

August 14, 1995

MEMORANDUM FOR HAROLD ICKES

FROM: JENNIFER O'CONNOR

SUBJECT: Tobacco -- First Amendment Talking Points

Attached are talking points on the First Amendment and our tobacco regulation, prepared by Harriet Rabb, the HHS General Counsel.

PREPARED BY RABB FOR THE SECRETARY

N.B.:

We are regulating commercial speech.

Our regulations are narrowly drawn to balance

(i) preventing children's involuntary exposure to positive tobacco ad images, and

(ii) preserving adults' ability to get information about the products they buy.

Q. Your opponents say the proposed regulation violates the First Amendment by "imposing restrictions on their ability to advertise and promote their products." What's your reply?

A. The Supreme Court has upheld restrictions on commercial speech so long as the government has a legitimate interest in imposing restrictions and where the restrictions imposed are a "good fit" with the government's objective. [Central Hudson]

Our legitimate interest is our children's health and long life. Our effort to reduce their involuntary exposure to pervasive, appealing images that attract them to smoking -- an addicting and ultimately deadly activity -- is narrowly tailored to achieve our purpose.

We ban billboards near schools and playgrounds and prevent giveaway and trinkets from becoming "walking billboards".

We would require that point of sale and other outdoor signs and billboards be black and white text only to reduce the attractive images that children see involuntarily in their daily lives.

We would require that magazines with significant children and adolescent readership also be free of attractive images but allow publications for adults to be free of any restrictions.

PREPARED BY DEPT/JUSTICE FOR THE POTUS

TALKING POINTS ON THE 15% / 2 MILLION YOUTH READER CUTOFF

- * The FDA's proposed restrictions on cigarette print advertising apply to publications with either 2 million youth readers or 15% or more youth readership.
- * We understand that the 15% cutoff is being challenged by some people as arbitrary.
- * Advertisements are provided some protection by the First Amendment, but they are commercial speech, and so we have greater ability to regulate them when the regulations serve a significant government interest than we would other sorts of speech, like political speech.
- * Reducing the level of youth smoking is a tremendously important interest, and studies show that young people are especially susceptible to attractive advertisements -- it is one of the things that contributes to kids trying cigarettes at an early age.
- * So we think we are justified in protecting children from attractive advertisements and other kinds of promotional material that they or their parents cannot easily avoid -- like billboards, and posters in stores.
- * When it comes to advertising in magazines, the proposed restrictions are aimed just at magazines that have a significant youth readership.
- * The FDA thinks that 15% youth readership is one reasonable way to define those publications that have significant youth readership. The other publications affected by the proposed restrictions are ones where the total number of young people reading the magazine is so large -- 2 million or more -- that they should be covered, too.
- * At the same time, the FDA has tried to balance the interests of adults in receiving unrestricted advertising if they want it. So they have tried to draw a line.
- * Some people may think the FDA has chosen the wrong line, but I don't know of anyone who thinks we cannot place some restrictions on advertising cigarettes to kids when it is illegal for kids to purchase cigarettes in all 50 states.
- * Now any percentage figure is going to be arbitrary in one sense -- why not 20%? why not 14%? why not cover all publications? I am sure that the FDA will be listening to the public's views about whether the 15% figure is the right one -- the process they have just begun is designed to give people the opportunity to make suggestions about what the regulations should say.

THE WHITE HOUSE
WASHINGTON

DATE: 4.3.96

TO: HAROLD ICUES

FROM: White House Counsel JACK Q.
2nd Floor, West Wing x6-2632

☒ FYI

☐ Appropriate Action

☐ Let's Discuss

☐ Per Our Conversation

☐ Per Your Request

☐ Please Return

☐ Other

Talking Points on Ken Starr's Argument Before the Fifth Circuit
in the Private Class Action against the Tobacco Companies

In the Castano case, a New Orleans District Judge (now deceased) certified a class consisting of "every nicotine dependent person" who smoked any cigarette brand in the last 50 years. As many as 50 million individuals would be in the class.

Representing the tobacco companies, Judge Kenneth Starr will argue today before the Fifth Circuit that the case is not appropriate for treatment as a class action.

Unlike other pending actions brought by Florida, West Virginia, Mississippi and several other states, the Castano case involves private plaintiffs. The United States is not a party and has not been involved in any way.

Unlike other tobacco litigation, which has focused the health consequences of smoking (e.g., cancer), the Castano plaintiffs focus on nicotine addiction itself as a compensable injury. Their complaint alleges that tobacco manufacturers intentionally addicted smokers by manipulating nicotine content in cigarettes.

The legal issue before the Fifth Circuit is whether this issue "predominates" or whether, as Starr contends, other highly individual issues, such as causation and damages, make this an inappropriate case for class treatment.

The case has been brought by 60 of the leading plaintiffs attorneys in the country, each of whom has pledged \$100,000 a year for an indefinite period to cover expenses. The lead plaintiff, Castano, died of smoking-induced lung cancer in his 40s, and was a close friend of the attorney who initiated the action.

The consequences for the industry if the case is permitted to go forward as a class action are potentially staggering.

While the Administration supports any initiative that would address the scourge of smoking among the nation's children, we are not involved in this case and do not have a position on the narrow legal issue before the Fifth Circuit.

JO: JO'C
From: Chuo
4/2/96

Talking Points on Ken Starr's Argument Before the Fifth Circuit
in the Private Class Action against the Tobacco Companies

BACKGROUND

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TALKING POINT

While the Administration supports any initiative that would address the scourge of smoking among the nation's children, we are not involved in this case and do not have a position on the narrow legal issue before the Fifth Circuit.

TALKING POINTS ON PIERCE STUDIES

John Pierce, Program Director and Sam Walton Professor for Cancer Research at University of California, San Diego is publishing two studies on the impact on children of tobacco company marketing. The first study, published in the Journal of the National Cancer Institute, shows that tobacco company marketing is more important than peer pressure in influencing children to begin to smoke. The second study, published in Health Psychology, tracks how major tobacco company marketing programs over the past century have increased smoking initiation rates among teenagers.

Q: What impact does Pierce study have on the President's initiative or the FDA rule?

A: If we want to be successful in preventing kids from beginning to smoke, we need to reduce the powerful appeal the industry's advertising and promotion is having. We know it's reaching our kids: 86% of underage kids who buy their own cigarettes purchase one of the three most heavily advertised brands. These studies underline the importance of the President's initiative.

THE WHITE HOUSE

WASHINGTON

17 October 1995

MEMORANDUM FOR LORRIE MCHUGH
GINNY TERZANO
MARY ELLEN GLYNN
EVELYN LIEBERMAN
JULIA MOFFETT

FROM: JENNIFER O'CONNOR

RE: TALKING POINTS

Attached is a copy of talking points on today's Wall Street Journal tobacco story and copy of the story. Calls should be referred to FDA.

NOTE TO: WHITE HOUSE/HHS PRESS OFFICES -- PLEASE REFER MEDIA CALLS TO FDA PRESS ON THIS ISSUE; THE FOLLOWING Q & A'S ARE WHAT WE WILL USE TO FIELD ANY INQUIRIES

AMMONIA TALKING POINTS

The Wall Street Journal of Oct. 18, 1995, reports on two Brown & Williamson documents concerning the importance of ammonia technology in the manufacture of cigarettes. The WSJ reports that the documents show how ammonia increases the delivery of nicotine to smokers -- an assertion that industry spokesman deny. The WSJ also reports that use of ammonia helped solve a problem for the industry: how to lower tar and maintain adequate delivery of nicotine. Quoted as supporting this assertion is a former scientist for the tobacco industry. The WSJ also reports that one of the documents was, in part, the basis of testimony by Dr. Kessler in June 1994; the story notes that Kessler did not identify the company during his testimony.

Q: What relevance do the documents reported in the Wall Street Journal have for the FDA and its proposals to regulate cigarettes?

A: In testimony in June 1994 and in the FDA legal analysis and factual findings made public in August 1995, we said the information available to the agency indicates that ammonia can be used in cigarette manufacturing to increase the amount of nicotine delivered to the smoker. Major medical and scientific organizations that have looked at the issue, all say that it's the nicotine in cigarettes that causes the addiction that eventually leads to the diseases and death from smoking.

