The Other Security Risk

FDA 'Reform' Threatens Transplant Supply

Part 4, by Linda Everett

Hard on the news that patients who have received organs and blood products from donors possibly infected with West Nile virus—requiring the government's intensified scrutiny over the testing and regulation of such biologics—the U.S. Food and Drug Administration (FDA), charged with oversight and safety of pharmaceuticals, human biological products, and medical devices in the United States, is about to relax its rules for inspecting drug-manufacturing plants. Worse, the Bush Administration is planning to privatize the FDA inspection of manufacturers of medical devices—joint implants, heart valves, diagnostic equipment, DNA tests, electronic devices that control blood pressure, and others.

In the first three parts of this series (*EIR,* Aug. 2, 9, and 23), we demonstrated how the unbridled "market-driven" pharmaceutical industry's control over what medications and vaccines will, or will not, be manufactured and available—and at what price—endangers lives. The deregulation of the oversight of *how* pharmaceutical drugs, biological products, and medical devices are manufactured, is another element of the same "free-market" disease destroying the Federal government's interest of protecting the general welfare of the nation.

FDA Letting Inspections Lapse

On Aug. 28, 2002, the FDA announced that, for the first time in 25 years, it is revamping its rules for inspecting drug-manufacturing plants—due to the government's inability to inspect factories as rigorously as it once did. As the FDA's Janet Woodcock readily admitted to the press, because Congress has, for years, failed to allocate enough funds for the FDA to function properly, the number of FDA inspections of drug factories dropped from 4,300 in 1980 to 1,600 in 2001.

Allegedly, the FDA rules change will allow drug manufacturers to modernize and automate pill production, with sensors that can tell if a batch of pills or powders is contaminated with a wrong ingredient. The FDA would then spot check a few pills here or there and let the sensors do overall quality control.

But, as *EIR* previously reported, drug manufacturers have continued to drop production of scores of drugs and vaccines, rather than invest in upgrading their plants to meet FDA regulations.

Consider that the FDA recently fined Schering Plough $500 million for major quality control violations at its manufacturing plant. In July, Eli Lilly & Co. said that five of their drugs would be delayed due to FDA-cited factory problems. Earlier, in 1999, Abbott Laboratories had to pay $100 million to clean up its laboratories. Even as the number of new drug products increased annually, the number of FDA inspectors has shrunk.

On Aug. 14, just a week before the FDA's announcement, its Center for Biologics Evaluation and Research, which oversees human tissue for transplantation, had ordered Cryolife, Inc.—the Kennesaw, Georgia-based human tissue processing firm—to recall distributed human tissue processsed since Oct. 3, 2001, and to withhold or destroy all tissue processed after that date. Not only could the company not ensure that its human tissue used in transplants was not contaminated with fungi and bacteria; it had improperly distributed tissue from a donor after the firm confirmed the presence of harmful microorganisms in the donor's tissue samples. One patient has already died and there are at least 25 other serious infections following knee surgery using Cryolife's contaminated tissue implants.

This sounds uncomfortably like the West Nile virus transplant case. The FDA states that contamination may be caused by a variety of infections disease agents, including viruses, bacteria, fungi, and transmissible spongiform encephalopathy-associated prions. Each piece of tissue must be tested for microbes before its use.

Current FDA regulations for human tissue require firms to prepare, validate, and follow written procedures to prevent infectious disease contamination or cross-contamination during tissue processing; *but,* processors usually make up their own procedure or follow guidelines from a voluntary trade organization, the American Association of Tissue Banks. Cryolife, which was not following FDA regulations—and, in fact, had several significant violations of them—is not part of that group, and has its own procedures for handling tissue, which it refuses to disclose.

Despite this dangerous situation, just weeks later another branch of the FDA, the Center for Devices and Radiological Health (CDRH), gave Cryolife a limp slap on its wrist for distributing suspect heart valves. CDHR merely "warned" heart surgeons nationwide that the Cryolife valves may cause infections in patients! Cryolife provides 70% of the nation's heart valves; about 41,000 patients have received them since 1984.

Privatize the FDA's Role?

If an FDA "reform" proposal (HR 3580) by Rep. James C. Greenwood (R-Pa.) were to pass, instead of having the FDA inspect the practices of medical device manufacturers, the latter could contract out to third parties to do their inspec-

tions—they'll find and pay for their own private inspectors. Greenwood's bill may have some useful proposals, but privatizing inspections creates a gigantic conflict of interest. Medical devices are a $78 billion a year business whose products include everything from breast implants to diagnostic cameras that can be swallowed.

