

Saturday, 30 October 2005

Interested Parties,

The following is essentially (with some minor changes) the response I posted to Wall Street Journal's (WSJ's) reply box concerning the cited document:

Having carefully read what was said, Dr. King offers the following review where the article's text is first quoted and then responded to in indented text.

[**Note:** The WSJ editorial was an obvious industry-paid editorial written to support a vile Senate bill, **S. 1873**, that, among other things, **takes away the right (*under the Constitution's Amendment 7*) of the American public to sue for the harm done to people by their drugs and components of drugs, in general, and, in specific, their vaccines and vaccine components, creates a secret agency** in which the drug industry and the government can do what they want, and **gives the government the "right" to force compulsory vaccination on the public on the pretext of a possible disease threat.**]

"Political Virus

Why there's only one drug to fight avian flu."

Factually, there are four drugs that may be able to fight avian flu, TamiFlu, Relenza, and two older drugs, whose efficacy seems to have been compromised by their misuse by some countries who have allowed it to be used in treating their poultry flocks instead of preserving these low-cost anti-viral drugs for treating their citizens.

"Saturday, October 22, 2005 12:01 a.m. EDT

Our political leaders keep telling us to fear the avian flu, and in one sense they're right: We should all be scared to death about how much damage our political leaders will do responding to the avian flu."

Rather than fearing the avian flu, we should fear those who use fear to push legislation that rewards and protects the pharmaceutical industry and, more importantly, abridges our Constitutional liberties under the false guise of protecting us — just as Senate bill S. 1873 does!

"Consider Secretary-General Kofi Annan, who declared this month that he hoped concern for 'intellectual property' wouldn't 'get into the way' of procuring widespread vaccines for a potential avian-flu outbreak. In other words, companies that make vaccines should abandon their patents at Mr. Annan's whim. This kind of hostility to property rights is precisely the reason we now have a shortage of vaccines and drugs to combat this potential pandemic."

First of all, as we all know, Mr. Annan's words are little more than empty rhetoric since the U.S. can veto any such attempted U.N. action.

Moreover, there is no real threat to the intellectual property rights of the international drug companies in the U.S.

Furthermore, the top ten pharmaceutical firms in the Fortune 500 list made more money last year than all of the other 490 firms on that list combined.

Based on the writer's rhetoric here, it seems as though he is much more concerned about the interests of the pharmaceutical industry than he is about the interests or the health of the American public.

"No one really knows how great the avian flu threat is. Public-health officials have been warning about it ever since new studies suggested that the infamous 1918 flu outbreak originated in birds. Warning is what these folks get paid to do."

So what you seem to be saying is that it is the job of our "Public health officials" to be fear mongerers rather than, *as they truly should be*, the promoters of public health by making sure:

- a. **our hygiene standards are maintained and improved and**
- b. **cost-effective health services are provided to the public.**

"Other experts argue that 1918 was a fluke and that the current avian virus is unlikely to become a mass killer of humans. Whatever the risk, some good will come out of this public alarm if we use it as an opportunity to understand why the U.S. is now so poorly armed to cope with a deadly flu outbreak."

The writer speaks of a non-existent pandemic, fear mongers a future disaster, and points to a past pandemic that, had there been antibiotics, would probably have killed less than 1/20th the number that it did, and then you have the Orwellian audacity to state, "some good will come out of this public alarm if we use it as an opportunity to understand why the U.S. is now so poorly armed to cope with a deadly flu outbreak."

"The reason is that our political class has spent the past 30 years driving the vaccine industry out of business with its own virus of over-regulation, price controls, litigation and intellectual-property abuse."

Without even identifying who you are, you speak of yourself as belonging to "our political class" and thereby admit that you view America as a society of classes.

Please tell us, who you are, who paid you to write this article, and what, in your view, are those "political" classes?

"The U.S. today has only three large vaccine makers--down from 37 in the 1960s."

You begin by misstating the facts because there are four large vaccine makers having vaccines licensed in the U.S. today, sanofi-aventis, Merck, Chiron, and GlaxoSmithKline.

In addition, there are a few smaller companies, like MedImmune and Bioport, who are in the business of making U.S.-licensed vaccines.

Moreover, the decline in the number of companies is more of an industry-consolidation phenomenon than anything else.

Finally, this consolidation has led to the remaining companies being increasingly profitable.

"This is the reason that, as recently as 2001, there was a shortage of eight of 11 critical childhood vaccines."

Factually, consolidation in the industry is *not*, and was *not*, the reason for the shortages.

