March 26, 2008

Cigarette Company Paid for Lung Cancer Study

By GARDINER HARRIS

In October 2006, Dr. Claudia Henschke of Weill Cornell Medical College jolted the cancer world with a study saying that 80 percent of lung cancer deaths could be prevented through widespread use of CT scans.

Small print at the end of the study, published in The New England Journal of Medicine, noted that it had been financed in part by a little-known charity called the Foundation for Lung Cancer: Early Detection, Prevention & Treatment. A review of tax records by The New York Times shows that the foundation was underwritten almost entirely by $3.6 million in grants from the parent company of the Liggett Group, maker of Liggett Select, Eve, Grand Prix, Quest and Pyramid cigarette brands.

The foundation got four grants from the Vector Group, Liggett’s parent, from 2000 to 2003.

Dr. Jeffrey M. Drazen, editor in chief of the medical journal, said he was surprised. “In the seven years that I’ve been here, we have never knowingly published anything supported by” a cigarette maker, Dr. Drazen said.

An increasing number of universities do not accept grants from cigarette makers, and a growing awareness of the influence that companies can have over research outcomes, even when donations are at arm’s length, has led nearly all medical journals and associations to demand that researchers accurately disclose financing sources.

Dr. Henschke was the foundation president, and her longtime collaborator, Dr. David Yankelevitz, was its secretary-treasurer. Dr. Antonio Gotto, dean of Weill Cornell, and Arthur J. Mahon, vice chairman of the college board of overseers, were directors.
Vector issued a press release on Dec. 4, 2000, saying that it intended to give $2.4 million to Weill Cornell to finance Dr. Henschke’s research. Articles in Business Week and USA Today mentioned the gift. No mention was made of the foundation, begun so hastily that its 2000 tax return stated “not yet organized.”

Paul Caminiti, a Vector spokesman, confirmed that the company donated $3.6 million to the foundation over three years. The company “had no control or influence over the research,” he said.

Prominent cancer researchers and journal editors, told of the foundation by The Times, said they were stunned to learn of Dr. Henschke’s association with Liggett. Cigarette makers are so reviled among cancer advocates and researchers that any association with the industry can taint researchers and bar their work from being published.

“If you’re using blood money, you need to tell people you’re using blood money,” said Dr. Otis Brawley, chief medical officer of the American Cancer Society. The society gave Dr. Henschke more than $100,000 in grants from 2004 to 2007, money it would not have provided had it known of Liggett’s grants, Dr. Brawley said.

In an e-mail message, Drs. Henschke and Yankelevitz wrote, “It seems clear that you are trying to suggest that Cornell was trying to conceal this gift, which is entirely false.”

“The gift was announced publicly, the advocacy and public health community knew about it, it is quite easy to look it up on the Internet, its board has independent Cornell faculty on it, and it was fully disclosed to grant funding organizations,” they wrote, adding that the Vector grant represented a small part of the study’s overall cost. The foundation no longer accepts grants from tobacco companies, they wrote.

In the Vector press release, Dr. Henschke was quoted as saying that, thanks to the Vector grants, “we have raised the initial funding needed to support this important research and data collection on the effectiveness of spiral CT screening.”

Dr. Gotto said in an interview that Dr. Henschke, Dr. Yankelevitz and another colleague set up the foundation initially without the university’s approval, which he said faculty members are allowed to do. He and Mr. Mahon joined the board some weeks or months after its creation to ensure that the Vector grants were handled correctly, he said.
“If we had been approached, we would not have set up the foundation,” Dr. Gotto said. “We would have accepted the gift directly. We think we behaved honorably. There was no attempt to set up a foundation to hide tobacco money.”

Days earlier, Andrew Ben Ami, assistant secretary of the foundation, said in an interview he would not disclose the source of the charity’s financing at the request of the university.

In another interview before Dr. Gotto agreed to speak, Mr. Mahon, another foundation director, said he did not know the source of the funds.

Dr. Robert C. Young, chancellor of the Fox Chase Cancer Center in Philadelphia and chairman of the Board of Scientific Advisors of the National Cancer Institute, said he had never heard of the Vector grants. “As someone who really hung around the inner sanctum of cancer research, I have never heard anybody — anybody — ever say anything about this,” Dr. Young said.

Dr. Jerome Kassirer, a former editor of The New England Journal of Medicine and the author of a book about conflicts of interest, said he believed that Weill Cornell had created the foundation to hide its receipt of money from a cigarette company. “You have to ask yourself the question, ‘Why did the tobacco company want to support her research?’ ” Dr. Kassirer said. “They want to show that lung cancer is not so bad as everybody thinks because screening can save people; and that’s outrageous.”