Once again, we're told that such "reforms" are necessary because Congress has not provided needed funds to the FDA to inspect the manufacturing processes for millions of medical devices. The FDA's Center for Devices and Radiological Health (CDRH) has lost over 110 inspectors since 1996. The agency can only inspect devices and diagnostic tests on an average of once every five years, instead of every two years as required by regulations. The solution, according to those beating the drums to privatize everything the Federal government does, is not to allocate more funds to the FDA—but, to have the manufacturers, themselves, pay for their own inspectors. Of course, if these "inspectors" don't give the manufacturers the approval they seek, nothing stops the manufacturers from finding a more compliant inspector. The manufacturers would pay "user fees" to the cash-starved FDA to pay for its salaries, computers, etc.

How well can these manufacturers be trusted? What is their track record? No better than the pharmaceutical industry's.

More than 1,000 of 80,000 medical instruments used in the United States are recalled every year. But, because these recalls are run by the product manufacturers themselves, with little government oversignt, they are ineffectual, leading to injuries and deaths. For instance, Olympus America, Inc., a manufacturer of lung examination instruments, or bronchoscopes, recalled its instruments because they harbored dangerous bacteria that spread among patients; when the recall notices to thousands of hospitals were sent to the wrong addresses, patients died. The Nov. 30, 2001 recall letter blamed the problem on the hospitals' improper washing of the instrument—instead of the manufacturer's own defective caps on the bronchoscopes. Hospitals were never told to immediately stop using the instrument. The company merely suggested that the hospital return the instrument "at your convenience."

Inadequate Congressional funding means the FDA's CDRH, which oversees recalls, can only pre-examine 1% of the more than 1,000 recalls a year.

Free-Market Mania

The mania for privatization goes back to President Ronald Reagan, who was ideologically committed to privatizing Federally sponsored drug research programs completely—the more the better, according to one source, *Prescription For Profits,* by Linda Marsa (1997). This occurred in a frenzy of deregulation, including brokerage and securities firms (1975), airlines (1976), trucking and railroads (1980), and the financial sector (1982 and following). In medical and pharmaceutical research, it led to a rapid shift from genuine excitement in new medical breakthroughs that would advance the nation's war on disease, to a climate of "cashing in" wherever possible, which eventually led to the abuse of medicine as a looter's paradise, with today's major pharmaceutical company scams and inadequate human tissue processing as in the case of Cryolife.

Abbey Myers, of the National Organization for Rare Disorders, says the whole culture around pharmaceutical and medical device patents changed with the Bayh-Dole Act of 1980, which gave companies exclusive licensing rights to discoveries arising from *Federally funded* research, and encouraged scientists with Federal grants to seek commercial applications for their work. An Office of Technology Assessment (OTA) report recommended that universities and nonprofit organizations, under the new law, could license their valuable inventions to commercial enterprises, and share with them the revenue the inventions generate. All deals made under Bayh-Dole are secret—there is no scrutiny or oversight.

According to the now-defunct OTA ("Pharmaceutical R&D: Costs, Risks, Rewards," 1993), in 1981 Congress gave corporations hefty tax credits for investing in university research, as an incentive to boost R&D spending. In 1986, the Federal Technology Transfer (FTT) Act augmented the Bayh-Dole Act, to provide financial and professional incentives to Federal scientists working in laboratories such as the National Institutes of Health (NIH), to actively pursue commercialization of their inventions. The FTT also permitted Federal laboratories to enter into formal "cooperative research and development agreements" or CRADAs, in which a Federal agency provides personnel, services, facilities, equipment, or resources, and a private company provides money, personnel, facilities, equipment, or other resources. The law leaves oversight of the CRADA policy up to the Federal agency, and allows for the Federal laboratory to grant licenses to the collaborating partner on any inventions resulting from the research.

When government agencies, such as the National Institutes of Health, issued a CRADA contract, the terms of the contract always included a clause that required that the products developed with Federal investment, were to be sold at "reasonable" prices. But there has been little or no implementation of that rule. In fact, the OTA reported, implementing the fair pricing clause could "conflict" with the Federal goal of technology tranfer, since it would mean government scrutiny of a drug company's books and manufacturing processes—which drug companies would never allow.

Treatments developed with Federal help or tax credits to treat rare or unusual diseases (see below) were also required to be sold at "reasonable" prices. This is, of course, an understandable policy necessary to protect both research investment and the public. Yet, in 1992, with enormous pressure from the pharmaceutical industry, the NIH deleted that clause.

