THE TOBACCO INSTITUTE
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RALPH VINOVICH
Vice President for
Legislative Affairs

March 14, 1990

The Honorable
Robert Dole
U. S. Senate
141 Senate Hart Office Building
Washington, DC 20510

Dear Bob:

This is to confirm arrangements made with Betty Meyer for you to speak to our Washington Working Group here at the Institute on Tuesday, March 20, at 8:30 a.m.

There will be about 35 people in attendance made up of our federal relations staff, our state relations staff, company representatives, and consultants. It is a bi-partisan group and you will probably know most of them.

We don't expect a "tobacco speech" and you can talk about anything you please, however, there are sure to be questions about S. 1883 introduced by Senator Kennedy. There has already been one day of hearings with a second scheduled for April 3, and markup set for April 13, so you can see it is on a fast track. The bill is filled with problems for our industry and proposes to spend millions of dollars for more bureaucracy, more regulation, and severe restrictions on advertising. I am enclosing a copy of our testimony before the Labor Subcommittee by one of our consultants, former Congressman Charlie Whitley. Also a fact sheet on the bill which may be helpful.

No doubt there will also be questions about the proposal by Chairman Rostenkowski which is a big topic of discussion lately.

Look forward to seeing you next week and promise to have you on your way out the door at 9:30 a.m.

Sincerely,

Ralph

Ralph Vinovich

Enclosure

We are on the 8TH floor.

The Case Against S. 1883

THE TOBACCO EDUCATION AND HEALTH PROTECTION ACT OF 1990:

Is this Legislation Necessary?

Senator Edward M. Kennedy (D-Mass.), calling for "a new national effort to reduce smoking and tobacco use in our society," has introduced the Tobacco Education and Health Protection Act of 1990 (S. 1883).

"The purpose of the legislation," he says, "is to help people stop smoking before they start and to assist smokers who wish to stop."

Its cost: $185 million in FY 1991, and "such sums as may be required" in the following two fiscal years.

Before considering the details of S. 1883, let's consider whether a new national tobacco policy is necessary.

Twenty-five years ago, Congress established a national policy regarding tobacco to inform the American people about claims concerning smoking and health so as to insure that the decision to smoke or not is an informed one.

Apparently, the policy of informed individual choice is working. Since 1965 --

- Tobacco use has declined dramatically. The prevalence of smoking by adults has dropped from 40 per cent to 29 per cent. (Source: 1989 Surgeon General's Report.)

- One out of every two American smokers has quit. Between 1965 and 1985 some 41 million people have given up smoking; nine out of ten did it alone, without outside help. (Source: 1988 Surgeon General's Report.)

- By 1985, the group of ex-smokers outnumbered people who smoked more than 25 cigarettes a day by a three-to-one margin. (Source: 1988 U.S. Statistical Abstract.)

IF REDUCING SMOKING IS THE GOAL, CURRENT POLICY IS WORKING. S. 1883 IS UNNECESSARY -- ESPECIALLY WHEN THE BILL CARRIES A FIRST YEAR PRICE TAG OF NEARLY $200 MILLION ... FUNDS THAT COULD BE USED INSTEAD FOR OTHER FEDERAL PROGRAMS SUFFERING SEVERE GRAMM-RUDMAN BUDGETARY CONSTRAINTS.

If there's a serious question about the need for passage of this bill in general, the details of S. 1883 raise similar questions. For example:

1. The legislation mandates a national anti-tobacco campaign against tobacco use by minors, blue collar workers, minorities and other groups that would include the use of paid advertising at a cost of $50 million a year.

   WHY SPEND ADDITIONAL MILLIONS OF FEDERAL FUNDS FOR PAID ADVERTISING OF A MESSAGE THAT AMERICANS HAVE BEEN AWARE OF FOR DECADES?

Survey research has established that 99 per cent of the American population is aware of what the Surgeon General and others have to say about the health effects of smoking (compared to only 89 per cent who know the name of our first president.) In 1985, a survey done by HHS showed not only had the American public heard that cigarette smoking posed a health threat, but 95% believed that cigarette smoking increased the risk of lung cancer; 92% believed it increased the risk of emphysema and 91% believed it increased the risk of heart disease. To assert that the anti-smoking message has not been seen, heard and understood borders on the absurd. Taxpayers' money can and should be better allocated to more pressing social problems.

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2. S. 1883 groups tobacco along with hard drugs in the Drug-Free Schools and Communities Act of 1986 and authorizes $25 million in grants for this program. It would also replace the carbon monoxide warning with an addiction label.

   SENDING OUT THE MESSAGE THAT "TOBACCO USE EQUALS DRUG ABUSE" ONLY SERVES TO CONFUSE THE DRUG ISSUE, ESPECIALLY TO YOUNG PEOPLE.

Former Surgeon General Koop has equated tobacco use with hard drug use. But what's the message? "Illegal drugs should be legalized?" Or "Legal products, like tobacco and alcohol, should be outlawed?"

Equating cigarettes with crack cocaine trivializes a major social problem. It's counter-productive to our national drug control program. When the Senate passed legislation implementing the President's 1989 National Drug Control

Strategy, it did not have tobacco or cigarette smoking in mind when it said:

> [T]he term "addiction" means the state of an individual where that individual habitually uses an illegal drug in a manner that endangers the public morals, health, safety, or welfare, or who is so addicted to the use of illegal drugs that such individual loses the power of self-control with reference to such individuals' addiction. (Section 529(B) of S.1711, by Senator Dole)

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3. S. 1883 would create a new bureaucracy under the Secretary of Health and Human Services (HHS). In addition to managing the $50 million campaign, discussed above, the new HHS bureaucracy would be empowered to make available --

   - o $50 million in grants to state and local governments, encouraging them to enact and enforce laws to retailers in the name of preventing tobacco sales to minors.
   - o $5 million in grants to unions, encouraging them to control smoking in workplaces.
   - o $5 million to health departments, encouraging them to develop smoking cessation programs.

PAYING STATES, CITIES, COUNTIES AND UNIONS TO ENACT AND ENFORCE LAWS PROHIBITING TOBACCO SALES AND PREVENTING SMOKING, OR PROMOTING SMOKING BANS IN THE WORKPLACE MAKES A MOCKERY OF FEDERALISM.

The proposal is a retreat from the present national policy of free and informed choice in the market place to a policy of coercive control over where cigarettes may be purchased or consumed. It conceals the federal prohibitionist hand inside the glove of state, local or private action.

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4. S. 1883 would empower the new agency to require disclosure of tobacco constituents and additives and to ban the use thereof under some circumstances, authorizing another $50 million for FY 1991.

