recommendations:

THE FEDERAL GOVERNMENT SHOULD:

- Support, through BARDA and other mechanisms, the development of inexpensive, accurate, and simple point-of-care diagnostic tests that can provide results in a timely manner to guide laboratory, clinical, and public health responses. The tests should be able to distinguish between influenza virus types and influenza A virus subtypes, including novel influenza A viruses with pandemic potential. The reagents, supplies, and tests should be stable at room temperature and able to be easily deployed in diverse national and international settings.
- Ensure industrial surge capacity is adequate for critical items and supplies to diagnose influenza and its potential bacterial complications.
- Develop evidence-based recommendations for health care providers on the use of diagnostic tests.

4

Accelerate Development of Countermeasures to Prevent, Treat, and Diagnose Pandemic Influenza Through Additional Legislative Action and Continue to Streamline Regulatory Approval Processes

CURRENT STATUS: In December 2006, Congress established BARDA within HHS as part of the Pandemic and All Hazards Preparedness Act to accelerate the development of new countermeasures (vaccines, drugs, and diagnostic tools) to prevent, treat, and diagnose pandemic influenza. BARDA will provide targeted funding at critical stages in a product's testing and development. IDSA strongly supported BARDA's passage but also endorsed additional incentives to advance infectious diseases product development such as the tax credits and enhanced intellectual property rights found in H.R. 3154, "The Infectious Diseases Research and Development Act of 2005." On the regulatory front, substantial progress has been made to streamline the approval process for pandemic countermeasures, including development of guidelines to assist industry as it moves forward to develop pandemic influenza vaccines. To this end, the Food and Drug Administration (FDA) has proposed that: licensure of pandemic influenza vaccines may be sought either as a supplement to an existing Biological License Application (BLA) or as a new BLA using the accelerated approval regulations; evaluation of the immune response elicited following receipt of the vaccine may serve as a surrogate endpoint that is likely to predict clinical benefit; guidance on clinical data to support the accelerated approval of a pandemic vaccine may apply to several types of vaccine, including cell culture-derived vaccines; and approval of existing vaccines for new routes of administration will be considered as a clinical supplement to a BLA. Finally, additional steps are being taken to harmonize international regulations in this area.

PRINCIPLE:

BARDA clearly will play an important role in advancing the research, development, and production of new pandemic countermeasures, such as vaccines, drugs, and diagnostic tools. However, the money promised for BARDA will need to be appropriately allocated. Additional incentives such as strong tax credits for R&D and manufacturing and enhanced intellectual property rights will further spur the development of countermeasures and expand U.S.-based production. Moreover, the U.S. must continue to standardize and streamline the regulatory approval process for pandemic countermeasures to ensure their availability when needed. The U.S. should work with its international partners to establish similar streamlined regulatory processes.

To achieve these goals, IDSA offers the following specific recommendations:

THE U.S. CONGRESS SHOULD ENACT NEW INCENTIVES TO SPUR COUNTERMEASURE R&D AND MANUFACTURING. CONGRESSIONAL LEADERS SHOULD CONSIDER:

- Tax credits for research, development, manufacturing, and the construction of new manufacturing facilities to ensure countermeasures are available in the United States during a pandemic.
- Ideas contained in the General Accountability Office's (GAO) November 2006 Report on New Drug Development, such as extending or reducing the period of patent protection associated with

a drug based on its therapeutic value. One panelist quoted in the GAO report states, "a patent could be extended to 25 or 30 years for drugs considered innovative or offering high therapeutic potential; while patents for drugs offering less innovative benefits could be only 10 years."

ON THE REGULATORY FRONT, THE FOOD AND DRUG ADMINISTRATION SHOULD:

- Work along with partners to harmonize international regulatory policies for pandemic vaccines to expedite global production and streamline global access.
- Standardize acceptable laboratory parameters and clinical trial requirements, including appropriate criteria that will allow foreign

clinical trial data to be acceptable for registering influenza vaccines in the United States, to speed access and reduce development costs.

- Identify benchmarks for regulatory evaluation and approval of pandemic influenza vaccines, with consideration to special conditions that may apply in a pandemic setting.
- Evaluate pandemic vaccines differently than seasonal influenza vaccines and provide for flexibility in interpreting meaningful differences between alternative products. The formulation for a pandemic vaccine that is approved by regulatory agencies in the United

States and elsewhere must be one that is appropriate for populations, not just individuals.

