

## MOUNTAIN VIEWS: FORCED INOCULATIONS BEGINNING OF BUSH'S BAD BIRD FLU PLAN

By John Hanchette

**OLEAN** -- Last week's column warned of imminent federal legislation that would toss powerful pharmaceutical companies billions of dollars and complete protection from liability suits in case untested and experimental bird flu vaccines damage American recipients. It drew heavy response.

The bill (S. 1873) -- a big congressional wet kiss to the drug industry -- is dressed up in a noble-sounding title: "Biodefense and Pandemic Vaccine and Drug Development Act."

In essence, however, it would force Americans to receive inoculations against a disease that has yet to kill one of them, while removing their constitutional right to seek redress in our courts in case of injury or death from the shots because of company negligence. The proposal, now moving its way through the Senate, would also ban citizens from using the Freedom of Information Act and other popular informational laws to discover whether the new vaccine (when it is finally produced) was effective and safe, and even whether anyone had suffered adverse reactions to it.

Some of the e-mails and letters were laudatory, but sadly and predictably, many readers missed the point.

One wrote that I could only have reached my conclusions if I started from the position that the pharmaceutical companies were "evil" and that the World Health Organization, the Centers for Disease Control, and "practically every virologist and epidemiologist in the world is part of a conspiracy." Or was I saying that I have "some sort of privileged information that H5N1 influenza will never mutate and begin to infect humans and even if it does, it won't reach the USA?"

He ended by quoting some venerable Chinese philosopher's advice to "plan for what is difficult while it is easy, do what is great while it is small."

Well, yes, point taken on the aphorism -- but that's exactly the philosophical tack I'm following here: identifying a cancerous piece of federal business and dissecting it while it is still an undivided cell. If this bill -- which is absolutely laden with hidden agendas -- metastasizes into actual law, Senate 1873 could further ruin an already devastated national health care system.

Sure, the bird influenza that has killed 62 Asians may mutate into easily contractible flu for humans. I acknowledge that. It may soon reach the United States. I acknowledge that. But my beef is the thematic hidden agenda in this dangerous Senate bill that is designed to protect wealthy corporate contributors from any consequences of money-motivated, irresponsible scientific research and development. The legal precedent would be ruinous and take decades to set right.

One thing the bill-backer friends of Big Pharma are trying to slip through with this legislation is a market exclusivity provision that would extend patents on hugely profitable drugs that are about to evolve into the category of cheaper generic medicines.

Further, it would prohibit federal drug buyers from contracting with generic medicine makers to save taxpayers billions of dollars -- a current admirable practice.

Further, it would allow federal health officials to purchase medicines, vaccines and other palliatives by simple fiat without taking bids.

Further, and most onerously, the bill would vastly broaden the definition of products eligible to be characterized as "countermeasures" to terrorism -- in other words, potentially classifying commonly purchased substances like ibuprofen and aspirin as terrorist-fighting devices.

I'm not the only one who's noticed the exclusivity aspect of this legislative turkey.

The Coalition for a Competitive Pharmaceutical Market (CCPM) is an unusually broad-based national coalition of organizations powerful on Capitol Hill in representing employers, health insurers, chain drugstores, generic drug makers and pharmacy benefit managers.

Last week, this huge group urged the Senate to revise the "biodefense" bill to remove the broadened definition of terrorism "countermeasures" because the proposal allows it to be done "in a way that could grant existing everyday medicines -- rather than novel products related to (defense) against bioterrorism - - multiple years of additional market exclusivity."

This, contends CCPM chairman Annette Guarisco, "would unnecessarily drive up prescription drug costs for private and public payers without advancing our nation's bioterrorism preparedness."

Even the big health insurance companies and pharmaceutical management lobbyists were startled by the brazen provisions at the expense of common citizens Senate 1873 portends.

Mark J. Rubino, chief pharmacy officer for Aetna Inc., states, "For private and public purchasers seeking to provide consumers with therapeutically equivalent, but more cost-efficient generic drugs, the market exclusivity provision included in the Biodefense bill takes us in exactly the wrong direction."

Mark Merritt, president of the Pharmaceutical Care Management Association, said, "This drug monopoly extension proposal is a sweeping and unprecedented measure that would rewrite drug-patenting and force working families, the disabled, and seniors to pay more for their prescription drugs. Perhaps most troubling of all, this measure has moved forward without any regard to the cost (effects) it would have on Medicare, Medicaid, and private payers. America's working families, seniors, and small businesses deserve better."

Some who read the column accused me of overstating the liability protections for Big Pharma contained in the bill. Surely, they wrote, I was guilty of hyperbole or making things up. Surely, federal legislators wouldn't remove the cherished American right to redress wrongs or seek compensation for uninvited injury.

