

November 15, 2005

The Honorable Bill Frist  
U.S. Capitol, Room S-230  
Washington DC 20515

The Honorable J. Dennis Hastert  
U.S. Capitol, Room H-232  
Washington DC 20515

The Honorable Harry Reid  
U.S. Capitol, Room S-221  
Washington DC 20515

The Honorable Nancy Pelosi  
U.S. Capitol, Room H-204  
Washington DC 20515

Dear Congressional Leaders:

We understand that House and Senate leaders are proposing that a sweeping legislative provision to immunize the drug industry from liability in the event of a pandemic outbreak be slipped into an appropriations bill before Congress adjourns for the year. While shielding the drug companies, the proposal provides **no** compensation or protection for first responders and ordinary individuals who may suffer serious illness or death as a result of taking a vaccine or other countermeasure against the pandemic. Moreover, the provision under consideration was not passed by either the House or the Senate, nor ever debated on either Chamber's floor. Any legislation that provides immunity to drug manufacturers without ensuring that first responders and others injured by emergency vaccines and drugs are compensated is extremely unfair and short-sighted.

We recognize the urgent need to adequately prepare for infectious disease outbreaks. The nation as a whole must work together and all sacrifice if we are to effectively confront the problem. It is unjust and unfair to ask the American people to take on all the risk of emergency vaccines, drugs and other countermeasures that will not have gone through standard safety testing before being administered. It may very well be that during public health emergencies expedited approval of vaccines and drugs is necessary for the nation's security. But we must also recognize that relaxation of testing requirements greatly increases the risk to the public that the vaccines and drugs will injure some recipients of them.

We must not forget that in 1976, vaccination against the swine flu was curtailed after only two months because the vaccine proved to be of limited efficacy against the disease on the one hand, and caused thousands of injuries on the other. Some 4,000 people were hurt by the vaccine, over 500 of whom developed Guillain-Barre syndrome, a paralyzing nerve disorder that ultimately claimed some 30 lives. Just one person died as a result of swine flu. More recently, the GAO reported on barriers to implementation of the smallpox vaccination program—in part due to reluctance among health workers and patients alike to take the vaccine because of its potential health risks and the uncertainty of compensation.<sup>1</sup>

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<sup>1</sup> Smallpox Vaccination: Implementation of National Program Faces Challenges, GAO, April 2003.

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Before any degree of legal immunity for drug companies is even contemplated, it is the responsibility and duty of Congress to make sure that first responders—doctors, nurses, public health workers, fire and rescue workers—and other individuals who are injured as a result of emergency pandemic countermeasures are protected.

In fact, there is much evidence that liability concerns are not causing vaccine shortages; rather a poorly structured vaccine market is the root cause.<sup>2</sup> Should Congress decide to immunize manufacturers, the scope of the liability shield should be limited to pandemic countermeasure supplies used during an emergency. Broadly shielding manufacturers from responsibility for gross negligence, recklessness and other egregious behavior and leaving victims with no recourse, may cause more public harm than the pandemic disease itself. Individuals could very well refuse immunization, thus undermining efforts to contain outbreaks.

We ask that you put the safety of the American people first and reject this unfair and dangerous proposal.

Sincerely,

Alliance for Justice  
Center for Justice and Democracy  
Consumer Federation of America  
Public Citizen  
USAction  
USPIRG

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<sup>2</sup>*Financing Vaccines in the 21<sup>st</sup> Century: Assuring Access and Availability*, Institute of Medicine, August 2003.; Mello MM, Brennan TA, “Legal Concerns and the Influenza Vaccine Shortage,” *JAMA*, October 12, 2005, 294:1820; David Brown, “How U.S. Got Down to Two Makers of Flu Vaccine,” *Washington Post*, October 17, 2004.