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## Threats to critics of Vioxx alleged

**Academics and doctors who spoke against the drug, which was recalled later, say a Merck executive leaned on them.**

**By Thomas Ginsberg**  
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One day in 2000 after lecturing about risks of the pain-reliever Vioxx, Harvard University professor Lee Simon got a call that shocked him.

It was from Louis M. Sherwood, then a senior vice president at Merck & Co. Inc., maker of Vioxx. Based in West Point, Montgomery County, Sherwood challenged Simon's view - later proved correct - that Vioxx could cause more strokes than a rival drug.

Sherwood didn't stop there. He said "he would hurt my career if I continued to lecture," Simon recalled. "I was astonished."

Sherwood's warning, said Simon and others allegedly also threatened, went beyond anything they had experienced before from drug companies trying to woo researchers and physicians to endorse and prescribe their products.

Today, Sherwood, 68, of Lower Gwynedd, is a figure in the worldwide legal fallout over Vioxx, the blockbuster drug whose recall rattled the industry and raised questions about drug regulation and safety.

Sherwood, an esteemed administrator and community benefactor, declined to be interviewed for this article. He and his role in the Vioxx saga provide a glimpse into the hard-nosed scientific debates and financial tensions with academia that can arise when a drugmaker sets its sights on huge profit.

Merck voluntarily recalled Vioxx on Sept. 30 after its own studies confirmed Vioxx's risks. Now the company faces thousands of lawsuits. Internal documents and e-mails submitted in one New Jersey fraud case show how Merck systematically tried to win over drug experts before and after Vioxx was launched in 1999.

While many drug companies undertake such efforts, the lawsuit alleges that Merck executives, including Sherwood, sought to "silence and intimidate critics of Vioxx" by questioning their objectivity, withdrawing their funding, or both.

Merck in court has defended its actions. In a statement, it denied intentional wrongdoing.

"We do not have and have never had the intent to intimidate nor retaliate," Merck said. "Consistent with [the] spirit of scientific debate, we believe we have the right to express our views when we believe information others have presented is not fair and balanced."

But outside researchers interviewed by The Inquirer said Merck had privately acknowledged to them that Sherwood and others acted improperly and had tried to distance itself from their tactics, evidently hoping to repair relations with experts whose assessments were key to Vioxx sales.

Sherwood's lawyer, Mark A. Berman, said Sherwood "did not set out to intimidate other doctors. He was a vigorous advocate for Merck and for full, open and balanced discussion of the issues."

Berman declined to comment on Merck's effort to distance itself from Sherwood's tactics.

Sherwood's Vioxx work, and Merck's subsequent apology for it, still mystifies some researchers about the man respected in both industry and academia.

"I always thought Lou was the epitome of an upstanding guy, smart and well-respected," said Simon, who said he lost a promotion and left Harvard after Sherwood called his superior. "It was pretty amazing. I had never heard of a company doing that before."

Louis Maier Sherwood, born in New York City during the Depression, spent 26 years in academia before moving to suburban Philadelphia in 1987 to work at Merck, then the world's biggest drugmaker.

People in academia sometimes deride industry as "the dark side" because of its financial motives. Sherwood earned accolades from both worlds: At retirement in March 2002, he was given two lifetime achievement awards, one from industry physicians and one from medical-school professors.

"He is dedicated to the community, to his synagogue, and is very charitable," said Roberta Matz, director of the Bucks-Montgomery region of the Jewish Federation of Greater Philadelphia, on whose board Sherwood serves.

In 1998, Merck's then-chief executive Raymond V. Gilmartin made a personal appearance at a Boston ceremony honoring Sherwood, saying: "We are fortunate and proud that you are with us at Merck," according to a text of the speech.

As senior vice president for medical and scientific affairs, Sherwood was, among other things, liaison to the nation's researchers and physicians, who can make or break a drug by recommending or rejecting it for patients and insurance-benefit plans.

From his office in Building 39 on Merck's West Point campus, Sherwood regularly communicated with many people in the medical community about dozens of Merck products, with no sign of controversy like the one around Vioxx.

To cultivate experts for their products, drug companies often donate to medical schools, finance research, and sponsor conferences, in addition to paying for clinical trials. Each institution has its own guidelines on whether to accept such financial support.

Companies dangle or withdraw the money at any time, but using it expressly to influence a researcher's opinion is considered by academicians a violation of open scientific debate.

In this environment, Merck and G.D. Searle & Co. - later acquired by Pfizer Inc. - went to battle in 1999 over the multibillion-dollar market in pain relievers called Cox-2 inhibitors. Corporate money quickly tinged the scientific debate by casting researchers as protagonists for one product or another.

