

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MAR 24 1994**

The Honorable Thomas J. Bliley, Jr.  
Ranking Minority Member  
Subcommittee on Health and the Environment  
Committee on Energy and Commerce  
House of Representatives  
Washington, D.C. 20515-4607

Dear Mr. Bliley:

This is in response to your letter dated March 18, 1994, to Commissioner Kessler, requesting all evidence in the Food and Drug Administration's (FDA) possession regarding the intent of cigarette manufacturers with respect to the presence of nicotine in cigarettes. FDA received your letter late in the afternoon on March 18. It was not received in this Office until Monday morning, March 21. We called your office on Monday morning to discuss your request and advise you that it was impossible for the agency to meet your deadline of March 21. Our call was not returned by your staff until after this office closed Tuesday evening.

Given the scope of your request, the resources that must be devoted to identifying, reviewing, and preparing documents for production, and the extremely short timeframe involved, we are able to provide only a partial response at this time. Consistent with the agency's regulations governing disclosure of information, we wanted to provide you as much publicly available information as possible prior to the March 25th hearing.

As Commissioner Kessler indicated to you yesterday, the agency stands ready to provide all appropriate assistance to you and your staff on this and any other matters involving FDA. I hope this information is helpful.

Sincerely yours,

Diane E. Thompson  
Associate Commissioner  
for Legislative Affairs

Enclosures

FN 12

cc: HFW-14 (2)  
HFW-1 (2)  
Roger McClung

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**Congress of the United States**  
**House of Representatives**  
**Washington, DC 20515-4607**

March 18, 1994

The Honorable David A. Kessler  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Room 14-71  
Rockville, Maryland 20857

Dear Dr. Kessler:

Your correspondence of February 25, 1994 to Scott D. Ballin, Chairman of the Coalition on Smoking OR Health, contained disturbing allegations concerning the intent of cigarette manufacturers with respect to the role of nicotine in cigarettes.

Specifically, your letter stated, "Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. The possible inference that cigarette vendors intend to achieve drug effects in some smokers is based on mounting evidence we have received that: (1) the nicotine ingredient in cigarettes is a powerfully addictive agent and (2) cigarette vendors control the levels of nicotine that satisfy this addiction."

As these are serious charges likely to be addressed before a Congressional hearing on March 25, I request that you provide the following information and documents to my office prior to the hearing.

- (1) All "evidence" in the FDA's possession "that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers," along with
  - (a) a written summary of such "evidence" if it was given orally to the FDA; and
  - (b) copies of any and all documents given to the FDA in connection with this allegation; and
  - (c) the names, addresses and titles of all individuals and organizations from whom you received evidence in

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connection with this allegation.

- (2) All "evidence" in the FDA's possession that "manufacturers commonly add nicotine to cigarettes to deliver specific amounts of nicotine," along with

(a) a written summary of such "evidence" if it was given orally to the FDA; and

(b) copies of any and all documents given to the FDA in connection with this allegation; and

(c) the names, addresses and titles of all individuals and organizations from whom you received evidence in connection with this allegation.

- (3) All "evidence" in the FDA's possession supporting your statement that "There is also evidence discovered in recent litigation that some of the individuals involved in the manufacture of cigarettes in the 1970s regarded their products as nicotine-delivery systems," along with

(a) a written summary of such "evidence" if given orally to the FDA; and

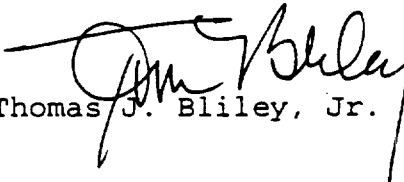
(b) copies of any and all documents given to the FDA in connection with this matter; and

(c) the names, addresses and titles of all individuals and organizations from whom you received evidence in connection with this allegation.

- (4) All other "information" or "evidence" brought to the FDA's attention or otherwise received by the FDA that you relied on to support the statements made in your February 25 letter to Mr. Ballin regarding the intent of cigarette manufacturers concerning nicotine\*. In addition, please indicate whether you received any or all of the "information" or "evidence" before or after your February 25 letter was released.

Please provide this information to my office no later than March 21, 1994.

