New York Sun, October 18, 2005

"First, Do No Harm"

John E. Calfee
American Enterprise Institute, Washington, D.C.

Almost everyone has a reservoir of resistance to many versions of the flu virus. New versions arrive every year. The standard flu vaccine, which is re-engineered every year to deal with the latest human flu virus, reinforces that immunity and saves a lot of lives by keeping most of us from getting sick at all. But a brand new flu bug is a different ballgame. The best way to play it is to avoid being swept by hysteria into serious policy mistakes.

In the past few years, a virulent bird flu virus, called H5N1, has spread through most of Asia and recently reached the fringes of Europe. At least 117 people have caught the H5N1 virus, usually from chickens, and at least 60 have died. Except possibly in extreme circumstances, H5N1 isn't passed from one person to another. But viruses mutate rapidly. If this one mutates into a form that spreads easily among humans, while retaining a substantial portion of its virulence, the result could be a pandemic flu that would spread around the world in months and kill tens of millions of people. That is what happened in 1918, and the specter of the 1918 flu is driving unprecedented international conferences and debate.

What to do? First, avoid panic. Avian flu viruses seldom jump to humans, having done so only three times in the last century. When a virus does jump, it is usually not especially lethal, as seen in the two more recent pandemic flus, those of 1957 and 1968.That's because a virus that causes only a mild illness has far more opportunities to spread as its host moves about freely among friends and fellow travelers. The extraordinary power of the 1918 virus was probably due to the equally extraordinary conditions in which it mutated: combat trenches, mass transit of the sick and wounded, and military hospitals. We should also note that many, if not most, of the 1918 deaths would be prevented with today's superior medical technology, especially antibiotics to defeat pneumonia and other lethal secondary infections.

But avoiding panic is not the same as doing nothing. This is an excellent time to fix some of the things that are broken in the flu vaccine industry. Fortunately, a few H5N1 vaccines are in development. A French firm, Sanofi, has one in testing at the National Institutes of Health. Unfortunately, it's not a very good vaccine. It may not induce a powerful immune reaction in everyone and it must be taken in large quantities, meaning that it is almost impossible to manufacture in sufficient quantities to head off a pandemic flu. Also, it may not work against the mutated virus that would be a real threat, and if it were given to millions of Americans, its side-effects, not yet fully known, could trigger crippling liability litigation.

Congress should pass legislation insulating flu vaccine manufacturers from liability suits as long as they meet Food and Drug Administration standards of testing and manufacturing. The vaccine industry and the FDA need to phase out a decades-old vaccine manufacturing technology in

which individual doses are grown in millions of chicken eggs and replace it with one based on cell culture similar to what is used for many other drugs. Other useful changes would permit alternatives to the traditional injections and the addition of adjuvants - active ingredients that facilitate the action of the vaccine itself. These measures could improve potency and reduce the gap between vaccine approval and mass distribution from the current six months or so to one or two months.

In the meantime, two anti-viral drugs used to treat the traditional flu appear to be active against the H5N1 avian flu bug. Roche is ramping up production of Tamiflu, the most promising anti-viral, while Glaxo-Smith-Kline is doing the same with its Relenza. The governments of France, Germany, the United Kingdom, and other nations, along with the World Health Organization, have placed orders for the Tamiflu supply for the next year or so, while America recently joined the queue.

But already, there is talk of compulsory licensing to break Roche's patent and let other firms manufacture Tamiflu for sale to governments around the world, not least from Senator Schumer, who yesterday called for just this action. This extraordinarily dangerous movement should be nipped in the bud. Tamiflu and Relenza are no solutions to the avian flu problem. If they are distributed in a massive and uncontrolled fashion they will quickly generate drug-resistant mutations - some of which have already been detected - leaving us worse off than we are now. Just as seriously, we will suppress incentives to create even better drugs, which we desperately need because the ones we have now are no more than stop-gaps. The pharmaceutical industry has not forgotten the threat of the Secretary of Health and Human Services, Tommy Thompson, against the Cipro patent during the 2001 anthrax crisis. The last thing we need now is a repetition of what everyone hoped was a onetime-only mistake.

Mr. Calfee is a resident scholar at the American Enterprise Institute. AEI receives a portion of its financial support from pharmaceutical firms.