

August 24, 2003

Congress Weighs Drug Comparisons

By ROBERT PEAR

WASHINGTON, Aug. 23 — Over fierce resistance from the drug industry, Congress is moving to authorize research that systematically compares the effectiveness and cost of top-selling prescription drugs.

Proponents say that if Medicare is to spend \$400 billion on new drug benefits over the next 10 years, it should have objective, reliable information about which medicines are most effective.

"Often there are a number of competing drugs to treat the same condition," said Senator Hillary Rodham Clinton, Democrat of New York, a leader of bipartisan efforts on the issue. "But which is more effective? Oftentimes we just do not know."

The House voted last month to provide \$12 million to the Public Health Service to conduct "research on the comparative effectiveness" of prescription drugs. The money was in an appropriations bill for the fiscal year that will begin on Oct. 1.

Drug companies say they fear that such studies will be used to restrict patients' access to medicines perceived as too expensive. But supporters of the research say it will improve the quality of care. Doctors, patients and insurers need help in making informed choices, said Representative Doug Bereuter, Republican of Nebraska.

Representative Nancy L. Johnson, Republican of Connecticut, said the proposal was "absolutely key to reducing the cost of drugs."

"There are many expensive products on the market that are no better than aspirin," said Mrs. Johnson, the chairwoman of the Ways and Means Subcommittee on Health. "We need to be able to demonstrate that and provide senior citizens and all Americans with that information so they can choose the most cost-effective, medically effective pharmaceutical for their particular needs."

Researchers said they might address questions like these: How does Lipitor stack up against Zocor for lowering cholesterol? How does Prilosec compare with Protonix for ulcers and heartburn? How do the long-term effects of Vioxx and Celebrex compare with those of older drugs for arthritis, like Motrin and Naprosyn?

Mrs. Clinton and Representatives Tom Allen, Democrat of Maine, and Jo Ann Emerson, Republican of Missouri, have proposed spending \$75 million on comparative studies by the National Institutes of Health and the federal Agency for Healthcare Research and Quality. The studies would focus on drugs widely used by Medicare and Medicaid beneficiaries.

Mr. Allen said, "Our proposal would ensure that doctors and patients have credible, unbiased

information, as an antidote to the claims made in so many pharmaceutical TV commercials."

But Bruce Lott, a spokesman for the Pharmaceutical Research and Manufacturers of America, the main lobby for brand-name drug companies, said they had many reasons for resisting the proposal.

In a memorandum to members of Congress, the trade group said: "Cost-effectiveness analysis in the private sector can provide useful information. When employed by centralized decision makers, however, it often becomes just another term for health care rationing."

With studies comparing various drugs, federal officials could make "simplistic, one-size-fits-all decisions about which patients should have access to new medicines," the industry said.

The Pharmaceutical Research and Manufacturers of America also made these arguments:

¶The federal studies would almost surely influence private insurers. "As a result, the government's cost-based decisions about medical access would be imposed on many patients in both public and private health plans."

¶Cost-effectiveness studies show which drug works best, on average, for large numbers of patients, but the studies often overlook the value of specific medicines for individuals or subgroups, like racial minorities. "Different people need different medicines" because they respond differently.

¶Federal studies could stymie "incremental innovation." The government often does not appreciate the value of the incremental benefits of a new drug over existing treatments, but a series of modest gains can produce a major improvement — a much safer, more effective medicine.

Private insurers and health plans evaluate and compare drugs all the time. The Department of Defense, which provides health care to more than eight million people, has a team of experts who continually assess the clinical effectiveness and cost-effectiveness of drugs.

"`Cost-effective' does not equal `cheap,'" said Dr. Joseph C. Torkildson, director of clinical operations at the department's Pharmacoeconomic Center, at Fort Sam Houston, Tex.

The military experts often discourage use of a drug that is more costly but no more effective than other medicines. On the other hand, Dr. Torkildson said, "the cost of very effective therapy may be high but justified."

Consumer groups like Consumers Union and Families USA support the proposal for comparative federal studies.

Gail E. Shearer, a health policy expert at Consumers Union, said drug companies were resisting the legislation because it threatened sales of their less effective products.

"These studies would provide objective scientific evidence, freeing consumers from reliance on biased advertising and reducing doctors' reliance on marketing information from the pharmaceutical industry," Ms. Shearer said.

The proposal also has support from Rx Health Value, a coalition of employers, patients and insurers that includes AARP, the A.F.L.-C.I.O., General Motors, Kaiser Permanente and the American Academy of Family Physicians.

Dr. Robert M. Califf, director of the Clinical Research Institute at Duke University, said he understood the drug companies' concerns. But, Dr. Califf said, doctors and patients desperately need information from "head-to-head clinical trials to determine if one treatment is better than another."

The Food and Drug Administration can approve a drug if it is safe and effective for its intended use, but does not usually ask whether the drug is "safer and more effective than the alternatives," he said.

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