- Emphasize antigen-sparing formulations to optimize vaccine efficacy and immunogenicity.
- Participate in the development of assays to measure mucosal immunity so that more specific guidance can be provided to manufacturers of live vaccines.
- Address peptide-based vaccines through development of additional guidance to industry.
- Continue to streamline the licensure process and issue appropriate industry guidelines for vaccines, antiviral drugs and other therapeutics, and diagnostic tools.

5 Update U.S. Plans for Countermeasure Distribution and Prioritization of Use

CURRENT STATUS: The National Vaccine Advisory Committee (NVAC) and the Advisory Committee on Immunization Practices (ACIP) have issued prioritization guidelines for pandemic vaccine. A federal interagency task force will revise and expand these guidelines to include recommendations for the prioritization of pre-pandemic and pandemic influenza vaccine based on various pandemic severity and vaccine supply scenarios. In October 2006, the WHO issued “WHO Rapid Advice Guidelines on pharmacological management of humans infected with avian influenza A (H5N1) virus,” which provides recommendations related to where additional research is needed, chemoprophylaxis, including priority setting for distribution based on potential exposure, and antiviral supply. HHS’s Pandemic Influenza Plan and the White House’s Implementation Plan provide general steps for countermeasure distribution. HHS and the Healthcare Distribution Management Association (HDMA) are developing a model antiviral distribution plan for states to adapt locally. Development of a near real-time countermeasure tracking system to monitor distribution and administration is underway to support vaccine and countermeasure distribution during a pandemic. However, adequate tracking systems for distribution and utilization of influenza vaccine do not exist in the United States.

PRINCIPLE:

National guidelines for the prioritization of pandemic influenza vaccines and antiviral treatment and prophylaxis should be revised with input from key stakeholders and technical experts, including experts in biomedical ethics. More detailed antiviral and vaccine distribution templates should be provided by the federal government and distributed for each state and locality to adapt. Countermeasure prioritization and distribution plans should be re-visited and updated according to the prevailing pandemic situation and as antiviral production capacity increases. A comprehensive real-time countermeasure tracking system should be developed to measure distribution, uptake, and efficacy at the federal, regional, and local levels.

To achieve this goal, IDSA offers the following specific recommendations:

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CENTERS FOR DISEASE CONTROL AND PREVENTION SHOULD:

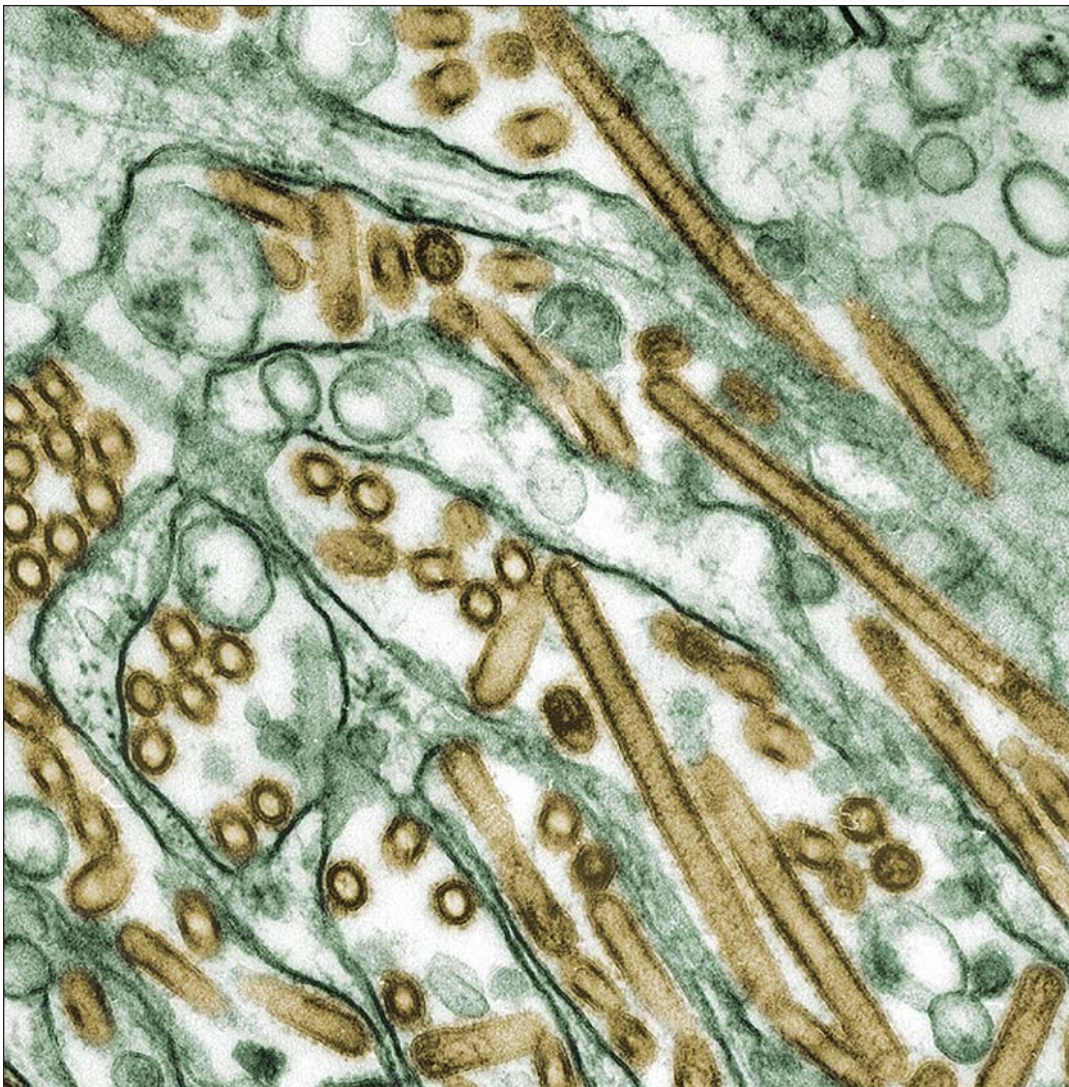
- Develop national guidelines for antiviral drug use, most effective dosing, timing, and best methods of administration.
- Develop, publicize, and distribute detailed antiviral distribution protocols for the request, receipt,

