Bush FDA Protects Profit Rather Than Health

by Mary Jane Freeman

At Congressional hearings held Nov. 17 and 18, documentary evidence was released showing President Bush and his Administration's culpability for the avoidable deaths of Americans due to the gross negligence of his Food and Drug Administration (FDA). These hearings inquired into, first, this and previous years' increasingly drastic flu shot shortages; and second, how it is that the arthritis drug Vioxx was ever allowed onto the market for use. Both hearings showed that the FDA failed to do its job: safeguard the public's health.

At the Nov. 17 hearing before the House Government Reform Committee, over 1,000 pages of FDA documents proved that the failure to secure enough flu vaccine—as Lyndon LaRouche had charged, pre-election, in a series of mass-circulated warnings to Americans—was a colossal, and deliberate, failure by the Bush/Cheney Administration which adheres to a murderous "free market" policy, especially vis-à-vis health care. The Nov. 18 hearing before the Senate Finance Committee provided devastating testimony from a 20-year veteran FDA scientist that the needless deaths from use of Vioxx, an FDA-approved drug, were a result of FDA higher-ups favoring pharmaceutical companies over public safety.

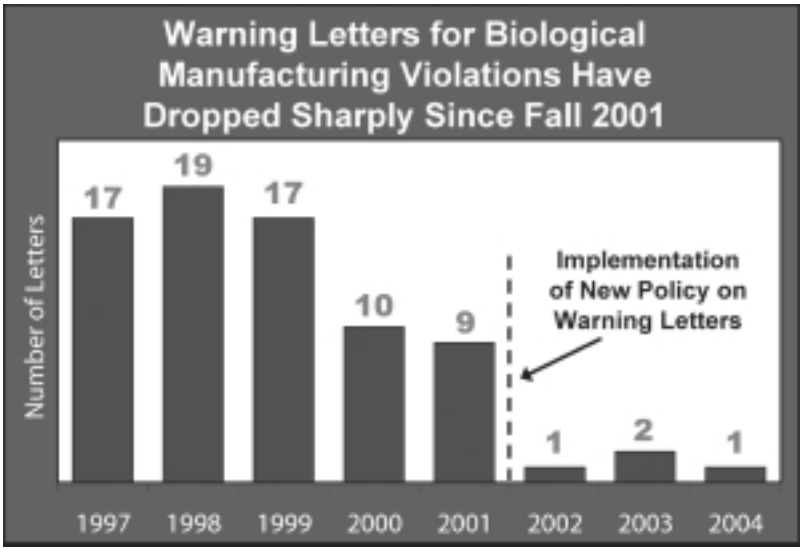
LaRouche's Negligence Charges Vindicated

In the weeks before the Nov. 2 election, LaRouche hit the Bush White House's negligence hard, with millions of leaflets—entitled: "LaRouche: Bush-Cheney Could Cause More Americans to Die of the Flu Than Were Killed in the 9/11 Attack"; "Bush to Americans: Drop Dead!"; and " 'Go Flu Yourself': Bush-Cheney Cut CDC Budget in Vaccine Crisis"—warning the nation that Bush and his Administration's malfeasance as to the public's health will lead to untold avoidable deaths, not just from vaccine shortages, but from their profits-over-public-health agenda.

Before the election, a White House lid—exposed by Rep. Henry Waxman (D-Calif.)—was on, to prevent FDA release of information to the Congress, and the public, which could have verified these charges. But, the lid blew off at the Nov. 17 Government Reform Committee hearing on the flu shot shortage. Representative Waxman, the ranking minority member of the committee, finally had FDA documents—requested by the committee back on Oct. 8—showing that "expert scientists at FDA knew about serious problems at the Liverpool facility in June 2003," where half of America's flu vaccine supply was to be made. The significance of the documents is, in Waxman's words: "The Chiron plant in Liverpool was not an ordinary FDA-regulated facility. It's a facility with a history of contamination problems that makes half of the U.S. supply of flu vaccine. [It] should have received the highest priority from FDA. Yet the agency ignored glaring problems . . . and missed repeated opportunities to correct them."

According to a Congressional source, the date on the cover letter releasing the documents was Oct. 18, but they weren't handed over to the Committee until Nov. 4, the day after Bush claimed victory! On Oct. 22, FDA acting director Dr. Lester Crawford had told the committee the documents could not be found because his staff were too busy dealing with shot shortages—clearly a misstatement, at least. But consider the irony that on Nov. 19, Illinois Gov. Rod Blagojevich reported that 400,000 doses of flu vaccine he'd located abroad, for his state and for other governors, now might not be allowed into the country by the FDA due to alleged insufficient documentation from the Aventis Pasteur facility which was ready to provide the shots—even though this company is already licensed by the FDA to make the flu vaccine. Crawford's pre-election excuse must be judged a lie.

At the same hearing, Rep. Janice Schakowsky (D-Ill.)



