The Other Security Risk

Unregulated Drug Multis Hold Nation Hostage

Part 3, by Linda Everett

The recent battles in Congress on the issues of providing a Medicare prescription drug benefit for older and disabled Americans, and tackling the overall problem of prohibitive costs of most name-brand prescription drugs, are, in many ways, emblematic of the major crisis crippling a country held hostage by a totally unregulated pharmaceutical industry. As one specialist told *EIR*, when it comes to the pharmaceutical industry, "The situation is totally out of control, no country can control the drug industry."

Indeed, the industry is a formidable force: The number of lobbyists working in the United States for the drug industry is now close to 700, more than one in Washington to work over every member of Congress. However, it is also an industry that, like Enron, through its perfidious appetite for looting every part of the population, appears to have shot itself in the foot several times, and now faces an avalanche of legal suits, legislation, and voter outrage.

Although it is unlikely that a bill will pass Congress this year, there are both Democratic and Republican bills for a Medicare prescription drug benefit, and a more forceful Senate-passed bill to make generic drugs readily available. There are a growing number of Federal, state, and consumer lawsuits against drug companies. In almost every instance, the lack of regulation of the drug industry has given rise to the crisis.

$4,000 per Person per Year for Medicines

Canada and the countries of Europe have some form of price regulation of pharmaceuticals, which includes either large discounts negotiated with the drug manufacturers, or outright government-fixed drug prices. Even with the considerable differences in regulations between Europe and the United States, it is claimed that—since the United States is the only country where major drug companies can get their asking price for their products—America's 46% of all global drug sales is in fact subsidizing the cut-rates of European countries.

A similar phenomenon occurs within the United States. Large U.S. corporations, managed care organizations, health insurers, hospitals, the Office of Veterans Affairs, and the Department of Defense, among others, all negotiate large discounts from pharmaceutical companies for their products. The people who end up paying the full price of prescription drugs are those who can afford it least—the uninsurable (because of disabling or chronic health problems), the uninsured or underinsured, the poor, and the elderly.

There are numerous studies that demonstrate the hard fact that the uninsured, indigent, and chronically ill, unable to afford to purchase their medications, are far sicker than the rest of the population and have higher mortality rates. So, too, with those people who are over age 65 or disabled, who make up the 40 million beneficiaries of the Medicare program.

Medicare does not provide coverage for prescription drugs, a major and growing component of medical care. According to a new Henry J. Kaiser Foundation study, nearly one in four seniors is skipping doses of prescribed medicines, or not filling prescriptions because of high costs. A July study by the consumer group Families USA found the costs of many major drugs that seniors use increased up to eight times the (understated) rate of inflation in the last year.

A decade ago, the crisis was much the same: Prescription drugs were the largest out-of-pocket expense for retirees, greater than doctors or hospitals. Right now, some 30% of Medicare beneficiaries spend between $2,000 and $4,000 of their own income on drugs annually. By 2005, most Americans over 65 will spend up to $4,000 annually—some $80 every week—on medications.

Thus, the heightened pressure for a drug coverage benefit under Medicare; but, after several months of rhetoric, Congress broke for Summer recess on Aug. 2, with all bills defeated in the Senate and a truly terrible Republican bill passed in the House. There is little hope for the issue to be resolved when Congress returns in September, as the differences are ideological. House and Senate Republican bills would have given sporadic coverage and allowed private insurance companies to run the program—this would essentially privatize this part of Medicare. The Democrats sought bills that would have made prescription drug coverage universal, and an integral part of Medicare, covering everyone.

The Infamous Republican 'Donut Hole'

On June 28, after using several underhanded tactics, House Republicans passed their bill (HR 4954) which would give private insurers the right to loot seniors blind. If made law, the bill would quickly become a negative "free market" lesson on the country's critical health care needs.

