

TOO LITTLE, TOO LATE:
THE BUSH ADMINISTRATION'S RECORD OF FAILURE
IN PREPARING FOR PANDEMIC FLU

HELP Committee Minority Report

May 3, 2006

Executive Summary

Comprehensive flu pandemic preparedness will require a commitment of resources. While the Democrats have proposed significant new funding for important public health activities, the White House and Republican led Congress have not been willing to fund preparedness programs at the necessary level. And, in fact, the President's most recent budget would slash funding for important public health programs.

The 2006 Defense Appropriations Act included supplemental appropriations for pandemic preparedness. However, key areas of preparedness continue to be inadequately funded, including:

- Public health infrastructure;
- State and local preparedness activities;
- Disease surveillance;
- Vaccine capacity and stockpiling;
- Antiviral and other medical supply stockpiling;
- Workforce training and risk communication;
- Seasonal flu activities; and
- International activities.

The Republicans have also not addressed the issue of compensating people who may be harmed by an experimental pandemic flu vaccine. While the Defense Appropriations Act of 2006 did provide sweeping liability protection for a broad class of countermeasures, the legislation only included vague language establishing a compensation program for people harmed by these products, and it did not fund the compensation program.

The liability protections that were part of the Defense Appropriations Act would make it very difficult for a plaintiff to prevail even if a manufacturer engaged in reckless or even criminal conduct. The immunity potentially covers a poorly defined and extremely broad range of products, including products that are used every day to treat diabetes, obesity, low blood pressure, or pain. A broad class of persons, from vaccine manufacturers to health care providers, would be immune from suit and liability. While there is an exception from immunity for willful misconduct, the exception is very narrow and excludes any negligence or recklessness and even intentional criminal acts.

I. Introduction

In December 2005, the Republican-controlled Congress approved a set of emergency supplemental appropriations as part of the 2006 Defense Appropriations Act.¹ The appropriation provided \$3.8 billion to help protect the nation from a pandemic—significantly less than the \$8 billion provision passed by the Senate, \$3.3 billion less than requested by the President in 2006, and well below the level of funding recommended by health advocacy groups.

This report analyzes these appropriations for pandemic preparedness and assesses how effective the appropriations will be. The report also compares the appropriations with funding levels for pandemic preparedness and prevention activities proposed by Democrats;² requested by the President in his President in FY 2006 and FY 2007 requests; and recommended by public health experts, international organizations, and academic and policy institutes.

An aggressive plan to prevent an avian flu pandemic must immediately address three national priorities. First, to track and detect avian influenza before it develops into an epidemic, we must improve global surveillance and containment of human and animal disease; build our domestic surveillance and national preparedness efforts; and network our national and regional public health information systems using advanced information technology. Next, to contain the spread of disease once it reaches our shores, we must expand the national strategic stockpile and increase domestic seasonal and pandemic influenza vaccine manufacturing capacity. Finally, to build our capacity to respond to a public health emergency, we must strengthen state and local public health infrastructure; support training and expansion of our health care workforce; and communicate risks and prevention strategies to the public.

One immediate concern with the 2006 Defense Appropriations Act is that the emergency supplemental for pandemic flu allocates money to the Departments of Agriculture, Defense, Homeland Security, Interior, Health and Human Services, Veterans Affairs, State and the Office of the President, with a wide latitude in allocation of funds, yet it is not clear who will coordinate and oversee that spending government-wide. The Comptroller General, David Walker, identified this lack of coordination as a major failure in the federal response to Hurricane Katrina in a briefing earlier this year,³ and the non-partisan Trust For America's Health (TFAH) has recommended that both the federal and

¹ Title II of Division B of the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006

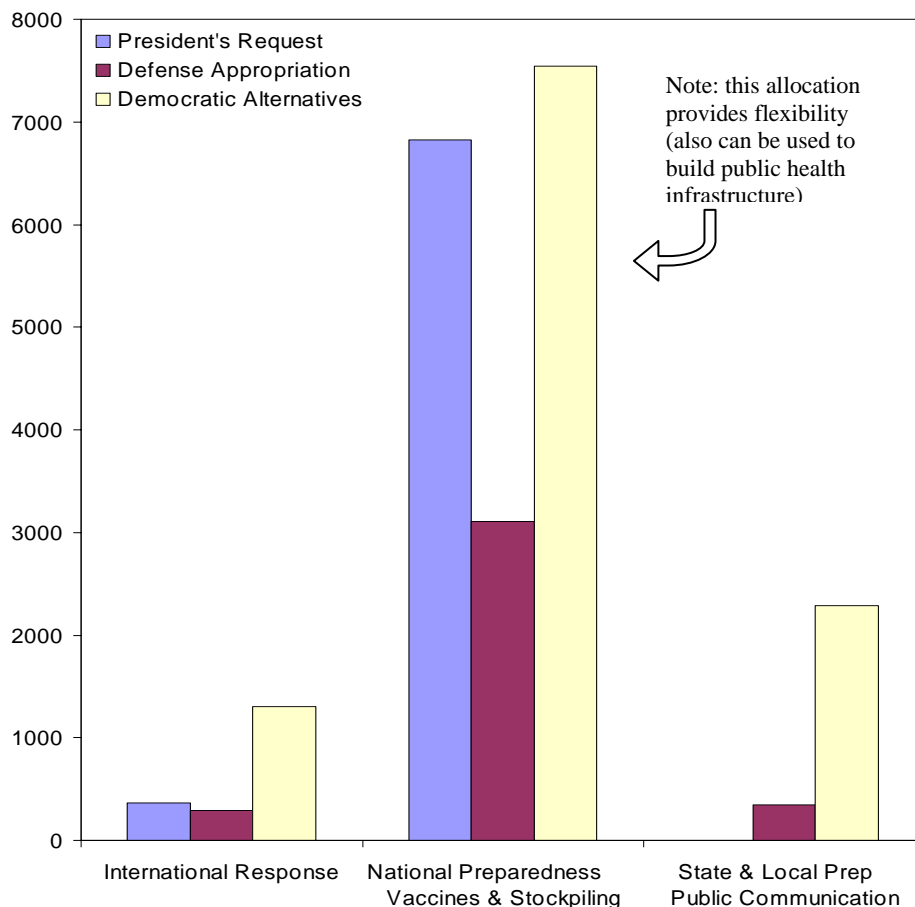
² See H.R. 4603, ('Pandemic and Seasonal Influenza Act of 2005') introduced by Representative Nita Lowey; S. 1821, ('Pandemic Preparedness and Response Act') introduced by Senator Harry Reid; and S.Amdt. 2283 ('To make available funds for influenza preparedness', amendment to H.R. 3010) offered by Senator Harkin and passed by the full Senate (10/27/1005).

³ Statement by Comptroller General David M. Walker on GAO's Preliminary Observations Regarding Preparedness and Response to Hurricanes Katrina and Rita; February 1, 2006.

state governments define a clear chain-of-command, in order to ensure that rapid and efficient control and response is maintained during a potential outbreak.⁴

Another major concern is that the one-year emergency appropriation approved by the Congress signals only a short-term commitment to funding pandemic preparedness activities for public health departments, vaccine manufacturers, and other stakeholders. The long-term commitment required for novel influenza vaccine production, strong public health infrastructure, and global surveillance and containment efforts will not be satisfied by this legislation.

Finally, while the President's FY 2006 request and the Defense Appropriations approved by a Republican-controlled Congress begin to address the threat of a pandemic influenza, they are primarily focused on just one component of the national response: bolstering our domestic vaccine and antiviral industries and markets. In contrast, the Democratic-sponsored alternatives place a more even focus on vaccine and antiviral research and development; international surveillance and containment efforts; and public health infrastructure. Figure 1 below provides a clearer sense of relationships between the three approaches to funding a pandemic influenza preparedness enterprise.



⁴ *A Killer Flu? 'Inevitable' Epidemic Could Kill Millions* Trust for America's Health, June 2005.

II. Analysis

National Preparedness

Neither the President nor the Republicans in Congress have proposed sufficient funding for national preparedness. In fact, the President's most recent budget request would slash funding for important public health programs.

Health Services: According to the Dr. Eileen Ouellette, President of the American Academy of Pediatricians, "If we are to be prepared for the next disaster, we need to invest in health care services." Much of the nation's health care infrastructure is already overburdened during yearly influenza seasons; this situation will only be exacerbated by an outbreak of highly pathogenic flu.

- **The President's FY 2006 Pandemic Flu Request:** The flu supplemental provided \$100 million to CDC for pandemic-related activities. No funds were specifically requested for shoring up our overtaxed health care system.
- **The President's FY 2007 Budget Request:** The President slashes many of the basic public health programs that provide important protections against pandemic flu in 2007—including more than \$200 million in cuts to public health preparedness and training funded by the Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA). The CDC loses \$179 million overall in 2007, and HRSA loses \$252 million, for a total of \$431 million. In turn, the President allocates \$352 million to support national preparedness at the Department of Health and Human Services (HHS).
- **2006 Defense Appropriations:** The Defense Appropriations provided no direct funds for national preparedness.
- **Democratic Proposals:** The Senate and House Democrats' legislative proposals focused on strengthening state and local public health and health services capacity, as outlined in later sections of this report. In addition, H.R. 4603 would have provided funds as required for FDA post-market studies and facilities upgrading for pandemic influenza products. It would also have provided funds as required for CDC pandemic influenza and epidemiology research.