breakdown, transport, and distribution of the Strategic National Stockpile (SNS).

- Consider modifying guidelines on the use and distribution of antiviral drug stockpiles as antiviral production capacity increases and additional relevant information becomes available.
 - On a regular basis and as needed, reassess, revise, and publicize guidelines for prioritization of pandemic influenza vaccine.
 - Develop, publicize, and distribute detailed national protocols for conducting mass vaccinations and for local implementation.
 - Develop the adequate distribution systems and administration procedures necessary to rapidly immunize large numbers of health care workers.
- Establish an accountable, comprehensive, and integrated system for tracking vaccine distribution, storage, and utilization to help assess vaccine supply at the national, regional, and local levels. This system also could be used to track vaccine re-distribution during shortages and emergencies and to measure population-based vaccine efficacy.
 - Continue to develop, refine, and support immunization information systems (vaccine registries).

STATE AND LOCAL GOVERNMENTS SHOULD:

- Adapt mass vaccination and antiviral distribution protocols to local jurisdictions.



6

Expand Vaccine Uptake, Stabilize Vaccine Manufacture, and Test and Evaluate Vaccine Distribution Plans During Annual Influenza Seasons

CURRENT STATUS: Preparedness and response to activities related to seasonal influenza can serve an important role in preparing for pandemic influenza. Vaccine production capacity increased only modestly for the 2006-2007 annual influenza season. Progress has been made in developing policies aimed at increasing seasonal influenza vaccinations among health care workers. A new infection control standard from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), enacted January 1, 2007, as an accreditation requirement for the Critical Access Hospital, Hospital, and Long Term Care accreditation programs, requires organizations to offer influenza vaccinations to staff, including volunteers and licensed independent practitioners with close patient contact. CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) made new recommendations to increase influenza vaccination coverage among health care workers in order to protect both patients and staff from influenza.

PRINCIPLE:

The U.S. should adopt policies to increase the public's uptake of seasonal influenza vaccinations and to determine the most effective vaccination strategies for the population. Such policies will help to reduce the morbidity and mortality of annual influenza and help stabilize vaccine manufacturing capacity. Strengthened policies should include mandatory annual influenza vaccination among health care workers (with an allowance for a written declination to permit health care workers to object for religious or philosophical reasons, or if medically contraindicated). Annual influenza vaccine distribution should be used as an opportunity to test vaccine protocols and distribution plans.