Vioxx and Celebrex, a Cox-2 inhibitor that is still on the market, were designed to cause fewer stomach problems than traditional pain-relievers. But after a flurry of positive studies, some researchers began expressing concern that Vioxx could cause cardiovascular, hypertension or kidney problems, and wanted more data from Merck.

One skeptic was M. Thomas Stillman, a professor at University of Minnesota Medical School and a director at the Hennepin County Medical Center.

He had questioned Vioxx's safety at conferences sponsored by Pfizer, Merck and others. In one e-mail, a Merck sales executive described Stillman as a "vocal adversary of Merck and Vioxx" who was stifling sales in Minnesota.

Sherwood and his staff tried in vain to change Stillman's mind. In a June 2000 memo, Sherwood told other Merck executives that he had complained to Stillman's boss. The same month, according to a separate letter, Sherwood persuaded the Minneapolis VA Medical Center to remove Stillman's "unfavorable" review of Vioxx from educational programs.

In response, Stillman wrote Sherwood and accused Merck of "inappropriate censorship" by withdrawing funding for some of his presentations.

Two years later, after Sherwood retired, his successor, John Yates, called to apologize. "He said it could've been better handled," Stillman recalled. "Then one or two Merck people actually came out and apologized."

Yates, now president of global research and development at Takeda Pharmaceuticals North America Inc. in Chicago, declined to be interviewed.

Simon, the former Harvard professor who had received consulting and speaking fees from both Merck and Searle, said Sherwood called him and his boss alleging he was biased against Vioxx - an assertion Simon denied.

"No specific action was taken against me. But there was a reputational issue," said Simon, who moved to the U.S. Food and Drug Administration and now works at the Boston-based consulting firm MEDACorp.

His boss at Harvard, Steven Weinberger, now a vice president at the American College of Physicians in Philadelphia, confirmed getting Sherwood's call but said it "had nothing to do" with Simon's promotion.

"Lou Sherwood was not at all threatening me," Weinberger said, adding that he had skipped over Simon because of unrelated questions about his record running the school's graduate medical-education program.

Nonetheless, Yates contacted Simon in 2002 and said Sherwood's behavior "would never happen again, that it was unnecessary, that it was not the behavior of Merck," according to Simon.

Gurkirpal Singh, an arthritis expert at Stanford University, who had received funds from both Merck and Pfizer, had raised questions in lectures about Vioxx and suggested data was being hidden.

On Oct. 4, 2000, a Merck memo to Sherwood listed Singh's presentations and background, beginning with the line: "Perceived as an advocate for Searle." It was a description Singh rejected in an interview. The memo also said Merck, in reaction, barred Singh from Merck-sponsored conferences in the western United States, leading to conference cancellations.

Three weeks later, Sherwood telephoned Stanford professor James F. Fries - Singh's boss - at home. Sherwood said Singh was "anti-Vioxx" and "suggested that if this continued, Dr. Singh would 'flame out,' and there would be consequences for myself and for Stanford," according to a letter Fries later wrote to Merck.

In an interview, Fries, who noted he takes no money from drug companies, said he interpreted Sherwood's call as "a veiled threat. There wasn't anything he could do to me personally, although I suppose there may be funding" from Merck to Stanford.

The Stanford medical school confirmed it has received Merck money.

In January 2001, Fries sent a four-page letter to Gilmartin citing Sherwood and accusing Merck of using "damage-control by intimidation."

He cited Singh, Simon and Stillman and five other researchers. Two of them, former Arthritis Institute director Peter Lipsky and Johns Hopkins University professor Andrew Whelton, said in interviews that they had heard of Merck complaints about their work, but had never felt threatened nor had gotten calls from Sherwood. Three did not respond to interview requests.

Responding to the letter, Gilmartin told Fries he took the charges seriously and had ordered officials to "look into the situation," Fries recalled.

Within days, Fries got a call from David Anstice, then president of Merck's Human Health-Americas division in West Point. Anstice characterized the flap as a "loose-cannon issue" that was not the norm at Merck and promised to take action, according to Fries' paraphrasing of their conversation.

Later, Singh said Anstice took him to dinner during a conference in California and tried to disavow Sherwood's actions.

Anstice said he "was not aware of Sherwood doing these things, because he was a senior person and didn't know what everybody did," Singh recalled. "He said he would have stopped it if he knew. And then he did stop it."

Anstice declined to be interviewed. He also has been named in the lawsuits.

Sherwood never contacted the researchers or their bosses again, they said.

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