Human Surveillance: Public health surveillance is disjointed and inconsistent across the United States, with hospitals unable to communicate rapidly with public health departments or each other. CDC's BioSense, a nationally-networked disease surveillance system connecting emergency rooms across the country, currently has just 32 hospitals in 10 cities online.

- **The President's FY 2006 Pandemic Flu Request:** In 2006, domestic surveillance and preparedness in the President's pandemic flu budget requested \$47 million for Department of Homeland Security (DHS). The President requested \$27 million for the Veterans Administration (VA) for domestic surveillance, detection, and containment.

- **The President's FY 2007 Budget Request:** In 2007, the President is requesting an additional \$188 million for CDC's domestic and global flu-related activities, but the President's budget would also cut an additional \$42 million from anthrax and other biodefense research programs.
- **2006 Defense Appropriations:** The Defense Appropriations bill funded the FY 2006 DHS request of \$47 million, and also provided \$20 million for the Food and Drug Administration (FDA), for establishing regulatory procedures and technical capacity. The Defense Appropriations also directed \$50 million to restore CDC research funds, but funded surveillance capacity and other preparedness efforts at just \$96 million.
- **Democratic Proposals:** The Senate Democrats proposed \$100 million to build CDC laboratory capacity for disease surveillance in S.A. 2283. The Senate bill, S.1821, would have provided funds for grants to states and private health care entities, to improve surveillance infrastructure, and would have built animal health lab capacity.

Animal Surveillance: The federal government currently lacks a system to track and share data from different databases. For example, the CDC's BioSense database, which collects and integrates local public health data from all 50 states, cannot interface with the Zoo Information Management System, which collects data on animal health in urban and rural areas. In addition, John Lauder, a senior fellow at intelligence and homeland security with Arete Associates, has stated that HHS and the intelligence community have no contact with each other, even though they have valuable foreign nation data to share.⁵

- **The President's FY 2006 Pandemic Flu Request:** The President's FY 2006 request would have funded interagency domestic animal surveillance activities at \$91.6 million.
- **The President's FY 2007 Budget Request:** No further requests were made for FY 2007.
- **2006 Defense Appropriations:** The Defense Appropriations fulfilled the FY 2006 request, but failed to provide additional funds for an electronic database to enable rapid tracking of disease outbreaks and nation-wide networking of local animal health surveillance, as proposed in the Senate Democrats' bill.
- **Democratic Proposals:** As mentioned in the international response section, both H.R. 4603 and the Senate bill would provide \$10 million per year to build a global influenza network to track animal disease.

State and Local Preparedness

Public Health Infrastructure and Surge Capacity: Effective pandemic influenza preparedness depends upon strengthened support of both state and local public health infrastructure. WHO has advised member nations to develop software to detect outbreaks

⁵ Minority Briefing, House Committee on Homeland Security, Jan 2005.

and “tabletop” exercises to practice pandemic plans. Plan practice and implementation is an essential activity for nations not yet hit by a pandemic flu.⁶ According to TFAH, plans must account for the likelihood that current healthcare facilities will be quickly overwhelmed during a pandemic, and as such auxiliary sites such as shelters, schools, hotels must be prepared for surge capacity treatment and for the treatment of the “walking well”.

In addition, healthcare facilities must be prepared to deliver adequate laboratory surveillance of the flu, including the ability to isolate and subtype the virus year-round.⁷ With over 100 million annual visits to emergency rooms, the current capacity of the nation’s 4,000 hospital emergency rooms would not be adequate to accommodate a pandemic influenza outbreak. To meet CDC’s projection of a 25% increase in demand for hospital beds, ventilators, emergency medical staffing and equipment in the case of a pandemic, \$1.5 billion would be required.⁸ Furthermore, the major users of emergency room services, the 45.8 million Americans who are currently uninsured, are particularly vulnerable to a pandemic outbreak. In order to meet their needs, the federal government should expand funding for programs that provide safety-net health services to this cohort during an emergency.

- **The President’s FY 2006 Pandemic Flu Request:** President Bush requested \$100 million in additional funds for state and local preparedness, on top of bioterrorism and general public health grants provided to states and localities. However, \$100 million out of a \$3.8 billion budget is inadequate considering that emergency response occurs locally, not at a national level. The request also neglected funding for the identification and preparation of hospital and provider surge capacity regionally and locally.
- **The President’s FY 2007 Budget Request:** The FY 2007 President’s budget follows the trend established in 2006. Grants for hospital bioterrorism preparedness and state grants for public health preparedness are flat-funded in 2007, with no adjustment for inflation.
- **2006 Defense Appropriations:** The Defense Appropriations bill provided \$350 million for upgrading state and local public health capacity, which restores and updates the State and Local Terrorism Cooperative Agreements. The Defense Appropriations did not explicitly provide funds for surge capacity.
- **Democratic Proposals:** The Democratic alternatives, including the House and Senate bills and the Senate-passed amendment, would have provided significantly more funding to restore public health infrastructure and surge capacity at the state and local levels. H.R.4603 provided \$200 million in state and local planning grants, plus \$1.5 billion over 5 years for ongoing pandemic preparedness and surge capacity. Senate amendment 2283 provided \$600 million for state and local preparedness grants.

⁶ WHO, *Responding to the Avian Flu Threat*, Aug 2005

⁷ TFAH, *National Pandemic Checklist*, 10/22/05

⁸ CDC, National Vaccine Program Office.

National Vaccine Capacity and Stockpiling

Vaccine Purchasing and Capacity: The United States does not have the capacity to quickly produce enough flu vaccine to quell a pandemic. CDC recommends that 60% of the population be successfully vaccinated in the event of a pandemic.⁹ The current vaccine requires two injections, taken weeks apart. Assuming that 10% of the vaccine will be lost to spoilage and individuals who neglect to get the second shot, approximately 352 million doses of vaccine will be needed. With CDC estimates of \$15 per dose, the cost of vaccination is \$5.3 billion. In addition, vaccine production will take from 6 to 9 months, leaving Americans unprotected during the first wave of a pandemic.

Seasonal shortages have highlighted the need for a system to track and distribute flu vaccines. Currently, over 90% of flu vaccine is produced, distributed and administered by the private sector. There is no system in place for federal agencies to assess or redirect the distribution of vaccine to address regional or local shortages.

Vaccine production infrastructure in the United States is antiquated, relying on chicken eggs and 40 year old techniques. New, cell-based technologies could speed vaccine production and boost production capacity. Industry representatives seek a predictable market and a reasonable liability and compensation program to invest in these new technologies and expand domestic infrastructure.

- **The President's FY 2006 Pandemic Flu Request:** President Bush requested \$2.8 billion in FY 2006 to develop technology for vaccine production, along with \$1.519 billion for the purchase of vaccine.
- **The President's FY 2007 Budget Request:** In FY 2007, the President has requested an additional \$2.3 billion to fund, among other priorities, vaccine antiviral and vaccine research, stockpiles, and domestic production capacity. Overall, funds for contract research, production, and procurement of vaccines and antivirals represent 72% of the President's \$7.1 billion pandemic flu supplemental request.
- **2006 Defense Appropriations:** The Defense appropriations bill allocated \$2.65 billion to HHS for a variety of purposes, including the development and purchase of vaccines, antivirals, and necessary medical supplies, and for planning activities. The funds may also be used for construction or renovation of privately owned facilities, all at the discretion of the Secretary of HHS. The DoD appropriation contained no assurance of a domestic vaccine market, and created an inadequate compensation program for people injured by the vaccine. In addition, the emergency supplemental did not signal industry that the U.S. government would make a long-term commitment to vaccine purchasing.
- **Democratic Proposals:** S.A. 2283 would have allocated \$3.3 billion to HHS for vaccine purchase, infrastructure developments, and R&D. S. 1821 would have allocated funds as required by the HHS Secretary, to purchase vaccine, establish a

⁹ "Modeling the economic impact of pandemic influenza in the United States: Implications for setting priorities for intervention", *Emerg Infect Dis*, CDC, Dec 05

vaccine tracking system, and build infrastructure through programs to increase seasonal flu vaccination rates. H.R. 4603 would have allocated funds, as required by the HHS Secretary, to build capacity by creating a stable market by purchasing excess seasonal flu vaccines, in addition to increasing R&D. It would also create a vaccine tracking and distribution system.

Antiviral Drugs: The US currently has enough antiviral medication to treat 5 million people, or about 2% of the population. The World Health Organization recommends stockpiling enough antiviral medication to treat 25% of the population, or 66 million courses of medicine. This will cost \$567 million (using CDC estimates of \$8.90 per therapeutic course of Tamiflu).

