EDITORS: EMBARGOED UNTIL 7:00 PM EDT MAY 15, 2003

FOR MORE INFORMATION, CONTACT: David Sampson American Cancer Society 213 368-8523 david.sampson@cancer.org

Shawn Steward American Cancer Society 404 417-5850 shawn.steward@cancer.org

American Cancer Society Condemns Tobacco Industry Study for Inaccurate Use of Data

Study Part of Organized Effort to Confuse Public About Secondhand Smoke

ATLANTA — May 15, 2003 — The American Cancer Society today strongly criticized a misleading tobacco industry-funded study that compromises Society data by using flawed methodology to falsely conclude environmental tobacco smoke (ETS) may not affect lung cancer risk. Dr. James Enstrom, the author of the study published in the *British Medical Journal*, received funding from a tobacco industry group linked to coordinated attempts to confuse the public about the dangers of secondhand smoke.

"We are appalled that the tobacco industry has succeeded in giving visibility to a study with so many problems it literally failed to get a government grant," said Michael J. Thun, MD, the Society's national vice president of epidemiology and surveillance research. "The American Cancer Society welcomes thoughtful, independent peer review of our data. But this study is neither reliable nor independent."

Scientific Flaws of the Study

The new study uses data from the American Cancer Society's Cancer Prevention Study I (CPS-I). During the course of the analysis, Society researchers repeatedly advised Dr. Enstrom that using CPS-I data to study the effects of secondhand smoke would lead to unreliable results.

- The analysis is based on a small subset (10%) of the CPS-I data.
- The study suffers from a critical design flaw: the inability to distinguish people who were exposed to secondhand smoke from those who were not:
 - Participants were enrolled in 1959, when exposure to secondhand smoke was so pervasive that virtually everyone was exposed to ETS, whether or not they were married to a smoker.

- No information was collected on other sources of ETS exposure besides spousal smoking.
- No information on smoking habits after 1972 was included in the analysis,
 even though the observation period continued for another 26 years.
- Study participants were, on average, 52 years old at enrollment. Many spouses who reported smoking in 1959 would have died, quit smoking, or ended the marriage during the 38-year follow-up, yet their surviving partners are still classified as "exposed" to ETS in this analysis.
- Much of the follow-up of CPS-I through 1998 pertains to older age groups where the effects of many environmental risk factors become less apparent.

Study Problems Lead to Tobacco Money

The study was initially funded by the Tobacco-Related Disease Research Program, the group that oversees research funds earmarked from proceeds raised by California's state cigarette tax. When Dr. Enstrom was denied additional funding from the program's scientific, peer-review panel, he sought and received substantial funds from the Center for Indoor Air Research (CIAR), a tobacco company 'research group' funded by Philip Morris, among others.

A confidential 1988 industry memo points to CIAR as part of a strategy to "set up a team of scientists organized by one national coordinating scientist and American lawyers, to... carry out work on ETS to keep the controversy alive." News of that memo was reported in the *British Medical Journal*, the journal publishing the current study (BMJ, May 31, 1997).

In a January 15, 1997 letter, Dr. Enstrom tells Richard Carchman, PhD, Philip Morris' director of scientific affairs, that "[a] substantial research commitment on your part is necessary in order for me to effectively compete against the large mountain of epidemiologic data and opinion that already exists regarding the health effects of ETS and active smoking."

Philip Morris apparently shared doubts about his methods. An internal document dated February 6, 1997 ("Short Comments to the Proposed Research... Submitted by J.E. Enstrom") reads: "Death certificates are generally considered to be not the best source of information," and "the amount of money asked for seems rather high when considering the work proposed. The outcome, most probably, will not add much new scientific information." The reviewer did see at least one use for Dr. Enstrom: "The applicant seems to have good connections/resources which might be useful in the future for other issues." Dr. Enstrom received the funds.

What Is the Relationship Between Secondhand Smoke and Lung Cancer?

Far more reliable data exist which clearly show an effect of secondhand smoke. One of those is a much more comprehensive study, also done by the American Cancer Society, called the Cancer Prevention Study II (CPS-II). CPS-II:

- Enrolled patients in the 1980s, when there was much less exposures to tobacco smoke outside the home, and therefore far less 'background noise'
- Is about 10 times as large as Dr. Enstrom's study
- Has much better follow up, with more than 99% of those originally entered into the study having been successfully contacted and followed up
- Clearly shows an increased risk of lung cancer and heart disease

"CPS-II is one of more than 50 studies now published that have shown non-smokers married to smokers have an increased risk of lung cancer," said Harmon J. Eyre, MD, the Society's national chief medical officer. "These studies have been scrutinized by multiple independent scientific consensus committees, as well as the U.S. Surgeon General, all of which certify their credibility. Most recently, the International Agency for Research on Cancer (IARC) reviewed the evidence and concluded secondhand or environmental tobacco smoke is carcinogenic to humans.

"Bad science can haunt us for generations," added Dr. Eyre. "And regrettably, if questionable studies make it to publication, the damage is done."

The American Cancer Society is dedicated to eliminating cancer as a major health problem by saving lives, diminishing suffering and preventing cancer through research, education, advocacy and service. Founded in 1913 and with national headquarters in Atlanta, the Society has 17 regional Divisions and local offices in 3,400 communities, involving millions of volunteers across the United States. For more information anytime, call toll free 1-800-ACS-2345 or visit www.cancer.org.