The GOP bill caters to the pharmaceutical industry, which paid a conservative front group $3 million to promote it. Seniors would pay $400 a year in premiums and spend $250 per year in drug costs (a deductible) before the benefits start. Of the next $250 to $1,000 a senior spends, 80% would be covered under the plan; 50% of the next $1,000 to $2,000 of drug costs would be covered. *Nothing at all* is covered for those patients—30% of all seniors—who spend between $2,000 up to $4,800 a year on medications. This is the "hole" in the

donut (seniors who spend more than $4,800 would have all drug costs covered).

By one estimate, if a Medicare patient spends $500 a year out of pocket, he'd have to pay $400 in premiums to get $200 in benefits under the Republican bill. If he spends $1,000 a year in drug costs, he'd have to pay the $400 premium cost to get $600 in benefits—a gain of only $200. Spend as much as $4,800 a year on medication, and the maximum net gain is only $700.

Private insurers shun prescription drug coverage since it is usually the sickest people who will use it the most. But, under this plan, those who run the program can increase premiums and deductibles; can pick and choose what geographic areas, if any, they will offer coverage—just like Medicare HMOs. Of course, if you are really ill, and can't get coverage through any other plan, there is no guarantee that insurers will sign you up at all.

The Democratic House bill called for government to cover 50% of annual costs of prescription drugs up to $4,000, and 100% of all costs above that. Medicare patients would pay a $25 monthly premium but have no deductible.

The original Senate Democratic bill, proposed by Bob Graham (D-Fla.) and Zell Miller (D-Ga.), was fought by the pharmaceutical lobby because it would have used the negotiating power of the huge Medicare program to bargain for lower drug prices from the drug companies. Medicare beneficiaries would have paid a $25 monthly premium with no deductible, and only a $10 co-payment for any generic drug. The government would cover 100% of beneficiaries' annual out-of-pocket prescription drug costs that exceed $4,000. Low-income seniors would pay reduced premiums and co-payments. The bill was defeated, 52 to 47.

The "tri-partisan" Senate bill, proposed by Senators Charles Grassley (R-Iowa), John Breaux (D-La.), and James Jeffords (I-Vt.), would have private insurers offer insurance plans to cover prescription costs. The insurers would be allowed to set their own premiums, and alter the co-payments and benefits proposed in the bill. Medicare beneficiaries would pay a $24 a month premium. After a one-time $300 deductible, the government would cover 50% of the beneficiaries' annual drug costs up to $3,450, and 90% of drug costs once annual out-of pocket drug spending exceeds $3,700. This was defeated 51-48.

In a 50-49 vote, the final compromise proposal in the furious battle, before Congress adjourned, was defeated in the Senate on July 31. The proposal, offered by Senators Bob Graham (D-Fla.) and Gordon Smith (R-Ore.), would have helped the very poor and those with catastrophic drug costs. About 39% of Medicare beneficiaries live at, or below, 200% of the Federal poverty level—200% equalling $17,720 for a single individual and $23,880 for a couple. Under the plan, beneficiaries in this catagory would have had their prescription drug costs completely covered by Medicare. Medicare would also cover the costs for drugs over $3,300 or more a year, with beneficiaries paying a $10 co-pay per prescription.

Move over, Enron, make way for Bristol-Myers Squibb. In the pharmaceuticals inflation crisis which pits the health of America's elderly against the highest-profit large industry of all, the 2002 Congress has proven unable to act, so far, to protect the general welfare.

What Did Pass the Senate

In a 78-21 vote, despite heavy pressure from the largest pharmaceutical companies, a three-part bill aimed at trimming prescription drug costs overall was passed in the Senate on July 31. The bill eliminates a loophole that major drug companies used, in the 1984 Hatch-Waxman law, that gives

them repeated, automatic patent extensions on name-brand products.

In the United States, when a pharmaceutical company finds a promising compound or drug, it gets a 20-year patent that starts the day it makes patent application. The patent ensures that pharmaceutical companies, which may invest as many as eight years of research into a drug, will get years of exclusive patent protection once the drug comes to market—assuring that they thoroughly recoup funding spent on research and development of the drug.