HHS SPENT $40.5 MILLION ON SMOKING CONTROL PROGRAMS IN FY 1987. CLEARLY, THE COUNTRY DOESN'T NEED YET ANOTHER LAYER OF FEDERAL BUREAUCRACY TO DUPLICATE ACTIVITIES NOW HANDLED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AT LESS COST.

Under current law, additives are the responsibility of the Secretary of HHS. Each year, cigarette manufacturers submit a list of ingredients added to cigarettes. HHS can recommend to Congress action which should be taken with respect to such ingredients. HHS properly treats this information as trade secrets, protected like those of other manufacturers. S. 1883 violates the principle of trade secrets.

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5. S. 1883 would largely eliminate existing federal preemption of state and local regulation of cigarette advertising displayed within such jurisdictions.

THIS IS THE BACK DOOR ROUTE TO A BAN ON CIGARETTE ADVERTISING AND PROMOTION. A PROLIFERATION OF LOCAL AND STATE RESTRICTIONS WOULD MAKE IT DIFFICULT IF NOT IMPOSSIBLE FOR TOBACCO COMPANIES TO EXERCISE THEIR RIGHT TO FREE COMMERCIAL SPEECH UNDER THE FIRST AMENDMENT.

With enactment of the Federal Cigarette Labeling and Advertising Act in 1965 and in subsequent legislation enacted in 1969 and 1984, Congress has recognized the need to avoid a tangle of diverse and confusing labeling and advertising regulations. The proposed bill would overturn 25 years of a federal policy of national uniformity. The proposed legislation also ignores the substantial constitutional concerns involved in mandating compliance with a patchwork of conflicting state and local advertising regulations.

Joyce

Speak

March 20
Tues
Hilt

February 3, 1990

8:30 am

TO: Senator Dole

FROM: Betty

RE: Speaking request by the Tobacco Institute

Ralph Vinovich has asked if you would speak at a breakfast meeting of the Tobacco Institute. Attendees would be Federal and State staffs and consultants (about 35 total).

The date is Tuesday, March 20.

It would be at their office - 1875 Eye St., N.E.
Suite 800

Format would be an informal roundtable type discussion -- following brief comments.

Honorarium of $2,000.

Do you want to do?? Yes ____ No _____

Contact: Ralph Vinovich 457-4854
4822

2/9 Advised Dee Dunn, Ralph's sec'y, Sen. would do Senator only guest
8:30 - 9:15 not longer than 9:30
8:45 senator to arrive

M E M O R A N D U M

March 15, 1990

TO: SENATOR DOLE
FROM: JIM WHITTINGILL
SUBJECT: TOBACCO INSTITUTE

You are scheduled to address the Washington representatives of several tobacco companies and the trade association staff at the Tobacco Institute breakfast at 8:30 A.M. on Tuesday, March 20.

You have addressed the group several times before, and it will be the same cast of characters. They are expecting about 35 to attend. As usual, they would like a general legislative update. However, they are interested in two specific items: the Kennedy "Tobacco Education and Health Protection Act of 1990," S. 1883, and the Rostenkowski budget balancing plan, which includes a proposal to increase excise taxes on cigarettes and tobacco products.

S. 1883

Labor Committee -- one hearing already held, second scheduled for April 3, with mark-up scheduled for April 13.

Establishes new agency at HHS and authorizes $185 million for FY '91, and such sums thereafter.

- o $50 million for anti-tobacco advertising
- o $50 million for reviewing and listing of tobacco composition and additives and authority to ban specific additives
- o $25 million for Drug-Free Schools and Communities Act for anti-tobacco programs
- o $50 million in grants to state and local governments to enforce laws against selling tobacco to minors
- o $5 million in grants to unions to control smoking in the workplace
- o $5 million to state health departments to develop smoking cessation programs

As you expected, the measure has been cosponsored and is strongly supported by Senator Hatch. However, his staff has informed me that he is working with tobacco state Republicans to craft an "acceptable" compromise.

To the Hatch staff, this probably means creating the new Agency, but stripping the $50 million for advertising and $50 million for grants to state and local governments. They also believe that additives will be regulated in any event and that cigarettes violate the Delany Clause (although the last time I checked, the Delany Clause referred to additives which cause cancer, not when the underlying product causes cancer.

The tobacco groups argue that 99% of all Americans are aware that smoking cigarettes has adverse health effects, smoking by adults has dropped from 40% to 29%, one out of every two smokers has quit, ex-smokers outnumber heavy smokers by three-to-one, etc., etc., etc., meaning there is no need for anti-smoking campaigns by the Federal government during this time of limited resources.

A topic on which you might get questions unless you mention it up-front is Secretary Louis Sullivan's recent attacks on the tobacco industry. He has lashed out particularly at two planned advertising campaigns -- one toward urban blacks and the other to "virile females" (the 18 to 30 year-olds that go to tractor pulls, professional wrestling matches and rodeos [my kinda gal]).

I had an interesting conversation with B. Oglesby about this the other day (he is with RJR Nabisco). When I asked if any of the CEOs were Bush supporters who could get the White House to ask him to cool it a little, he said the White House appears to like that Sullivan is getting good press and, therefore, probably would not intervene. Pretty good observation.

Rostenkowski is proposing a doubling of excise taxes on cigarettes -- to $0.32 per pack. Needless to say, the group won't be real big on this item. Carolyn is preparing a separate document on this issue.

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TALKING POINTS

TOBACCO EXCISE TAXES

- AS PART OF HIS 5-YEAR DEFICIT REDUCTION PLAN, CHAIRMAN ROSTENKOWSKI PROPOSES TO DOUBLE THE FEDERAL EXCISE TAX ON CIGARETTES TO 32 CENTS PER PACK -- ITS HIGHEST LEVEL EVER -- ALLEGEDLY BECAUSE OF THE ENORMOUS HEALTH CARE COSTS ASSOCIATED WITH SMOKING.

- ALTHOUGH CIGARETTE TAXES ARE AMONG THE MOST REGRESSIVE TAXES CURRENTLY IMPOSED BY THE FEDERAL GOVERNMENT, THIS PROPOSAL HAS BEEN A FAVORITE AMONG DEMOCRATS; SENATOR BIDEN ALSO INCLUDED IT AMONG THE REVENUE OPTIONS AVAILABLE TO FUND HIS DRUG BILL.

- TO CORRECT FOR THE REGRESSIVITY OF HIS TAX PROPOSALS, CHAIRMAN ROSTENKOWSKI WOULD SET ASIDE 20% OF THE REVENUE FROM HIS PROPOSED 15 CENT PER GALLON GAS TAX INCREASE TO SUPPLEMENT THE EITC FOR THE WORKING POOR. WHILE EITC HELPS VERY LOW INCOME FAMILIES, IT DOES NOTHING FOR LOWER AND MIDDLE INCOME FAMILIES ABOVE THE POVERTY LINE WHO WOULD BEAR THE BRUNT OF THESE INCREASES.