Q: Were the Brown and Williamson documents the basis for Kessler's testimony and the FDA legal analysis?

A: The FDA has not revealed the sources of any confidential company information obtained during its investigation and is not prepared to do so now.

'Impact Booster'

Wall St. Jnl.: 10-18-95 p. 1

**Tobacco Firm Shows
How Ammonia Spurs
Delivery of Nicotine****Brown & Williamson Papers
Claim Wide Industry Use
Of Additive in Cigarettes****Inside 'the Soul of Marlboro'**

By ALIX M. FRIEDMAN

Staff Reporter of The Wall Street Journal

Leading U.S. tobacco companies enhance nicotine delivery to smokers by adding ammonia-based compounds to their cigarettes, according to two major internal reports by Brown & Williamson Tobacco Corp.

The six million tobacco industry vehemently denies that it seeks to keep smokers hooked by increasing nicotine levels in cigarettes. But the confidential reports obtained by this newspaper indicate that, while cigarette makers may not bolster nicotine content per se, most are adding chemicals that increase the potency of the nicotine a smoker actually inhales.

The lengthy internal reports by the nation's No. 3 cigarette maker are remarkable because both were drafted in the early 1990s and thus provide a rare window into recent activities of B&W and its leading competitors. One of the confidential documents is especially intriguing because of its competitive analysis of ammonia use in Marlboro, Philip Morris U.S.A.'s market-dominating brand.

At a time when America's tobacco sellers are already under intense legal and regulatory attack, the Brown & Williamson research could create new problems for the industry. In particular, the analysis of how B&W and its rivals use chemicals that, the reports assert, enhance nicotine delivery could assist efforts by the Food and Drug Administration to regulate tobacco as a drug.

Company Statement

Brown & Williamson, a unit of London-based B.A.T. Industries PLC, wouldn't respond to specific questions about the documents, saying they "relate to B&W's proprietary manufacturing processes and competitive product research, all of which constitute B&W trade secrets." The company emphasizes that it has spent a great deal of money on the reports and that their release "would be invaluable to competitors and cause damage to B&W."

Despite the assertions in its own reports about improved nicotine delivery, the company adds that "the use of ammonia in the processing [of tobacco] does not increase the amount of nicotine absorbed by

the smoker."

Other tobacco companies, while acknowledging use of ammonia-releasing chemicals to enhance flavor, also deny that ammonia affects nicotine delivery. Lorillard Tobacco Co., a unit of Loew's Corp., says that interest in the subject "probably proceeds from incorrect indications by the FDA that this substance increases the transfer of nicotine or the per-puff delivery of nicotine to the smoker. Neither of those things is correct."

Handbook for Blenders

The first of the two Brown & Williamson documents to be circulated within B&W was a 1991 handbook for leaf blenders and product developers laying out the rudiments of ammonia chemistry. FDA Commissioner David A. Kessler quoted briefly from the primer last June in congressional testimony, but he neither elaborated on its contents nor revealed which company was responsible for it.

The 54-page handbook explains how ammonia scavenges nicotine from tobacco and converts it into a form with greater impact on smokers. Nicotine in this "pharmacologically active" or "free" form has a more powerful effect than nonammoniated nicotine because it gets absorbed more quickly into a smoker's bloodstream, according to government and independent scientists. Thus, by harnessing ammonia-producing additives, a manufacturer can enhance nicotine delivery without actually adding nicotine, these scientists say.

The leaf blenders' manual says that Brown & Williamson adds ammonia-releasing chemicals to "almost all" its non-menthol brands, which include Viceroy, Raleigh and GPC. The chemicals supplement ammonia occurring naturally in tobacco. The "free" nicotine liberated by the additives "is associated with increases in impact and satisfaction reported by smokers," the B&W manual concludes.

Hot Buttons

In using the terms "impact" and "satisfaction," the Brown & Williamson document obliquely addresses the hot button issue of smokers' nicotine cravings. These terms are among those consistently used by the industry as euphemisms for the effects of nicotine, FDA officials say. "Despite the buzzwords used by industry, what smokers are addicted to is not 'rich aroma' or 'pleasure' or 'satisfaction.' What they are addicted to is nicotine, pure and simple," Dr. Kessler has testified in Congress.

Ammonia increases "impact," says Neil Benowitz, a professor and nicotine-research specialist at the University of California in San Francisco, because "the faster nicotine is absorbed, the more reinforcing or satisfying it is and the greater its psychological effect."

Nicotine is widely viewed by scientists as the active component that makes cigarettes addictive, according to several Surgeon General reports. In contrast, the industry has always described nicotine as

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providing better flavor, in addition to other benefits, and has denied that it promotes addiction. Tobacco companies also maintain that any links between cigarette smoking and heart disease, cancer or other ailments are unproven.

The second document, dated Oct. 23, 1992, is Brown & Williamson's competitive analysis of Marlboro—an outgrowth of a B&W effort code-named the Worldwide Best Project. In a Dec. 6, 1991, strategy memo, the company described its ultimate objective as "beating Marlboro" by developing products that were "significantly superior" and "significantly preferred" to Marlboro. Brown & Williamson scientists and marketing staffers then collaborated on the 1992 study, titled "PM's Global Strategy: Marlboro Product Technology."

B&W's abstract of the document—the full report includes 46 pages of text and dozens of charts and tables—says the information in the paper "has been summarized and reviewed by scientists in the various groups and represents a collective judgment of the critical product technologies utilized by PM."

After providing an analysis of Marlboro's composition and design, the report concludes: "What product technology, then, makes Marlboro a Marlboro? Looking at all of the technology employed in Marlboro on a worldwide basis, ammonia technology remains the key factor. . . . Ammonia technology is critical to the Marlboro character, taste, and delivery."

Philip Morris U.S.A., a unit of Philip Morris Inc., didn't respond to questions about the Brown & Williamson documents. Earlier, in response to inquiries about use of ammonia in cigarettes, Philip Morris said it "does not use ammonia in the cigarette manufacturing process to increase the amount of nicotine inhaled by the smoker or to affect the rate of absorption of nicotine inhaled by the smoker" or to "affect the rate of absorption of nicotine in the bloodstream of the smoker."

In highlighting the role of ammonia in nicotine delivery, the Brown & Williamson documents appear at odds with certain past statements by industry representatives. For instance, after visiting Brown & Williamson's headquarters in Louisville, Ky., in May, FDA officials asked the company about the effects of diammonium phosphate, or DAP, one key ammonia additive. In a June 14 letter to the FDA, company law firm King & Spalding responded: "The primary purpose for using DAP is to increase taste and flavor, reduce irritation, and to improve body." The letter acknowledged that DAP also increases nicotine delivery but called this "an incidental effect."

Also in June, after the FDA's Dr. Kessler testified before Congress about ammonia in cigarettes, Philip Morris issued a statement saying the implication that "tobacco companies are adding ammonia to their cigarettes to increase nicotine deliveries in an attempt to 'addict' smokers" is "not true." Philip Morris acknowledged using "small amounts of ammonia and related compounds" in the cigarette-manufacturing process for reasons such as flavoring. But it said: "There is no indication that ammo-

nia compounds in our cigarettes alter the amount of nicotine the smoker inhales."

However, Brown & Williamson's Marlboro report characterizes each effect of Marlboro's ammonia technology including "ammonia in smoke" and "free nicotine/nicotine transfer"—as among "key chemicals." Other listed include enhancing flavor and reducing the harshness of smoke. And the leaf blenders' handbook, while also linking ammonia to better taste and less irritation, is explicit in describing ammonia as an "impact booster" and in detailing how it affects nicotine delivery.

"Ammonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine," the manual explains. "As a result of such change the ratio of extractable nicotine to bound nicotine in the smoke may be skewed in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in cigarette smoke and this is how ammonia can act as an impact booster."

SMOKING MACHINE

Smokers have no way of gauging the effect of ammonia on nicotine delivery, says Jack Henningfield, chief of the pharmacology branch at the government's National Institute on Drug Abuse. This is because the industry's "smoking machine"—which takes small puffs of smoke from cigarettes to measure tar, nicotine, carbon monoxide and other chemicals—registers only the total nicotine content. The device, used in compliance with Federal Trade Commission rules, doesn't distinguish between the nicotine-acting salt-bound nicotine and the more potent "free" nicotine that ammonia helps release. So an ammonia-treated cigarette that delivers more potent nicotine to smokers would measure the same as a cigarette with no such additives, Mr. Henningfield says.