This graph by the House Government Reform Committee Minority staff shows the collapse in FDA warning letters after the Bush Administration changed its guiding policy in 2001. The warning not issued in 2003 to Chiron Corp. was the difference between America having its whole flu vaccine order in 2004, and only half of it.

took up a critical point made in the LaRouche PAC mass leaflets, when she chided "Vice-President Cheney's 'explanation' " for the lack of flu vaccine being "that vaccine production just isn't profitable enough for private pharmaceutical companies." She asked, "Is that going to be the consideration, that profits of the companies are going to take precedence over the health of the American people?"

Throughout the hearing, Crawford was grilled on the FDA's failure to have detected or acted on the 2004 contamination problem in 2003, when its inspection found it, and for FDA's willful failure to impose its own adopted corrective measures at the plant. Crawford played a game of sophistry, arguing that the dates of FDA reports didn't match the time sequence of batches of vaccine at issue now. The Committee's Minority Staff report points out that Crawford repeatedly "assured the public" that the FDA provided "adequate oversight" of the Liverpool lab after the FDA's 2003 inspection findings of contamination; but the FDA's own documents show that over the 16-month period between June 2003 and the lab's October 2004 shutdown by British authorities, "FDA failed to inspect—even once—whether the defects . . . had been fixed."

Had LaRouche's pre-election charges of fatal malfeasance been confirmed before Nov. 2, as they are now by these explosive Congressional proceedings, the outcome on Election Day might have been different.

Vioxx Use Killed Americans

On Nov. 18, the U.S. Senate Finance Committee's hearings were called to look at the FDA's culpability in the disastrous approval of the anti-inflamatory drug Vioxx. The hearing topic was, "FDA, Merck and Vioxx: Putting Patient Safety First?" At the heart of the committee's inquiry was whether pharmaceutical companies' profits were protected by the FDA at the expense of the lives of tens or hundreds of thousands of Americans who were either killed or severely harmed by this drug's use.

Opening the hearing, chairman Sen. Charles Grassley (R-Iowa) set the stage: "Of the 20 million Americans who reportedly took Vioxx, an untold number are Medicare and Medicaid beneficiaries." Over $1 billion was paid by the government to Merck & Co. for Vioxx prescriptions during its five years on the market, Grassley said. Then, he read from a June 4, 1999 Merck internal document—recalling the infamous internal Enron e-mails. It was titled, "IN IT TO WIN IT," and read in part: "As of yesterday, Vioxx became reimbursable on Medicaid in 42 states with the other 8 states close behind." Grassley asserted, "The Medicaid market was clearly going to be a moneymaker for Merck," and worried that the FDA's relationship with drug companies "is too cozy."

Grassley then dropped a bombshell by rebuking the thuggery of FDA's Crawford, who had publicly stigmatized Dr. David Graham, the associate director for Science and Medicine at the FDA's Office of Drug Safety, as an irresponsible "maverick." Graham was the committee's lead witness at the hearing. "Dr. Crawford appears [to have] intended to intimidate a witness on the eve of hearing," Grassley charged. Graham has worked at the FDA for 20 years with an impeccable record of defending the public's safety. And indeed, he provided eye-opening testimony that Vioxx was a dangerous drug and that the FDA had sufficient information to know it, but chose to approve it for use anyway.

"Vioxx is a terrible tragedy and a profound regulatory failure. I would argue that the FDA, as currently configured, is incapable of protecting America against another Vioxx. We are virtually defenseless," Graham testified. He showed that despite pre-approval and post-marketing findings that use of this drug portended a five- to seven-fold increase in heart attack risk, the FDA approved it and refused to remove the drug from the market. (Merck finally withdrew Vioxx from sale.)

An FDA report, released on Election Day 2004, estimated that Vioxx caused 28,000 excess cases of heart attack or sudden cardiac death. But, Graham testified, if one applies the risk factors found in Merck's own studies—one pre- and one post-marketing—then the "more realistic and likely range of . . . excess cases in the U.S." is "from 88,000-139,000 Americans" who either died or were physically damaged by this drug. "Of these, 30-40% probably died" and "for the survivors, their lives were changed forever," he said.

Graham also detailed the threats and intimidation he has been subjected to by FDA officials over the last two years as he has pursued exposing the health risks of Vioxx, with the hope and intent to have its FDA approval lifted. He pointed out that just eight days before Merck "voluntarily" pulled the drug off the market on Sept. 30, he was denounced by superiors. To this day the FDA has refused to allow his research to be published, despite having been peer-reviewed and approved for publication in a prestigious medical journal.

Following Graham's forthright, explosive testimony, the acting director of Science and Medicine at the FDA's Center for Drug Evaluation and Research, Dr. Steven Galson, issued a press release "categorically" rejecting accusations that the agency "has done a poor job of protecting the public against dangerous drugs." Further, as the stock values of five drug companies fell after Graham named drugs made by them as unsafe, Galson insisted, "Dr. Graham's testimony does not reflect the views of" the FDA. Speaking on NBC's "Today" show, Galson whined, "The drug industry would be astounded at [Senator Grassley's] charges we're too cozy with them."

Graham had also scored the "corporate culture" at FDA, which "views the pharmaceutical industry it is supposed to regulate, as its client." Grassley said the Vioxx affair is one of the "worst drug disasters in history." Plenty of "red flags" were up, but the FDA failed to make "the health and safety of the public" its "first and only concern."