- **The President's FY 2006 Pandemic Flu Request:** President Bush requested \$1.029 billion to stockpile antiviral medications in FY 2006.
- **The President's FY 2007 Budget Request:** His FY 2007 request includes another \$2.3 billion, as discussed above, to provide antiviral and vaccine research, stockpiles, and domestic production capacity, among other priorities. However, just \$200 million would be directed toward research to develop new antivirals. This is concerning given recent reports of Tamiflu-resistant strains of the H5N1 virus.
- **2006 Defense Appropriations:** The Defense appropriations bill allocated \$2.65 billion for a variety of purposes, including the development and purchase of vaccines, antivirals, and necessary medical supplies, and for planning activities. The funds may also be used for construction or renovation of privately owned facilities, all at the discretion of the Secretary of HHS. In addition, HHS will reimburse only 25% of the cost for states to establish local and regional antiviral stockpiles.
- **Democratic Proposals:** The Senate Amendment 2283 would have allocated \$3.08 billion to stockpile antiviral medications and medical supplies. S. 1821 would have allocated funds as required by the HHS Secretary to prevent or treat at least 50% of the population. H.R. 4603 would have allocated funds as required to acquire an amount of antiviral medicines as determined by the HHS Secretary. It would also have provided \$510 million for state antiviral stockpiles, to remove the unfunded mandate that state purchase supplies for regional and local stockpiles.

Workforce and Risk Communication

Workforce Training: As the threats to health and safety increase, the health care and public health workforce continues to shrink. However, in a public health emergency, more health care workers are required. Effective pandemic preparedness requires expanding the professional and volunteer health care workforce, through development programs that support and train professionals and provide targeted preparedness and response programs for public health emergencies. HHS should enhance programs aiding

areas with health professional shortages or medically underserved populations (i.e., rural areas) to maximize response capacity. However, the House and Senate FY2006 Labor/HHS appropriation bills differed by approximately \$500 million in funding for general workforce development in HRSA.

- **The President's FY 2006 Pandemic Flu Request:** This request did not address the issue of ongoing development and dissemination of education for health professionals and volunteers.
- **The President's FY 2007 Budget Request:** As above, no funds are requested for pandemic workforce training in 2007. Even worse, the bioterrorism curriculum development project at HRSA is cut by \$8.4 million.
- **2006 Defense Appropriations:** The Defense appropriations bill allocated no funds for workforce training.
- **Democratic Proposals:** Although neither the President's requests nor the FY2006 Defense Appropriations addressed the issue of ongoing pandemic flu training and education for health professionals and volunteers, the Democrats would have provided funding for emergency training.

Seasonal and pandemic flu campaign: In the U.S. one million two-year olds have not received at least one of the recommended vaccinations, and as many as 500,000 adults needlessly die each year from vaccine-preventable diseases—influenza, pneumococcal infection and hepatitis B. A targeted program to educate adults about routine immunizations will play an important role in pandemic preparedness and prevention. In addition, an effective public information campaign is necessary to disseminate vital information during a high-anxiety public health emergency.¹⁰ Without adequate information, individuals will likely make ineffective and expensive efforts to protect the health and safety of themselves and their families.

- **The President's FY 2006 Pandemic Flu Request:** This request did not address the issue of public education and outreach.
- **The President's FY 2007 Budget Request:** As above, no particular funds are requested to develop pandemic flu communications for the public.
- **2006 Defense Appropriations:** The Defense appropriations bill allocated no funds for public communications and outreach.
- **Democratic Proposals:** The House Democrats' bill would have provided funding to expand research on communication and behavioral strategies, to assist the general public during public health emergencies. It would also have funded public education and awareness campaigns. The Senate Democrats' bill would have provided public campaigns both for adult immunization with seasonal influenza vaccine and for pandemic influenza awareness

International Response

¹⁰ TFAH, *National Pandemic Checklist*, 10/22/05

International Assistance: The health care systems and economies of nations impacted by avian flu can be crippled by even a limited outbreak of the disease. In 2003, outbreaks in the Netherlands, Thailand and Vietnam cost \$1.3 billion in agricultural losses alone.¹¹ International assistance to maintain national health care systems is essential to prevent and contain further outbreaks. The World Bank estimates that \$1.2 billion will be required to finance multinational prevention and containment efforts. So far, donors have pledged \$1.9 billion to the WHO, FAO, and other U.N organizations. The donor funds include just \$334 million from the U.S, which is far less than the standard one-third contribution to U.N. initiatives. TFAH has argued for increased U.S. contribution to global infectious disease prevention and preparedness, since this is the most effective means for preventing a pandemic.¹²

- **The President's FY 2006 Pandemic Flu Request:** In 2006, the President requested \$145 million in supplemental funds, for international disaster assistance, stockpile of supplies, and direct aid in his emergency supplemental budget request. This figure excludes the funds for international surveillance and containment, which are outlined below. This is less than 4% of total funds, even though international activities are the first line of defense.
- **The President's FY 2007 Budget Request:** In 2007, the President is requesting an additional \$127 million for global disease surveillance and control.
- **2006 Defense Appropriations:** The Defense Appropriations bill included just \$132 million for international aid. Of this, \$56 million would be allocated to drug stockpiles for international use and the remainder would be for response to public health emergencies.
- **Democratic Proposals:** The House Democrats' bill provided a significantly higher level of funding or international assistance, recognizing the importance of preventing a pandemic abroad before it reaches the U.S. Their alternative would provide \$750 in bilateral and multilateral aid to qualifying nations.

Human Surveillance: Existing U.S. contributions to global surveillance include technical support from the Centers for Disease Control and Prevention (CDC), which currently serves as one of four Collaborating Centers comprising the WHO Global Influenza Surveillance Network. However, the agency's current budget for this global disease detection program is just \$12 million, and researchers in other countries have complained that CDC's sharing of data on influenza outbreaks, including virus genetic sequences, has been inadequate. The CDC Director claims that the agency does not currently have the capacity to comply with international requests for information.¹³ Clearly, the budget for CDC must be significantly expanded to enable participation in international research and prevention efforts. Department of Defense programs (including the Bioweapons Proliferation Prevention, Bioweapons Threat Agent Detection, Global Emerging Infections System, and Cooperative Biological Research programs) also provide disease

¹¹ *Nature*, 05/27/05

¹² TFAH, *National Pandemic Checklist*, 10/22/05

¹³ *Nature*, 9/22/05

surveillance in Central Asia and Eastern Europe and should be expanded to include avian flu tracking, particularly in light of recent disease outbreaks in Turkey, Bulgaria, Afghanistan, and Iraq.

- **The President's FY 2006 Pandemic Flu Request:** The supplemental request for human surveillance and containment (both abroad and at home) was for \$210 million. The supplemental request for Operation and Maintenance Defense-Wide provided just \$10 million at a time when several anti-proliferation and bioterrorism programs have seen their budgets cut by the Administration.
- **The President's FY 2007 Budget Request:** The FY 2007 request would direct \$188 million to domestic and international surveillance and containment via CDC. Out of a \$7.1 billion budget for pandemic preparedness, the total contribution to disease surveillance and control would be less than 6 percent.
- **2006 Defense Appropriations:** The Defense Appropriations provided \$150 for international surveillance and containment through the CDC, along with \$10 million for the Defense Department as requested by the President.
- **Democratic Proposals:** H.R. 4603 would provide \$500 million for international detection and containment.

Animal Surveillance: WHO states that early disease detection, diagnosis, and treatment in countries affected by avian influenza—particularly those with dysfunctional public health systems—is the best way to contain outbreaks and halt further progression.¹⁴ Avian flu is currently spreading through bird populations in Asia, Europe, and Africa, and bird migration patterns threaten to spread the virus to continents so far unaffected. The United Nations' Food and Agriculture Organization (FAO) has called for \$100 million to implement animal surveillance activities; it has so far secured \$20 million through donor pledges, including \$6 million from the U.S.¹⁵ FAO also advises education of rural farmers and veterinarians, to ensure rapid diagnosis of avian flu and reporting of outbreaks.¹⁶

- **The President's FY 2006 Pandemic Flu Request:** President Bush requested \$10 million for international animal disease tracking in FY 2006.
- **The President's FY 2007 Budget Request:** No monies are requested in the 2007 pandemic request.
- **2006 Defense Appropriations:** The Defense Appropriations provided no funds for international animal health surveillance.
- **Democratic Proposals:** H.R. 4603 included \$10 million each year, for five years, to create a Global Network for Influenza Surveillance; the Harkin-Kennedy Senate amendment included \$10 million to start such a network.

¹⁴ Pandemic Preparedness Checklist? World Health Organization, 2005.

¹⁵ FAO Press release, September 26, 2005.

¹⁶ FAO, *Global Strategy for the Progressive Control of HPAI*, May 2005

III. The Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act, which became law as division C of the 2006 Defense Appropriations Act, amends the Public Health Service Act (PHSA) by adding section 319F-3, Targeted Liability Protections for Pandemic and Epidemic Products and Security Countermeasures, and section 319F-4, Covered Countermeasure Process. Section 319F-3 provides an effectively complete immunity from liability for a potentially broad class of medical products. Section 319F-4 establishes a fund from which certain people injured by such medical products are supposed to receive compensation.

This report examines how sections 319F-3 and 319F-4 came to be inserted in the 2006 Defense Appropriations conference report, how the provisions will work, and potential constitutional problems with them.

The Inclusion of the Public Readiness and Emergency Preparedness Act in the 2006 Defense Appropriations Act.

The Public Readiness and Emergency Preparedness Act was added as the last division of the 2006 Defense Appropriations Act at the very end of the conference process on the defense appropriations bill. The Republican leadership abused the conference process in order to ram through a very broad liability protection that they likely could not have passed had they gone through regular order.