Put simply, the government's nicotine addict. "The machines aren't measuring the effects that ammonia has on nicotine delivery in smokers."

The direct health effects of nicotine appear to be relatively minor, although a 1989 surgeon general report says nicotine can be a factor in heart disease and pregnancy problems. It is by hooking smokers on cigarettes—which deliver numerous carcinogenic substances in tar—that nicotine most clearly contributes to illness and death, federal health officials say.

The industry's use of ammonia-releasing compounds that enhance nicotine delivery is having far-reaching consequences, government scientists and former tobacco-industry researchers believe. In addition to making full-flavor cigarettes more appealing, they say, the use of ammonia helps explain how tobacco companies have been able to reduce tar levels in their cigarettes over the past two decades while still furnishing smokers with sufficient nicotine to satisfy smokers' cravings.

"With ammonia, you get a bigger jag with less nicotine

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Wall St. J., 10-18-95

Fine-Tuning Marlboro

When Brown & Williamson delved into the mysteries of Marlboro, it dug out more than just ammonia.

The study of Marlboro states, for instance, that the amount of sugar in a U.S. Marlboro had risen to 12.3% of the blend by the end of 1988, up from 9.3% before 1982. Although the study doesn't explain the reason for this increase, the FDA's report on nicotine manipulation says that sugars are often added to tobacco blends to smooth out the harsh taste of smoke. The taste becomes harsher as nicotine levels rise, according to the FDA.

Brown & Williamson's report also observes that Philip Morris has increased the level of "moisture sugars"—those sugars that specifically interact with ammonia to enhance tobacco flavor—to 3.6% from 3.3% during the same period.

Philip Morris didn't respond to questions about the Brown & Williamson documents.

Retaining Moisture

Brown & Williamson further reported an increase in certain

other Marlboro additives. Its analysis says that after 1988, Marlboro's level of two so-called humectants—glycerine and propylene glycol—jumped 15% and 30% respectively. The Marlboro study says these humectants "can influence the blend's equilibrium moisture content, moisture retention capability, and smoke quality."

The FDA has said that by maintaining moisture, humectants ensure that the nicotine content of a blend doesn't fall. They also help smoke particles that contain nicotine to combine into larger particles, making smoke smoother and easier to inhale, the FDA report says.

Levels of acetone, a class of chemicals in smoke, have risen, too, the Brown & Williamson competitive report shows. The data reflect a 40% increase between 1982 and 1991 in available levels in U.S. Marlboro King Size. In its report on nicotine manipulation, the FDA said that, in the early 1980s, Philip Morris conducted research into the optimal ratio of acetone to nicotine

nicotine "that would maximize the positive reinforcing effects of cigarettes; i.e., maximize their potential to produce dependence in smokers."

Letting Air In

Besides fine-tuning Marlboro's chemistry over the past two decades, Philip Morris has also changed certain aspects of how the product is put together. Brown & Williamson's report says. Among those changes, the report says, has been a sharp increase in the amount of air that smokers can draw through the filters of U.S. Marlboro. The competitive analysis says that Philip Morris didn't ventilate its Marlboro King Size filters at all in 1978. However, ventilation was apparent by 1979, and it had increased significantly by the end of the following decade.

The Marlboro study doesn't elaborate on the reason for this increase. The FDA's report says that with ventilation the manufacturer has selectively reduced tar while delivering a higher percentage of available nicotine to the smoker.

—Alia M. Friedman

From Brown & Williamson's response to questions raised for this article:

Based entirely on publicly available information, you should be aware that:

1. Ammonia occurs naturally in foods (e.g., coffee and roast beef), and in tobacco.
2. Our bodies naturally produce ammonia at levels thousands of times higher than amounts found in cigarette smoke.
3. Ammonium hydroxide is an approved additive for food, and processes using it are widely used in the manufacture of caramel, baked goods, meat products, and confectioneries.
4. The use of ammonia in the processing does not increase the amount of nicotine absorbed by the smoker. Therefore, the deliveries of nicotine measured using the Federal Trade Commission methodology are in no way affected.
5. The use of ammonia technology by our industry has been known for decades as it relates to cigarette manufacturing, and has been a matter of public record through patent filings for over 25 years. In addition, ammonia compounds are among compounds found in the publicly-released 1993 Tobacco Additives List.

In summary, you can see from the above that ammonium hydroxide is used extensively in consumer goods. In our case, we use it to enhance flavor.

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because it is absorbed faster," says John Kreisher, a former associate scientific director for the Council for Tobacco Research, an industry-sponsored group that funds independent scientists. "Ammonia helped the industry lower the tar and allowed smokers to get more bang with less nicotine. It solved a couple of problems at the same time."

"Consumers want lower tar and nicotine ratings but still need high nicotine, and ammonia gives them both," Mr. Henningsfeld says. About two-thirds of smokers now buy cigarettes with reduced tar and nicotine.

The Brown & Williamson disclosures come at a time when the industry faces a variety of legal proceedings in addition to the FDA's regulatory effort. These include a pending grand-jury investigation in Washington into whether industry executives committed perjury in their congressional testimony regarding nicotine manipulation. In addition, tobacco companies have lawsuits brought by New States seeking reimbursement for the costs of

usual Marlboro because the added ammonia liberated nicotine from the non-burning brand. In the Marlboro report, Brown & Williamson says its 1991 data clearly show the nicotine pickup potential of ammoniated handcast.

Marlboro's introduction of handcast in the 1950s—when Philip Morris was the nation's smallest cigarette maker—roughly coincided with a dramatic change in the image of the brand, which had been introduced in 1924 primarily as a women's cigarette. Marlboro was relaunched in 1954 with its now-famous red and white box and with cowboys among its mix of manly advertising images. Philip Morris made the cowboy its sole "Marlboro Man" in 1961. The company says it introduced DAP into handcast in the 1960s.

In the 1970s, Philip Morris began shifting to a different kind of reconstructed tobacco that was cheaper than handcast to manufacture. The Brown & Williamson manual says, but by adding ammonia-releasing chemicals—including DAP and urea—to the new filler, the company was able to maintain its level of nicotine delivery, according to data in the report on Marlboro.

The company, however, never abandoned handcast altogether, leading B&W to conclude in the manual that DAP-treated handcast is "the soul of Marlboro."

The manufacturing adjustments mentioned in the Brown & Williamson manual says, with "explosive growth" in Marlboro sales. The brand now boasts a 30% share of the U.S. cigarette market.

IMITATING MARLBORO

Philip Morris's use of ammonia in nearly all its brands has been widely emulated within the tobacco industry. According to the Brown & Williamson handbook, Brown & Williamson itself developed and now uses a reconstructed tobacco called CPCL, specifically designed to replicate Philip Morris's version, the handbook says.

When Brown & Williamson made an experimental cigarette using 100% CPCL, the cigarette registered what the manual calls "nicotine transfer efficiencies" of 22%, against normal values of 12% to 15% for tobacco. The manual characterizes the enhanced nicotine transfer as "unusually high."

Brown & Williamson's manual says its actual product specifications call for CPCL to make up as much as 10% of its blend. It notes that a cigarette containing 1% CPCL has, among other benefits, "higher impact" than the same blend without the ammoniated tobacco.

In 1992, the year the Marlboro report was completed, B&W changed some of its products, according to an internal memo dated Jan. 8, 1992. The memo reports that newly reformulated brands include Richmond and Viceroy 700s. It couldn't be determined whether the changes included adding ammonia.

'SENSORY IMPROVEMENTS'

The memo also states that, among smokers on test panels, Brown & Williamson had achieved "sensory improvements" in 1992, in part by applying mild "root" technology, a company term for adding ammonia-releasing chemicals. The document, which summarizes research and development improvements in 1992, doesn't disclose whether Brown & Williamson actually marketed this version of Kool.