To achieve these goals, IDSA offers the following specific recommendations to be undertaken during annual influenza seasons:

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, WITH THE U.S. CONGRESS' SUPPORT, SHOULD:

- Include influenza vaccine coverage rates as a quality measure for hospitals and individual practices.

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND CENTERS FOR DISEASE CONTROL AND PREVENTION, WORKING IN CONCERT WITH STATE AND LOCAL GOVERNMENTS, SHOULD:

- Test and evaluate national protocols for conducting mass vaccination and antiviral distribution campaigns. State and local governments should communicate evaluation results back to their federal partners.
- Use seasonal influenza as a test of federal and local surveillance systems and measure effectiveness and performance at the federal, state, and local levels, including the health care community.

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND CENTERS FOR DISEASE CONTROL AND PREVENTION, IN CONCERT WITH HEALTH CARE ORGANIZATIONS, SHOULD:

- Offer annual influenza vaccination onsite to all health care workers with direct patient care contact at hospitals, clinics, and other health care facilities. Vaccinations should be paid for by the employees' health insurance or employers. Health care workers should be allowed to decline vaccination for religious or philosophical reasons, or if medically contraindicated.
- Use strategies proven to improve vaccination coverage among health care workers, such as education to combat fears and misconceptions, the use of reminders to staff, and having leadership set an example by getting vaccinated. Declination forms should be used to help monitor vaccine uptake.

7

Protect the Health Care Workforce During a Pandemic

CURRENT STATUS: A federal interagency task force will draft guidance on the prioritization of pre-pandemic and pandemic influenza vaccine based on various pandemic severity and vaccine supply scenarios and will consider health care workers as a high risk group. Some Congressional leaders have attempted to create an injury compensation fund to protect health care workers who receive pandemic vaccine during a declared public health emergency.

PRINCIPLE:

The U.S. must preserve medical readiness by ensuring that health care workers, including physicians, nurses, pharmacists, allied health personnel, first responders, and others, are able to perform their duties during an influenza pandemic. By its very nature, their work puts these individuals at higher risk during a pandemic. To this end, the U.S. should ensure the availability of influenza vaccinations, antiviral treatment (and ideally prophylaxis), a guaranteed, pre-determined injury compensation, and liability protection to eliminate barriers to health care workers' participation during an influenza pandemic.

To achieve this goal, IDSA offers the following specific recommendations:

A. INCREASE INFLUENZA VACCINATION RATES AND ESTABLISH HEALTH CARE WORKERS AS A PRIORITY GROUP TO RECEIVE PANDEMIC VACCINE

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SHOULD:

- Make pandemic influenza vaccine available to health care workers and other essential responders.
- Establish health care workers with direct patient contact in the first-tier priority group for receiving vaccines.

THE U.S. CONGRESS SHOULD:

- Pursue legislation requiring health care workers to receive pandemic influenza immunization and allow for written declination due to religious or philosophical reasons, or if medically contraindicated.

B. PRIORITIZE ANTIVIRAL TREATMENT AND PROPHYLAXIS FOR HEALTH CARE WORKERS

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES SHOULD:

- Establish health care workers with direct patient contact during a pandemic in the first-tier priority group for antiviral drug treatment. Periodically re-evaluate antiviral supply, and consider health care workers for long-term prophylaxis, as supplies become available.

C. CREATE AN INJURY COMPENSATION FUND TO PROTECT HEALTH CARE WORKERS AND PROVIDE LIABILITY PROTECTION FOR CLINICIANS

THE U.S. CONGRESS SHOULD:

- Establish an injury compensation fund for any health care worker injured by receipt of a pandemic influenza vaccine during a declared influenza emergency. Reimbursement should cover medical costs and lost earnings. Such a fund could be similar to the compensation fund that was developed and proved necessary to immunize civilian health care workers against smallpox.
- Provide liability protection for clinicians who adhere to local guidance consistent with national recommendations regarding altered standards of care while responding to a declared public health emergency.

8

Build National, Regional, and Local Health Care Systems Capable of Responding to Mass Casualty Events

CURRENT STATUS: The HHS Pandemic Influenza Plan provides a theoretical framework for developing regional medical surge capacity, but the effort requires significantly more detail. Key issues pertaining to community-based and hospital-based mass casualty care remain unaddressed. The recently enacted Pandemics and All-Hazards Preparedness Act is intended to strengthen public health infrastructure and medical surge capacity, and improve health information technology.