- WHILE PRAISING THE LEADERSHIP OF CHAIRMAN ROSTENKOWSKI IN PROPOSING A SERIOUS DEFICIT REDUCTION PLAN, PRESDIDENT BUSH HAS MADE IT CLEAR THAT HE IS NOT ABANDONING HIS NO NEW TAXES PLEDGE. AND THAT EXCISE TAX INCREASES ARE NEW TAXES.

- THE DEMOCRATS WHO HAVE CHALLENGED PRESIDENT BUSH'S CAPITAL GAINS INITIATIVE BECAUSE OF ITS ALLEGED REGRESSIVITY AND EMBRACED $55 BILLION IN PAYROLL TAX CUTS WITHOUT REGARD FOR OUR DEFICIT REDUCTION GOALS, SHOULD NOW BE HARD PRESSED TO CALL FOR EXCISE TAX INCREASES ON LOWER INCOME AMERICANS.

Statement of Charles O. Whitley

on behalf of

The Tobacco Institute

before the

Committee on Labor and Human Resources
United States Senate

February 20, 1990

Mr. Chairman and distinguished members of the Committee, we appreciate this opportunity to testify on S. 1883, the "Tobacco Product Education and Health Protection Act of 1990."

S. 1883 would add a new Title IX to the Public Health Service Act, creating a Center for Tobacco Products.[1/] This new agency, which would have powers and duties similar in some respects to those of the Food and Drug Administration, would be located within the Public Health Service at the Centers for Disease Control. S. 1883 would authorize $185 million to carry out the activities of the Center and other antismoking programs under the bill in Fiscal Year 1991.

1/ The Public Health Service Act does not contain a "Title VIII." The Act refers to subchapters, not titles, and there is no subchapter VIII or VII. Presumably, the provisions designated as "Title IX" in S. 1883 would appear as subchapter VII of the Public Health Service Act.

Among other things, the Center would be directed to regulate "tobacco additives" and to inform the public of such additives and "harmful tobacco smoke constituents." The Center also would be directed to underwrite a broad range of antismoking initiatives by private entities and state and local authorities, including antismoking campaigns in schools and workplaces, and to "coordinat[e] with film makers, broadcast media managers and others regarding the impact of media on tobacco use behavior."

S. 1883 would permit state and local governments to regulate "the placement or location of tobacco product advertising that is displayed solely within the geographical jurisdiction" of the state or local government involved. This would include advertising on billboards and mass transportation facilities, point-of-sale advertising and, possibly, event sponsorship and other promotional activities. In addition, S. 1883 would authorize state and local restrictions on the advertising, promotion, sale or distribution of cigarettes to persons under 18. Finally, S. 1883 would replace the Surgeon General's carbon monoxide warning with an "addiction" warning.

In addressing S. 1883, Mr. Chairman, I want to stress the common ground we share: The cigarette industry does not want young people to smoke. We believe that

smoking is for those adults who choose to smoke. S. 1883, however, is ill-advised and should be rejected. It proposes regulation and spending as ends in themselves without any legitimate rationale.

* S. 1883 would establish a new federal agency to investigate tobacco "additives" -- even though the safety of additives is currently the responsibility of the Secretary of Health and Human Services under existing law and there has been no suggestion of health concerns based on the additive information supplied to the Secretary by the cigarette manufacturers to date.

* S. 1883 would require blanket disclosure of tobacco additives -- even though disclosure of tobacco additives to the Secretary of Health and Human Services is required by existing law and comparable additive information is exempt from public disclosure on trade secret or impracticality grounds under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.

* S. 1883 would require disclosure to the new agency of "tar," nicotine and carbon monoxide levels of tobacco products -- even though such information already is disclosed to the Federal Trade Commission and the public by voluntary agreement or on the request of the Commission.

* S. 1883 would distribute $50 million a year to antismoking groups for antitobacco advertising campaigns

-- even though Americans are already universally aware of the claimed risks of smoking.

* S. 1883 would make $50 million a year available for antismoking programs in schools and workplaces -- even though state and local governments are already pursuing such programs aggressively on their own.

* S. 1883 would require an "addiction" warning on cigarette packages and cigarette advertising -- even though one of every two smokers has quit, most of them without professional assistance, and even though calling smoking an "addiction" trivializes our nation's serious drug problem.

* S. 1883 would encourage state and local governments to attempt to restrict cigarette advertising to adults in the name of protecting minors, despite the Supreme Court's repeated admonitions that government "may not reduce the adult population * * * to reading only what is [deemed] fit for children."

* S. 1883 would allow each state and local government to establish its own rules and regulations for the placement or location of cigarette advertising within its borders, thereby inviting censorship in violation of the First Amendment and abandoning to that extent Congress's consistent 25-year policy of nationally uniform regulation of cigarette advertising.

I will discuss these points in detail.

1. Center for Tobacco Products. Sec. 901(a) of the new title created by S. 1883 would direct the Secretary of Health and Human Services to establish a Center for Tobacco Products within the Public Health Service, at the Centers for Disease Control. The Center would assume the functions and duties of the Interagency Committee on Smoking and Health. Sec. 903(b)(1).[2/]

(a) Additives. Under Subtitle A of new Title IX, the Center would be directed to "inform the public regarding constituents of, and additives to, tobacco products," and to "restrict the use of additives that represent a significant health risk to the public." Sec. 901(b)(3) and (4).[3/] The Center would be directed to investigate the additives contained in tobacco products and to determine whether such additives "represent a significant added health risk to

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2/ At the same time -- apparently by design (*see* Sec. 927(1)) -- the bill would reestablish the Interagency Committee (*see* Sec. 928(c)), without altering the Committee's functions or duties and without repealing the existing law establishing the Committee (Sec. 3(b) of the Comprehensive Smoking Education Act (15 U.S.C. § 1341(b))). Meanwhile, Sec. 4 of S. 1883 would add a new paragraph (7) to Sec. 3(a) of the Smoking Education Act, even though that new paragraph is not incorporated in Sec. 928(b), which otherwise reproduces Sec. 3(a).

3/ "Constituent" would be defined as "any element of a tobacco product that is not an additive." Sec. 961(3). "Tobacco additive" would be defined to mean "any ingredient that is added to a tobacco product in the process of manufacturing or producing a tobacco product." Sec. 961(15).

consumers of such products." Sec. 902(a)(1). If the Center "determines that any tobacco additive, either by itself or in conjunction with any other additive, presents unnecessary increased risks to health," the Center would be authorized to prohibit the use of a tobacco additive or allow its use only at reduced levels. Sec. 953(b)(2).