However, once the original patent for a brand-name drug is finally up, generic competitors can bring the same product to market at a much lower cost. But, major drug companies often "extend" their exclusive marketing rights to a drug by making incidental changes in it, thereby automatically receiving more years of patent protection. The new legislation would stop the automatic extended patents, known as "evergreening patents," and bring generics to market sooner.

This bill now goes to the House, where the drug company lobbyists promised the *New York Times* "herculean" efforts to keep it off the floor.

The 1984 Hatch-Waxman bill was once promoted as the way to cut drug costs by increasing competition in the marketplace. Nothing of the sort happened. Drugs prices escalated.

A second provision of that law ensures there is no competition to name-brand drug companies. Often, when a generic company is about to bring to market its generic substitute for a brand-name drug whose patent is about to expire, even as the loaded trucks are leaving the generic manufacturing plants, the major drug company files suit for patent infringement, and automatically gets a lucrative 30-month extension on its patent during the ensuing legal battle. The patent infringement charges are often ludicrous. In one case, a brand-name drug company filed suit because for a moment, while its cheaper, generic form was swallowed and absorbed in the stomach, it appeared to have the same molecular make-up as the name-brand drug.

That automatic 30-month patent extension, experts told *EIR*, does not exist in any other industrial or engineering patent process—only for pharmaceuticals. It goes into effect whether the brand-name company wins the case or not. And, the generic company, unable to bring its product to market for that time, loses many millions of dollars—even if it were found not to have impinged on the brand-name drug patent.

The new Senate bill will still allow drug makers to receive a 30-month patent extension—but only one. One attorney familiar with the field suggested, in addition, that the drug multi have to post a bond it would forfeit if it fails to block the generic drug in litigation—but this useful "teeth" feature was not included.

Complete Lack of Regulation

The bill would also prevent brand-name companies from paying off generic makers, to keep their cheaper drugs off the market. For instance, a class action suit was filed in state and Federal courts (for Federal anti-trust violations) against Zeneca, Inc., its successor AstraZeneca, PLC, the maker of tamoxifen—the most widely prescribed breast cancer drug—and Barr Laboratories, the sole distributor of the generic form of tamoxifen. The suit charged that Barr and Zeneca reached an illegal, confidential agreement that allows Zeneca to retain a monopoly over the manufacture, distribution, and sales of the drug.

There is little Food and Drug Administration regulation of these practices in the United States, or any other Federal agency oversight. In fact, as representatives of the U.S. Patent office told *EIR*, even when a drug company lists a whole series of frivolous patents (the color of a pill, a new container, the dosage size) in the FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations" (known as the "Orange Book"), the FDA does not investigate if there are abuses involved. FDA personnel claimed to *EIR* that that is the job of the U.S. Patent and Trademark Office. The U.S. Patent Office says it's the FDA's job. When the National Pharmaceutical Alliance, now part of the Generic Pharmaceutical Association, alerted the FDA in February 2000, to three dozen patent abuses by 16 major drug companies, the FDA never even responded.

The Federal Trade Commission (FTC) is about to release a report that charges that the brand-name pharmaceutical companies have used the loopholes in Hatch-Waxman Act to delay competition from generic companies. The FTC found eight cases where brand-name companies filed for numerous additional patents on original drugs, for which the companies had already received 30-month extensions on the original patents.

One expert suggested that perhaps one way to cut through this quagmire is that the CEO and other heads of pharmaceutical companies be forced to sign an affidavit stating that their new patent is legitimate. If it were then found not to be legitimate, the officers could be charged, jailed, fined, etc. We might not have enough jails.