Liability language granting an immunity to manufacturers, and those involved in administering, of medical products for addressing the consequences of a terrorist attack first appeared on July 20, 2005, in the Senate in legislation introduced by Senator Gregg, S. 1473. A similar immunity provision was included in S. 1873, the Biodefense and Pandemic Vaccine and Drug Development Act of 2005, which was introduced by Senator Burr. On October 17, 2005, S. 1873 passed out of the Senate Health, Education, Labor, and Pensions Committee on a voice vote, with the understanding that the majority would work with the minority on remaining differences about the bill, which included significant concerns about the immunity provision and the lack of an associated compensation program. Despite protracted discussions, Senate Republicans and Democrats were not able to resolve their differences, and the full Senate never took up S. 1873 for further consideration.

Immunity language like that in S. 1473 and S.1873 was introduced in the House by Representative Issa on October 6, 2005, and Representative Lewis on November 7, 2005. Those bills, H.R. 3970 and H.R. 4245, respectively, were never taken up by the House committees to which they were referred, nor did the full House take up these bills. In short, immunity language was never approved by either the House or the Senate after anything like what would be considered regular order, and the immunity language appeared dead, at least for the first session of the 109th Congress.

It was revived, however, during negotiations between the White House, congressional Republicans, and representatives of the drug and biotech industries regarding pandemic flu. Democrats were not part of those negotiations, nor was there any formal effort to keep Democrats informed of the progress of these talks. Despite weeks of negotiations, apparently no agreement on an approach to liability was reached.

Preparing for a potential flu pandemic became part of the House/Senate Conference on DoD Appropriations. The Republicans responded to the President's request for \$7 billion by cutting that request in half. During a meeting of the conferees, in response to a question from Representative Obey about why the rest of the request was not being funded, he was advised that, because liability language was not being added to the conference report, long-term funding should be withheld.

Nonetheless, 40 pages of liability language that many of the conferees had never seen were included in the conference report. It was only after the language had already become part of this "must-pass" legislation that conferees were able to understand that the liability protections applied not just to drugs and vaccines for combating pandemic flu, but to a very broad range of drugs and vaccines.

Section 319F-3, Targeted Liability Protections for Pandemic and Epidemic Products and Security Countermeasures

This section summarizes and analyzes the liability provision (section 319F-3 of the PHSA) in the Public Readiness and Emergency Preparedness Act.

Section 319F-3 provides an essentially complete immunity from liability to each so-called "covered person" involved in the production or administration of a "covered countermeasure" that is specified for use in a "declaration" issued by the Secretary of Health and Human Services (the Secretary). An injured person can in theory breach the immunity when a covered person has acted with "willful misconduct." Willful misconduct is very narrowly defined, however, and there are complete defenses to piercing the immunity, such as the failure of the Food and Drug Administration (FDA) or the Attorney General to successfully conclude one of a number of narrowly defined enforcement actions against the covered person. When the immunity is broken, the injured person may bring the suit only in the United States District Court for the District of Columbia, and the injured person faces a number of procedural hurdles to prosecuting her case, such as heightened pleading requirements, limited discovery, limited non-economic damages, and required sanctions for procedural violations.

This summary of section 319F-3 begins with a review of most of subsection (i), the last subsection of section 319F-3, which includes many of the definitions that define the scope of products and persons protected by the immunity.

A broad class of medical products is potentially eligible for immunity, including potentially products used every-day by patients to treat diabetes, obesity, low blood

pressure, or pain.—A medical product that is a “covered countermeasure” is eligible for the immunity provided by section 319F-3 if the Secretary issues a declaration specifying the countermeasure. The term “covered countermeasure” is defined in section 319F-3(i)(1), and is so broad as to include many products used every day by American patients as well as products that will never be used to respond to pandemic influenza.

A “covered countermeasure” is one of three types of products, a “qualified pandemic or epidemic product,” a “security countermeasure,” or a drug, biological product, or device authorized for emergency use under section 564 of the Federal Food, Drug and Cosmetic Act (FFDCA).

The term “qualified pandemic or epidemic product” is defined in section 319F-3(i)(7) as a drug, biological product, or device that is made, used, licensed, or procured to “diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic,” to “limit the harm” a pandemic or epidemic “might otherwise cause,” or to “diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease” that is caused by a product made, used, licensed, or procured to respond to a pandemic or epidemic, provided the product is approved or cleared for marketing under the FFDCA or section 351 of the PHS Act, subject to an investigational exemption from such requirements, or authorized for emergency use under section 564 of the FFDCA.

According to the Merriam Webster dictionary, “epidemic” is defined as “affecting or tending to affect a disproportionately large number of individuals within a population, community, or region at the same time.” At various times, diseases ranging from obesity to diabetes to arthritis have been described as epidemics. For example, the New York Times (January 9, 2006) reports that New York City Health officials describe diabetes as a “bona fide epidemic,” with more than 1 in 8 New Yorkers suffering from the disease. Accordingly, under the term “qualified pandemic or epidemic product,” any drug, biological product or device used to treat or diagnose a disease such as obesity, diabetes, or arthritis, as well as products to address serious side effects of those products, could be given the immunity protection. For example, Vioxx, a drug produced to treat arthritis, falls squarely within the definition under section 319F-3(i)(7). Anemia, low blood pressure, or high cholesterol can be side effects of drugs, and drugs to treat them could receive liability coverage under section 319F-3.

The term “security countermeasure” is defined redundantly both in section 319F-3(i)(1)(B) and in section 319F-3(i)(9) as having the meaning of the term given in section 319F-2(c)(1)(B) of the PHS Act. These are drugs, biological products, and devices to treat, identify, or prevent harm from biological, chemical, radiological, or nuclear agents that present a material threat against the United States population sufficient to affect national security, as well as products to address adverse health effects of such products. Essentially these are drugs, vaccines, and diagnostics needed to respond to smallpox, anthrax, and other biological, chemical, radiological, and nuclear weapons that may be used by terrorists. They are not vaccines against, or treatments for, pandemic flu, but could be commonly used drugs to treat pain, high or low blood pressure, depression, high cholesterol, or any other condition that could be a side effect of a drug.

The third prong of the definition of “covered countermeasure” likely covers a subset of the first two prongs of the definition: namely, products that, because of an attack on the United States or a quickly emerging natural disease, such as pandemic flu, will need to be deployed before FDA can formally approve them for use. In particular, the third prong extends liability protections to products given emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act. This authority is limited to products intended for use in three types of emergencies: a domestic emergency involving an attack with specific biological, chemical, radiological, or nuclear agents; a military emergency involving an attack on military forces with specific biological, chemical, radiological, or nuclear agents; or a public health emergency involving specific biological, chemical, radiological, or nuclear agents. A public health emergency certainly includes pandemic influenza outbreak but may include other natural disease outbreaks, such as SARS or West Nile Virus. The first two emergencies—domestic and military emergencies—are limited to attacks by those such as terrorists using smallpox, anthrax, a nuclear or radiological bomb, or a chemical agent, such as a nerve agent.

A broad class of persons—from vaccine manufacturers to health care providers—would be immune from suit and liability.—The term “covered person” is defined in section 319F-3(i)(2) with respect to the administration or use of a countermeasure to include the United States, a “manufacturer,” “distributor,” or “program planner” of the countermeasure, a “qualified person” who prescribes, administers, or dispenses the countermeasure, as well as officials, agents, or employees of such persons. The terms “distributor,” “manufacturer,” “program planner,” and “qualified person” are defined in paragraphs (3), (4), (6), and (8) of section 319F-3(i).

A “distributor” is a person or entity that engages in the distribution of drugs, biologics, or devices, and includes manufacturers, repackers, common carriers, contract carriers, air carriers, own-label distributors, private label distributors, jobbers, brokers, warehouses, wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies.

“Manufacturer” is defined to include a contractor or subcontractor of a manufacturer, a supplier or licensor of any product, intellectual property, service, research tool, or other component used in the design, development, clinical testing, investigate, or manufacturing of a countermeasure, as well as parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

“Program planner” is defined to mean a state or local government, including an Indian tribe, a state or local government employee, or other person who supervises or administers a program to administer, dispense, distribute, provide, or use a security countermeasure or a qualified pandemic or epidemic product. It includes persons who establish requirements, provide policy guidance, or supply technical or scientific advice or assistance, or provides a facility to administer or use a covered countermeasure.

A “qualified person,” used with respect to the administration or use of covered countermeasure, is a licensed health care professional who is authorized to prescribe, administer, or dispense a countermeasure under the law of the state where the countermeasure is prescribed, administered, or dispensed, or a person within a category of persons so identified in a declaration by the Secretary.

Section 319F-3(i)(5) defines a “person” to include an individual, partnership, corporation, association, entity, or public or private corporation, and includes a federal, state, or local government agency or department.

The immunity provided under a declaration is extremely broad, and may cover even irresponsible drug company promotions of a product or injuries caused by the normal use of a drug prescribed to patients everyday.—Section 319F-3(a)(1) of the PHSA provides an essentially complete immunity from suit and liability for “covered persons” under both federal and state law for claims of any loss caused by the use of a “covered countermeasure” subject to a declaration by the Secretary under section 319F-3(b).

Section 319F-3(a)(2)(A) defines “loss” as any type of loss, including death; physical, mental, or emotional injuries; fear of such injuries; and loss of or damage to property, without regard to when they occur or are discovered. Section 319F-3(a)(2)(B) applies the immunity to any loss that has a causal relationship to the administration to or use by an individual of a covered countermeasure, including a range of causal relationships from the design, development, or clinical testing of the countermeasure to the dispensing, prescribing, or use of the countermeasure.