The Center would be directed to require public disclosure, through labels or package inserts, of tobacco product additives and "harmful tobacco smoke constituents." Sec. 902(a)(1) and (2). Cigarette manufacturers would be required to provide to the Center "a complete list of each tobacco additive used in the manufacture of each tobacco product brand name and the quantity of such additive" (Secs. 953(a), 951(a)(1)), and "a complete list of all brands of such tobacco products that includes the levels of the tar, nicotine, carbon monoxide, and other constituent (as determined by the Center) for each brand as determined by the manufacturer" (Secs. 954, 951(a)(2)).

Mr. Chairman, many of these provisions substantially duplicate existing law. To the extent these provisions would change existing law, the change would serve no demonstrable policy objective. These provisions also would threaten public disclosure of commercially sensitive information that currently is protected from public disclosure as trade secret or confidential information. Such disclosure would produce no public benefit.

Under the Comprehensive Smoking Education Act, enacted in 1984, the cigarette manufacturers are required to provide the Secretary of Health and Human Services on an annual basis "a list of the ingredients added to tobacco in the manufacture of cigarettes." 15 U.S.C. § 1335a(a). The list provided to the Secretary need not identify the company involved or the brand of cigarettes that contains the ingredients. *Ibid.* Congress considered the disclosure of cigarette ingredient information on this basis to be adequate to "permit the federal government to initiate the toxicologic research necessary to measure any health risk posed by the addition of additives and other ingredients to cigarettes during the manufacturing process." H.R. Rep. No. 805, 98th Cong., 2d Sess. 21 (1984).

The Secretary, in turn, is directed to transmit to Congress periodic reports advising Congress of any information pertaining to such ingredients "which in the judgement [*sic*] of the Secretary poses a health risk to cigarette smokers." 15 U.S.C. § 1335a(b)(1)(B). Each year since 1986, the six major cigarette manufacturers have jointly submitted ingredient lists to the Secretary as required by the 1984 legislation. The most recent list was submitted just this past December. In 1988, Surgeon General Koop indicated that the Department of Health and Human Services was actively reviewing the ingredient lists that had been submitted. There is no reason to believe that this existing

review mechanism is inadequate and needs to be expanded or replaced.

Neither is there any justification for requiring public disclosure of tobacco additives. Because information concerning the ingredients used to manufacture particular cigarette brands is competitively sensitive, Congress provided in the Comprehensive Smoking Education Act that the ingredient information supplied to the Secretary "shall be treated as trade secret or confidential information." Such information is exempt from disclosure under the Freedom of Information Act and criminal penalties are established for unauthorized disclosure. *Id.* § 1335a(b)(2)(A). The Act specifically requires the Secretary to establish "written procedures to assure the confidentiality of [such] information." *Id.* § 1335a(b)(2)(C). He has done so. *See* 50 Fed. Reg. 49,617 (1985).

In 1984, Congress considered and rejected public disclosure of ingredient information -- and for good reason. As originally introduced in the 97th Congress, the House version of the legislation ultimately enacted in 1984 would have required ingredients to be listed on cigarette packages.[4/] Opposing such a requirement, The Tobacco Institute's witness explained:

4/ H.R. 5653, 97th Cong., 2d Sess., p. 7 (March 1, 1982).

> "Cigarette manufacturers use a variety of ingredients to enhance flavor and appearance and preserve shelf life. These ingredients are among each manufacturer's most closely held trade secrets. There is no justification for denying cigarette manufacturers the trade secret protection extended to every other consumer product industry."5/

The Institute's witness also pointed out that requiring package disclosure of additives, "combined with the * * * health warnings and tar, nicotine and carbon monoxide numbers, would turn cigarette packages into little textbooks, likely causing smokers to ignore it all." *Ibid.*

Congress responded to these objections in the 1984 legislation by providing trade secret protection to the ingredient information supplied to the Secretary. In addition, it made clear that ingredient information was to be submitted to the Secretary in a manner that does not identify the company involved or the brand of cigarettes containing particular ingredients.

The considerations that supported Congress's decision to treat ingredient information in this way in 1984 remain valid today. Similar considerations are reflected in broad ingredient disclosure exemptions under the Federal Food, Drug and Cosmetic ("FD&C") Act and the Fair Packaging

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5/ *See Comprehensive Smoking Prevention Education Act: Hearings on H.R. 5653 and H.R. 4957 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 97th Cong., 2d Sess. 355 (1982).

and Labeling ("FP&L") Act. Indeed, Mr. Chairman, it is fair to say that most tobacco additives would be exempt from disclosure under these laws and the implementing regulations of the Food and Drug Administration.

(1) Food. Congress explicitly has exempted flavorings, colorings and spices used in food from disclosure under Sec. 403 of the FD&C Act, 21 U.S.C. § 343.[6/] It requires the FDA, moreover, to establish further exemptions from disclosure for food ingredients "to the extent that [disclosure] is impractical, or results in deception or unfair competition." *Ibid.* *See, e.g.*, 21 C.F.R. § 101.100(a)(3) (1988) (exempting "incidental additives," including "processing aids," from disclosure).

(2) Cosmetics. The FDA, exercising its authority under Sec. 5(c)(3) of the FP&L Act, 15 U.S.C. § 1454(c)(3), likewise has exempted from disclosure the ingredients of flavors and fragrances used in cosmetics. 21 C.F.R. § 701.3(a) (1989). The FDA explained that these were "the two types of

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6/ Sec. 403(g)(2) requires the label of any food for which a "standard of identity" has been prescribed by regulation to list, insofar as may be required by regulation, "the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food." Sec. 403(i)(2) requires the label of any food fabricated from two or more ingredients, for which a standard of identity has not been prescribed, to list "the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each."

cosmetic ingredients which would be the most likely of any to create trade secret issues." 38 Fed. Reg. 28,912 (1973). The FDA also noted that disclosure of such ingredients "would be impractical." *Id.* at 28,913. *See, e.g.*, 21 C.F.R. § 701.3(l)(2) (1989) (exempting "incidental ingredients," including "processing aids," from disclosure). The FDA concluded that it would not be impractical to disclose by name colors used in cosmetics but the agency carefully provided that a color whose identity is a trade secret may be exempted from disclosure. 38 Fed. Reg. 28,913 (1973). The FDA has recognized, generally, that Sec. 5(c)(3) of the FP&L Act does not authorize it to promulgate ingredient labeling regulations that require the divulging of trade secrets. *Id.* at 28,912. *See* 21 C.F.R. § 720.8 (1988) (specifying procedure for exempting ingredients from public disclosure on trade secret grounds).

(3) Drugs. Sec. 502(e)(1) of the FD&C Act, which addresses disclosure of ingredients used to manufacture drugs, does not require disclosure of "inactive ingredients." *See* 21 U.S.C. § 352(e)(1). Such ingredients typically include binders, flavors, colors, preservatives and fillers. The FD&C Act requires the FDA to establish further exemptions from disclosure for active ingredients "to the extent that [disclosure] is impractical." *Ibid.*

Most of the ingredients added to tobacco in the manufacture of cigarettes are flavorings and fragrances.