Among competitors, No. 2 ranked R.J. Reynolds Tobacco Co. appears to ammoniate its tobacco sheets in certain brands, most notably Winston, according to the Brown & Williamson handbook. Reynolds, a unit of R.J.R. Nabisco Holdings Corp., won't comment on any particular brand, citing competitive concerns. In general, the company says it adds "minuscule" amounts of ammoniated compounds to the reconstructed tobacco it uses in certain brands. It says it considers these compounds "processing agents," not "additives," because almost all of the ammonia has reacted with materials in tobacco before the cigarette is lit.

The company uses the compounds only in make "smoke smoother" and its "product taste smoother," says Robert A. Reynolds, the company's director of health and environmental sciences. "What we are saying is we sell sensory impact in tobacco products, smoke feel in the mouth, flavors and types of tobacco—not just nicotine, as Dr. Kessler would have people believe," he adds.

R.J. Reynolds's addition of ammoniated compounds is so negligible that there is no difference in the amount of ammonia or nicotine in smoke from cigarettes made with or without them, Mr. Suber says. He adds that the company doesn't have a way to measure "free" nicotine which he calls "a theoretical thing."

Lorillard, maker of Kent and Newport, has been applying DAP directly to tobacco leaves for many years, the B&W manual says, and "we now find a considerable amount of DAP in the reconstituted tobacco in many Lorillard brands."

In addition to saying that ammonia doesn't affect nicotine delivery in its cigarettes, Lorillard questions whether DAP can produce such an effect. "In the research lab, we have looked at the use of DAP in even greater amounts than we use it commercially, and even in those greater amounts we have observed no increase in the transfer of nicotine," a spokesman says.

The B&W test blenders' manual says that American Tobacco Co., acquired by Brown & Williamson last year, also uses a filler containing DAP in some new brands.

Only Liggett Group, a unit of Double Group Ltd., appears not to have used ammonia technology, according to the B&W manual. Liggett, which declined to comment, citing competitive concerns, is the nation's smallest tobacco firm, with a market share of 2.3%.

What product technology, then, makes Marlboro a Marlboro?

Looking at all of the technology employed in Marlboro on a worldwide basis, ammonia technology remains the key factor.... Ammonia technology is critical to the Marlboro character, taste and delivery.

—Brown & Williamson report on the bestselling rival brand



breeding smoking-related illnesses. Meanwhile, in a federal suit in New Orleans, the industry is the target of a giant federal class-action lawsuit claiming that smoking is an addiction and that the industry withheld this fact from consumers.

The industry is vigorously fighting all these efforts. Of the FDA's action, Philip Morris says: "We believe that Congressional Reporter's allegations regarding the use of ammonia in the cigarette manufacturing process are scientifically unfounded, lack merit, and do not support the FDA's illegal assertion of jurisdiction over the cigarette industry."

Ammonia chemistry isn't the only way the tobacco industry exerts control over nicotine delivery, according to the FDA. In a report it released in August in support of its proposed regulation of cigarettes, the agency detailed the methods it says the industry uses to "manipulate nicotine delivery at each stage of production." FDA officials believe that ammonia technology works in tandem with additional techniques, such as blending different varieties of tobacco to ensure sufficient nicotine levels and using filters that, by letting in more air, deliver proportionately more nicotine than tar. The industry has denied that any such techniques are designed to promote addiction.

LONG HISTORY

But the Brown & Williamson documents emphasize the importance and long history of ammonia technology in nicotine delivery, tracing Philip Morris's quiet use of this technology back more than 30 years. According to the last tobacco manual, U.S. cigarettes were made entirely of various types of tobacco not until the early 1950s, when Philip Morris began introducing tobacco fillers such as stems, dust and broken leaves as a smoke-saving filler in its cigarettes.

The reports don't say why ammonia entered the picture, but two former Philip Morris employees link the introduction of the additive to a problem the company faced with its reconstructed tobacco filler, called handcast. "The product just fell apart during processing," says Howard Spielberg, manager of Philip Morris's flavor group until 1992, when he took early retirement.

Grasping for a way to make the filler hold together in a strong sheet of tobacco, Philip Morris experimented with ammonia. Mr. Spielberg and another former employee say. The company found that the ammonia compound DAP, which released glue-like pectins, did the job. Brown & Williamson says Philip Morris's manufacturing hitch, DAP turned out to suit the company's needs in other ways as well, the last blenders' manual says.

The new thing, applying the odorless, white crystalline powder to the reconstructed tobacco "dramatically altered" the taste of the cigarette. "Was this by design or by accident?" the manual writers wonder. "We don't know the sure, but it is a major player in establishing the taste of Marlboro." In addition to affecting flavor, DAP serves as an "impact booster" and a "satisfaction promoter," the manual says.

NICOTINE PICKUP

The B&W report on Marlboro cites an experiment showing the effectiveness of Marlboro's ammonia-rich handcast filler in scavenging nicotine from the rest of the tobacco in the cigarette. The experiment showed that the firm's nicotine level in the filler almost tripled once it was placed in an ac-

Urgent!

talkin
PB

Smoking advertisements: Talking points

May 13, 1996 -- HHS and FDA (Zonana & O'Hara)

Today, the Supreme Court struck down the state of Rhode Island's ban on advertisements that refer to liquor prices. Some observers have speculated that the ruling could undermine the Clinton Administration's effort to limit cigarette advertisements that appeal to children.

* We haven't yet reviewed the ruling. However, based on news reports, there are many differences between the FDA's notice of proposed rule making and the Rhode Island law. We are confident that the Supreme Court decision will have little practical effect on the rules proposed last August.

* The Rhode Island law was a complete ban on any liquor advertising that referenced prices. The FDA proposal does not envision a complete ban.

* The Rhode Island ban is very broad. The FDA proposal is narrowly drawn and carefully tailored to reduce the appeal of tobacco products to children. 3,000 children begin smoking each day, and 1,000 of them will have their lives shortened because of it.

* The FDA proposal is appropriately crafted to match the public health goal of reducing the appeal of tobacco products to children. Even in cases where the FDA proposal restricts imagery, information could reach consumers in black and white, text - only advertisements.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

*talking
points*

December 8, 1995

STATEMENT BY DAVID A. KESSLER, M.D.
FOOD AND DRUGS COMMISSIONER

"This is one more example of what tobacco industry officials knew and said about nicotine before we did."

In response to Wall Street Journal article, headlined "Philip Morris Memo Likens Nicotine to Cocaine," December 8, 1995.

Philip Morris Memo Likens Nicotine

By ALIX M. FREEDMAN

Staff Reporter of THE WALL STREET JOURNAL

Tobacco-company executives have long maintained that people smoke because they enjoy the taste and sensation. The industry publicly rejects the allegation that cigarettes function primarily as nicotine dispensers.

But with unprecedented bluntness, an internal Philip Morris Cos. draft report freely acknowledges what critics have charged: Cigarettes are a "nicotine delivery system"; the main reason people smoke is to get nicotine into their bodies; and nicotine is chemically "similar" to such drugs as cocaine.

The confidential internal document, which is undated but cites data from as recently as 1992, is a proposal for a "safer" cigarette with the code name Table. Steven Parrish, Philip Morris's top spokesman, says the document was written by a non-scientist and doesn't reflect the views of the company on nicotine or smoking. An individual at the company further explains that the task force working on Project Table disbanded in late 1992 after making a presentation to senior management.

Public-health officials say that information about the cigarette project, while intriguing, is less important to regulators than the draft report's extraordinary summary of why people smoke and how nicotine affects the brain.

This is because the role of nicotine is central to current attacks on the industry by class-action lawyers and federal regulators. Plaintiffs' attorneys and four state governments have filed lawsuits alleging that tobacco companies have known for years that smoking is addictive but have hidden this information from the public.

And the Food and Drug Administration is seeking for the first time to regulate cigarettes as drugs, arguing that cigarettes' main function is to supply nicotine to smokers. Government scientists say nicotine is the addictive component in cigarettes, a conclusion that the industry rejects.

In congressional testimony and other public statements, top cigarette-company executives have denied the FDA's allegation about cigarettes' chief purpose. The Philip Morris document, however, appears to lend some support to the claim by asserting that the "the primary rea-

The document calls nicotine a 'similar, organic chemical' to the drugs cocaine, morphine, quinine and atropine.

son" people smoke is "to deliver nicotine into their bodies."