Sincerely,

  
Thomas J. Bliley, Jr.

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**March 24, 1994**

**Experts with whom we have consulted:**

**Dr. Neal Benowitz, Ph.D.**

**Division of Clinical Pharmacology and Experimental Therapeutics**

**University of California, San Francisco**

**Building 30**

**San Francisco General Hospital Medical Center**

**San Francisco, CA 94110**

**Gregg Connolly, DMD, MPH**

**Director, Tobacco Control Program**

**Department of Public Health**

**150 Tremont Street**

**Boston, MA 02111**

**Dr. John N. Diana, Ph.D.**

**Director, Tobacco and Health Research Institute**

**University of Kentucky**

**Cooper and University Drives**

**Lexington, KY 40546**

**Neil E. Grunberg, Ph.D.**

**Professor of Medical and Clinical Psychology and Neuroscience**

**Uniformed Services University of the Health Sciences**

**4301 Jones Bridge Road**

**Bethesda, MD 20814**

**Dr. John R. Hughes**

**Behavioral Medicine Service**

**Department of Psychiatry**

**University of Vermont**

**Burlington, VT 05401**

**Dr. John Slade**

**Department of Medicine**

**St. Peter's medical Center**

**254 Easton Avenue**

**New Brunswick, NJ 08903**

**Government:**

**Jack E. Henningfield Ph.D.**  
**Chief, Clinical Pharmacology Branch**  
**The Addiction Research Center**  
**National Institute on Drug Abuse (NIDA)**  
**Baltimore, MD 21224**

**Judith Wilkenfeld, J.D.**  
**Assistant Director, Division of Advertising Practices**  
**Federal Trade Commission (FTC)**  
**Washington, DC 20580**

**Robert Daugherty**  
**Chief, Revenue Programs Division, and**  
**Robert Mosely**  
**Chief, Distilled Spirits and Tobacco Branch**  
**ATF - 650 Massachusetts Avenue, NW**  
**Washington, DC 20226**

---  
**Gary Giovinno and Michael Erikson**  
**CDC - Office on Smoking or Health**  
**Atlanta, GA**  
**(404) 488-5703**

**Lorenda Daniels**  
**CDC-Office on Smoking or Health**  
**Washington Office**  
**(202)205-8500**

-----  
**Verner Grise, Ph.D.**  
**USDA- Economic Research Service**  
**1301 New York Avenue**  
**Washington, DC**

**Jim Repace**  
**EPA**  
**(202) 262-9131**

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1 May 14, 1991	United States Patent-Patent Number: 5,015,741
2 May 20, 1986	United States patent-Patent Number: 4,590,278
3 May 22, 1979	United States Patent-4,155,909
4 March 23, 1982	United States Patent-4,321,387
5 September 2, 1980	United States Patent-4,220,781
6 April 10, 1984	United States Patent-4,442,292
7 June 1, 1982	United States Patent-4,332,945
8 June 5, 1984	United States Patent-4,452,984
9 May 16, 1989	United States Patent-4,830,028

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DATE OF PATENT

10 4,590,278	May 20, 1986
11 4,452,984	June 5, 1984
12 4,442,292	April 10, 1984
13 4,332,945	June 1, 1982
14 4,321,387	March 23, 1982
15 4,220,781	September 2, 1980
16 4,155,909	May 22, 1979
17 5,015,741	May 14, 1991
18 5,138,062	August 11, 1992
19 5,033,484	July 23, 1991
20 5,260,205	November 9, 1993
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(Patient Number 5,015,741)
42. 5/20/86 United States Patent - Edwards, III - Nicotine Analogs  
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43. 6/5/84 United States Patent - Edwards, III - Optically Active  
Nicotine Analogs and Process for their Preparation  
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44. 4/10/84 United States Patent - Edwards, III - Optically Active  
Nicotine Analogs and Process for their Preparation  
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45. 6/1/82 United States Patent - Edwards, III - Optically Active  
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46. 3/23/82 United States Patent - Chavdarian - Process for the  
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47. 9/2/80 United States Patent - Sanders - Process for Preparing  
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48. 5/22/79 United States Patent - Sanders - 2-ALKYL Nicotinoids  
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