Such ingredients would be exempt from disclosure under Sec. 403 of the FD&C Act and Sec. 5(c)(3) of the FP&L Act or otherwise would qualify for exemption from disclosure on trade secret or impracticality grounds.

Mr. Chairman, you have been quoted as suggesting that cigarette manufacturers should be required to disclose tobacco additives because "Nabisco [must] provide the ingredients to Oreo cookies."[7/] However, Nabisco is not required to disclose the flavorings, colorings and spices used in Oreos and is entitled to seek disclosure exemptions for other ingredients on trade secret or impracticality grounds. When you stated that "it is time to stop permitting the industry to treat additives to tobacco as trade secrets,"[8/] you were asking, in effect, to apply to tobacco products a standard *different* in all relevant respects from the standard applied to foods, cosmetics and drugs.[9/]

7/ *Chicago Tribune*, Nov. 16, 1989, p. 5.

8/ 135 Cong. Rec. S15,723 (daily ed. Nov. 15, 1989).

9/ Although S. 1883 would repeal Sec. 7(b)(2) of the Federal Cigarette Labeling and Advertising Act, which treats ingredient information as trade secret or confidential information and prohibits the unauthorized disclosure of such information, the bill does not purport to repeal Sec. 7(a), which requires cigarette manufacturers to provide the Secretary annually with ingredient lists that do not "identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients." Thus, cigarette manufacturers conceivably would continue to be required

(footnote cont'd)

(b) **Constituents.** As in the case of tobacco additives, the provisions concerning tobacco smoke "constituents" are redundant. Pursuant to a voluntary agreement and program entered into with the Federal Trade Commission, the major cigarette manufacturers already disclose in their advertising "tar" and nicotine ratings for the advertised brands.[10/] The Commission also publishes carbon monoxide ratings on a brand-by-brand basis, supplied by the cigarette manufacturers at the Commission's request.[11/] The Tobacco Institute Testing Laboratory (TITL), monitored closely by an on-site representative of the Commission, measures the "tar," nicotine and carbon monoxide levels of cigarettes sold in the United States.

The Commission has told the House Subcommittee on Transportation, Tourism, and Hazardous Materials that it is satisfied that its current arrangement with TITL enables it

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(footnote cont'd)

to provide one ingredient list (which does not disclose brand or manufacturer information) to the Secretary pursuant to Sec. 7(a) of the Labeling Act, and would be required to provide another list (which would disclose such information) to the Center under Sec. 953(a) of the new Title IX created by S. 1883.

10/ *See* Letter of October 23, 1970, to Federal Trade Commission from Brown & Williamson Tobacco Corporation, *et al.*

11/ *See, e.g.*, Federal Trade Commission, *Report of Tar, Nicotine and Carbon Monoxide Content of 272 Varieties of Domestic Cigarettes*, 54 Fed. Reg. 1787 (Jan. 17, 1989).

to ensure the accuracy of the "tar," nicotine and carbon monoxide figures supplied by the cigarette manufacturers.[12] With respect to any other "constituents" of tobacco smoke, a representative of the Oak Ridge National Laboratory (ORNL) told the same Subcommittee in 1988, based on research conducted by ORNL, that testing for other constituents would not affect the relative ranking of cigarettes as determined by "tar" and nicotine or provide information that would affect a smoker's choice among the different brands of cigarettes that are available.[13]

There is no reason to enact legislation requiring further disclosure of tobacco smoke "constituents," for shifting responsibility for overseeing such disclosure to a new federal agency or for incurring the substantial additional costs that such further oversight would entail.

12/ *FTC Nicotine Program: Hearing before the Subcomm. on Transportation, Tourism, and Hazardous Materials of the House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. 5-6 (1987) (statement of the Federal Trade Commission); *id.* at 10-11, 47 (testimony of William C. MacCleod, Director, Bureau of Consumer Protection, FTC); *id.* at 13, 47 (testimony of Daniel Oliver, Chairman, FTC).

13/ *Cigarettes -- Advertising, Testing, and Liability: Hearings on H.R. 4543 before the Subcomm. on Transportation, Tourism, and Hazardous Materials of the House Comm. on Energy and Commerce*, 100th Cong., 2d Sess. 204 (1988) ("*1988 Hearings*") (statement of Michael D. Guerin). Dr. Guerin testified that the potential additional constituents of tobacco smoke are not, *per se*, harmful compounds. *Id.* at 211.

(c) **Antismoking campaigns.** The Center would be directed to prepare and distribute antismoking materials, including "paid advertising campaigns to inform targeted populations * * * of the health effects of using tobacco products." Sec. 903(a)(1) and (2). Secs. 911-913 would direct the Center to make grants to public and private entities that would use the funds to conduct antismoking campaigns through public service announcements, paid advertising messages and "counter advertising." Sec. 911(b)(2). The Center also would be responsible for "coordinating with film makers, broadcast media managers, and others regarding the impact of media on tobacco use behavior." Sec. 903(a)(3).

Mr. Chairman, these provisions of S. 1883 appear to be based on the mistaken premise that Americans are unaware of the claimed health risks of smoking. In fact, as one authority told a House subcommittee not long ago, "the level of public awareness on smoking and health issues is virtually unprecedented in our national experience."14/ More Americans are aware of the allegations with respect to smoking and health than can identify George Washington or know when our Nation declared its Independence. Nearly

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14/ *See 1988 Hearings, supra* note 13, at 443 (statement of Gerald M. Goldhaber, Chairman, Department of Communications, State University of New York (Buffalo)).

every American believes smoking is harmful but only 1 of 3 Americans knows who delivered the Sermon on the Mount.[15]

Young people, especially, are aware of the risks attributed to smoking. As the Surgeon General has stated, "[b]y the time they reach seventh grade, the vast majority of children believe smoking is dangerous to one's health."[16] Of 895 children and adolescents questioned in a recent survey, over 98 percent said they believed smoking is harmful and "accurately named one or more body parts that are adversely affected by smoking."[17] Young people start to smoke not because they are unaware of the claimed health risks of smoking or because of cigarette advertising. The only significant influences on smoking by young people are family and peers, and these influences have been shown to be both powerful and direct.[18]

15/ *Id.* at 442-43.

16/ *Smoking and Health: A Report of the Surgeon General*, p. 17-10 (1979).

17/ Leventhal, *et al.*, "Is the Smoking Decision an 'Informed Choice'?", *JAMA*, vol. 257, pp. 3373-76 (1987).