The makers' *inability to: a) make and b) deliver safe vaccine lots* were the *reasons for the shortages*.

"It is also the reason the U.S. fell drastically short of flu vaccine a year ago, after a shut-down of one of two major flu-vaccine makers."

Industry consolidation was *not* the reason for the shortage "of the flu vaccine a year ago."

The maker's deficient production facilities and lack of sterility in the finished doses is the "reason" for shortage – and the British and *not* the U.S. FDA pulled their license – so "outsourcing" of the production of this vaccine to a foreign country was also a reason for the non-availability of this vaccine.

Thus, *outsourcing and contaminated vaccines* were the real *reasons for these shortages*.

"And it is the reason only one company, Switzerland's Roche, is being counted on for a drug that would potentially protect against bird flu."

Again, the writer's view of reality seems to be faulty.

The reason that Roche is the only company that produces the drug Tamiflu® is that they hold the intellectual property rights for this drug and its manufacture – intellectual property rights – *something that you claimed earlier that you want to protect*.

Just as GlaxoSmithKline (which is a consolidation of several pharmaceutical companies, including, but not limited to Beacham, Glaxo, and "SmithKline,") owns the intellectual property rights for Relenza®, another drug for treating the influenza viruses that you seem to have overlooked.

"Despite these warning signals, Washington has done almost nothing. One problem is the Food and Drug Administration, which puts safety above developing rapid cures. Flu-vaccine makers face particular difficulties because they must effectively gain approval for a new product (for each new flu strain) every year."

So you are now:

- a. **Saying that *unsafe* medicines should be sold and**
- b. **Forgetting that, as Vioxx shows, the FDA's current safety controls are *not* even adequately protecting the American public from unsafe drugs.**

"The vaccine is still grown in chicken eggs--a process that takes up to eight months. The industry has revolutionary new technologies--reverse genetics and mammalian cell culture--that would dramatically reduce the time and cost of development. Europe is moving toward products using these new techniques, but the FDA refuses to adapt and allow more rapid approval."

The writer forgets that the highly profitable vaccine makers have had years to adopt these technologies and prove them safe, but, *not wanting to have to invest their own capital*, have continued to use their old technologies.

Yet, the writer seems to want to blame the FDA for the industry's failures to invest in these "new" technologies.

"The feds have also done their best to remove any financial incentive--i.e., profit--for developing new vaccines. The Vaccines For Children program, a pet project of Hillary Clinton back in her First Lady days, has been especially destructive. The program now buys more than 50% of all private vaccines, and it uses this **monopsony** (sic; *monopsonistic*) clout to drive prices down to commodity levels."

The writer again seems to be more interested in increasing the net profits of the industry, which already average more than 10%, rather than containing the pharmaceutical industry's greed that typically leads the firms to increase their prices at 3 times, or more, the rate of inflation while those vaccines are "limited" to annual cost-of-living increases – something that many industries would be more than happy to receive since these other industries are *not* guaranteed any automatic price increases.

"When one pharmaceutical company offered to sell a new pneumococcal vaccine to the government for \$58 a dose, the Centers for Disease Control demanded a \$10-a-dose discount."

And,

1. **Did the Centers for Disease Control (CDC) get that discount?**
2. **Did the company still make a profit because, *knowing the CDC would want a discount*, they had priced already priced the "new pneumococcal vaccine" \$15.00 dollars per dose higher?**
3. **Why did the writer *not* consider that "new" vaccines are deliberately overpriced to ensure a good profit after the "government" discount?**

"Politicians want companies to take all the risk of developing new vaccines, but they don't want the companies to make any money from taking those risks. Then the politicians profess surprise and dismay that there's a vaccine shortage."

First, the writer ignores the millions of dollars the NIH spends each year on vaccine-related research.

Apparently, the writer is also "unaware of," or has chosen to ignore, the recent activities of the American politicians, of whom he claims to speak, to pass legislation that protects and rewards the general pharmaceutical industry at the expense of the public, like the current Senate bill, S. 1873.

"Vaccine makers are also a favorite target of tort lawyers, who've spent 20 years trying to get around the 1986 Vaccine Injury Compensation Program (VICP)--which was specifically designed to protect vaccine makers from liability abuse."

First, the writer seems to be ignoring the current Vioxx suits, the Baycol suits, and the other drugs' suits for the harm caused by those drugs, or does the writer think that these drugs are vaccines?