Move Over, Enron

Aggressive lawsuits may also change this standard operating procedure of brand-name companies. In one case, a U.S. District Court ordered the FDA to approve a generic company's application to market its cheaper drug. The Boston-based Prescription Access Litigation Project (PAL), a coalition of 70 organizations in 30 states, along with 29 Attorneys General and the AARP (formerly known as the American Association of Retired People), filed Federal and state lawsuits against Bristol-Myers Squibb Co. for improperly submitting to the FDA a new patent which misrepresented to the FDA what the patent covers. Although this was a false patent, the Bristol-Myers' patent submission required the FDA to deny applications to other companies to market generic versions of BuSpar, the brand name of a widely prescribed anti-

anxiety medication. It's important to note, that any regulation to rein in these practices is strongly opposed by the Bush Administration. President Bush, repeating the major pharmaceutical drug industry line, says any regulation would stymie their research and development (R&D) efforts on new breakthrough drugs.

Mylan, the generic manufacturer, also sued the government and Bristol-Myers. On March 14, 2001, U.S. District Court Judge Ricardo M. Urbina agreed with Mylan, and ordered Bristol-Myers to request the FDA to delist its patent extension. The Court ordered the FDA to approve Mylan's application to market its generic BuSpar. On Feb. 14, 2002, a U.S. District Court ruled that Bristol-Myers Squibb acted improperly when it filed additional patents on its treatment BuSpar, to try to keep the generic companies from selling their product. The decision allowed the anti-trust lawsuits filed by 29 states and three generic companies to proceed.

The Securities and Exchange Commission is also investigating Bristol-Myers for offering improper incentives to wholesalers to load up on Bristol-Myers products, in an attempt to boost its sales to $1 billion in 2000.

There are at least 25 similar lawsuits in process against brand-name pharmaceutical companies, for illegal practices to monopolize the market. In one, PAL and plaintiffs allege that Schering-Plough, Upshier-Smith, and American Home Products Corporation conspired illegally to keep generic versions of the widely prescribed K-Dur 20, a potassium supplement, off the market.

Another, much-watched section of the Senate-passed bill will allow wholesalers, pharmacies and individuals to reimport pharmaceutical drugs approved by the FDA, from Canada. Since Canada purchases drugs at a discounted rate from U.S.- and Europe-based manufacturers, the costs of drugs are up to 80% cheaper than the same drugs sold in the United States. Some dispute the safety of such drugs, but because the chain of custody of a drug from the U.S. manufacturer to the Canadian supplier is strictly controlled, safety issues are said to be at a minimum.

State Discounts and Budget Crises

The third part of the Senate bill would allow states to use their bargaining power to negotiate deep Medicaid discounts on prescription drugs used for poor and disabled beneficiaries on the Federal-state Medicaid—assistance to the poor and disabled—health insurance program. The 50 states have been hit with a combined $50 billion revenue deficit for Fiscal 2002, and face worse for Fiscal 2003, because of the collapsing economy. Their Medicaid budgets have increased 25%, due to the increased costs of prescription drugs. States are passing legislation for such discounts and are following the test case of a Maine drug-discount law, which the Pharmaceutical Manufacturing and Research Association (PhMRA), the brand-name drug industry trade group, is contesting before the U.S. Supreme Court in the Fall.

But at the same time, state Medicaid programs are trying a myriad of murderous actions to balance their state budgets through cuts in the Medicaid program, such as requiring the poor and disabled to pay higher co-pays for their medications, which is often impossible.

Idaho would change its law so that Medicaid patients can't have more than four prescriptions at once without special approval (elderly patients and chronically ill patients often need over a dozen medications at a time). Nebraska is eliminating so-called "unnecessary and wasteful drugs." North Carolina is eliminating 30 medications that are deemed too expensive. West Virginia will let Medicaid patients have only approved (cheaper) medications on their lists of allowable drugs—despite doctors' orders. Mississippi, which says Medicaid "is a cancer on the state budget," will only allow patients to be on seven medications at once, and is increasing what Medicaid patients must pay to get them.

Short of general economic recovery measures, these budgets cannot be balanced—through human blood or otherwise. State governments will have to stop denying the reality of the collapse, and go for LaRouche's policy of Federal credit creation for both "hard" infrastructure building and "soft"—including health care. There is no other way, any longer, to ensure that those who need medications don't fall into chronic illness, or die, for lack of them.