18/ *See, e.g., Smoking Prevention Act: Hearings on H.R. 1824 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 98th Cong., 1st Sess. 53 (1983) (statement of Mortimer B. Lipsett, M.D., Director, National Institute of Child Health and Human Development) ("The most forceful determinants of smoking [by young people] are parents, peers, and older siblings."); Aaro, Wold, Kannas & Rimpella, "Health Behaviour in

(footnote cont'd)

When the antitobacco lobby complains that government spends "too little" on disseminating the antismoking message, it conveniently overlooks the value of the "free media" that the antismoking message receives daily. Yet the Advocacy Institute -- a prominent arm of the antitobacco lobby -- has noted "the vast outpouring of media attention to smoking," and has commented that, "[b]y standards which apply to most running stories, coverage of smoking has enjoyed an extraordinary run in the media."19/ It would seem profligate, to say the least, in the face of the federal budget deficit, for Congress to authorize an additional $50 million to promote a message that Americans already understand and believe and that is reinforced continually and pervasively by the news media.

I should add, in this connection, that we view with particular concern the provision of S. 1883 directing the Center to "coordinat[e] with film makers, broadcast media managers, and others regarding the impact of media on tobacco use behavior." Sec. 903(a)(3). It is not appro-

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Schoolchildren: A WHO Cross-National Survey," *Health Promotion*, vol. 1, no. 1, pp. 17, 21 (May 1986) ("When young people start smoking, the most important predictor is the smoking behaviour and smoking-related activities of 'significant others'.").

19/ *Media Strategies for Smoking Control -- Guidelines*, p. 9 (Jan. 14-15, 1988).

priate for government to tell artists, writers and others in the media how to portray smoking or smokers in their work, or to suggest that some portrayals are more politically "correct" than others. It is one thing for government officials to speak out on an issue but quite another for the government to "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion."20/ Action by the Center pursuant to Sec. 903(a)(3) would chill expression protected by the First Amendment -- effectively imposing a system of prior restraints on speech deemed to be insufficiently "unfriendly" to smoking.

(d) State programs. The Center would be directed to "provide assistance to States to enhance their efforts to enforce existing State laws concerning the sale of tobacco products within the State to minors." Sec. 901(b)(5). Secs. 915-920 would direct the Center to make grants to states and political subdivisions of states to assist state and local efforts to prevent initial tobacco use by minors and encourage the cessation of tobacco use, especially by members of high-use groups. Sec. 915. States that enact and enforce laws prohibiting tobacco sales to minors and prohibiting cigarette vending machines except at locations

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20/ *West Virginia State Board of Education v. Barnette*, 319 U.S. 624, 642 (1943).

where minors are not allowed would be rewarded with additional grants. Secs. 919 and 920.

Mr. Chairman, no one can seriously suggest that state and local governments need additional federal encouragement in this area. Virtually every state prohibits the sale or distribution of tobacco products to minors and many state and local governments currently are considering a variety of measures to strengthen further existing laws in this regard. Moreover, during this decade, many state and local jurisdictions have enacted laws restricting smoking in public places and workplaces and implementing other anti-smoking measures. In his 1986 report, the Surgeon General referred to "a wave of social action regulating tobacco smoking in public places."21/ Most recently, the Surgeon General's 1989 report stated:

> "Since the 1986 Report, the pace of action appears to have increased in both the public and private sectors. Restrictions on smoking in public places are the result of government actions at the Federal, State, and local levels, particularly state and local legislation."22/

In short, this is not a case in which Congress must bribe or coerce the states into pursuing federal policy.

21/ *The Health Consequences of Involuntary Smoking: A Report of the Surgeon General*, p. 263 (1986).

22/ *Reducing the Health Consequences of Smoking: A Report of the Surgeon General*, p. 552 (1989).

(e) **Other programs.** Secs. 921-925 would direct the Center to make grants to unions and other organizations to support activities, coordinated with employers, to "prevent the initiation, and encourage the cessation, of the use of tobacco products among workers and their families, especially those individuals with the highest prevalence of tobacco use." Sec. 922. The bill also would direct the Secretary of Education to provide "incentive grants" to establish smoke-free schools. Sec. 926. With respect, we submit that additional federal spending is not required to stimulate antismoking activity in these areas.

2. State and Local Regulation of Cigarette Advertising and Promotion. Sec. 955 would provide as follows:

> "Nothing in this subtitle, section 5 of the Federal Cigarette Labeling and Advertising Act * * * or the Comprehensive Smokeless Tobacco Health Education Act * * * shall prevent any State or local government from enacting additional restrictions on the advertising, promotion, sale or distribution of tobacco products to persons under the age of 18, or on the placement or location of advertising for tobacco products that is displayed solely within the geographic area governed by the applicable State or local government, such as advertising on billboards or on transportation vehicles, as long as the restrictions are consistent with and no less restrictive than the requirements of this subtitle and Federal law."23/

23/ For purposes of Title IX, "advertisement" would mean --

(footnote cont'd)

It is unclear what this provision would accomplish. The first part of Sec. 955 likely would be invoked by anti-smoking advocates at the state and local levels in an attempt to justify sweeping restrictions on the advertising, promotion, sale and distribution of tobacco products in the name of reducing smoking by young people. This could result in an end run around Congress' consistent policy of national uniformity in this area. Moreover, by arguably licensing state and local measures that would render cigarette advertising and perhaps cigarettes themselves invisible to young people, this part of Sec. 955 would fly in the face of the Supreme Court's repeated admonition that "the government may

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(footnote cont'd)

> "(A) all newspaper and magazine advertisements and advertising inserts, billboards, posters, signs, decals, banners, matchbook advertising, point-of-purchase display material (except price information), and all other printed or other material used for promoting the sale or consumption of tobacco products to consumers; and
>
> (B) any other means used to promote the purchase of tobacco products." Subtitle E, Sec. 961(1).

For purposes of Title IX, "promotion" would mean --

> "any marketing communication method that informs, persuades or reminds consumers of a tobacco product or the attributes, image or brand name of such product or, [*sic*] motivates consumers to sample or try that product." Subtitle E, Sec. 961(11).

not 'reduce the adult population * * * to reading only what is [deemed] fit for children.'"[24/]

The second part of Sec. 955 -- authorizing state and local restrictions on the placement or location of advertising displayed solely within the jurisdiction involved -- could Balkanize regulation of the advertising and promotion of a nationally marketed product. Such an outcome would be seriously at odds with First Amendment values. In addition, antismoking advocates undoubtedly would attempt to use S. 1883 to justify prohibitive state and local advertising requirements, or even outright bans. For all of these reasons, similar legislation in the House has been opposed in the last two Congresses by the American Civil Liberties Union, the Washington Legal Foundation, the Freedom To Advertise Coalition, the Association of National Advertisers and the American Association of Advertising Agencies, among others.[25/]

24/ *Bolger v. Youngs Drug Product Corp.*, 463 U.S. 60, 73 (1983) (quoting *Butler v. Michigan*, 352 U.S. 380, 383 (1957) (invalidating statute that prohibited reading materials deemed inappropriate for children)). *See also Health Protection Act of 1987: Hearing on H.R. 1272 and H.R. 1532 before the Subcomm. on Transportation, Tourism & Hazardous Materials of the House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. 99 (1987) (testimony of Professor Burt Neuborne, New York University Law School).