The 15-page Philip Morris draft report likens nicotine to a drug in both its composition and its effects on the brain. In calling nicotine a "similar, organic chemical" to the drugs cocaine, morphine, quinine and atropine, the document states that "while each of these substances can be used to affect human physiology, nicot-

ine has a particularly broad range of influence."

Government and independent scientists say they are astonished at what they regard as admissions in an internal document of the nation's biggest cigarette maker. But they say they have no quibble with the draft report's statements about nicotine and smoking.

The draft report is a "blunt recognition of what public-health scientists have been saying all along — that the critical effects of nicotine are those in the brain and not in the mouth," says Jack Henningfield, chief of the pharmacology branch at the government's National Institute on Drug Abuse. Neal Benowitz, a nicotine-research specialist at the University of California in San Francisco, says, "This sounds like an excerpt from the Surgeon General's report. This is very much the current view on the role of nicotine acting on the brain to produce addiction."

Nicotine travels to the brain about eight to 10 seconds after a smoker inhales and "alters the state of the smoker," according to the Philip Morris draft report. Nicotine does this, it says, by becoming both a neurotransmitter, a chemical substance that transmits signals from one nerve cell to another, and a stimulant. "Nicotine mimics the body's most crucial neurotransmitter, acetylcholine (ACH), which controls heart rate and message sending within the brain," the draft report states.

In this way, the document continues, "nicotine is used to change psychological states leading to enhanced mental performance and relaxation." The draft re-

to Cocaine

port adds that "a little nicotine seems to stimulate, while a lot sedates a person. A smoker learns to control the delivery of nicotine through the smoking technique to create the desired mood state."

Mr. Parrish, the Philip Morris spokesman, responds, "We have acknowledged

'A little nicotine seems to stimulate, while a lot sedates a person,' the Philip Morris draft report states.

in public documents that nicotine, like many, many other things, has pharmacological effects, but that doesn't mean that cigarette smoking is addictive." He adds, "This document nowhere says that nicotine produces addiction — the document doesn't even discuss addiction."

The cover page of the Philip Morris document, which identifies it as a "1st draft," is signed by B. Reuter. At the time, Barbara Reuter says, she was part of the operations group, which deals with manufacturing the company's products. Ms. Reuter is currently employed at Philip Morris as category director of premium-brands marketing planning. She declines to comment on the contents of the document. An individual familiar with the project says that Ms. Reuter wasn't asked to prepare anything on how nicotine works and that she never presented her

conclusions about nicotine to senior management.

Cigarette-company executives have described the role of nicotine much differently than does the Philip Morris document. Last April, for instance, William Campbell, then head of Philip Morris's tobacco unit, testified at a congressional hearing that "nicotine contributes to the taste of cigarettes and the pleasures of smoking. The presence of nicotine, however, does not make cigarettes a drug or smoking an addiction."

Mr. Parrish, the Philip Morris spokesman, says that Mr. Campbell "spoke truthfully" and that "this document doesn't support any claims to the contrary."

In the same April 1994 hearing, Thomas E. Sandefur, former chairman and chief executive of Brown & Williamson Tobacco Corp., described equating cigarettes with hard drugs as "nothing more than rhetoric." And James W. Johnston, chairman and chief executive officer of R.J. Reynolds Tobacco Worldwide, said that nicotine "enhances the taste of the smoke and the way it feels on the smoker's palate, and it contributes to the overall smoking enjoyment." In written testimony, Mr. Johnston added that under the FDA's definition of addiction, "cigarette smoking is no more addictive than coffee, tea or Twinkies." He also said, "Cigarettes are clearly not in the same class as addictive, mind-altering [drugs] like heroin and cocaine."

Mr. Sandefur didn't respond to a request for comment made through Brown & Williamson. Mr. Johnston was unavailable for comment, but an R.J. Reynolds spokeswoman said the Twinkie reference was intended to show that "the term 'addiction' has been so broadened as to be virtually useless scientifically."

A federal grand jury is currently looking into whether any cigarette-company executives or scientists may have perjured themselves in congressional testimony or other sworn statements concerning nicotine addiction and the alleged manipulation of nicotine in their products. Prosecutors are understood to be reviewing executives' statements in light of internal industry documents that have surfaced in recent months.

The Philip Morris draft report discusses the role of nicotine in the context of the company's consideration of a new cigarette that would continue to deliver nicotine while apparently reducing substances such as tar that have been linked to disease.

Ever since 1964, when the surgeon general stated unequivocally that cigarettes cause lung cancer and other diseases, tobacco companies have pursued the quest for a cigarette with reduced risks. In its Table project, Philip Morris followed in the footsteps of R.J. Reynolds, which introduced the "smokeless" cigarette Premier in 1988.

Premier significantly reduced smoke and virtually eliminated tar, which includes the chemicals that many scientists believe increase the risk of cancer. An R.J. Reynolds spokeswoman says the company never claimed Premier was "safer";

rather the product was billed as "cleaner." R.J. Reynolds, a unit of R.J.R. Nabisco Holdings Corp., withdrew Premier just five months after its test-market launch because smokers found it hard to light and didn't like its taste or smell.

Even so, the Philip Morris document praises Premier for a "number of key attributes," including "zero biological activity." Government scientists say the term "biological activity" is used by the tobacco industry as a euphemism for the health risks associated with cigarettes. But Philip Morris's Mr. Parrish disputes the contention that "biological activity" refers to health effects in humans.

The document describes Philip Morris's own proposed entry as a "nicotine delivery device." And it lumps cigarettes with products that have no other function than to dispense nicotine: "Nicotine delivery devices range from snuff, chewing tobacco, cigars, pipes and conventional cigarettes to unique smoking articles, chewing gum, patches, aerosol sprays and inhalers." This statement is potentially useful to the FDA in its effort to prove that tobacco companies are in the drug business, health officials say.

Like Premier, Philip Morris's new cigarette would involve "heating rather than burning the tobacco," the draft report says. The result is "a cleaner, safer smoking experience." The document predicts that the product "has the potential to replace the conventional cigarette."

It is not clear whether the cigarette described as safer in Project Table will ever be marketed. Asked about the current status of the effort, Mr. Parrish said the company's policy is not to comment on product development. But another person familiar with the initiative describes its status as "neither dead nor ready for introduction." This individual explains that one obstacle to marketing something that isn't "as good or as sexy" as a conventional cigarette is that "you turn a person who smokes for pleasure into someone who looks like an addict pumping something into their arm."

Still, it now appears that all three of the top cigarette companies have contemplated a move toward a new kind of cigarette. In addition to Philip Morris and R.J. Reynolds, Brown & Williamson, a unit of B.A.T. Industries PLC, has taken out patents related to such a project, the draft report says. This "illustrates extensive interest in the development of a superior nicotine delivery device," the draft report states. A spokesman for B&W says, however, that the company is in the business of selling cigarettes "which aren't nicotine-delivery devices."

With the exception of R.J. Reynolds, no U.S. tobacco company has taken a product such as Premier to the public.

-The full text of the Philip Morris document is available from The Wall Street Journal's Money & Investing Update at <http://update.wsj.com> on the Internet's World Wide Web.

August 10, 1995

TOBACCO AND KIDS

- o Tobacco is the number one preventable health problem in this country. It kills more than 400,000 Americans each year, more than AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.
- o There are two facts about why people smoke that make these deaths especially tragic.
 - First, smoking starts during childhood. 82% of all smokers begin smoking before their 18th birthdays.
 - Second, almost all smokers smoke because they are addicted. They start during childhood; get addicted; and can't stop.
- o Today and every day until we do something, 3,000 kids will start using tobacco. Nearly 1,000 of them will eventually die from smoking-related diseases. Unfortunately, while tobacco use among adults is declining, tobacco use among kids is on the rise.
- o There are two fundamental problems with the way tobacco is sold in this country.
 - First, even though sale to kids under 18 is illegal in every state, the fact of the matter is that today in the United States kids have easy access to tobacco products.
 - Second, tobacco companies are allowed to advertise tobacco products in a way that subtly persuades children that smoking cigarettes or using smokeless tobacco products is socially acceptable, even socially desirable.
- o As a result, parents who want to teach their kids about the dangers of smoking don't have a chance. Think about it --
 - stores are filled with tobacco ads in the form of clocks and signs; one recent survey found an average of 25 promotional items per store;
 - unattended vending machines are common; any ten-year-old can easily buy cigarettes from a vending machine if he or she wants to;
 - the highways are filled with billboards;
 - tobacco is associated with sports, youth and fun.