Second, the only reason vaccine makers are currently a target is that they *knowingly* (as that term is defined in the US Code for drugs) used a highly toxic, bioaccumulative, systemic poison, Thimerosal, in some of their vaccines, without proving the safety of Thimerosal at the preservative concentration in the appropriate toxicological studies, as required by law [Title 21 of the U.S. Code of Federal Regulations, Section 610.15(a)] and, as a result, *knowingly* and *unnecessarily* damaged hundreds of thousands of children, who were mercury poisoned by the Thimerosal in those vaccines.

These companies continued to leave Thimerosal in vaccines without proof of safety even though, as the 1991 Merck memo clearly indicates, they knew the cumulative mercury poisoning was more than 50 times the safe level for adults.

Since a 1948 JAMA article by Morton et al clearly proved:

- a. *Thimerosal is not*, at the usable levels (up to 0.01% [100,000 parts per billion]), *an effective preservative* and
- b. *It is highly toxic* to human tissues *at levels below 20 parts per billion*,

the vaccines manufacturers who continued and continue to use Thimerosal as a "preservative," have been knowingly doing so without any sound science to support their actions and, for whatever reasons, the FDA has apparently looked the other way even after the 1968 law, 21 CFR 610.15(a), required proof of safety for all compounds used as a preservative.

Now, when the parents of the children who have been harmed are simply seeking redress for the harm knowingly done as the law provides them under the seventh amendment to the Constitution, you seem to be writing in behalf of the politicians (and the industry that seems to be behind them) who are sponsoring S. 1873, which, among other things, abridges those rights.

Since this "editorial" is unattributed, it must be that this is the paper's position on this issue - hopefully, all who read this review will both recognize this assault on their basic freedoms and reward the Wall Street Journal appropriately for this apparently Orwellian piece of journalism.

"Senate Majority Leader Bill Frist has been trying to update the VICP for several years, and Republicans did pass a liability provision as a rider to a homeland security bill in 2002. But three GOP Senators--Susan Collins, Olympia Snowe and Lincoln Chafee--created a media ruckus and demanded that it be killed. The Senators promised more debate on the subject, yet once the headlines vanished so did their interest."

The 3 GOP Senators promised hearings if the law was *not* rescinded and, because it was quietly stricken in the next appropriations bill, there was no need for hearings.

Apparently, the writer of this article has confused hearings with interest, and headlines with substantive corrective action.

"The larger point is that if politicians want private industry to develop new cures and vaccines, they can't steal their patents or confiscate their hope of making money. Private companies developed the AIDS drugs that have extended millions of lives, but countries like Brazil want to force those companies to give the drugs away at cost."

First, since government researchers and *not* the "private" companies initially identified and developed many of the AIDS drugs, and these "private" companies currently spend more on advertising than they do on research and development, this writer seems to be confused about who, if anyone in America, is stealing from whom.

Second, since U.S. politicians are *currently* engaged in the opposite of the stated conduct and what "countries like Brazil want to" do, or *not* do, is their business and *not* the concern of the American public, and this has nothing to do with the topic at hand, this reviewer is at a loss to see the relevance of these remarks *especially* when the 10 pharmaceutical companies in the Fortune 500 list made more profit last year than all of the other 490 companies on the list combined.

"The solutions to getting more vaccines aren't complicated: Push the FDA for faster approvals, shield companies from tort robbery and get the government out of the business of buying routine vaccines."

As the recent approvals of 4 more vaccines and the pending approval of another 4 more clearly demonstrate, there is no need for a solution to a problem that does *not*, in fact, exist.

As far as this reviewer can see, this article is simply a pharmaceutical-industry-backed advertisement for an 88-page bill, S. 1873, that they seem to have drafted and given to the good Senators, who introduced it on one day (17 October 2005) and passed it through the "HELP" (Health, Education, Labor, and Pensions) committee the very next day (18 October 2005)!

Does anyone believe that all the Senators and their staffs on the "HELP" committee really had or took the time to read and understand all 88 pages of S. 1873 in one day?

Or isn't clear that this bill is being railroaded through by members of the Senate who seem to be the lackeys of the pharmaceutical industry rather than the servants of the interests of the American public – so that there is no need to read the bill or to understand it?

"Politicians can't be held responsible for knowing when the next animal virus will strike the human race. But they will be responsible if their hostility to business leaves us unable to cope with its consequences."

This reviewer finds it hard to believe that anyone could conceive of our current of members of Congress as having any "hostility to business."