25/ *Tobacco Issues (Part 1): Hearing on H.R. 1250 before the Subcomm. on Transportation and Hazardous Materials of the House Comm. on Energy and Commerce*, 101st Cong., 1st Sess. (1989); *1988 Hearings, supra* note 13.

We oppose this provision of S. 1883 for the same reasons. There is no reason to retreat from Congress's consistent 25-year policy of national uniformity in this field.

3. An "Addiction" Warning. Section 10(b) of S. 1883 would replace the Surgeon General's carbon monoxide warning with the following warning: "SURGEON GENERAL'S WARNING: Smoking is Addictive. Once you start you may not be able to stop."

Mr. Chairman, this issue was the subject of a hearing in 1988 before the House Subcommittee on Health and the Environment. At that hearing, we testified against an addiction warning on the ground that calling cigarette smoking an "addiction" trivializes, and almost mocks, the serious narcotic and other hard drug problems faced by our society and undermines efforts to combat drug abuse.[26/] In addition, we noted that the "addiction" claim with respect to smoking is without medical or scientific foundation, notwithstanding the comments of former Surgeon General Koop. Such a claim defies all logic when, according to the Surgeon General, nearly half of all Americans who ever smoked have

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26/ Secs. 6 and 7 of S. 1883, which would amend the Drug-Free Schools and Communities Act of 1986 and the Anti Drug Abuse Act of 1988 to cover tobacco products, suffers from the same defect. These provisions of S. 1883 would divert the limited funds appropriated under these acts to anti-tobacco programs without appropriating any additional funds for such programs.

quit,[27] and most of the 41 million smokers who quit did so without formal treatment programs or smoking cessation devices.[28] Ironically, the presence of an "addiction" warning could serve to discourage some smokers from quitting.

Rather than repeat my testimony from that hearing, I respectfully request that my testimony, and the supporting testimony of Dr. Stephen M. Raffle and Dr. Theodore H. Blau, be included in the record of this hearing.[29]

* * *

At some point, Mr. Chairman, any industry faced with the prospect of still further regulation is entitled to say "enough." We clearly have reached that point with the regulation of tobacco products. S. 1883, which proposes regulation that is not needed and spending the federal government can ill afford, should be rejected.

I would be glad to answer any questions.

27/ *1989 Report, supra* note 22, at 292.

28/ *The Health Consequences of Smoking -- Nicotine Addiction: A Report of the Surgeon General*, p. 466 (1988). *See also id.* at 577, 580-81 (trends in quitting activity).

29/ *Health Consequences of Smoking -- Nicotine Addiction: Hearing before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong., 2d Sess. 299-39 (1988).

Statement of Floyd Abrams

on behalf of

The Tobacco Institute

before the

Committee on Labor and Human Resources
United States Senate

February 20, 1990

Mr. Chairman and distinguished members of the Committee, I appreciate this opportunity to add my voice to that of Mr. Whitley with respect to S. 1883 and to do so with particular focus on a number of grave constitutional questions raised by the proposed legislation. Those questions relate to certain specific provisions of S. 1883 and, more generally, to the thrust of the proposed legislation.

I offer you a few general thoughts at the start. One is that tobacco is a product that adults may lawfully purchase in every state in the country. Another is that the tobacco industry, no less than any other, is entitled to its First Amendment rights. A third is that the public has as much a First Amendment interest in hearing from a genuinely free marketplace with respect to tobacco as to any other topic -- commercial, political or otherwise.

These are, I would urge upon you, unexceptionable propositions. But how can they possibly be squared with a proposed statute that, for example, seeks to

establish a publicly funded Center for Tobacco Products authorized, among other things, to grant moneys to private antismoking advocacy groups to prepare advertisements for use on television (Sec. 911(a)(c)) at a time when tobacco manufacturers are precluded by statute from advertising on television?[1/]

It is one thing for government to express its views on television about smoking; there are always risks when government speaks, sometimes tolerable, but always real. Those risks are of a qualitatively different and more threatening order altogether when the power of government is used to fund attacks on smoking by private advisory groups while the government simultaneously inhibits the ability of the cigarette manufacturers to speak.

That is precisely what S. 1883 would do. It would not only place the full weight of government on one side of an ongoing debate about smoking; it would, at considerable violence to First Amendment principles, do so at a time when government attempts to silence the other side. S. 1883 would give the Government a virtual monopoly on

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1/ Public Health Cigarette Smoking Act of 1969, § 6, 15 U.S.C. § 1335 (1982).

communication on television and radio about tobacco use. There is no way such legislation can be squared with the First Amendment, let alone with basic principles of fairness.

S. 1883 would do more. The proposed Center for Tobacco Products would be responsible for "coordinating with film makers, broadcast media managers, and others regarding the impact of the media on tobacco use behavior." Sec. 903(a)(3). If I read this provision correctly, a government-created and funded entity is to play the role of adviser of, counselor to, and "coordinator" with the media as to how they should cover -- what they should say about and how they should depict -- smoking.

Presumably, individuals employed by or funded by the Center will view films, watch television programs, read newspapers and the like to guage the likely "impact" of the media on what the statute characterizes as "tobacco use behavior." Then they are to start the process of "coordinating" with film makers, it is fair to predict, not to show characters smoking, or not to make smokers attractive. Broadcasters, one can reasonably predict, who are licensed by the Government itself are to be advised on how best -- as the new Center views it -- to discourage smoking on television programs. If newspapers and magazines are included in the statutory scheme, as they appear

to be, the Center is to "coordinate" with journalists and publishers as well to influence their coverage of smoking issues.

This is surely an extraordinarily troubling level of governmental involvement with the content of what is contained in films, on television, and in the press. Were the government seeking to involve itself by the establishment of a government-funded agency with the "impact" of the media's treatment of any other lawful activity, the outcry would be loud indeed. Manipulation of the media -- planned, funded government manipulation of the media -- is simply unacceptable under the First Amendment.

In addition to authorizing a government-funded Center to monopolize, or at least manipulate, public debate on the issue of tobacco use, S. 1883 would retreat from the 25-year Congressional policy of nationally uniform regulation of tobacco advertising. The proposed provision would allow "any State or local government" to enact "additional restrictions on the advertising [and] promotion . . . of tobacco products to persons under the age of 18, or on the placement or location of advertising for tobacco products that is displayed solely within the geographic area governed by the applicable State or local government." Sec. 955.