- o I have always felt that one of the most important roles for government is to protect our children. The states have tried for years to enforce laws against sale of tobacco products to children. It seems to me that it is appropriate for the federal government to help.
- o Today I am announcing that the Food and Drug Administration will propose a set of regulations that are designed to cut in half the use of tobacco products by kids.
- o I have personally reviewed these proposals. I believe that they are reasonable. They are designed to cut the number of kids who smoke by 50%, and I believe that they will be effective.
- o In short they will do two things.
- o First as to access. Access to tobacco products will be permitted only in a face-to-face transaction between an adult and the retailer. We will no longer allow the companies to send cigarettes through the mail or to give them away free.
- o Second, we want to cut down the appeal of tobacco advertising.
 - More than 20 countries have banned tobacco advertising. We are not going that far. But we will cut down on the advertising that appeals to kids.
 - In particular we will ban tobacco brandname give-aways -- the hats, tee shirts and bags. Half of the kids who smoke, and one quarter of all kids own one of these items.
 - Cigarettes are a dangerous product and these items send exactly the wrong message.
 - We will ban advertising near schools and playgrounds, and we will restrict environmental advertising -- including billboards and ads inside stores -- to being black and white, text only. Advertising in magazines with substantial kids readership will also be restricted to text only, black and white.
 - We will require the establishing of ad campaign to educate children about the dangers of smoking.
 - Finally, we will prohibit sponsorship of sporting events in the brand name. Like the hats, and tee shirts, this link between tobacco brands and sports sends our kids the wrong message.

- o In this room we have both adults and kids. For the kids here, I hope that you never smoke. This is a dangerous product, and if you use it you have a good chance of dying from it. The decision about whether to smoke will be one of the most important decisions you ever make. I hope that you never use this product.
- o To the adults, it is my hope that this program will give you a fighting chance in keeping your kids from smoking. This is an ambitious program. I believe that it will work, but it will take a lot of work to get it into place. There is nothing more important that we can do, and I hope that we will have your help.
- o We need to work together -- parents and children; local, state and the federal government; community and religious groups; the public health and medical communities.

TALKING POINTS FOR CALLS

- The [Secretary, Director] has asked me to call and brief you on President Clinton's new program to protect children from tobacco. This comprehensive proposal is designed to significantly reduce the number of children and adolescents who become addicted to cigarettes and smokeless tobacco.

- THE PROBLEM

Smoking is the leading preventable cause of death in the United States, killing more Americans each year than AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined. Since more than 80% of smokers have tried cigarettes as children, the President's proposal is focused on preventing children from smoking.

Although every state now prohibits the sale of tobacco to children under age 18, each day thousands of children become addicted to nicotine. In fact, smoking among 8th and 10th graders has risen sharply since 1991.

Illegal tobacco sales to minors, free tobacco giveaways, sports promotions and cartoon/lifestyle advertising contribute to the increase in tobacco use among young people. By reducing the number of young people who become addicted to tobacco, the President hopes to reduce the number of adults who will die of tobacco-related diseases. Studies show that if people do not begin to use tobacco as teenagers, it is unlikely they will ever do so as adults.

- THE SOLUTION

- The President's initiative has two components: (1) reducing children's easy access to tobacco and (2) reducing tobacco's appeal to children.
- To reduce access, the proposal:
 1. establishes 18 as the federal minimum age for tobacco sale and requires retailers to verify sales with a photo identification;
 2. prohibits distribution of cigarettes through vending machines;
 3. prohibits free sampling;
 4. prohibits self-service displays;
 5. prohibits single cigarette sales; and
 6. prohibits so-called "kiddie pack sales" by requiring that cigarettes be sold in packs of not less than 20 cigarettes.

- To reduce appeal, the proposal:

1. bans outdoor advertising within 1,000 feet of schools and playgrounds;
2. requires all outdoor advertising and in-store promotion to be black-and-white text only;
3. requires black-and-white text only advertising in all publications with significant youth readership under the age of 18 (e.g., *Sports Illustrated*);
4. prohibits the sale or giveaway of caps, tee shirts and gym bags that carry tobacco product brand names or logos;
5. prohibits sponsorship of sporting or entertainment events by tobacco brand names (e.g., Virginia Slims Tennis, Winston Cup Racing), but allows sponsorship in the corporate name (e.g., Philip Morris Tennis; RJ Reynolds Racing); and
6. requires the tobacco industry to spend \$150 million each year on an educational campaign to counter the imagery and reduce the appeal created by pro-tobacco advertising over the decades.

- WHAT YOU CAN DO

- The public comment period on the President's childhood tobacco initiative is scheduled to close on January 2, 1996. Persons with an interest in the proposal should be encouraged to submit their written comments to the Federal Register.¹
- Due to the historic scope of the President's initiative there may be other members of your [board, association, committee] who may inquire and want to know more about the proposal. We have a series of FACT SHEETS describing the childhood tobacco initiative and would be please to make them available to you. Would you like me to send a package of material?
- Finally, are you aware of any upcoming meetings of your [board, association, committee] at which you might like a more detailed presentation of the President's initiative? The [Department, Agency] would be pleased to provide a speaker to explain the proposal if that would be of interest to your members.

¹ Submit written comments and recommendations to: The Dockets Management Branch (HFA-305), Food and Drug Administration, Room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

TOBACCO TALKING POINTS

I. Kids-Oriented Regulation is Necessary

- * Although it is illegal in all 50 states to sell tobacco products to minors, smoking by both children and teenagers continues to rise.
- * On any given day, approximately 3000 young people become regular smokers, with total youth consumption of cigarettes exceeding 500 million packs per year.
- * Over 80% of adult smokers began as minors, beginning, on average, at age 14. If an individual does not become a smoker as a teen, it is unlikely that he or she ever will become one.
- * The consequences of these statistics are tragic. According to the CDC, of the two million Americans who will die in 1995, approximately 420,000 will die of conditions associated with tobacco.
- * This number is almost ten times the annual highway toll and more than the combined deaths last year from accidents, murders, suicides, AIDS, drugs, alcohol-related diseases and fire.
- * Taking steps to prevent more even more children and teens from adding to these grim statistics is obviously both important and appropriate.

II. Principal Components of the Rule

- * Permits sale of tobacco products only through a face-to-face transaction with an adult. Under this principle, vending machines, self service displays, and mail order purchases would not be permitted.
- * Prohibits all outdoor advertising (e.g., billboards) within 1000 feet of schools and playgrounds.
- * For all other outdoor advertising, permits only black and white, text-only advertising.
- * For magazines with significant youth readership, limits advertising to black and white, text-only format; no restrictions on advertising in other publications.
- * Prohibits sale or giveaways of products (like caps or gymbags) that carry a tobacco brand name.

- * Prohibits brand-name sponsorship of sporting and entertainment events, but permits it in corporate name. (For example, the "Phillip Morris Tennis Tournament" would be permissible, but "The Virginia Slims Tournament" would not be.)
- * Requires the industry to fund (\$150 million per year) a public education campaign designed to prevent kids from smoking.

III. What the Rule Does Not Do

- * The rule does not in any way restrict adults' ability to purchase or consume tobacco products; it does not affect cigars or pipe tobacco at all.
- * The rule does not follow the course -- already adopted in 20 countries -- of simply banning all tobacco advertising. (Countries include France, Canada, and Norway.)

IV. Status of the Rulemaking Proceeding

- * Existing evidence supports the conclusion that nicotine is a drug and is therefore subject to regulation by the FDA. Nonetheless, because of the unique importance of the issue, the FDA has not asserted jurisdiction at this time. Instead, it has solicited comments from all interested parties on that question and is committed to giving careful consideration to any submissions it may receive.
- * Interested parties have 90 days to submit comments on the jurisdictional issue as well as the particulars of the proposed rule. The Only after receipt and consideration of these comments will the FDA be in a position to issue its final rule.

Talking Points for Oval Office

You will make a very brief statement, in front of the press, about why you are meeting with this group.