PRINCIPLE:

The federal government should act now to establish a national strategy to ensure a coordinated continuum of care during a pandemic. This involves building national, regional, and local health care systems capable of responding to a mass casualty event by establishing the protocols necessary to develop and sustain medical surge capacity; providing training, education, and credentialing to public health and medical personnel; and developing detailed, evidence-based guidance.

To achieve these goals, IDSA offers the following specific recommendations:

A. ESTABLISH THE PROTOCOLS NECESSARY TO SUSTAIN MEDICAL SURGE CAPACITY

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ITS LEAD AGENCIES SHOULD:

- Consult with health care professional societies, health care system administrative leaders, and public health authorities to first define, and then develop, a federal plan for regional and institutional medical surge capacity that is sufficiently detailed to be implemented at the local level. The plan should provide practical, standardized guidelines for clinical triage, use of altered standards of care, prioritization of limited medical resources, personnel management including surge staffing models and volunteer recruitment and training, personnel transport and housing during community mitigation measures, development of alternate care facilities, stockpiling of material resources and pharmaceuticals, and local and regional coordination and communication. Recommendations should be informed by best practice models from leaders and experts in the field.
- Issue detailed recommendations for development of a robust national volunteer health emergency reserve corps.

- Support states and local jurisdictions' ability to recruit and train volunteers to enhance community-wide health care system response.
- Develop exercises and evaluation tools to test the effectiveness of local, regional, and national plans, standards, and guidelines.
- Require hospitals, other health care organizations (such as ambulatory care facilities and community clinics, home health agencies, and emergency medical services), and public health agencies to engage in regional medical emergency response planning and capacity building.
- Assist in strengthening laboratory staffing, training, reporting and supplies at the local and state levels to perform large numbers of high quality influenza diagnostic tests.

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN CONCERT WITH PUBLIC HEALTH DEPARTMENTS AND STATE AND LOCAL GOVERNMENTS, SHOULD:

- Test and evaluate systems and response capacity regularly through exercises with health care facilities, public health, and emergency management agencies.

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, HOSPITALS, AND OTHER HEALTH CARE INSTITUTIONS SHOULD:

- Develop a template plan for hospitals to engage in regional planning.

THE U.S. CONGRESS SHOULD:

- Create a stand-by Medicaid authority that would permit the HHS Secretary to declare a public health emergency and grant immediate, temporary Medicaid eligibility to individuals who are uninsured or underinsured during a pandemic to ensure hospitals have the financial support to keep their doors open during a pandemic.

B. PROVIDE TRAINING, EDUCATION, AND CREDENTIALING TO PUBLIC HEALTH AND MEDICAL PERSONNEL

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CENTERS FOR DISEASE CONTROL AND PREVENTION SHOULD:

- Develop and promote standardized, timely, and practical education materials, exercises, and drills to increase health care worker knowledge about pandemic influenza response, prophylaxis, treatment, and prevention in the context of improving the all-hazards medical response to health emergencies.

- Continue to work on a national, standardized system to credential health care professionals responding to health emergencies.

C. DEVELOP EVIDENCE-BASED GUIDANCE

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CENTERS FOR DISEASE CONTROL AND PREVENTION, HOSPITALS, AND OTHER HEALTH CARE ORGANIZATIONS SHOULD:

- Work to develop evidence-based, standardized guidelines related to: medical triage; allocation of scarce resources, including prioritization and distribution of personal protective equipment (PPE), supplies (e.g. masks, including N95s), and medical care items (e.g. ventilators); liability protection; hospitalizations; and altered standards of care during a pandemic event.
- Identify and address inconsistencies among existing standards developed by different health care organizations.



9

Develop and Test Community Mitigation Measures

CURRENT STATUS: CDC recently developed a proposal for interim guidance using a “Targeted Layer Containment” (TLC) model for community mitigation interventions with technical expert and stakeholder input. However, many important issues remain unresolved. An Institute of Medicine (IOM) review panel recently reviewed the role of mathematical modeling and its use in formulating response and mitigation strategy and policy and published their findings in a letter report. The WHO plans to issue a report in January 2007 on ethical issues raised by pandemic influenza planning.

PRINCIPLE:

National guidance on community mitigation measures such as social distancing, school closures, and isolation should be developed in collaboration with key stakeholders and technical experts and should articulate a standardized, scientifically rigorous, and locally adaptable approach to community containment. The scientific basis and public health rationale for the prescribed measures should be clearly communicated to stakeholders responsible for implementing the strategies and to the public. The discussion should encompass limitations, assumptions, and potential social and economic consequences of such measures on local communities.

