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Groups Question Doctors' Ties to Drug Firms

Federal cholesterol guidelines promoted by physicians paid by private companies prompt conflict concerns

by Marilynn Marchione

They led influential medical groups, starred at prestigious meetings, published in top journals and were undisputed giants in their field. But when these famous doctors advised the government recently on new cholesterol guidelines for the public, something else they had in common wasn't revealed.

Eight of the nine were making money from the very companies whose cholesterol-lowering drugs they were urging upon millions more Americans. Two own stock in them. Two others went to work for drug companies shortly after working on the guidelines. Another was a senior government scientist who moonlights for 10 companies and even serves on one of their boards.

Consumer groups and others now are questioning not only the advice these doctors gave but also their fundamental ability to act in the public's best interest.

It comes as some of these companies lobby the government to let drugs at the center of this controversy — statins such as Lipitor and Zocor — be sold over the counter. Prominent doctors with ties to statin makers are urging approval.

There's little doubt that statins save lives or that too few people take them now. But critics say the doctors' coziness with drug companies compromises their credibility and undercuts their latest advice that more people would benefit from these medications.

Conflicts of interest are increasingly common now that two-thirds of medical research at universities is funded by private industry. Twenty years ago, only one-third was.

"The government is not producing drugs. All the big statin trials have been paid for by the companies," said Dr. Scott Grundy, a University of Texas Southwestern Medical Center cardiologist who headed the cholesterol panel.

Government has its own problems. A ban on private consulting was lifted a decade ago, and recent years have seen one scandal after another involving federal scientists taking money from companies directly affected by their decisions.

Conflicts also have bedeviled trusted groups like the American Heart Association, which rely on private cash for meetings and activities, and the continuing medical education system, which often gives doctors credits for attending drug-company-sponsored talks.

The drug industry spent $2 billion in 2001 on events for doctors — double what it spent five years earlier, Dr. Jerome Kassirer, former editor-in-chief of the New England Journal of Medicine, reports in his new book, "On the Take."

"The time has come to ask whether all of the money floating around medicine has created a pattern of corruption," he writes.

Some say it's naive to think a panel of true experts with no industry ties could be assembled today.

Christopher Seymour, executive director of the National Lipid Association, a group that promotes cholesterol control and is largely funded by drug companies, has six of the nine guideline doctors on his board.

"Who in America is going to write these guidelines if you don't go to the thought leaders? Should I call Dr. X in the middle of Peoria? What gives them credentials to be on my board?" he asked.

But at the University of Illinois in Peoria, they think quite a lot of Dr. Frank Gold, who in 30 years as a cardiologist has taken no consulting or lecture fees from industry.

"I'm squeaky-clean," he says, and "would jump at the opportunity" to serve on a guidelines panel. "There are tons of people like me, and they're even in places like Des Moines, Iowa."

The statin flap involves drugs with so much science behind them and proven benefits that doctors only partly joke about putting them in the water supply.

More than half of American adults have high cholesterol, raising their risk of heart attack. Doctors tell them to eat right and exercise, but that usually produces only modest improvement. Statins drop cholesterol dramatically and almost overnight.

The government's National Cholesterol Education Program periodically asks experts to help set cholesterol guidelines, and rules issued in 2001 advocate using statins to curb it.

New studies prompted a new panel to be convened to revise the guidelines. Seven of its nine members had been on the previous one. The newcomers — Dr. Sidney C. Smith of the University of North Carolina in Chapel Hill and Dr. C. Noel Bairey Merz of Cedars-Sinai Medical Center in Los Angeles — represented the heart association and the American College of Cardiology, respectively.

These groups in July endorsed and published the new guidelines. A day later, the Center for Science in the Public Interest said the advice was tainted by doctors' industry ties, which weren't disclosed. They ranged from long-ago research grants to stock ownership and deals providing thousands of dollars in income from statin makers.

The most complicated situation is that of Dr. H. Bryan Brewer, chief of the molecular disease branch of the National Heart, Lung and Blood Institute, which houses the federal cholesterol program.

He is on the scientific advisory board of Lipid Sciences Inc., a private biotechnology firm developing cholesterol treatments, and Seymour's National Lipid Association. He also is a consultant or speaker for 10 companies, and even attended a meeting in July 2003 of a federal Food and Drug Administration advisory committee debating whether to recommend approval of Crestor, a statin made by one of them — AstraZeneca.

The meeting was on a Thursday, and it couldn't be determined whether Brewer was there on government time. He refused requests for an interview. In a memo to National Institutes of Health director Dr. Elias Zerhouni, Brewer wrote that he was "only an observer and did not participate" in the meeting, which led to the drug's approval a month later.

Some guideline panel members talk candidly about their industry ties. Grundy said he makes less than $10,000 a year in speaker fees and refuses to promote a particular drug in a talk.

Dr. Neil J. Stone of Northwestern University Medical School in Chicago, said he takes speaker fees when a talk forces him to miss work and often donates them to universities.

Smith said he owns about $10,000 in stock in Johnson & Johnson, which has partnered with Merck & Co. to sell a statin over the counter in England.

"I didn't even know I had it till I called the fellow that handles the accounts," Smith said. "Nobody volunteers time for one of these committees because they think a small amount of stock they may have in a retirement plan is going to benefit."

Bairey Merz listed stock in Johnson & Johnson plus consulting, lecture or research money from nine, including several statin-makers. She declined to be interviewed but said in a brief statement that she had not breached any ethics rules.

Efforts to interview three other panel members — Dr. Luther T. Clark of State University of New York Downstate Medical Center in Brooklyn, Dr. Donald B. Hunninghake of the University of Minnesota in Minneapolis, and Dr. Richard C. Pasternak of Massachusetts General and Harvard Medical School in Boston — were unsuccessful. Multiple requests to interview Clark and Pasternak were not answered by spokesmen; Hunninghake could not be located through the university.

Hunninghake quit before the guidelines were released to become a full-time industry consultant, according to the cholesterol program. Pasternak joined Merck soon after the guidelines came out.

Financial conflicts aren't the only danger. "Group think" can set in when a panel doesn't include people who can look at the science with different views than cardiologists.

"These folks made their careers on being aggressive on treating risk factors," but internal medicine doctors might feel differently, said Dr. Harlan Krumholz, who runs a center for medical outcomes research at Yale University.

Indeed, many doctors making the case for statins helped establish their effectiveness.

"Most of us did all the original trials of the statins," said Stone, who was motivated by family members dying of heart disease, including his father in 1985.

"He never got a chance to get a statin," Stone said. "I'm actually stunned that people who know the evidence don't see the enormous value of this class of drugs."

The only panel member with no financial conflicts — the federal program's coordinator, Dr. James Cleeman — is upset by attacks on the guidelines like the letter signed by 35 scientists and doctors asking NIH to launch an independent review.

"They are science-based," Cleeman said. "The public should have confidence in them. I'm an unconflicted person, and I read the science the same way."

On the Net:

Center for Science in the Public Interest database on doctor conflicts:
http://www.cspinet.org/integrity/index.html

National Cholesterol Education Program's guidelines:

http://www.nhlbi.nih.gov/guidelines/cholesterol/

Disclosures by guideline panel members:

http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04_disclose.htm

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