Factually, the reports out of Japan seems to indicate that the "avian flu" has bioengineered DNA sequences in its make up – indicating that someone may have inadvertently or otherwise be helping the "avian flu" become more easily transmitted to humans – hopefully that is *not* the case.

However, since the current annual "flu vaccines" are *not* effective (< 50% on average; but ineffective in those 2 and under, or in those 65 and older) in stopping anyone from getting the "flu" when there is an 8-months lead time; how can the vaccine industry expect to develop an effective vaccine for the "avian flu" with much less lead time unless they have created the virus and know its exact make up and weaknesses?

Hopefully, these remarks will be heard by those who read this email because I doubt, *except for possible excerpts taken out of context*, that the WSJ will publish it.

Respectfully,

Dr. King

<http://www.dr-king.com>

PS: The original file is listed on the following page.

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<http://www.opinionjournal.com/weekend/hottopic/?id=110007444>

Political Virus

Why there's only one drug to fight avian flu.

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Our political leaders keep telling us to fear the avian flu, and in one sense they're right: We should all be scared to death about how much damage our political leaders will do responding to the avian flu.

Consider Secretary-General Kofi Annan, who declared this month that he hoped concern for "intellectual property" wouldn't "get into the way" of procuring widespread vaccines for a potential avian-flu outbreak. In other words, companies that make vaccines should abandon their patents at Mr. Annan's whim. This kind of hostility to property rights is precisely the reason we now have a shortage of vaccines and drugs to combat this potential pandemic.

No one really knows how great the avian flu threat is. Public-health officials have been warning about it ever since new studies suggested that the infamous 1918 flu outbreak originated in birds. Warning is what these folks get paid to do. Other experts argue that 1918 was a fluke and that the current avian virus is unlikely to become a mass killer of humans.

Whatever the risk, some good will come out of this public alarm if we use it as an opportunity to understand why the U.S. is now so poorly armed to cope with a deadly flu outbreak. The reason is that our political class has spent the past 30 years driving the vaccine industry out of business with its own virus of over-regulation, price controls, litigation and intellectual-property abuse.

The U.S. today has only three large vaccine makers--down from 37 in the 1960s. This is the reason that, as recently as 2001, there was a shortage of eight of 11 critical childhood vaccines. It is also the reason the U.S. fell drastically short of flu vaccine a year ago, after a shut-down of one of two major flu-vaccine makers. And it is the reason only one company, Switzerland's Roche, is being counted on for a drug that would potentially protect against bird flu.

Despite these warning signals, Washington has done almost nothing. One problem is the Food and Drug Administration, which puts safety above developing rapid cures. Flu-vaccine makers face particular difficulties because they must effectively gain approval for a new product (for each new flu strain) every year. The vaccine is still grown in chicken eggs--a process that takes up to eight months. The industry has revolutionary new technologies--reverse genetics and mammalian cell culture--that would dramatically reduce the time and cost of development. Europe is moving toward products using these new techniques, but the FDA refuses to adapt and allow more rapid approval.

The feds have also done their best to remove any financial incentive--i.e., profit--for developing new vaccines. The Vaccines For Children program, a pet project of Hillary Clinton back in her First Lady days, has been especially destructive. The program now buys more than 50% of all private vaccines, and it uses this monopsony clout to drive prices down to commodity levels.

When one pharmaceutical company offered to sell a new pneumococcal vaccine to the government for \$58 a dose, the Centers for Disease Control demanded a \$10-a-dose discount. Politicians want companies to take all the risk of developing new vaccines, but they don't want the companies to make any money from taking those risks. Then the politicians profess surprise and dismay that there's a vaccine shortage.

Vaccine makers are also a favorite target of tort lawyers, who've spent 20 years trying to get around the 1986 Vaccine Injury Compensation Program (VICP)--which was specifically designed to protect vaccine makers from liability abuse. Senate Majority Leader Bill Frist has been trying to update the VICP for several years, and Republicans did pass a liability provision as a rider to a homeland security bill in 2002. But three GOP Senators--Susan Collins, Olympia Snowe and Lincoln Chafee--created a media ruckus and demanded that it be killed. The Senators promised more debate on the subject, yet once the headlines vanished so did their interest.

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The solutions to getting more vaccines aren't complicated: Push the FDA for faster approvals, shield companies from tort robbery and get the government out of the business of buying routine vaccines. Politicians can't be held responsible for knowing when the next animal virus will strike the human race. But they will be responsible if their hostility to business leaves us unable to cope with its consequences. '4

From the on-line Editorial Page of the **Wall Street Journal** as sent to this reviewer by a fellow researcher.