Dr. Henschke’s work, while controversial among cancer researchers, has been embraced by many lung-cancer advocacy organizations, which have pushed for legislation in California, New York and Massachusetts to create trust funds to pay for lung cancer screening — often with language tailored to benefit Dr. Henschke’s group.

In New York, a bill would create a $10 million fund “to carry out lung cancer early detection research using computer tomography (CT) scanning” at a place “that was established by the multi-institutional, multi-disciplinary research program that began at 22 sites in the state in the year 1991,” a description that could only fit Dr. Henschke’s group.

But the disclosure that Dr. Henschke’s work was in part underwritten by grants from a cigarette maker will undercut those efforts, prominent cancer researchers said.
“She’s the biggest advocate for widespread spiral CT screening,” said Dr. Paul Bunn, a lung cancer expert and executive director of the International Association for the Study of Lung Cancer. “And now her research is tainted.”

Corporate financing can have subtle effects on research and lead to unconscious bias. Studies have shown that sponsored research tends to reach conclusions that favor the sponsor, which is why disclosure is encouraged. The tobacco industry has a long history of underwriting research — sometimes through independent-sounding foundations — to make cigarettes seem less dangerous.

Since 1999, Dr. Henschke has asserted that annual CT scans of smokers and former smokers would detect lung cancer when tumors are small enough to be cured, preventing as many as 80 percent of the 160,000 deaths a year from lung cancer, by far the biggest cause of cancer deaths in the United States.

Her 2006 study said that, after screening 31,567 people from seven countries, CT scans uncovered 484 lung cancers, 412 of them at a very early stage. Three years later, most of those patients were still alive, and she projected that 80 percent would be alive after 10 years and assumed that they would have died without the screens.

Critics question both her survival projections and her assumption that all would have died without screening. Indeed, most in the cancer establishment say that Dr. Henschke has yet to prove her case. CT scans have radiation risks and sometimes detect cancers that would not have progressed, leading to risky procedures like biopsies and lung surgery when not needed.

To settle the dispute, the National Cancer Institute started in 2002 the $200 million National Lung Screening Trial comparing death rates among 55,000 people randomly assigned to have CT scans or chest X-rays. Results are not expected until 2010. Dr. Henschke has asserted that allowing hundreds of thousands of people to die in the meantime is unethical.

The Cancer Letter, a newsletter, recently reported that Drs. Henschke and Yankelevitz had failed to disclose in articles and educational lectures a patent and 10 pending patents related to CT screening and follow-up. General Electric, a maker of CT scanners, licensed the issued patent beginning in 2001.
Jonathan Weil, a Weill Cornell spokesman, said Dr. Henschke did not disclose the patents in some articles and lectures because she did not deem them relevant.

On Monday, The Journal of the American Medical Association published corrections about unreported financial disclosures from Drs. Henschke and Yankelevitz. The patent and pending patents reported by The Cancer Letter are relevant to these publications,” an editors’ note stated. Editors at the journal were not aware of Dr. Henschke’s association with Liggett, said Dr. Catherine D. DeAngelis, the journal’s editor in chief.

“I would never publish a paper dealing with lung cancer from a person who had taken money from a tobacco company,” Dr. DeAngelis said.

Universities are responsible for policing conflicts of interest and, in many cases, the required disclosures of their faculty. But Weill Cornell shared in the proceeds of Dr. Henschke’s patent and pending patents, and university officials were on the foundation board.

“We have a very strict oversight policy” for conflicts of interest, Dr. Gotto of Weill Cornell said. He dismissed any suggestion that the university could not police and benefit from faculty members’ financial deals.

But Dr. Kassirer said, “The problem is that universities, because they’re so conflicted themselves, ignore the conflicts of interest of their faculty.”

Legislation being considered in Congress would require drug and device makers to post registries of payments to doctors.

An increasing number of doctors and institutions are setting up foundations to accept money from companies without having to disclose its source, said Dr. Murray Kopelow, chief executive of the Accreditation Council for Continuing Medical Education.

“This is the third time in the past few weeks that one of these has been identified to us,” said Dr. Kopelow, whose organization is investigating how widespread the practice is.
Laurie Fenton Ambrose, president and chief executive of the Lung Cancer Alliance, a nonprofit patient advocacy group, said she still trusted Dr. Henschke and still believed in widespread CT scanning to prevent lung cancer deaths.