Statement Congressman Henry A. Waxman Chairman, Subcommittee on Health and the Environment March 31, 1994

Today I am releasing a copy of a previously secret tobacco industry funded research study substantiating the addictive nature of nicotine. The research was submitted for publication five years before the Surgeon General issued a report which concluded: (1) "Cigarettes and other forms of tobacco are addicting; (2) Nicotine is the drug in tobacco that causes addiction; and (3) The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." The research paper was entitled "Nicotine as a Positive Reinforcer for Rats: Effects of Infusion Dose and Fixed Ratio Size." The research was conducted by scientists working at the Philip Morris Research Center in Richmond, Virginia.

The existence of this important research was revealed by FDA Commissioner David Kessler in response to a question during a hearing of the Subcommittee on Health and the Environment last Friday. Dr. Kessler cited the work as evidence that the tobacco industry had initiated a program of animal research which confirmed that nicotine is an addictive drug. This research was submitted to the scientific journal Psychopharmacology and approved for publication after undergoing peer review. Prior to publication, the editor of the Journal was notified by the Philip Morris researcher that the article was being withdrawn "due to factors beyond [the researcher's] control."

Subsequently, the researcher left Philip Morris and in 1986 resubmitted a revised version of the article to the journal. After the article was accepted for publication a second time, the researcher was forced to withdraw it because, according to the journal's editor, Philip Morris had obtained a court injunction against publication. The Subcommittee has also learned that Philip Morris closed the laboratory where the research was conducted. I am also releasing today copies of correspondence between the researcher and the editor of Psychopharmacology documenting the course of events surrounding the study.

The results of this study are significant not just because they were suppressed, but also because the tobacco industry has steadfastly maintained that nicotine is not addicting despite assertions to the contrary by the Surgeon General, the FDA and medical authorities such as the American Medical Association and the American Psychiatric Association. The secret study I am releasing today underscores two vital points: (1) The nation's largest tobacco company has had relevant information for years about the important role nicotine plays in preventing smokers from quitting; and (2) Despite this information, the tobacco industry has denied that nicotine is addictive.

Last year The Wall Street Journal published the results of a powerful investigation of the confidential research program of a tobacco industry's Council for Tobacco Research. The Journal concluded it was common practice within the Council to terminate or suppress research which suggested cigarette smoking was a cause of cancer, low birth weight or other illness. Now we know that similar practices were also supported within the internal corporate research laboratories of Philip Morris.

Revelations of Philip Morris' secret nicotine research project raise serious questions about the company's credibility when its spokesman denies that nicotine is addictive. Philip Morris' scientists knew as early as 1983 that nicotine was addicting and company executives apparently went to extraordinary lengths to prevent this finding from becoming public. The efforts of Philip Morris to suppress this knowledge of addiction is understandable given the importance of nicotine to maintaining addiction among smokers and the important role such information may play in product liability.

The tobacco industry likes to talk about smoking as a free choice. But smokers addicted to nicotine don't have a free choice. We are just beginning to understand the nature and extent of the tobacco industry's secret research program. The addiction study made public today provides only a brief glimpse of the research agenda of Philip Morris, but it is consistent and complementary of the company's other programs to search for chemical look-alikes of nicotine and to develop more effective methods of manipulating nicotine levels in tobacco, in the paper wrapper and even in the filter.

We must find out whether tobacco companies make deliberate decisions to assure a minimum level of nicotine in their products and whether the purpose of such level is to maintain addiction, and what extraordinary efforts are made to keep this information secret. If true, this is corporate irresponsibility on a grand scale. If true, these practices may violate the Federal Food, Drug and Cosmetic Act and subject cigarettes to Federal regulation.

Last week Dr. Kessler told our Subcommittee that the tobacco companies have the capability of removing nicotine from tobacco and replacing it with a nonaddicting less hazardous and equally flavorful substance. Dr. Kessler said he was unaware of any explanation for the industry's manipulation of nicotine except the promotion of addiction.

Let me caution - we do not have a full picture of tobacco industry manufacturing practices. We do not know the full extent of their confidential nicotine research projects. Accordingly, we can not draw final conclusions. We need to know which of the nicotine manipulation patents approved or under development are in use today or scheduled for use tomorrow. It is clear that if the American people are to obtain this information we must hear directly from the Chief Executive Officers and their respective research directors.

For more than thirty years tobacco company CEOs have generally avoided appearing before the Congress to explain the conduct of their companies. They have instead relied upon public relations specialists to obfuscate Congressional and regulatory scrutiny.

It is essential that the Congress hear, under oath, from the men responsible for running these companies and the scientists who direct their nicotine research programs.

The Rules of the House of Representatives charge the Energy and Commerce Committee and its Subcommittee on Health and the Environment with maintenance of the public health and assuring that laws like the Food, Drug and Cosmetic Act are faithfully executed. To fulfill these Constitutional responsibilities, formal letters of invitation have been sent to the Chief Executive Officers and the scientific research directors for Philip Morris, R.J. Reynolds, Brown & Williamson, American Tobacco, Liggett Group and U.S. Tobacco. These individuals have been asked to appear before the Subcommittee on April 14, 1994 to answer questions raised by our March 25th hearing and the Subcommittee's ongoing investigation.

CHRONOLOGY OF EVENTS

- May 16, 1983 Dr. Victor J. DeNoble, Associate Senior Scientist, with Philip Morris submits manuscript #83-1400, entitled "Nicotine as a Positive Reinforcer in Rats: Effects of Infusion Dose and Fixed Ratio Size," to Psychopharmacology. [Doc. 1 a summary of the article; Doc 5 is a draft of the article, given to Dr. Jack Henningfield, National Institute of Drug Abuse, Addiction Research Center.]
- Aug. 8, 1983 Editor of <u>Psychopharmacology</u>, Dr. Herbert Barry, returns manuscript with comments of two reviews so that revisions can be made in anticipation of publication.
- Aug. 30, 1983 Dr. DeNoble sends Dr. Barry letter withdrawing publication of the manuscript. [Doc. No. 2 is a copy of the letter.] Subsequently Philip Morris's animal research lab was closed and the researcher was fired.
- Dec. 31, 1985 DeNoble, now working for Ayerst Laboratories
 Research, submits revised version of 1983
 manuscript, entitled "Intravenous Nicotine SelfAdministration in Rats: Effects of Mecamylamine,
 Hexamethonium and Naloxone," for publication in
 Psychopharmacology. [Document No. 3 is a copy of
 the letter submitting the article.]
- April 9, 1986 Manuscript is returned to DeNoble with comments of two reviewers so that revisions can be made in anticipation of publication.
- Aug. 4, 1986 Revised version of manuscript received by Psychopharmacology.
- Aug. 30, 1986 Dr. DeNoble sends letter to Barry withdrawing the manuscript.
- Sept. 22, 1986 Letter from Dr. Barry to Dr. DeNoble stating "I share the distress you expressed in your phone conversation of 18 September that the Philip Morris Company has issued an injunction against publication of this paper." Letter also states that the manuscript is ready for publication. [Doc. No. 4 is a copy of this letter.

- May 18, 1988 Surgeon General C. Everett Koop issues the report

 The Health Consequences of Smoking: NICOTINE

 ADDICTION. The report concluded that "nicotine is
 the drug in tobacco that causes addiction."
- March 25, 1994 Food and Drug Administrator Commissioner David
 Kessler confirms the existance of the secret
 addiction study in a congressional hearing before
 the House Subcommittee on Health and the
 Environment. Kessler called the selfadministration, as demonstrated by the study, "a
 hallmark of a drug that has the potential to
 addict."