This obviously would encourage, if not invite, state and local attempts to censor cigarette advertising. But "there is surely no area in which Congress can permit the States to violate the Constitution."[2/] And even if there were, it would hardly be in the area of the First Amendment.

The proposed legislation would, as well, allow the states to enact conflicting legislation for the protection of "persons under the age of 18." While there is no doubt that children may be protected by the government in different ways than adults, the legislation's paternalistic purpose does not save it from a head-on clash with the First Amendment. More than 30 years ago, the Supreme Court struck down a state law whose effect was, as Justice Frankfurter wrote, "to reduce the adult population . . . to reading only what is fit for children."[3/]

Almost two decades later, the Supreme Court noted, in the case I quoted earlier, with respect to an advertising prohibition, "[t]here is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself

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2/ *Tyler Pipe Industries, Inc.* v. *Washington State Department of Revenue*, 483 U.S. 262, 263 n.4 (1987).

3/ *Butler v. Michigan*, 352 U.S. 380, 383 (1957).

harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them."4/

Here, too, there is an alternative to the highly paternalistic -- and First Amendment-insensitive -- provisions of S. 1883. It is to trust in the good sense of the American public by allowing it to decide for itself about cigarettes without placing the heavy and dangerous hand of government on the scale.

I would be glad to answer any questions.

4/ *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976).

Statement of Taylor M. Quinn

on behalf of

The Tobacco Institute

before the

Committee on Labor and Human Resources

United States Senate

My name is Taylor M. Quinn, and I am submitting this statement on behalf of the Tobacco Institute for the record in connection with the Committee's consideration of S. 1883, the "Tobacco Product Education and Health Protection Act of 1990." This statement addresses certain aspects of the cigarette ingredient reporting and disclosure requirements of the bill.

I am currently the President of Taylor Quinn Consulting, Inc., Washington, D.C. Prior to entering the consulting business, I worked for the federal Food and Drug Administration (FDA) from 1951 until 1985. I began with FDA as a District inspector and rose through a number of different positions of increasing responsibility, culminating with service as Director, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, D.C., from 1976 until 1985. In that position, I had broad responsibility for food and cosmetic regulatory matters. My responsibilities and those of my staff included review and approval of proposed

regulations, recommendations with respect to enforcement actions, review and direction of inspection and field activities, analysis and recommendations with respect to proposed federal legislation, guidance to industry and consumers on FDA legal requirements, and coordination with state and local government regulatory agencies.

As Associate Director for Compliance, I had direct responsibility for food and cosmetic ingredient labeling matters. It is from this perspective that I provide these comments on the cigarette ingredient reporting and disclosure requirements of S. 1883. As explained in this statement, the cigarette ingredient labeling requirements under the bill are inconsistent with current statutory and regulatory requirements for food and cosmetics, and would mandate far broader ingredient disclosure than that required for FDA-regulated products.

Under S. 1883, cigarette manufacturers would be required to provide to the newly created Center for Tobacco Products Control and Education ("Center") "a complete list of each tobacco additive used in the manufacture of each tobacco product brand name and the quantity of such additives" (Secs. 951(a)(1) and 953). The Center, in turn, would be authorized to require public disclosure, through labels or package inserts, of the identity and quantity of all tobacco product additives. Sec. 902(a)(1) and (2).

Tobacco additive is defined under section 961(15) as "any ingredient that is added to a tobacco product in the process of manufacturing or producing a tobacco product." This definition is very broad and could be interpreted to include processing aids, migrants from cigarette paper and packaging, and all flavors, regardless of the level of the flavor present in the finished product. There is no provision in the bill for protection of trade secret formulas and no authorization for exemption from ingredient disclosure requirements on grounds of impracticability. This is in sharp contrast to the ingredient labeling requirements for food and cosmetics. A guiding principle behind the food and cosmetic ingredient labeling requirements is that ingredient disclosure should not jeopardize trade secrets or impose impracticable burdens on manufacturers. These principles are ignored in S. 1883.

Food

Under section 403(i)(2) of the federal Food, Drug and Cosmetic Act (FD&C Act), the label of each food fabricated from two or more ingredients must bear the common or usual name of each ingredient, except that spices, flavorings and colorings, other than those sold as such, may be designated as spices, flavorings and colorings without naming each. The primary purpose of this labeling exemption was to protect trade secret information. Congress recognized that spices,

flavors and colors impart distinctive characteristics to individual food products and that the identity of specific spices, flavors and colors in food formulations is properly regarded as highly sensitive commercial information.

Section 403(i) of the FD&C Act also authorizes FDA to establish exemptions from food ingredient labeling requirements where compliance is impracticable. Under this authority, FDA has issued regulations exempting incidental additives from food ingredient labeling requirements. 21 C.F.R. § 101.100(a)(3). Incidental additives are defined as substances that are present in foods at insignificant levels, and that have no technical or functional effect in the finished food and include (1) substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the food did have a functional or technological effect, (2) processing aids, and (3) substances migrating to food from packaging.

FDA regulations require food ingredients to be declared on the label in descending order of predominance by weight. 21 C.F.R. 101.4(a). There is no requirement, however, for quantitative declaration of ingredients on food labels, except with respect to certain major characterizing ingredients. 21 C.F.R. § 102.5. Congress and FDA have refrained from requiring quantitative ingredient labeling on food

in recognition of the commercial sensitivity of this information.

Cosmetics

FDA cosmetic ingredient labeling requirements were issued under authority of section 5(c)(3) of the Fair Packaging and Labeling Act (FPLA). That section provides that each package of a consumer commodity shall bear the common or usual name of each ingredient in descending order of predominance by weight, but that this shall not be deemed to require that any trade secret be divulged. Exercising its authority under this provision, FDA has exempted from disclosure specific flavors and fragrances used in cosmetics and made provision for exemption of ingredients that were shown to be trade secrets. 21 C.F.R. § 701.3(a). As with flavors, colors and spices in food, FDA recognized that flavor and fragrance formulations in cosmetics as well as some other ingredients are regarded as trade secrets and that their disclosure would cause substantial competitive damage.

As with food products, FDA regulations exempt incidental additives from cosmetic ingredient disclosure requirements. 21 C.F.R. § 701.3(L). Incidental additives are defined to include processing aids, as well as other ingredients that are present in the finished product in insignificant amounts and that have no technical or functional effect in the finished product. Also, Congress and FDA have declined to impose any

general requirement for quantitative declarations of cosmetic ingredients to avoid compulsory disclosure of trade secrets or confidential commercial information.

In summary, the ingredient disclosure requirements under S. 1883 are inconsistent with FDA ingredient labeling requirements for food and cosmetics, and the bill does not include trade secret protections and incidental additive exemptions that have been widely adopted for other consumer products.