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Unease on Industry's Role in Hypertension Debate

By STEPHANIE SAUL

Three pharmaceutical companies donated $700,000 to a medical society that used most of the money on a series of dinner lectures last year to brief doctors on the latest news about high blood pressure.

The same three companies — Merck, Novartis and Sankyo — also gave the money that the medical society used to formulate the main talking point of those briefings, an expanded concept of high blood pressure that many doctors say would increase the number of people taking drugs.

The seven dinners at Ruth's Chris Steak Houses around the country are just one example of why the small medical society, the American Society of Hypertension, has been in the midst of a dispute over the influence of drug industry money.

"This is about the monetarization of medicine," Dr. Michael H. Alderman, a past president of the organization, said in a recent interview.

The dinners promoting a new definition of high blood pressure illustrate connections — among the pharmaceutical industry, academic physicians and societies that formulate opinion — that can ultimately affect patient treatment. And the dispute within the society reflects a growing unease that industry money is influencing scientific discourse in medical societies and elsewhere.

At a recent speech before another society, the American College of Cardiology, its new president, Dr. Steven E. Nissen of the Cleveland Clinic, suggested that the medical profession had become addicted to industry money just as the nation was addicted to foreign oil.

After months of controversy within the American Society of Hypertension that included accusations of industry influence, the society's president, Dr. Thomas D. Giles, said yesterday that the group's leadership would be required to disclose more details about the money they receive from industry.

Dr. Giles said the organization had always maintained a firewall between its activities and industry funding. "We don't take money that has strings attached to it," Dr. Giles said, emphasizing that its industry grants are not earmarked for any specific purpose.
The added disclosure had been sought by a board member, Jean E. Sealey, a biochemist and a longtime blood pressure researcher affiliated with Weill Medical College of Cornell University, who was among those also involved in a leadership struggle within the organization.

Dr. Alderman, a professor of medicine and epidemiology at the Albert Einstein College of Medicine in the Bronx, is one of several doctors who withdrew from a group formed by the society to write the new blood pressure definition.

He complained that the definition was derived from a hodgepodge of opinions not supported by hard science, and also questioned whether the society of 1,600 could insulate itself from the drug company donations it used to operate.

Controlling blood pressure has long been a mainstay of the pharmaceutical industry. About 65 million Americans have high blood pressure under the current definition and they help fuel a $17 billion annual market in drugs for hypertension. But another 59 million people are on the borderline, and many doctors believe the new definition of hypertension could make drugs a standard treatment for many of them, drastically expanding the potential drug market.

Dr. Giles of Louisiana State University's medical school in New Orleans was the driving force behind the new definition. The work of the group that developed it was financed by $75,000 in unrestricted drug industry grants from Merck, Novartis and Sankyo, according to Susan Rood, a spokeswoman for the Society of Hypertension. Ms. Rood also confirmed that the dinners were financed by $700,000 in grants, also unrestricted, from the same companies. The new definition that resulted was written by some of the leading experts in blood pressure medicine.

Pre-hypertension has been considered a blood pressure reading of 120/80 to 139/89, according to guidelines developed by a National Institutes of Health panel, which first identified the pre-hypertension category in 2003. Currently, pre-hypertension is generally not treated with drugs.

The new definition proposes assigning some of the people with pre-hypertension to a new category called Stage 1 hypertension. Hypertension is currently defined as blood pressure readings of 140/90 and above.

Dr. Giles estimated that the proposed definition would move half of those whose blood pressure readings are currently considered pre-hypertension to the Stage 1 hypertension category.

That determination would be based not just on their blood pressure readings, but also on other risk factors.

The proposed definition makes no specific treatment recommendations. But some specialists who have read the proposed definition say it is a short step from labeling someone with high blood pressure to prescribing pills. And
they predict that if the new definition is embraced, it will expand the use of medications.

Dr. Curt D. Furberg, a professor of public health science at Wake Forest University, who was among those who withdrew from the writing group, citing concerns that its work was not evidence-based, said, "The industry wants to sell drugs and to as many people as possible."

But Dr. Giles said it was possible that the use of medication could actually contract under the new definition, with some doctors recommending lifestyle modifications rather than medication. And he said industry money or influence did not play a role in the proposed definition, which he said reflected a concern that too many people with diagnoses of pre-hypertension ended up having strokes.

"I will tell you that if you've ever sat there and watched patients in the prime of life get a stroke or a heart attack, it's heart-wrenching," Dr. Giles said last week.

The recommendations by Dr. Giles and his group are considered influential in the evolving thinking over what constitutes high blood pressure. In addition, the discussion about whose blood pressure should be treated is also being driven by a new study that concluded that a drug called Atacand by AstraZeneca could reduce the risk that people with pre-hypertension will develop hypertension.

Treating pre-hypertension was among the topics at a meeting this week of the society at the New York Hilton. The meeting ends today.

The debate is in some ways similar to questions about changing thresholds for defining high cholesterol, diabetes and obesity — areas where accusations have been leveled in the past that the pharmaceutical industry has tried to exert influence.

"All of this has got the ring of seeming to be of great benefit to the pharmaceutical industry without clear evidence that it's going to be the same benefit to the public," Dr. Alderman said recently.

In statements, spokeswomen for Merck and Novartis confirmed that their companies had helped finance the society's work, but said that they had no influence over the outcome of the new definition or the content of the dinner briefings held last fall in seven cities.

Sankyo did not return calls seeking comment.

Of the seven doctors who wrote the proposed new definition, six have said that they served as consultants and speakers for pharmaceutical companies that make blood pressure medications. The seventh is a consultant and stockholder in a company that markets a diagnostic method to measure damage to blood vessels.

Such industry affiliations are not unusual among prominent doctors at academic research centers. And for years,
the American Society of Hypertension, known as ASH, has operated with industry support.

But some members of ASH have become vocal critics of the influence wielded by the drug industry, including the person who was next in line to become the society's president, Dr. Sealey, who has been embroiled in a longstanding dispute with the organization's current leadership over that and other issues.

"The truth of the matter is that we have many members who are leaders in our society who are making well into the six figures from their pharmaceutical-company-supported activities," Dr. Sealey, a research biochemist and physiologist, said in an interview two weeks ago.

But many members of the society have taken umbrage at suggestions that their work for drug makers affects their scientific independence.

"There are those who accuse us of being nothing more than shills of industry; a lot of us take pretty great offense at that," said Dr. Joseph L. Izzo, a professor of medicine at the University of Buffalo who was part of the group that developed the new definition. "We've basically devoted our careers to researching this disease and how to treat it."

Dr. Sealey's assertions had fueled dissension within the society and were among the reasons that a vote to block her presidency had been expected at yesterday's business meeting of the society.

Instead, an agreement was forged under which Dr. Sealey gave up her term as president and, according to written statements circulated among those attending the meeting, the organization's leadership agreed that its board would soon submit detailed financial disclosure forms, which Dr. Giles said had been in development for more than a year.

Dr. Giles said those disclosures would go beyond the affiliations that were currently disclosed and would require leaders of the group to state how much they received, in broad categories.