The Other Security Risk

U.S. Hospitals Face Critical Drug Shortages

Part 2, by Linda Everett

As President Bush was releasing his proposal for a Cabinet-level Department of Homeland Security on July 16, calling for the most sweeping changes in government since 1947 to protect the United States against a "new wave of terrorism," hospitals across the United States were findng it impossible to meet the basic, daily needs of their patients, due to the worst-ever shortage of 39 critical hospital drug products. The shortages are not only crippling hospitals in terms of time and resources spent, they are also contributing to an increase in hospital medical errors, related deaths, and "near misses."

As Homeland Security Director Tom Ridge tells the country's approximately 5,000 hospitals to prepare to treat thousands of emergency victims of terror attacks, hospital doctors cannot even procure a whole range of basic sterile injectable drugs, from antibiotics to certain surgical anesthetics, and corticosteriods for premature infants.

Other national shortages and delayed drugs as of July, included medications for snake bites, emphysema, hepatitis A and B, and more. During 2001, thousands of patients needing tetanus went untreated; children with hemophilia were warned not to play sports, because there was a shortage of medical pharmaceuticals to treat them if they are injured. The American College of Physicians and the American Society of Internal Medicine warned in December 2001, that their doctors have to scramble to find everything from beta-blockers and fungicides to hard-to-find antibiotics like oxacillin, gentamicin, and penicillin G.

Federal Agencies Are Not Acting

When *EIR* first discovered this crisis months ago, we asked the Office of Emergency Preparedness, the Office of Homeland Defense, the Secretary of the Department of Health and Human Services, the Food and Drug Administration (FDA), and the U.S. Centers For Disease Control and Prevention: "How can American hospitals become adequately equipped in terms of emergency preparedness, if they cannot respond to the daily needs of patients now?" No Federal agency or its representative had heard of the crisis, either in media or government warnings, and most believed that none existed. These are agencies charged with protecting the general welfare; and as Democratic Presidential pre-candidate Lyndon LaRouche observes, a government's true authority exists entirely on the foundation of its ability to promote and protect the general welfare.

The FDA told *EIR* that the issue of medical shortages is not under its purview. But the United States faces here an emergency that is demonstrative of the global economic collapse, and one driven by "shareholder values" that have allowed pharmaceutical giants and "health maintenance organizations" to loot the entire field of health care.

The University of Utah Center for Drug Information told *EIR* that drug shortages have become a "crushing" problem for hospitals, and are wreaking havoc. Some hospitals have had to cancel surgeries and resort to designating a full-time pharmacy staff member to do nothing but look for alternative sources for drugs, or to find substitutes for those that are no longer available. Hospitals are rationing drugs, and spending more and more unreimbursed time and resources in training doctors and nurses how to use unfamiliar drugs and deliver new, untried smaller dosages of those on hand. For instance, when some surgical anesthetics in particular dosages are not available, doctors are forced to use stronger drugs, whose dosages they are not experienced with, increasing the likelihood of overdoses and deaths. A representative of the American Association of Health Systems Pharmacists (AAHP), the organization representing hospital pharmacists, told *EIR* that there have already been patient deaths due to this, and that medical errors are increasing as hospitals try to contend with these shortages.

Note that the 1999 Institute of Medicine report, "To Err Is Human," found that 98,000 preventable deaths occur annually in U.S. hospitals due to medical errors. A report this year has established that an equal number of patients die annually from diseases acquired while hospitalized. The results when hospitals or pharmacies are forced to compound "new" medications on the spot, are predictable. In June 2001, three patients at one California hospital died of bacterial meningitis, contracted after receiving injections of a medication which was contaminated, when a pharmacy compounded it as a substitute for marketed injectable corticosteroids, which were not available. In 2000, two Navy recruits died of adenovirus infections (thousands of others were sickened), which are usually rampant in boot camp barracks. Until then, the spread of the virus had been prevented by immunizing recruits, but Wyeth Laboratories decided to stop producing vacine that year.

'An Omen of What's To Come'

The shortages or long delays on back-orders of hospital drug products (including childhood vaccines) did not exist five or ten years ago, AAHP representatives told *EIR*, but now, they are growing daily. Throughout the 1990s, there was considerable consolidation of both the brand-name and generic drug industries. The recent takeover of Pharmacia by the drug giant Pfizer created the world's largest pharmaceutical company. GlaxoSmith-Kline, Europe's biggest drug

While emergency response to terror attacks or other disasters is the focus of attention, Federal agencies ignore America's "other security threat": the growing shortages—at any price—of 40 vital hospital drugs and vaccines.

maker, was also reported to be at the point of another mega-merger. Where there were half a dozen manufacturers of a given vaccine or drug product a decade ago, today there is often one.

The drug companies themselves can have any number of problems. They may have manufacturing difficulties; or because the production of many biologics, such as blood products, and new medications requires very controlled, sterile conditions, companies may fail the FDA's more stringent inspection of the drug-manufacturing process. Very often, the companies simply decide to end production of what they consider "unprofitable" drugs, such as those used only by a small population, who, nonetheless, depend upon them. The National Organization of Rare Disorders warned in the late 1980s, that the crisis in supply of little-used but needed drugs (called "orphan drugs") for unusual disorders, was "an omen of what's to come" to common diseases." They have been proven right.

A small component of the shortages stems from the increased costs and difficulty of procuring bulk quantities of raw materials. Some 80% of such raw materials are imported. The causes of unavailability of raw materials are varied—anything from natural disasters to economic, political or social upheaval in the countries of origin. To track which raw materials are at risk and what countries are involved is difficult—information is often proprietary, and drug companies don't want to reveal the ingredients of their products.

