

Generic drugs may be tested to insure safety

United Press International
WASHINGTON — Reminded of a 1937 prescription drug tragedy that killed more than 100 people, the Supreme Court has agreed to decide whether generic drugs must be fully tested before they are put on the market.

The justices Monday agreed to review a ruling the federal government claims would allow "potentially unsafe and ineffective" drug products to escape Food and Drug Administration inspection and go on sale to consumers.

A lower court found the FDA has no authority under current law to block the sale of generic drugs it has not approved.

The government will argue before the justices next fall that the FDA must be allowed to inspect all generic drugs, which are fast emerging as cheaper substitutes for brand-name products, to make sure they are safe.

It doesn't matter that the active drug agents copied by generic products already have been approved by the FDA, the government contends.

It was an inactive ingredient innocently added to prescription sulfa drugs that killed more than 100 people in 15 states in September and October 1937, it points out.

Finding sulfa pills were too big to be easily swallowed — especially by children — a chemist diluted the main ingredient for use in liquid form to fight bacterial infections, including sore throats. The product was called Elixir Sulfanilamide.

Only after a string of violent deaths was the liquid identified as diethylene glycol, a chemical now used in antifreeze.

It was the Elixir Sulfanilamide incident that spurred Congress in 1938 to pass the Food, Drug and Cosmetic Act requiring the FDA to inspect and approve new drug products before they can be marketed.

"It would be contrary to the clear congressional intent for courts to eliminate the requirement of pre-marketing safety review simply because another drug containing the same active ingredient has been proved safe and effective," the government argued in court documents.

Attacking the government's arguments, a Florida generic drug distributor claims the Elixir Sulfanilamide incident is not comparable to today's situation, which involves no claims that generic drug companies are using harmful additives.

The government has expressed a new worry that different ingredients in generic brands could change the quanti-

ty and speed in which active ingredients are transferred to a users' bloodstream.

Generix Drug Corp., which was sued after it started marketing products without FDA approval, says full government inspection of generic brands are needless, costly and time-consuming.

New book denounces humanism

Abortion big issue, author says

United Press International
Imagine Bible-believing Christians marching into the chambers of the Supreme Court and, like anti-war protesters of a decade ago at draft boards, sitting in to protest court rulings they find unconscionable.

Unimaginable? Not according to Francis A. Schaeffer, the influential evangelical author and lecturer. Schaeffer, in a new book aimed at rallying the evangelical constituency against humanism, holds that civil disobedience is a central part of Reformation theology and needs to be looked at again by Christians opposed to the secular trends in the United States.

The book, "A Christian Manifesto," denounces humanism and especially singles out the abortion as an "issue that is crucial for the future of the church in the United States."

Schaeffer, founder of L'Abri Fellowship, an international study center in Switzerland, is

the author of 22 books, many of them widely read in evangelical and fundamentalist circles. Most recently he co-authored, with

If there is no final place for civil disobedience, then the government has been made autonomous, and as such, it has been put in the place of the Living God — author Francis A. Schaeffer

Dr. C. Everett Koop, President Reagan's controversial assistant secretary for health, "Whatever Happened to the Human Race?", a strong attack on abortion.

As a "manifesto," Schaeffer's book tends to see the world in simple "us" against "them"

terms, with everyone who is not a biblical literalist being at least an unwitting ally of the humanists.

Secular humanists would argue his definition of them is committed to a view of humanity as only a collection of matter and energy.

And certainly a number of non-fundamentalist Protestant, Roman Catholic and Jewish believers find a different version of truth in their reading of the Bible and the Judeo-Christian tradition as "humanism in theological terms."

And a large number of both religious and non-religious people would take issue with his contention that his version of humanism "today controls the consensus in society, much of the media, much of what is taught in our schools, and much of the arbitrary law being produced by the various departments of government."

Manifestos, however, are meant to be provocative and Schaeffer's blunt prose and simplistic reading of history are certainly that.

In evangelical circles, where the book will get its widest reading, the provocation will come

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from Schaeffer's demand that civil disobedience be part of the conservative evangelical agenda

— thought that is abhorrent to most conservative believers.

"If there is no final place for civil disobedience, then the government has been made autonomous, and as such, it has been put in the place of the Living God," Schaeffer writes.

Civil disobedience, he says, "the bottom line" in the struggle against a state — in this U.S. federal government — has become controlled by humanism.

He uses the abortion issue as an example.

"To repeat: the bottom line is that at a certain point there is only the right, but the duty to disobey the state," Schaeffer said.

"State officials must know that we are serious about stopping abortion," he writes. "This may include doing such things as sit-ins in legislatures and courts, including the Supreme Court, when other constitutional means fail."

Warped



By Scott McCulloch

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Teamsters get raise; no more until '85

United Press International
WASHINGTON — The nearly 300,000 Teamsters union members covered by a nationwide trucking contract will receive a 40-cent-an-hour pay raise April 1, but that may be the last increase for some time.

The National Master Freight Agreement ratified by rank-and-file members Monday does not include a basic wage increase during the life of the pact — which expires March 31, 1985.

According to union spokesman F.C. "Duke" Zeller, the

members will get a cost-of-living adjustment on April 1 — under terms of the outgoing contract — that will boost their pay from an average \$12.80 per hour to \$13.20.

The only pay items in the new agreement with Trucking Management, Inc., the industry's bargaining arm, are two cost-of-living reviews on April 1, 1983 and April 1, 1984.

The pay will then be adjusted one cent for each 0.3 percentage point increase in the Consumer Price Index.

Despite the three-year freeze, Teamsters President Williams is hopeful the pact will restore jobs for laid-off drivers.

"Considering the economic problems facing the industry as well as the nation, I think we have done very well," Williams said in announcing the ratification.

"One hope is that agreement will get back to Teamsters who have been off their jobs."

Social Security plans to update computers

United Press International
WASHINGTON — Social Security officials announced plans Tuesday to spend \$478.5

million over five years to modernize the antiquated computer system that now makes getting out retirement benefit checks a daily miracle.

Social Security's computer system is up to three years behind in recording wage records and four years behind in computing benefits. It is perennially lagging in recording new claims applications and now faces a backlog of 120,000 hours of work.

"We have reached the point where we cannot afford to delay modernization efforts any longer," Commissioner John Svahn said. "We are now only marginally capable of performing critical program functions and continue to fall behind in processing existing workloads."

"The people who are run-

ning the system, and who are running it through the transition, are performing a miracle enabling us to get Social Security checks out month."

Svahn said the new system aimed at improving service with minimal disruption; reducing public confidence; improving data quality and timeliness and bettering staff effectiveness and productivity and technology.

Although new equipment needed, the first priority is development of better computer programs, he said.

Svahn blames inadequate equipment, plus low pay, for troubles attracting a quality staff. He told Congress in December he had 700 vacancies of a 2,600-person workforce.



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