So now, AIDS drugs discovered and developed with taxpayers' money, along with hundreds of other treatments, are sold at exorbitant prices, which patients can ill afford. For the drug manufacturers, this is indeed, a "free" market—at the taxpayers' expense.

Where 'Deregulation of Science' Arose

All this was the outcome of the growing movement for deregulation of science and technology, starting about 1976. At that time, under existing patent law, if a researcher took one dime of Federal money, then the rights of his discovery were in the public domain. This patent law was targetted for change by advocates of (cheap) "technology transfer" from Federal scientists and universities to industry. Democrats, under Jimmy Carter, jumped on the bandwagon, leading to the Bayh-Dole bill that was supposed to jump start the economy. Adm. H.G. Rickover, father of the nation's nuclear Navy, said Bayh-Dole was one of the biggest giveaways in history, and would promote "greater concentration of economic power in the hands of large corporations."

The law, however, still did not provide enough incentives for drug companies to invest in R&D. A recent report by the National Institute for Health Care Management Foundation, found that two-thirds of all prescription drugs approved by the FDA in the last 11 years were identical to existing drugs, or were simply modified versions of them. Only one-third of drugs approved by the FDA in that period were based on totally new "molecular entities" that are effective in treating diseases in new ways.

The report fuels the argument that the pharmaceutical companies are putting most of their resources into extending patents on their most lucrative drugs, those which can bring in $1-6 billion in annual revenues—by producing a new time-release formulation of the same drug, or simply changing the dosage or shape of the pills. As a recent Families USA report states, drug companies spent almost two-and-a-half times as much on marketing and advertising in 2001, as they did on research and development of drugs. By contrast, in 1989, twenty-two percent of a drug's costs went to marketing; 16% went to R&D.

Preventing a Catastrophe

In 2000, *EIR* investigated the nationwide shortage of influenza vaccine. Experts admitted that the nation had experienced "an excess of mortality" for the previous four years due to influenza. Despite this—and despite what the experts called an imminent threat of a pandemic influenza, the production of vaccine was not increased. Drug companies routinely manufacture only the amount of vaccine they say they are sure will sell—not the amounts needed by the entire country to protect against an annual flu, let alone a pandemic one.

There was then, and is now, not even enough vaccine for those populations whom the Centers for Disease Control and Prevent recommended should receive it, such as the chronically ill (93 million people) and the elderly (40 million people). Eliminating 30 million from the total to account for those elderly who also have chronic diseases, that leaves 103 million people whom CDC says should be vaccinated. Originally, the CDC recommended vaccination for everyone over age 50—an additional 65 million Americans, and for health care workers, an additional 11.3 million people. That's a total of about 180 million who, by Federal scientists' recommendation, should get flu vaccine.

But the actual amount of vaccine produced in 2000 was just 75 million doses.

Dr. Paul Glezen of the Influenza Research Lab of Baylor School of Medicine told *EIR* at the time that the average number of deaths due to influenza is 46,000 annually. No one has investigated how many of these deaths could be prevented if vaccine were produced for universal coverage (which the city of Quebec did that year). But, if we don't attempt to save those lives by producing adequate vaccine, the country is essentially turning back the clock to a time before such medical breakthroughs were available to us. It is time that we muster the political mandate to uphold the needs of the nation before a Wall Street stock.

This is eminently achievable, as seen in the country's 1983 Orphan Drug Act, passed to encourage firms to develop new treatments for commercially unviable therapies. Firms were given sizeable tax credits for developing and producing drugs that treat rare diseases—which affect about 25 million people in the United States. Such drugs might bring in, commercially, as little as $1 million a year or, as much as $25 million. Without them, people languish, become severely disabled for life, or die.

There is no need to micro-manage the pharmaceutical industry in this country. But government must reassume its responsibility to assure the availability and safety of pharmaceutical products, biologics, and medical devices as part of the nation's "soft infrastructure." Within a mobilization for the overall infrastructure reconstruction program put forward by Lyndon LaRouche, proposals from U.S. lawmakers—otherwise surrounded by pharmaceutical industry lobbyists and money—can work.

One proposal by Sen. Debbie Stabenow (D-Mich.) would limit the expenses a drug manufacturer can claim as a tax deduction, to the amount of money that the company spends on research and development, not what it spends on marketing. Consider the billions pharmaceutical companies spend on mass marketing through television ads, magazines, and medical journals. Consider the "educational" conferences, free gifts, and free lunches that pharmaceutical "detailers" shower on every doctor in America. There's no need for tax breaks for this marketing when the American taxpayer has already paid for the discovery, development and possibly, even the clinical trials that went into the pharmaceutical products themselves.