The more unique or rare the plant products used as a basis in a drug, the more limited the raw material, and the more likely the shortage. The Generic Pharmaceutical Association, the trade companies' group, told *EIR* that as the costs of raw materials go up, smaller manufacturers will also stop production, because they cannot afford the diminished returns.

But such shortages are not apparent in Canada, where thousands of Americans now go regularly to fill their presciptions. Thus, when a manufacturer says it has discontinued production of a drug due to a raw material shortage, the true reason may lie elsewhere. An example of an America-only shortage is tubocurarine chloride, a long-acting neuromuscular blocking agent, which has been discontinued by drug makers Abbott, Geneva, and Eli Lilly, all three of which say they cannot obtain the raw material. But over the last year, both

Abbott and Lilly have had a lot of what FDA calls "good manufacturing procedure problems," and have dropped production of dozens of medications. They chose to "clean house," as one source said, to weed out what they thought were unprofitable products.

Hospitals, too, are caught short, due to the post-industrial policy of "just in time inventories." With the financial strictures of "managed" health care, hospitals can only afford to stock a 24- to 48-hour supply of drugs; they lack any backup supplies. But no matter how dire this crisis, *EIR* was told repeatedly that the government, and specifically the FDA, cannot tell the unregulated drug companies what to do or what to produce. It may be time, *EIR* was told by those working on the problem, to start treating drug production like an essential utility—regulating it—to assure the nation's medical and public health needs.

Profit Is the Driving Force

A major driver in the shortages is the free-market control over drug manufacturing and drug availability in the country. "Profit is the driving force here," *EIR* was told. Drug companies may say they are having "manufacturing difficulties," but more likely they are increasingly failing to pass FDA regulations, because they refuse to upgrade their equipment. Such investment doesn't provide the quick turnaround in profits that Wall Street "shareholder value" demands. On May 18, 2002, the FDA fined Schering-Plough $500 million for poor manufacturing practices in 90% of its drug products since 1998. The FDA fine covered 125 prescription and nonprescription drugs produced by Schering-Plough. As part of the settlement, the company was to pay an additional $175 million if it failed to improve manufacturing practices at all four of its plants. Rather than upgrade its laboratories and factories, Schering-Plough simply decided to suspend production of 73 products. As with suspension of influenza vaccine production by two makers last year, the result is instant shortages.

Companies now must give the FDA some notice when they suspend production of a drug. But as recently as 1997, when the National Organization of Rare Disorders (NORD), among others, tried to pass legislation to force drug companies to give a one-year mandatory notice of discontinuance, the Pharmaceutical Research and Manufacturing Association (PhRMA)—the drug industry trade group—"fought like crazy" to eliminate the provision, according to Abby Myers, Executive Director of NORD. The health of the sickest in America depends upon the for-profit whims of this industry.

Drug companies often don't tell hospitals how long a shortage might last or why it exists, because this may have unfavorable impact on their stock price (and be good news for their competitors). For instance, in August 2001, Merck alerted hospitals that it was having manufacturing difficulties with several of its vaccines, which would be delayed for a few weeks. But, the company knew these products were going to be "off-life" (not produced) for some time. It was only in January 2002, that hospitals had finally found out the truth: the FDA had cited Merck for regulatory problems.

A small percentage of the shortages may be contrived through illegitimate hoarding, evidence of which came to light when some hospitals reported that, as soon as a shortage becomes apparent, they were hit with faxed offers to provide the needed drug at a two or three times its original costs. How much organized crime is involved in such actions is not yet known. But there are several instances, over the last two years, in which drug products have been tampered with after they left the manufacturing plant, or in which counterfeit lots of the most expensive drugs have been found. The counterfeits include growth hormones—often used by athletes—and an anemia treatment for patients in renal failure or dialysis. A single treatment of either costs thousands of dollars. Generally, the main ingredient in the counterfeit lots is dangerously diluted. The FDA has undertaken a criminal investigation.

FDR Example of the 1930s

When a brand-name drug company, or even a generic drug maker decides a drug is no longer profitable and discontinues its production, that crisis hits that minority of patients whose lives and well-being depend on little-used or older drugs. Although the FDA already consults with companies that broker among various manufacturers to find those that might take up production of a particular drug, more aggressive action is needed to head off the increasingly endangered production of medicines critical to the survival and decent standard of living for the entire population. The current situation has reduced hospitals to finding their own medicines—a ludicrous and dangerous situation.

Government action could offer entrepreneurs a "parity payment" to assure the production costs of manufacturing necessary drugs that would not otherwise be produced, due to low volume of sales, lack of profitability, or default of big producers. This would make it worthwhile for small companies to commit years, and a considerable amount of retooling of their manufacturing capability, to produce these. When a smaller manufacturer steps forward to produce a drug that a pharmaceutical giant discontinues, it can take years to start up production, get it approved, and get the product into hospitals. This can only be done quickly enough, if the country bears in mind the example of the 1930s' urgent, sweeping recovery President Franklin Delano Roosevelt achieved, in transforming the nation's economy through capital-intensive investment and infrastructure.

The potentials for Federal-state legislation and regulatory action against drug companies' underproduction and induced shortages, will be dealt with in the third part of this series. Whatever the limits we now face in producing medicines needed, we must launch such a mandate for scientific progress, beyond the present and future limits of our dominion over nature, its diseases, and its disabilities.