To achieve these goals, IDSA offers the following specific recommendations:

THE CENTERS FOR DISEASE CONTROL AND PREVENTION SHOULD:

- Consider the findings of the IOM review panel when formulating national strategy on community mitigation measures.
- Clearly identify the limitations, assumptions, and feasibility of the conclusions of the mathematical models used in developing containment strategies and assure ongoing critical review of these issues as new data become available.
- Identify ways to validate and strengthen key assumptions through testing and reformulation of the models.
- Identify both potential benefits and adverse social and economic consequences (second and third order effects) of community mitigation strategies and consider the implications for successful policy implementation.
- Assure that necessary actions and corresponding resources are identified to minimize or prevent adverse consequences of community mitigation measures.
- Include diverse stakeholders in the guidance development and evaluation processes, including respected representatives of state, local, and tribal public health and governmental agencies, business leaders, medical professionals, educational system, professional societies, school officials, and state and local elected officials.
- Assure that guidance on community containment includes clear, practical recommendations such as thresholds and criteria for implementation, discontinuation, and modification of specific containment measures and how the impact of the measures will be assessed and evaluated.
- Educate the public and stakeholders regarding the guidance, its scientific rationale, remaining uncertainties, limitations, and costs of implementation.
- Assure periodic evaluation, review, and revision of community mitigation guidance as new information becomes available.

10 Improve and Coordinate Influenza Surveillance

CURRENT STATUS: HHS, CDC, the Department of Defense (DoD), WHO, and other international bodies and countries, have greatly enhanced international surveillance efforts, particularly in Asia, Africa, South America, and the Middle East. Domestically, CDC, the U.S. Department of Agriculture (USDA), the Department of the Interior (DOI), and the Department of Homeland Security (DHS) have upgraded surveillance efforts by state and local health, agriculture, and wildlife agencies; hospitals; and clinicians. Current surveillance activities include reports such as influenza-like illness from a national network of sentinel providers; reports of outbreaks from institutional settings; laboratory submissions from the WHO network of participating laboratories; and the 122 city pneumonia and influenza death reporting system.

PRINCIPLE:

Surveillance is a critical component in identifying the emergence of a novel influenza A virus and its subsequent spread within a population. A sustainable level of funding is critical to maintain and enhance surveillance systems at the international, national, state, and local levels and to monitor in a timely manner seasonal virus strains as well as novel influenza A subtypes. Traditional influenza surveillance systems should be enhanced and strengthened with a renewed emphasis on linking data with clinical laboratory and reference laboratory reports, existing electronic health data, and new systems for influenza-like illness syndromic surveillance in an effort to improve the consistent measurement of the burden of severe disease. Excess reliance on any one system, especially an untested new system, should be avoided. Establishing effective surveillance systems for influenza viruses with pandemic potential will foster cooperative networks between U.S. health care, public health, and animal health sectors as well as between the U.S. and other countries. Strengthening surveillance will support refinement of mathematical and epidemiologic models of disease transmission.

To achieve this goal, IDSA offers the following specific recommendations:

THE CENTERS FOR DISEASE CONTROL AND PREVENTION, IN CONCERT WITH THE COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS, SHOULD:

- Continue to develop surveillance systems as needed to reflect changing patterns of disease, technological advances, and migration/movement of populations.
- Engage public health professionals and medical system stakeholders in the development and implementation of new surveillance systems that meet the needs of state and local public health officials and the federal government.
- Assure new surveillance programs are thoroughly tested and evaluated by objective public health experts before routine or widespread implementation.
- Ensure coordination of federally and locally based systems to leverage each other's strengths.

- Develop systems across state and local boundaries that are similar in methodology and can be interpreted across geographical boundaries.
- Develop and integrate new technologies for data collection, management, and interpretation at the local level and conduct assessments of these methods and tools.



- Continue to expand the library of molecular genotypes and of their patterns of spread and examine their development of resistance to build our knowledge base.
- Continue to work with veterinary and wildlife partners at the state and local levels to monitor for the emergence of a potentially pathogenic avian influenza strain.
- Support the expansion of sustained human and animal influenza surveillance in countries in accordance with the WHO Global Influenza Program, the DoD Global Emerging Infections Surveillance and Response System, the World Animal Health Organization, and the United Nations Food and Agriculture Organization.