"I have brought together the [fill in groups -- get from Marilyn Yager} to talk to them about my commitment to ending youth smoking. This issue is critical to our efforts to improve the health of our nation. According to the CDC, of the two million Americans who will die in 1995, approximately 420,000 will die of conditions associated with tobacco. I'm proud that later today I will announce my strategy for combatting this problem."

After the press leaves, you will have a discussion with the group, and will explain what you plan to do. Here are some suggested talking points:

PRESIDENT CLINTON ANNOUNCES TOUGH, NEW INITIATIVE TO FIGHT TEEN SMOKING

August 10, 1995



Challenge to the Nation Today, the President will announce his strategy to combat one of the gravest threats to the health of young Americans: *teen smoking*. His strategy is based on one simple idea: We should do everything in our power to keep tobacco out of the hands of children and teenagers.

Teen Smoking is a Critical Health Problem Smoking among young people is a critical public health problem. Every single day, 3,000 young people become regular smokers and nearly 1,000 of them will die prematurely as a result.

Teen Smoking is On the Rise Since 1991, as adult smoking dropped, the percentage of teen smokers has risen steadily and rapidly:

- 30% increase in the number of 8th graders who smoke;
- 22% increase in the number of 10th graders who smoke;
- fewer teenagers think smoking is dangerous;
- by the age of 16, the average teen smoker is smoking every day - and will not stop.

Teen Smoking Kills Over 80% of adult smokers begin as minors. And smoking kills far too many Americans:

- More than 400,000 Americans will die this year of conditions associated with tobacco.
- That's more than one in five deaths in the entire country.
- It's almost ten times the number of people who will die on our highways.
- It is more than the combined deaths last year from accidents, murders suicides, AIDS, drugs, alcohol-related diseases and fire.

We Have a Responsibility to Act We have a responsibility to head off this tragedy. We must help parents keep cigarettes and chewing tobacco away from their kids. It is far too easy for children to buy and use tobacco products.

Tough Action Today, the President will unveil his strategy to stop children from smoking -- *and to stop them from starting to smoke*. The actions he announces will be tough, and they will be mandatory.

Seizing the Opportunity -- Creating a Better Future We have an opportunity to change the entire health care dynamic in America by saving our children from the dangers of smoking. If we do not act, we will spend years and years paying for the health damage that smoking causes. Reducing teen smoking is one of the best and most important things we could do to improve the health of all Americans -- and to make a better future for our kids.

Talking points for Oval Office

You will make a very brief statement, in front of the press, about why you are meeting with this group.

"I have brought together young people and advocates concerned about the healthy future of our children to talk about my commitment to ending youth smoking. This issue is critical to our efforts to improve the health of our nation. According to the CDC, of the two million Americans who will die in 1995, approximately 420,000 will die of conditions associated with tobacco. I am proud that later today I will announce my strategy for combatting this problem."

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- * The evidence before the FDA at this time supports the finding that nicotine in cigarettes and smokeless tobacco is a drug, but the agency is accepting further evidence and comment on that issue and will give them careful consideration.
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SAMPLE SPEECH

TEEN TOBACCO ADDICTION: THE TIME TO ACT IS NOW

WHY DID THE PRESIDENT AUTHORIZE THE PROPOSED FDA RULES?

Today in this country cigarette smoking kills more Americans than AIDS, illegal drugs, homicide, suicide, and car crashes combined. More than 400,000 Americans die prematurely each year from smoking, resulting annually in more than 5 million years of life lost and over \$50 billion in medical expenses.

We must prevent the addiction from occurring in the first place -- and that is why we need to focus on children and the teenage years: the time when adolescent decisions are made that have lifetime consequences.

Quite simply, young people who smoke like adults become addicted like adults. More than 80% of adult smokers lit their first cigarette before their 18th birthday.

WHAT IS THE ADMINISTRATION PROPOSING?

The President's proposal would reduce children's easy *access* to cigarettes and smokeless tobacco by clamping down on the illegal sale of cigarettes and smokeless tobacco. And it would reduce the *appeal* of tobacco products to children by restricting advertising and promotions that influence young people.

Make no mistake, despite objections you may hear from the tobacco industry, the President's initiative is *not* about adults who use tobacco. The initiative is about protecting our children from an addiction that will cost many of them their lives. The stakes could not be higher.

We must not be fooled: the tobacco industry would have you believe this is not about our kids and their futures. Tobacco companies would like the public to believe that the President's action is just a clever attempt at backdoor prohibition; that it's an attack on our First Amendment freedoms; and that it's another example of "government run amok" -- a government that is intruding into matters best left to parents to solve.

Speaking as a [parent, adult, etc] myself, I wish parents *could* solve the problem of teen tobacco use. But we [parents] are not in a fair fight. The tobacco industry's \$6 *billion* annual marketing campaign serves as our children's third parent, whispering constantly in their ears that it's cool and adult to use tobacco.

All the President is trying to do is level the playing field and put power back in the hands of parents. He said this in his August 10 news conference:

When Joe Camel tells young children that smoking is cool, when billboards tell teens that smoking will lead to true romance, when Virginia Slims tell adolescents that cigarettes may make them thin and glamorous, then our children need our wisdom, our guidance, and our experience. We're their parents, and it is up to us to protect them.

HOW YOU CAN HELP?

The President has done something that no President before him had the courage to do. And he will continue to show leadership on this issue.

Late in the afternoon on August 10, Vice President Gore spoke to a group of professionals concerned about health and young people. He said that Americans have a chance to change history by standing up to strong special interests that are profiting at the expense of our children. Future historians will look back on our response, he said, and either draw courage from it or conclude that some causes, no matter how noble, are simply not worth the fight.

When it comes to protecting our Nation's youth from tobacco, we have on our side two powerful allies: public health and public opinion. There is no more single important strategy to prevent disease and contain health care costs over the long run than reducing teen tobacco use. And Americans, though they want less government regulation in general, say in survey after survey that they support greater government action to keep kids from smoking.

But there's a missing ingredient in our fight -- and that is public passion that leads to action. Americans support tobacco control in their heads, but not in their hearts. And unless Americans take this issue to heart, we won't be able to sustain their interest and involvement over the long run.

It will take work to build and fan public passion about tobacco control. We need to enlist the support of those people who have a strong ties with their communities: the local PTA president; the high school football coach; the local DARE officer; the columnist for the town newspaper. We need to work in our own spheres of influence to make a difference for the health of our next generation.

To make a difference, it's not enough to be informed of the issue.

The President's initiative offers those of us concerned about children and public health a once-in-a-lifetime opportunity. It is an opportunity to change the course of a deadly disease. It is an opportunity to secure a future for our children free from the shadow of nicotine addiction. It is an opportunity to change history.

As of October 17, 1995

TOBACCO QUESTIONS AND ANSWERS

Public Reaction

- Q: Won't Congress stop this? What's your strategy to fight an industry lawsuit?
- A: We hope Congress and the industry will agree with us. The President is firmly committed to the goals and has released his proposed regulation. However, he is open to other avenues to achieve the goal such as a statute which enacts the same measures as in the proposed regulation.

Voluntary Approaches

- Q: Why can't you just use a voluntary approach? Why are regulations needed?
- A: The tobacco industry has had a voluntary advertising code in place since 1964 to keep kids from beginning to smoke. And yet, 3,000 kids a day become smokers, and the numbers are getting worse, not better: smoking among eighth graders has risen 30 percent in the last three years. Either the code is insufficient or the code is not followed.
- Q: Isn't this a "big government" fix to a problem that should be addressed by the private sector?
- A: No. Other countries have taken much more extreme measures, such as banning all advertising. The Administration proposal is narrowly aimed at the real preventable problem: kids smoking. State laws prohibiting sales to or use by minors already exist in all 50 states. But we haven't done a good job -- in either the public or private sector: 3,000 kids become regular smokers each day.
- Q: What is the difference between what you are proposing and what the industry voluntarily has initiated so far?
- A: Tobacco industry programs consist primarily of awareness materials for retailers and educational materials for parents and teachers. The industry implies that these programs are all that is needed to reduce the sale of tobacco to minors. In recent weeks, the industry has suggested that it will take additional actions. (For example, Philip Morris indicated that it would add pack

notices about underage sales; discontinue sampling and direct mail marketing; provide support to retailers; revise retailer incentive programs; and restrict use of company logos on children's products.)