Section 319F-3(a)(3) ostensibly limits the scope of the immunity. Paragraphs (A) and (B) say that the immunity applies with respect to a countermeasure only if it was administered or used during the effective period of a declaration under section 319F-3(b) for the diseases or threats to health specified in the declaration. Paragraph (C) says that the immunity applies only to a covered person who is a “program planner” (a person who administers a program to administer the countermeasure) or a “qualified person” (a person, usually a health care provider, authorized to prescribe or administer a countermeasure) if, in addition, the countermeasure was administered to an individual in a population specified in the declaration to receive the countermeasure and physically present in, or with a connection to, the area specified in the declaration. The “in addition” phrase in paragraph (C) reads the conditions in subparagraphs (A) and (B) of section 319F-3(a)(3) into subparagraph (C). This fact is critical to understanding paragraph (4) of section 319F-4(a), as described below.

Section 319F-3(a)(4)(A) loosens the restrictions on the immunity described in section 319F-3(a)(3). It says a manufacturer or distributor of a countermeasure is immune even with respect to an administration of the countermeasure that is not in accordance with the conditions in paragraph (3)(C) of section 319F-3(a). Although this provision is presumably motivated by the fact that a manufacturer or distributor may not generally be responsible for the direct decision to administer a countermeasure to a

person, it is nonetheless extremely problematic because it immunizes against liability for injuries for which drug companies should be liable.

First, the provision lets a manufacturer or distributor off the hook for irresponsible promotion of a countermeasure. A manufacturer or distributor may promote the use of a countermeasure outside the scope of a declaration, either to individuals not in a population or a geographic region specified in a declaration, or outside the effective period of a declaration or for a use not specified in a declaration. Why should a manufacturer or distributor be immune from any liability for injuries or losses sustained by others who administer or use the countermeasure because the manufacturer or distributor has promoted the product to people or in a region not specified in a declaration, or because it has promoted the product outside the effective period of a declaration or for a use not specified in the declaration?

Second, when the countermeasure is a product that has a commercial use (such as a pain reliever, an antibiotic, or an antiviral that can be used against both annual flu and pandemic flu), the manufacturer and distributor would receive immunity from any liability for losses caused by the commercial use of the product. For example, a manufacturer of an antibiotic specified in a declaration to treat a few hundred people exposed to anthrax in a single building would be immune from suit by any other person in the entire United States who used the antibiotic at any point in time. That is, if a commercially available product is specified in a declaration, section 319F-3 would extend immunity to any use of that product for all time! This result is unwarranted and unjust, but it is consistent with interventions by the Bush Administration in product liability suits involving drugs and medical devices to argue that the suits are preempted because FDA approved and regulates the product.

Section 319F-3(a)(4)(B) says a program planner or qualified person is also given the immunity if a countermeasure is administered to an individual in circumstances that the person reasonably could have believed were in accordance with the conditions described in paragraph (3)(C) of section 319F-3(a).

Section 319F-3(a)(5) says that the immunity applies to a countermeasure no matter how it is distributed, including by donation and commercial sale, unless the declaration specifies a particular means of distribution. This paragraph, like the previous paragraph, makes it clear that the immunity protection can extend broadly to products widely available through commercial sales to the public.

Section 319F-3(a)(6) creates a rebuttable presumption that any administration or use of a covered countermeasure, during the effective period of a declaration by the Secretary, was for the diseases, health conditions, or threats to health with respect to which the declaration was issued.

The Secretary of Health and Human Services is given complete discretion to issue a declaration providing immunity.—Section 319F-3(b)(1) provides the Secretary with the authority to issue a declaration in the Federal Register that recommends the

manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures and that states that section 319F-3(a) granting immunity is in effect with respect to the recommended activities. Section 319F-3(b)(1) states that the Secretary may make such a declaration if the Secretary determines that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may constitute a public health emergency in the future.

Section 319F-3(b)(2) described the contents of such a declaration. The Secretary must identify for each countermeasure specified in the declaration several things, including—

- the diseases, health conditions, or threats for which the Secretary recommends administering or using the countermeasure,
- the period or periods during which the immunity under subsection (a) is in effect (which may be described using dates or milestones or other event descriptions),
- the population or populations to whom the countermeasure can be administered or used and for which the immunity under subsection (a) applies,
- the geographic area or areas in which the immunity under subsection (a) is in effect (and the Secretary may specify that the immunity applies only with respect to individuals physical present in an area, or the Secretary may describe some other connection to the area that an individual must have for the immunity to apply), and
- whether and how the means of distribution of the countermeasure is restricted.

Section 319F-3(b)(3) gives the Secretary the authority to provide for different effective periods for different covered persons, for time after the effective period for the countermeasure manufacturer to arrange for disposition of the countermeasure and for covered persons to take actions to limit administration and use of the countermeasure, and for time to administer or use a countermeasure that is distributed or released from the strategic national stockpile under section 319F-2 of the PHSA.

Section 319F-3(b)(4) gives the Secretary the authority to amend a declaration by publication in the Federal Registration, although an amendment may not retroactively take away or otherwise limit the immunity under subsection (a) with respect to the administration or use of a countermeasure. Implicitly, the scope of the immunity could be broadened retroactively.

Section 319F-3(b)(5) exempts the Secretary from disclosing in a declaration any matter not required to be disclosed to the public under the Freedom of Information Act.

Section 319F-3(b)(6) directs the Secretary, when deciding whether and how to issue a declaration granting immunity with respect to a countermeasure, to consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale,

purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure.

Section 319F-3(b)(7) states that no federal or state court has subject matter jurisdiction to review any action of the Secretary under subsection (b). In other words, whether and how the Secretary issues a declaration granting immunity for a countermeasure is not reviewable by a court to determine whether it complied with the requirements of the law or was otherwise arbitrary or capricious.

Section 319F-3(b)(8) preempts, with respect to the countermeasure for the effective period specified in the declaration, state and local law and legal requirements that are different from or in conflict with federal requirements. This provision means that, if use of the countermeasure were authorized under section 564 of the FFDCFA, and the authorization required patients receiving the countermeasure to receive certain information about the risks of using the countermeasure, a state or local public health agency could not require that patients be given any additional information about risks, even if that agency had observed that certain patients faced a risk not addressed by the federal risk information. For example, if local officials observed that a significant proportion of children under the age of 6 suffered seizures when given the countermeasure, they could not inform parents of this serious risk until the Secretary permits it.

Section 319F-3(b)(9) requires the Secretary to provide to Congress within 30 days of making a declaration or amending a declaration a report that explains the reasons for issuing the declaration and for specifying the diseases or conditions, the populations, and the geographic areas covered, the effective period, and the means of distribution.

The immunity can fail if “willful misconduct” is proven by clear and convincing evidence, but “willful misconduct” is defined extremely narrowly, and excludes any negligence or recklessness and even intentional criminal acts.—Section 319F-3(d) provides that the immunity may be pierced with respect to a covered person if the covered person acts with “willful misconduct,” and section 319F-3(c) defines “willful misconduct.”

Section 319F-3(c)(1) defines “willful misconduct” as an act or omission that is taken—

- intentionally to achieve a wrongful purpose,
- knowingly without legal or factual justification, and
- in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

The section includes a rule of construction that requires that this definition be construed as establishing a standard of liability more stringent than a standard of negligence in any form, or recklessness.

This definition excludes negligent behavior, grossly negligent behavior, and reckless behavior. Indeed, it is a very narrow intent standard, requiring a plaintiff to prove three distinct states of mind, one as to wrongful purpose, a second as to both legal and factual justification, and a third as to known or obvious risk and how it weighs against benefit. Intentional behavior that does not meet this narrow standard is excluded and so granted immunity.

Section 319F-3(c)(2) includes the recognition that the definition in section 319F-3(c)(1) is restrictive, as it requires the Secretary of Health and Human Services, in consultation with the Attorney General, to issue regulations that further restrict the scope of acts or omissions by a covered person that may qualify as “willful misconduct.” Beyond the requirement that Secretary must “further restrict” the scope of acts or omissions that qualify as willful misconduct, only subparagraph (B) of section 319F-3(c)(2) gives additional direction to the Secretary, and it is not particularly instructive. It directs the Secretary to consider the need to define the scope of permissible civil actions—those involving willful misconduct—in a way that will not adversely affect public health. It appears that the Secretary may be able to exclude all acts or omissions by an entire class of covered persons, or even by all classes of covered persons, if it is the Secretary’s judgment that complete immunity will advance public health. It is therefore noteworthy that the current Administration argues that FDA regulation of a product should completely preempt state law, including actions under product liability law, and that this position advances the public health.

Section 319F-3(c)(2)(C) allows the regulations to specify their temporal effect, and section 319F-3(c)(2)(D) requires the Secretary to commence and complete an initial rulemaking further restricting what counts as willful misconduct within 180 days of enactment (which will presumably be in the form of an interim final rule without an opportunity for public comment in advance, as permitted under subparagraph (1)).

