May 10, 2007
Senators who weakened drug bill got millions from industry
By Ken Dilanian, USA TODAY
WASHINGTON — Senators who raised millions of dollars in campaign donations from pharmaceutical interests secured industry-friendly changes to a landmark drug-safety bill, according to public records and interviews.
The bill, which passed 93-1, grants the Food and Drug Administration broad new authority to monitor the safety of drugs after they are approved. It addressed some shortcomings that allowed the painkiller Vioxx to stay on the market for years after initial signs that it could cause heart attacks.

However, the powers granted to the FDA in the bill's original version were pared back during private meetings. And efforts to curb conflicts of interest among FDA advisers and allow consumers to buy cheaper drugs from other countries were defeated in close votes.

• A measure that blocked an effort to allow drug importation passed, 49-40. The 49 senators who voted against drug importation received about $5 million from industry executives and political action committees since 2001 — nearly three quarters of the industry donations to current members of the Senate, according to a USA TODAY analysis of data compiled by two non-partisan groups, Center for Responsive Politics and PoliticalMoneyLine.

• Sen. Pat Roberts, R-Kan., said he demanded removal of language that would have allowed the FDA to ban advertising of high-risk drugs for two years because it would restrict free speech. Roberts has raised $18,000 from drug interests so far this year, records show, and $66,000 since 2001. His spokeswoman, Sarah Little, said he "takes great pains to keep fundraising and official actions separate."

• Sen. Judd Gregg, R-N.H., claimed authorship of a change that reduced the FDA's power to require post-market safety studies. He said he wanted to target drugs only if there was evidence of harm.

Gregg has raised $168,500 from drug executives and PACs since 2001 and sided with them in four key votes.

• The bill's chief sponsors — Sens. Edward Kennedy, D-Mass., and Mike Enzi, R-Wyo., — agreed after consultations with industry officials and others to modify a proposal that all clinical drug studies be made public, said Craig Orfield, Enzi's spokesman. Under the change, only those studies submitted to the FDA would be available.

Enzi took in $174,000 from drug interests since 2001; Kennedy, $78,000. Their spokesmen said the money did not influence them.

Senators also voted down an amendment that would have made it harder for scientists who have accepted money from a drug company to advise the FDA on drug approval applications from that firm.

"It's not that money buys votes," said Sen. Bernie Sanders, I-Vt., the lone vote against the bill. "But you have a culture in which big money has significant influence. Big money gains you access, access gives you the time to influence people."

Orfield, Enzi's spokesman, said compromise is necessary in the Senate, where 60 votes are needed to overcome any single senator's objection. "Our objective is to get something that can pass," he said.

The pharmaceutical companies spend more money on lobbying than any other single industry — $855 million from 1998 to 2006, according to the non-partisan Center for Public Integrity.

"I don't think there is any lobbying group in town that has the clout of the drug industry," said Ron Pollack, director of Families USA, a left-leaning consumer advocacy group.

The biggest drug trade group, Pharmaceutical Research and Manufacturers of America, praised the bill after it passed. The group's spokesman, Ken Johnson, said its critics "never point out that a great

deal of this money is spent trying to defeat bills … that are designed to cripple this industry."

The bill, which now goes to the House, was based in part on the recommendations of a report by the Institute of Medicine, a division of the National Academy of Sciences. The Institute was asked by the FDA to examine drug safety in the wake of the scandal over Vioxx, which Merck withdrew from the market in 2004 amid evidence that the drug put users at increased risk for heart attack and stroke.

The report offered two dozen recommendations for improvement. Chief among those was that Congress should grant FDA the power to require a system of post-market surveillance, which the Senate bill would do. But two other key recommendations were not followed in the measure: That FDA should have the power to ban consumer advertising for the first two years of a drug's market life; and that FDA scientists who investigate post-market side effects should work in an office separate from those that approve drugs initially.

The bill "does not sufficiently address the underlying problems," said Sen. Chuck Grassley, R-Iowa, who in recent years held hearings featuring FDA whistle-blowers who said their concerns about drug safety were ignored.