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CENTERS FOR DISEASE CONTROL AND PREVENTION, WORKING IN CONCERT WITH THE DEPARTMENT OF DEFENSE, THE WORLD HEALTH ORGANIZATION, AND THE U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT, SHOULD:

- Engage international partners to strengthen coordination, collaboration, and communication on influenza surveillance between animal health and public health institutions.

Continue To Strengthen Leadership, International Collaboration, and Communication

CURRENT STATUS: Over the past several years, federal policymakers have made great strides to make pandemic influenza preparedness a national priority. These efforts included the issuance of HHS' Pandemic Influenza Plan and the Administration's National Strategy for Pandemic Influenza, and Implementation Plan as well as enactment of the Pandemic and All-Hazards Preparedness Act. In addition to engaging countries on a bilateral basis and working through existing multinational frameworks, the Administration has launched the International Partnership on Avian and Pandemic Influenza, which involves more than 93 countries and 20 international organizations working to improve global readiness. Most recently, the Administration released a progress summary of the Implementation Plan action items, reporting that ninety-two percent of all actions due within six months of release of the Plan have been completed. However, additional federal efforts are needed—in particular, more specific direction to states and local governments and other stakeholders.

PRINCIPLE:

The Pandemic and All-Hazards Preparedness Act has strengthened U.S. pandemic preparedness efforts by identifying the Secretary of HHS as the lead federal official for public health emergency preparedness and response, consistent with the National Response Plan. However, the HHS Secretary and the federal government as a whole must continue to strengthen leadership capacity for pandemic influenza response by regularly clarifying lines of authority and key responsibilities, holding table top and other exercises, involving technical experts and stakeholders, and issuing and updating national standards and guidance for planning based on the latest science and ethical guidelines. The U.S. also must continue to be a leader in fostering international collaborative efforts related to pandemic preparedness and in developing and issuing responsible messages to the public and health sectors.

To achieve these goals, IDSA offers the following specific recommendations:

A. STRENGTHEN LEADERSHIP BY THE FEDERAL GOVERNMENT

THE ADMINISTRATION AND LEAD AGENCIES SHOULD:

- Clearly demarcate lines of authority and decision-making at the White House, departmental and agency levels, and from top levels downward. Firm priorities must be set, and cross-departmental coordination ensured.

- Continue to hold Cabinet level table top exercises and other drills.
- Delineate the roles of all federal agencies involved in providing support to state and local offices and the specific nature of the support to be provided.
- Ensure rapid development of outstanding technical guidelines and national standards, including countermeasure prioritization, patient triage, limited resource allocation, altered standards of care, obligations of and to health care workers during a pandemic, hospitalization, liability protections, credentialing of health care professionals, and community mitigation measures.
- Develop and incorporate ethical guidance into all aspects of current domestic and international pandemic influenza plans, guidelines, and activities to ensure that public values inform U.S. pandemic preparedness policies.
- Continue to refine and update preparedness initiatives over time. Plans must be maintained as current documents, and systems should continue to be evaluated, tested, and revised.

B. FOSTER INTERNATIONAL COORDINATION

THE ADMINISTRATION, THE DEPARTMENT OF STATE, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND ITS LEAD AGENCIES SHOULD CONTINUE TO:

- Engage in joint preparedness planning and preparedness exercises with the WHO.
- Work together with the WHO and other international public health partners to rapidly mobilize and deploy epidemiologists and global resources to areas with suspected or documented human infection with potential pandemic influenza A virus strains.

C. CONTINUE TO DEVELOP AND ISSUE RESPONSIBLE COMMUNICATION MESSAGES TO BETTER EDUCATE THE PUBLIC AND HEALTH SECTORS

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN CONCERT WITH COMMUNICATIONS SPECIALISTS AND THE MEDIA, SHOULD:

- Develop clear and consistent messages regarding seasonal and pandemic influenza, outlining the likely impact on communities and the health care system and steps the public can take to mitigate morbidity and mortality.
- Direct localities to identify credible spokespersons such as infectious disease and public health physicians to carry messages to the public and the medical communities.