Section 319F-3(c)(3) requires that in a lawsuit a plaintiff must prove willful conduct and that the conduct caused death or serious physical injury by clear and convincing evidence. Although this standard of proof is not as exacting as the beyond-a-reasonable-doubt standard necessary to convict a person of a crime, it is more strict than the standard of evidence—preponderance of the evidence—usually required in a personal injury case. “Serious physical injury” is defined in section 319F-3(i)(10) as an injury that is life threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Those involved in administering a covered countermeasure are given a complete defense.—Section 319F-3(c)(4) provides a complete defense for program planners and qualified personnel, those involved in administering a countermeasure. A program planner or qualified person has not, as a matter of law, engaged in willful misconduct if the person acted consistently with the Secretary’s applicable directions, guidelines, or recommendations about administering or using the countermeasure and if the person has given either the Secretary or a state or local health authority notice about information

regarding serious physical injury or death from the administration or use of the countermeasure that is material to the plaintiff's alleged loss within 7 days of the person's actual discovery of the information.

Manufacturers and distributors of countermeasures are given a complete defense when there is no successfully completed government enforcement action.—Section 319F-3(c)(5) says that acts or omissions by manufacturers and distributors are not willful misconduct if FDA or the Attorney General has not successfully completed an enforcement action. In particular, section 319F-3(c)(5)(A) says that acts or omissions subject to regulation under the FFDCa or the PHSA are not willful misconduct if either FDA and the Attorney General has not begun an enforcement action with respect to the act or omission, or if the enforcement action was begun and terminated or resolved without the FDA or the Attorney General having achieved a particular outcome. It also provides that a plaintiff's lawsuit is stayed while an enforcement action is pending.

Section 319F-3(c)(5)(B) defines “enforcement action,” “covered remedy,” and “final.” The term “enforcement action” is defined to mean many different enforcement actions the government can take under the FFDCa or the PHSA, including a criminal prosecution; an injunction action; a seizure action; a civil monetary proceeding based on willful misconduct; a mandatory recall of a product because voluntary recall was refused; a proceeding to compel repair or replacement of a product; a termination of an investigational drug or investigational device exemption; a debarment proceeding; an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer; a revocation, based on willful misconduct, of an emergency use authorization under section 564 of the FFDCa; or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of the FFDCa or of a licensure under section 351 of the PHSA.

The term “covered remedy” means a “final” outcome to these enforcement actions that would commonly be understood to be a successful outcome, such as a criminal conviction, an injunction, a condemnation of seized product, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an investigational new drug or investigational device exemption, a debarment, an investigator disqualification, a revocation of an emergency use authorization under section 564 of the FFDCa, or a suspension or withdrawal of an approval or clearance under chapter V of the FFDCa or of a licensure under section 351 of the PHSA.

The term “final” is defined in two ways. With respect to a court determination, or to a final resolution of an enforcement action that is a court determination, “final” means a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal (there appears to be a drafting error in this provision). With respect to an agency action, or to a final resolution of an enforcement action that is an agency action, “final” means an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal.

Section 319F-3(c)(5)(C) includes three rules of construction. The first says that paragraph (5) may not be construed to affect the interpretation of any provision of the FFDCA, the PHSa, or of any other applicable statute or regulation. The second says that the paragraph may not be construed to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under the PHSa, under the FFDCA, under the Federal Criminal Code, or under any other applicable statute or regulation. The third provides that a mandatory recall called for in a declaration under subsection 319F-3(b) is not an enforcement action of the FDA.

This provision gives a drug manufacturer a complete defense if FDA and the Attorney General decide not to act, even in the face of strong evidence of malfeasance. A decision not to begin an enforcement action is normally not subject to judicial review, because it is considered an act within the discretion of the prosecutor. The rule of construction specifically upholds this enforcement discretion principle. So inaction by the FDA and Attorney General completely immunizes the drug company from any liability. If the FDA or the Attorney General were investigating but failed to initiate an enforcement action before the statute of limitations for the tort suit ran, an injured tort suit would be dismissed if begun before the statute of limitations, and of course it would be too late if filed after the statute of limitations ran. Only if the FDA or the Attorney General initiates an enforcement action before the statute runs is a lawsuit preserved, and it is allowed to continue after being stayed only if the enforcement action is successfully concluded. This provision gives unnecessary and unjust weight to the action or inaction of the FDA and Attorney General.

Injured persons are given only a federal remedy as an exception when there is willful misconduct to the immunity for covered persons.—Section 319F-3(d) gives an injured person and her representatives a single exception to the immunity provided under section 319F-3(a): an exclusive federal cause of action against a covered person, only for death or serious physical injury proximately caused by willful misconduct by the covered person.

Several different procedural hurdles in the federal suit stack it against the injured person, including heightened pleading requirements and severe limits on discovery.—Section 319F-3(e) lays out a series of procedural hurdles for a plaintiff pursuing a suit under section 319F-3(d), most of which make it more difficult for a plaintiff to bring the suit or make it exceptionally easy for the drug company or other covered person who is sued to delay or achieve a successful resolution of the litigation. First, the suit must be filed and maintained only in the United States District Court for the District of Columbia. In the suit, the substantive law for decision must be derived from the law, including choice of law principles, of the state in which the alleged willful misconduct occurred, unless that State law is inconsistent with or preempted by federal law.

Second, in her complaint, the plaintiff must plead with particularity each element of her claim, including—

- each act or omission, by each covered person sued, that the injured person alleges is willful misconduct;
- facts supporting the allegation that the alleged willful misconduct proximately caused the claimed injury; and
- facts supporting the allegation that the injured person suffered death or serious physical injury.

Third, in the complaint, the plaintiff must include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the plaintiff, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes them to be true. Material in the affidavit that is not specifically identified as being alleged upon the plaintiff's information and belief is to be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff (thereby setting up a criminal prosecution of the plaintiff). The plaintiff must also file an affidavit from a physician who did not treat the injured person certifying, and explaining the basis for the physician's belief, that the person suffered the alleged serious physical injury or death and that the alleged injury or death was proximately caused by the administration or use of a covered countermeasure, as well as certified medical records documenting the injury or death and the proximate causal connection. A complaint that does not substantially comply with these requirements may not be accepted for filing and does not stop the running of the statute of limitations.

Fourth, the lawsuit must be assigned initially to a panel of three judges for purposes of considering motions to dismiss, motions for summary judgment, and related matters.

Fifth, the court may not allow civil discovery before each covered person sued has had a reasonable opportunity to file a motion to dismiss; if a motion to dismiss is filed, before the court has ruled on it; and if a covered person files an interlocutory appeal after a motion to dismiss is denied, before the court of appeals has ruled on the appeal. The court may allow discovery only with respect to matters directly related to material issues contested in the action, and the court may compel a response to a discovery request only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in the action and that the likely benefits of a response to the request equal or exceed the burden or cost for the responding party of providing the response. In other words, every discovery request can be litigated at length by the drug company to avoid disclosure, and, if it would cost too much for a drug company to produce evidence needed, the drug company is not obligated to produce the evidence, even if the lawsuit fails.

Sixth, any award of damages made in such a lawsuit must be reduced by the amount of collateral source benefits to such plaintiff, and a provider of collateral source benefits may not recover any amount against the plaintiff, receive a lien or credit against

the plaintiff's recovery, or be equitably or legally subrogated to the plaintiff's rights. The term "collateral source benefit" is defined to mean any amount paid or to be paid in the future to, or on behalf of, the plaintiff, or any service, product, or other benefit provided or to be provided in the future to, or on behalf of, the plaintiff, as a result of the injury or wrongful death, whether from—

- a state or federal health, sickness, income, disability, accident, or workers' compensation law;
- a health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;
- a contract or agreement of a group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or
- any other publicly or privately funded program.

Seventh, noneconomic damages are limited, and may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. The term "noneconomic damages" is defined to mean damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses. This rule displaces rules in the various states. Not all of the states limit noneconomic damages and they do not typically limit the award of noneconomic damages in proportion to the defendant's responsibility.

Eighth, a United States district court is required to impose sanctions (it is now discretionary) if the court determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure. The sanction may include an order to pay the other parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee, and must be sufficient to deter repetition of comparable conduct by others similarly situated, and to compensate the parties injured by the conduct.

Ninth, the United States Court of Appeals for the District of Columbia Circuit is given jurisdiction of an interlocutory appeal by a covered person (but not of issues of importance to plaintiffs, such as discovery) taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit under section 319F-3(a) or the defense for drug manufacturers and distributors under section 319F-3(c)(5) (but curiously not for the defense provided to program planners and qualified persons under section 319F-3(c)(4)). There are usually not interlocutory appeals in civil suits except in unusual circumstances, in part because of the inefficient use of limited judicial resources that interlocutory appeals require.

The government's rights to prosecute and defend suits is preserved.—Section 319F-3(f) is a rule of construction that says the section may not be construed to abrogate or limit any right, remedy, or authority that the United States or an agency of the government may possess under any other provision of law, or to waive sovereign

immunity, or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of the Federal Tort Claims Act.

A severability clause is included.—Section 319F-3(g) provides that, if any provision of section 319F-3, or if the application of such a provision to any person or circumstance, is held to be unconstitutional, the remainder of the section and the application of the remainder of the section to any person or circumstance will not be affected.