Oh, yeah? The language seems pretty clear to me. It provides incredibly broad and iron-clad protection from any American seeking legal remedy from Big Pharma and just about everyone else involved in protecting against bird flu. Look up the draft bill's Section 319F-3 (a) if you don't believe me.

"Authority -- As provided in subsection (b), and subject to subsection (b) (1) C, a manufacturer, distributor, or administrator of a security countermeasure, or a qualified pandemic and epidemic product, or a health care provider shall be immune from suit or liability caused by or arising out of the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of a countermeasure, or a qualified pandemic and epidemic product, described in subsection (b) (1) (a)."

That just about covers the waterfront, as they say. The only avenue of relief an injured vaccine or medicine recipient or survivor could follow is requesting an investigation of their allegation by the Secretary of Health and Human Services -- who would have to find "clear and convincing evidence" of "willful misconduct" that "caused the product to present a significant or unreasonable risk to human health and proximately caused the injury alleged by the party."

There are at least seven tough legal tests contained in that one paragraph. And if the HHS Secretary refuses to even investigate the complaint of injury or death, such decision is completely "within the Secretary's discretion and shall not be subject to judicial review."

If the secretary does find for the complaining injured party -- which is extremely unlikely -- the drugmaker or distributor or health care provider named in the determination can petition the federal court in the District of Columbia for "judicial review" of the HHS ruling. But no subpoenas shall be issued, "nor shall other compulsory process apply," and no third parties can intervene. The drug company appeal "shall

automatically stay the Secretary's determination for the duration of the judicial proceeding."

There are six more pages of legal gobbledegook backing this up, one of them defining the scope of protection from lawsuit as extending to allegations "relating to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of product" defined as measures against pandemics or terrorism. There, is that specific enough for you? Is that an imaginative figment?

Interpretation of this congressional language: Pigs will fly backwards and upside down before the common citizen gets any redress or compensation for injury or death resulting from a bird flu vaccine or medicine.

Why are vaccine safety advocates so adamant that John Q. Public might get screwed by all this protect-Big Pharma bird flu legislation? Because it has happened before.

In the 1970s, the panic over swine flu led to an ill-advised vaccine push that crippled many recipients and cost the drug makers millions.

In the 1980s, a dangerously reactive vaccine against whooping cough injured and killed thousands when a safer foreign alternative was already available but stubbornly unapproved by the FDA.

In the 1990s, the federal health establishment insisted -- and still insists -- there is no connection between toxic mercury preservatives in mandated childhood vaccines and the astounding increase in autism (from 1 in 10,000 births to 1 in 166 births), despite ample scientific evidence to the contrary.

Experimental anthrax vaccine is still being tested on troops without informed consent, and was almost tested on infants until a big public fuss erupted.

The yearly hoopah over getting your flu shots to protect against contractible human flu results in less than desired protection because the scientists are always fighting the previous year's struggle that has already mutated or died out.

Both the federal government and big pharmaceutical firms will go to almost any length to protect themselves from blame when vaccines are involved.

Now we read the government experts and private researchers are predicting a minimum of 200,000 deaths and perhaps as many as 2 million deaths if the Asian bird flu mutates into a disease that can be passed from bird to human and then human to human.

"This is shoddy science at best and beyond belief that any reputable scientist could get away with such nonsense," writes Dr. Joseph Mercola, an alternative health physician and author of the popular Total Health Program. "Most of the people (in Asia) who acquired this infection were bird handlers who were in continuous contact with these sick birds. Does anyone in their right mind envision similar circumstances in the United States?"

The issue is certainly timely. This column's date of publication (Tuesday, Nov. 1) will see President George W. Bush go to the National Institutes of Health to tell us how he will spend -- at his executive discretion -- nearly \$8 billion that was quickly added to the 2006 funding bill for HHS last Thursday in light of the concern over bird flu. He is expected to devote much of it to stockpiling vaccines once they are developed. The federal government has already committed to buying \$162.5 million worth of experimental vaccines against the bird flu strain -- doses which may or may not protect humans -- from Chiron Corp. and Sanofi-Aventis. The feds are also ordering millions of doses of Relenza and Tamiflu, two human anti-flu drugs that seem to slow down the advance of bird flu but not completely halt it.

Meanwhile, the best possible outcome -- that the H5N1 bird flu strain fizzles out or never mutates to threaten humans -- is triggering a new concern among federal officials: that all the frantic warnings so far may have created a sense of public cynicism (or at least skepticism) over global health admonitions about pandemics.

"Will critics say we have been crying wolf?" worried HHS Secretary Michael Leavitt at the end of last week. Will the public "lose the sense of urgency we feel about this issue?"

Well, maybe, Mr. Secretary. But Americans would lend you a lot more credence if you ensured they were treated fairly.

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