12 Allocate Significant and Sustainable Funding for Long-term Planning and Action

CURRENT STATUS: Over the past several years, federal policymakers have made great strides to make pandemic influenza preparedness and response a national priority. President Bush requested \$7.1 billion to implement the strategies outlined in the 2005 National Strategy for Pandemic Influenza. To date, the U.S. Congress has provided approximately \$6 billion toward this effort. However, much of the funding has come in the form of one-time, emergency funding, and has been offset by cuts in other federal bioterrorism and emergency preparedness funding. The recently enacted Pandemic and All-Hazards Preparedness Act authorizes several critical new activities for which limited funding has been appropriated.

PRINCIPLE:

The Pandemic and All-Hazards Preparedness Act authorizes several critical activities that can result in improved U.S. readiness. However, federal, state, and local pandemic preparedness and response goals cannot be achieved without increased, long-term sustainable funding. Many of the activities being requested of state and local health agencies, hospitals, and other local institutions require certainty that on-going funding is assured. Long-term investments in this area will have collateral benefits in defending against other biological agents.

To achieve these goals, IDSA offers the following specific recommendations:

THE ADMINISTRATION AND THE U.S. CONGRESS SHOULD ENSURE SIGNIFICANTLY INCREASED AND SUSTAINED LONG-TERM FUNDING TO SUPPORT CRITICAL ACTIVITIES (MANY OF WHICH ARE AUTHORIZED BY THE PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT) RELATING TO:

A. COUNTERMEASURE DEVELOPMENT, STOCKPILING, AND DISTRIBUTION

Significant and sustained funding is needed for:

- The establishment of a Pandemic Influenza Vaccine Master Program (\$2.8 billion in 2007 and a multi-billion dollar investment between 2008-2011; see Principle 1).
- Advanced R&D of pandemic influenza vaccine, antiviral, antibacterial, and diagnostic tests under BARDA.
- Stockpiling appropriate countermeasures.
- Supporting states and municipalities unable to purchase adequate antivirals for stockpile.
- Proper deployment and evaluation of mass vaccination and countermeasure distribution templates

including administration of vaccine at the local level.

- Creating an accountable, comprehensive, and integrated system for tracking vaccine distribution, storage, and utilization to help assess vaccine supply.
- Increasing capacity to deliver seasonal influenza vaccines to children and adults for whom it is recommended (such as increasing funding through CDC's National Immunization Program 317 funds).

B. SURGE CAPACITY AND PLANNING

Significant and sustained funding is needed for:

- Establishing surge capacity and planning within hospitals and other institutions, and integrating medical and public health systems.
- Hospitals, other health care organizations (such as ambulatory care facilities and community clinics, home health agencies, and emergency medical services), and public health agencies to engage in regional medical emergency response, planning, and capacity building. Hospitals should be compensated accordingly, perhaps through the Health Resources and Services Administration (HRSA).

- Increasing the number of personal protective equipment (PPE), medical supplies (e.g. masks, including N95s), and medical care items (e.g. ventilators).
- Laboratory staffing, training, reporting, and supplies at the local and state levels to perform large numbers of high quality influenza diagnostic tests.
- Testing and evaluating systems and response capacity regularly through exercises.

C. PERSONNEL

Significant and sustained funding is needed for:

- Reimbursing health professionals for their time investment in preparedness planning and educational training.
- Funding injury compensation for any health care worker injured by receipt of a pandemic influenza vaccine during a declared influenza emergency.
- Continuing medical education credit for professionals at no cost for participants in preparedness training.
- State and local jurisdiction recruiting, training, housing, and transportation of staff and volunteers to enhance community-wide health care system response.

D. U.S. AND INTERNATIONAL SURVEILLANCE

Significant and sustained funding is needed for:

- Expanding and coordinating epidemiological and laboratory-based surveillance capacity for:
 - Human infections with novel influenza A viruses of pandemic potential in the U.S.
 - Avian, swine, and other influenza A virus infections of animals, including those raised for food sources and wild birds in the U.S.
- Strengthening, enhancing, and coordinating epidemiological and laboratory-based surveillance capacity for influenza A virus infections of animals and humans worldwide.

E. COMMUNITY MITIGATION STRATEGIES

Significant and sustained funding is needed for:

- Proper deployment of community mitigation measures.

STATE AND LOCAL GOVERNMENTS SHOULD ALLOCATE PREPAREDNESS FUNDS TO:

- Purchase annual influenza vaccine to test mass vaccination protocols, and to the extent possible, antiviral drugs.
- Meet the matching requirement contained in the Pandemic and All-Hazards Preparedness Act.





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