The Vaccine Injury Compensation Program is protected, but it is not clear that state lawsuits regarding vaccines covered under the program are preserved.—Section 319F-3(h) is a rule of construction that states that nothing in section 319F-3, or any amendment made by the Public Readiness and Emergency Preparedness Act, may be construed to affect the National Vaccine Injury Compensation Program. This provision protects only the VICP program, and does not clearly protect lawsuits brought under state law by those who elect not to use the VICP program. For example, it appears that, if the Secretary were to issue a declaration with respect to a childhood vaccine with respect to which lawsuits are currently pending in state courts, the immunity provided by section 319F-3 could extinguish those lawsuits.

C. Section 319F-4, Covered Countermeasure Process.

This section summarizes and analyzes the compensation provision (section 319F-4 of the PHSA) in the Public Readiness and Emergency Preparedness Act.

Section 319F-4 establishes a fund in the Treasury to which no money has been appropriated from which certain persons injured by countermeasures covered by a declaration under section 319F-3(b) may be compensated, similarly to how they would be compensated under the small pox compensation program. This summary and analysis begins with a review of the definitions, which establish the scope of those eligible to receive money from the compensation fund.

Not all persons against whom immunity is provided are eligible for compensation.—Section 319F-4 provides definitions for the compensation fund, the three most important of which are those for “covered individual,” “covered injury,” and “eligible individual.” An “eligible individual” is a person to whom compensation may be paid, and is defined as an individual who is determined to be a covered individual who sustains a covered injury. The term “covered injury” means only serious physical injury or death (so no other injuries are compensable under the program).

The term “covered individual” means an individual who is in a population specified in a declaration under section 319F-3(b) and with respect to whom the administration or use of the covered countermeasure specified in the declaration satisfies the specifications (e.g., population and geographic area) of the declaration, or an individual who uses or is given the covered countermeasure in a good faith belief that the individual satisfies the specifications in the declaration.

Section 319F-3(a)(4)(A) states that manufacturers and distributors of covered countermeasures are immune whether or not the individual person who used the countermeasure met the conditions for using the countermeasure (i.e., was in a population and a geographic area specified in the declaration, or was given the drug during the effective period of the declaration for a use specified in the declaration). The immunity with respect to individuals is therefore broad, while those individuals covered by the compensation program is a narrower group. Accordingly, there will be injured individuals who may not sue a drug manufacturer because of the immunity and who also may not seek compensation under the program.

The most egregious example is the situation where a drug used every day by patients for every day ailments is specified in a declaration for use to respond to pandemic flu or a bioterrorist incident. The immunity for the drug companies appears to extend not just to those who use the drug because of pandemic flu or the bioterrorist incident, but to all users of the drug. Yet only those users who could in good faith be thought to have used the drug in accordance with the specifications in the declaration will be eligible for compensation. Those who used the drug for the every day use will only have recourse (through a lawsuit) against those involved with administering the drug, such as the prescribing physician.

Section 319F-4(e) also gives “covered countermeasure” the meaning given it in section 319F-3, and defines “declaration” to mean a declaration under section 319F-3(b).

A compensation fund is established but no money is appropriated.—Section 319F-4(a) establishes in the Treasury a fund, designated as the “Covered Countermeasure Process Fund,” when the Secretary issues a declaration under section 319F-3(b). The purpose of the fund is stated as providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to the declaration. The fund consists of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, and the emergency designation remains in effect through October 1, 2006.

Section 319F-4(b) requires the Secretary, after issuing a declaration under 319F-3(b), and after amounts have by law been provided for the Fund, to provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure under the declaration. The compensation provided must have the same elements and be in the same amounts as those provided sections 264, 265, and 266 of the PHSA, which are provisions of the small pox compensation program. These elements include medical benefits; lost employment income equal to two thirds of the rate of pay, augmented for those with one or more dependents, with an annual cap of \$50,000 and a lifetime cap equal to the available death benefit (currently set at \$283,385), all secondary to benefits provided by other law or contractual provisions. Neither medical benefits nor total benefits for lost employment income are limited by the availability of the death benefit.

There is a high evidentiary standard for compensation under the program.—

Determinations whether a person is eligible for compensation, whether the person has sustained a covered injury, whether compensation is available, and what the amount of compensation should be are generally to be made according to the procedures for the smallpox compensation program outlined in section 262 of the PHSA. However, the Secretary may only make such determinations based on compelling, reliable, valid, medical and scientific evidence, rather than under the preponderance of the evidence standard using all medical and scientific evidence, as under the smallpox program. Such evidence is not needed where the injury is included in an injury table as provided for under section 263 of the PHSA (which provides for an injury table for smallpox countermeasures), except that the Secretary may include an injury on the table based only on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused the covered injury. The determination whether to include an injury on the table is not subject to judicial review. Determinations whether or not a person is eligible for, or the amount of, compensation are also not subject to judicial review.

Section 319F-4(c) requires the Secretary to ensure that state, local, and departmental plans to administer or use a covered countermeasure are consistent with the declaration under section 319F-3 and with applicable guidelines of the Centers for Disease Control and Prevention, and that potential recipients of a covered countermeasure are educated about contraindications, that they are not required to take the countermeasure, and about the availability of potential benefits and compensation under the program.

With two exceptions, section 319F-4(d) requires a person to seek compensation under the program before bringing a civil action under section 319F-3(d) against a covered person to pierce the immunity provided under section 319F-3(a). A person may sue under section 319F-4(d) without seeking compensation under the program if either amounts have not by law been provided for the Fund under section 319F-4(a) or the Secretary fails to make a final determination on a request for benefits or compensation under the program within 240 days after the request was filed.

Section 319F-4(d) also provides that the time limit for filing a civil action under section 319F-3(d) for an injury or death is tolled while a claim for compensation under section 319F-4(a) is pending. The remedy under section 319F-4(a) is exclusive of any other civil action or proceeding for any claim or suit under section 319F-4 (except of course for a proceeding under section 319F-3). In addition, if the Secretary determines that a covered individual qualifies for compensation under the program, the individual may elect to accept the compensation, and if the individual does so, the individual may not bring an action under section 319F-3(d).

D. Constitutional Concerns

There have been questions raised about the constitutionality of the immunity provision in section 319F-3 of the PHSA. For example, Professor Erwin Chemerinsky of the Duke University Law School has written a letter (Appendix VI) detailing serious constitutional concerns with the provision.

First, the provision delegates powers to the executive branch without the limitation of a prescribed standard. This delegation may violate the nondelegation doctrine, which says that Congress may not delegate its legislative authority to the executive branch.

Second, the provision preempts state causes of action and replaces them with a federal cause of action, and by doing so it violates the Constitution in two ways. It may therefore violate federalism principles by making the new federal cause of action depend on state law. It also makes the federal cause of action depend on the FDA or the Attorney General unfettered and unreviewable discretion to prosecute an enforcement action. Yet it is a violation of due process to allow official inaction to prevent a person from pursuing a lawsuit.

Third, the provision completely preempts judicial review of the declarations that provide drug companies with immunity. This raises serious “separation of powers” and due process concerns, as the Supreme Court has repeatedly stressed.

These concerns undermine the purpose of the liability provision, which is to remove disincentives for companies to develop and manufacture countermeasures and others, such as health care providers, to be involved in their administration and use. It would be unfortunate indeed if these concerns undermine the nation’s efforts to prepare for an influenza pandemic or the consequences of a terrorist attack using biological, chemical, nuclear, or radiological weapons, but such may be the effect of the ill-considered provisions of the Public Readiness and Emergency Preparedness Act.

APPENDIX I: 2006 Defense Appropriations for Pandemic Flu Preparedness.

Department of Defense: Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006.

Referred to in the text as the 2006 Defense Appropriations Act

International Response	
International surveillance through Defense:	\$10 M
International Surveillance and containment through CDC:	\$150 M
International Surveillance and Child Health Response through USAID:	\$75 M
International Disaster Assistance through USAID:	\$56 M
National Preparedness	
Animal Outbreak Detection through USDA:	\$91 M
Preparedness and Research for Pandemic Influenza through FDA:	\$20 M
Domestic Preparedness through DHS:	\$47 M
Domestic Surveillance and Science through CDC:	\$96 M
Lab capacity and research at CDC:	\$50 M
Health Support of Americans Abroad:	\$31 M
Domestic Vaccine Capacity and Stockpiling	
Vaccine stockpiles, surveillance through Defense:	\$120 M
Vaccine development and stockpiling (for states as well):	\$2,654 M
State and Local Preparedness	
Upgrading state and local public health capacity:	\$350 M

APPENDIX II: S.AMDT.2283, the Harkin-Kennedy amendment to LABOR/HHS Appropriations (allocation underlying calculations of funding included in the amendment).

International Response	
Detection, reporting:	\$60 M
International animal surveillance network:	\$10 M
National Preparedness	
Building lab capacity for disease surveillance:	\$100 M
Domestic Vaccine Capacity and Stockpiling	
Vaccine Research and Procurement:	\$3,300 M
Stockpiling of Antivirals and medical supplies:	\$3,680 M
State and Local Public Health Preparedness	
Grants, Hospital Surge Capacity:	\$600 M
Workforce and Risk Communication	
Public Outreach and Education:	\$75 M

**APPENDIX III: S. 1821, sponsored by Senate Minority Leader Harry Reid.
Summary of authorizations for FY 2006-2010.**

Such sums as are required to carry out the following:

International Response Global Pandemic Fund, administered by WHO, to provide targeted assistance Technical Assistance and demarches to key nations Scientists and medical personnel detailed to embassies and governments
National Preparedness Coordinating Director and Policy Committees Building animal health lab capacity and electronic database
National Vaccine Capacity and Stockpiling Procurement of Antivirals, Vaccines, and Essential Medicines Reimbursement to states for vaccine purchases and administration National Vaccine Tracking System Research and development of new vaccines and other drugs Purchase of both seasonal and pandemic influenza vaccines
State and Local Public Health Preparedness State grants to enable pandemic plan implementation Surveillance grants to states and private health care entities HHS and USDA federal employees detailed to states
Workforce and Risk Communication Emergency training for public health and health care workers Training of non-medical volunteer personnel Public pandemic influenza awareness campaign Adult immunization campaign for seasonal influenza vaccine

**APPENDIX IV: H.R. 4603, sponsored by Representative Nita Lowey.
Summary of authorizations for FY 2006-2010.**

International Response	
International Detection and Containment:	\$500 M
Global Surveillance Network (5 years):	\$50 M
International Assistance:	\$750 M
National Vaccine Capacity and Stockpiling	
Seasonal Influenza Vaccine Purchase:	\$465 M
Seasonal Vaccine Purchase of Unsold Doses:	as required
Tracking and Distribution System	
Procurement of antivirals, vaccines, essential medicines	
Vaccine, anti-Viral research through NIH (5 years):	as required
Pandemic research through CDC (5 years):	as required
FDA Facilities & PostMarket Studies (5 years):	as required
State and Local Preparedness	
State and Local Planning grants:	\$200 M
Ongoing Preparedness and Surge Capacity Grants (5 years):	\$1,500 M
State Antiviral Stockpile (remove unfunded mandate):	\$510 M
Grants and technical assistance to states:	as required
Workforce and Risk Communication	
Public education and awareness campaign	
Research on communications through NSF (5 years):	as required
Health professionals training:	as required
Compensation Fund	
Such sums as are required	

**APPENDIX V: Presidential Request for Emergency Supplemental Funding.
Summary of Request for FY 2006-2008.**

International Response	
Prevention and Containment through HHS:	\$200 M
Prevention and Containment through Defense:	\$10 M
Prevention and Containment through USDA:	\$11 M
International Outreach:	\$12 M
International Visitors' Program:	\$1.5 M
Surveillance and Children's Health Response:	\$75 M
International Stockpile:	\$54 M
International (Russian) Stockpile:	\$2 M
National Preparedness	
Animal Surveillance, Preparedness, Vaccines, Research at USDA:	\$80 M
Animal and Wildlife Surveillance at Interior:	\$11 M
Domestic Surveillance and Preparedness at DHS:	\$47 M
VA Domestic Surveillance:	\$27 M
Public Diplomacy Training (US Personnel):	\$58 M
Emergency Evacuations (US Personnel):	\$20 M
Domestic Preparedness:	\$640 M
National Vaccine Capacity and Stockpiling	
Vaccine Purchase:	\$1,200 M
Vaccine Development:	\$2,800 M
Vaccine Research:	\$800 M
Antivirals Stockpile:	\$1,020 M
Domestic Vaccines, Surveillance, Detection at Defense:	\$120 M

APPENDIX VI: Letter from Professor Erwin Chemerinsky.

Dear Senator,

December 20, 2005

I understand that the Congress is considering legislation that has been denominated as the "Public Readiness and Emergency Preparedness Act." This legislation would give the Secretary of Health and Human Services extraordinary authority to designate a threat or potential threat to health as constituting a public health emergency and authorizing the design, development, and implementation of countermeasures, while providing total immunity for liability to all those involved in its development and administration. In addition to according unfettered discretion to the Secretary to grant complete immunity from liability, the bill also deprives all courts of jurisdiction to review those decisions. Sec. (a)(7). I write to alert the Congress to the serious constitutional issues that the legislation raises.

First, the bill is of questionable constitutionality because of its broad, unfettered delegation of legislative power by Congress to the executive branch of government. Under the nondelegation doctrine, Congress may provide another branch of government with authority over a subject matter, but "cannot delegate any part of its legislative power except under the limitation of a prescribed standard." *United States v. Chicago, M., St. P. & P.R. Co.*, 282 U.S. 311, 324 (1931). Recently, the Supreme Court endorsed Chief Justice Taft's description of the doctrine: "the Constitution permits only those delegations where Congress 'shall lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform.'" *Clinton v. City of New York*, 524 U.S. 417, 484 (1998)(emphasis in original), quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). The breadth of authority granted the Secretary without workable guidelines from Congress appears to be the type of "delegation running riot" that grants the Secretary a "roving commission to inquire into evils and upon discovery correct them" of the type condemned by Justice Cardozo in *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 553 (1935)(Cardozo, J., concurring).

Second, the bill raises important federalism issues because it sets up an odd form of federal preemption of state law. All relevant state laws are preempted. Sec. (a)(8). However, for the extremely narrow instance of willful (knowing) misconduct by someone in the stream of commerce for a countermeasure, the bill establishes that the substantive law is the law of the state where the injury occurred, unless preempted. Sec. (e)(2). The sponsors appear to be trying to have it both ways, which may not be constitutionally possible. The bill anticipates what is called express preemption, because the scope of any permissible lawsuits is changed from a state-based to a federally based cause of action. See *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003).

Usually, that type of "unusually 'powerful'" preemptive statute provides a remedy for any plaintiff's claim to the exclusion of state remedies. *Id.* at 7 (citation omitted). Here, rather than displace state law in such instances, the bill adopts the different

individual laws of the various states, but amends them to include a willful misconduct standard that can only be invoked if the Secretary or Attorney General initiates an enforcement action against those involved in the countermeasure and that action is either pending at the time a claim is filed or concluded with some form of punishment ordered.

Such a provision raises two important constitutional concerns. One problem is that this hybrid form of preemption looks less like an attempt to create a federal cause of action than an direct attempt by Congress to amend state law in violation of *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938) and basic principles of federalism. Although Congress may preempt state law under the Supremacy Clause by creating a different and separate federal rule, see *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000), it may not directly alter, amend, or negate the content of state law as state law. That power, the *Erie* Court declared, "reserved by the Constitution to the several States." 304 U.S. at 80. It becomes clear that the bill attempts to amend state law, rather than preempt it with a federal alternative, when one realizes that States will retain the power to enact new applicable laws or amend existing ones with a federal overlay that such an action may only be commenced in light of a federal enforcement action and can only succeed when willful misconduct exists. The type of back and forth authority between the federal and state governments authorized by the bill fails to constitute a form of constitutionally authorized preemption.

The other problem with this provision is that the unfettered and unreviewable discretion accorded the Secretary or Attorney General to prosecute an enforcement action as a prerequisite for any action for willful misconduct violates the constitutional guarantee of access to justice, secured under both the First Amendment's Petition Clause and the Fifth Amendment's Due Process Clause. See *Christopher v. Harbury*, 536 U.S. 403, 415 n.12 (2002). In fact, the Court has repeatedly recognized that "the right of access to the courts is an aspect of the First Amendment right to petition the Government for redress of grievances." *Bill Johnson's Restaurants v. NLRB*, 461 U.S. 731, 741 (1983), citing *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). First Amendment rights, the Supreme Court has said in a long line of precedent, cannot be dependent on the "unbridled discretion" of government officials or agencies. See, e.g., *City of Lakewood v. Plain Dealer Pub. Co.*, 486 U.S. 750, 757 (1988). At the same time, the Due Process Clause guarantees a claimant an opportunity to be heard "at a meaningful time and in a meaningful manner." *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965). The obstacles placed before a claimant, including the insuperable one of inaction by the Secretary or Attorney General, raise significant due process issues. The Supreme Court has recognized that official inaction cannot prevent a claimant from being able to go forth with a legitimate lawsuit. See *Logan v. Zimmerman Brush Co.*, 455 U.S. 422 (1982). The proposed bill seems to reverse that constitutional imperative.

Third, the complete preclusion of judicial review raises serious constitutional issues. The Act, through Sec. 319F-3(b)(7), expressly abolishes judicial review of the Secretary's actions, ordaining that "[n]o court of the United States, or of any State, shall have subject matter jurisdiction," i.e., the power, "to review . . . any action of the Secretary regarding" the declaration of emergencies, as well as the determination of

which diseases or threats to health are covered, which individual citizens are protected, which geographic areas are covered, when an emergency begins, how long it lasts, which state laws shall be preempted, and when or if he shall report to Congress .

The United States Supreme Court has repeatedly stressed that the preclusion of all judicial review raises "serious questions" concerning separation of powers and due process of law. See, e.g., *Johnson v. Robison*, 415 U.S. 361 (1974); see also, *Oestereich v. Selective Service System Local Board No. 14*, 393 U.S. 233 (1968); *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991); *Reno v. Catholic Social Services*, 509 U.S. 43 (1993). Judicial review of government actions has long regarded as "an important part of our constitutional tradition" and an indispensable feature of that system, *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 365 (1973).

The serious constitutional issues raised by this legislation deserve a full airing and counsels against any rush to judgment by the Congress. Whatever the merits of the bill's purposes, they may only be accomplished by consideration that assures its constitutionality.

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