Did the Industry Offer You a Deal?

Q: Did the industry offer you a deal?

A: No. We let them know what we were thinking about and they came back with a proposal we considered. It was similar in many respects to what the President outlined today. However in the important areas of advertising on billboards and at the point of sale, we didn't believe their proposal would be effective at reducing kids' smoking. And the President wouldn't accept that.

Jurisdiction

Q: Are you today declaring nicotine a drug or asserting FDA jurisdiction?

A: The evidence before the FDA supports the finding that nicotine in cigarettes and smokeless tobacco products is a drug, but the agency is accepting further evidence and comment on that issue and will give them careful consideration.

This is a legal issue that is up to the FDA and does not require the President to act.

Enforcement

Q: How will this be enforced?

A: The federal government will work with the States to enforce the prohibition on selling tobacco products to children under 18 years old. In addition, the FDA will be responsible for monitoring advertising and promotion to ensure that they comply with any final regulation. Any enforcement action would have to be initiated by the Department of Justice.

Won't FDA Ban Tobacco?

Q: If nicotine in tobacco is a drug, doesn't FDA have to ban it?

A: No. FDA is not required to and will not ban cigarettes and smokeless tobacco products.

Q: Even if FDA doesn't ban tobacco now, isn't that where this is leading?

A: FDA does not believe that a ban would be an effective means of reducing the toll of death and disease from tobacco, because a ban would not be effective in stopping the 40 million currently addicted tobacco users from gaining access to tobacco.

Advertising

Q: What is the evidence that tobacco advertising actually influences teen smoking?

A: The proposed rule reviews in detail the evidence of how cigarette marketing practices affect teen smoking. Some of the most compelling data include:

- ° Teens (86%) are more than twice as likely as adults (35%) to smoke the three most advertised brands of cigarettes (Marlboro, Camel, and Newport).
- ° Teen preference for Camel cigarettes, approximately 3% before Joe Camel campaign was launched in 1988, increased to 13% by 1993. During this same time period, the percentage of adult sales was unchanged.
- ° From 1985-1989, adult smoking prevalence rates dropped and the affordability of cigarettes for teens also decreased. During this same period, teen smoking initiation rates increased and cigarette promotional expenditures quadrupled.

Educational Program

Q: Isn't the educational program really a tax on the tobacco industry?

- A: No. The money does not go to the federal government. It goes to combat the past tobacco industry advertising that has hooked kids. When misleading or new safety information is discovered about a drug product, FDA routinely uses its authority to require drug companies to inform, at their own expense, the health care community and consumers of the new and correct information.

Adults

- Q: Are the advertising restrictions in the proposed rules really geared to children? They look as though they will affect adults also.
- A: During its investigation, the agency was struck by the evidence of the chilling effectiveness of tobacco advertising on young people's decision to use tobacco products. Also, we know that advertising is very successful with kids. 86% of kids smoke one of the three most heavily advertised brands.

Safety and Effectiveness

- Q: How can FDA say these products are "safe and effective"?
- A: FDA is saying these are dangerous products and people become addicted as kids. We are proposing a strategy to prevent this from happening.

Free Choice for Adults

- Q: Isn't this proposal a threat to personal, free choice?
- A: No. Adults can still smoke or use what will continue to be legal products. But these products are unique -- no other legal product is as deadly or addictive when used as intended. The scientific and medical evidence is overwhelming: cigarettes contain nicotine in sufficient amounts to create and sustain an addiction and our kids are becoming regular smokers at a rate of 3,000 a day.

Message to kids

- Q: Won't these measures just make a cigarettes more attractive to kids by making them "forbidden"?
- A: No. We have already said kids shouldn't smoke, but we haven't done a good job of telling our kids that. We have continued to let these products be easily available and the industry promotions have told kids it's cool and glamorous to use them. Kids believe you if your actions match your words. For the first time, we're going to do that.

What Other Countries Do

- Q: Aren't the measures you are proposing today more severe than those that exist anywhere else in the world?
- A: No. In fact, approximately 20 countries have in place a total ban on advertising and promotion of tobacco products, including Canada and France. Others require that much larger portions of the pack contain much stronger warnings than in this country.

White House Review

- Q: Why did the President review the rule? Isn't that unusual? Is it appropriate?
- A: This is one of the most important public health issues that the country is facing. It is completely appropriate that the President review the proposed rule.

Effective Date

- Q: When is the initiative likely to become effective?
- A: The public comment period on the proposed rule will end on January 2, 1996. When the agency publishes a final rule, it will specify effective dates, which are likely to vary depending on the particular portion of the rule.

Public Reaction

- Q: What are the political implications of this action?
- A: Health should not be a partisan political issue, and our children's health should come before all other considerations. In taking this action, the President has allied himself with every recognized major health and medical authority in this country including the American Medical Association, the American Academy of Pediatrics, the American Academy of Family Physicians, the American Heart Association, the American Cancer Society, the American Lung Association, as well as President Jimmy Carter, former Senator Barry Goldwater, Secretaries of Health and Human Services Otis Bowen and Louis Sullivan, Surgeons General Jesse Steinfeld, Paul Ehrlich, C. Everett Koop, and Antonia Novello, and many religious organizations of all faiths. The support for protecting the health of our children is found among those with a broad spectrum of political beliefs.
- Q: Is there public support for these proposals, especially in tobacco-producing states?
- A: The public overwhelmingly supports efforts to keep children from smoking and to impose reasonable restrictions on tobacco advertising. Almost 75 percent favored a ban of vending machine sales of cigarettes in a poll done for the Robert Wood Johnson Foundation, and 73 percent said text only advertising will make these products less appealing to children. This support cuts across party lines, this support is in every city and state. This is not a proposal aimed against any group or region. This proposal is for our children and our families. This is about helping kids grow up healthy.

Effectiveness of these Proposed Restrictions

- Q: Do we have any evidence that restrictions on advertising will help keep kids from smoking?
- A: Yes. A recent report looked at data from countries with laws on youth smoking and concluded that the most substantial and meaningful reductions in youth smoking occurred in countries with bans on advertising.

Economic Impact

Growers

- Q: What is the economic impact on growers?
- A: The overall impact is both slight and gradual. The regulatory scheme is projected to reduce revenues from cigarette sales by 0.5 percent in the first year, 2.1 percent in the 5th year and 4.0 percent in the 10th year. Over this 10 year period, this would result in the loss of about 1,000 jobs annually among warehouses, manufacturers, tobacco growers and wholesalers.

Retail Stores

- Q: How will this proposal affect store owners?
- A: The major cost will be additional labor costs associated with verifying age, but those will be minimal. For instance, a typical small store will have a cost of \$320 in the first year, \$285 being the labor cost. If the store already verifies ages, the cost will be only \$35.

Vending Machines

- Q: What impact will FDA's proposal have on the vending machine industry?
- A: The impact on the vending machine industry will be minimal. The number of vending machines selling cigarettes has declined dramatically from 785,000 in 1983 to 480,000 in 1993. Cigarette vending machine yields about \$10 per day on average in sales, or less than 5 packs per day. In 1993, cigarette sales constituted only 3.4% of all vending machine sales. No new cigarette vending machines have been shipped in the United States since 1990.

TOBACCO
(most frequently asked questions)

Q: Everyone supports the idea of keeping kids from smoking, but what does banning tobacco companies from sponsoring NASCAR races have to do with kids and smoking?

A: There's been confusion on this point. The tobacco companies can still sponsor NASCAR races under our proposal. What they will have to do is to sponsor them in the corporate name, not in the brand name like they do now.

What we are trying to do is change the landscape. Kids who smoke today think a lot of people smoke, and that's because they are swamped with the images and brand names of these products. The Centers for Disease Control reported that 86 percent of underage smokers who purchase their own cigarettes buy one of the three most heavily advertised brands: Marlboro, Camel and Newport.

Q: Isn't the tariff-rate quota on tobacco imports in essence a way to support tobacco, and isn't that inconsistent with the Administration's recently announced initiative to keep children from smoking?

A: Keeping children from beginning to smoke or using chewing tobacco is a goal all Americans share and to which this Administration is totally committed. We know that if we can keep children from beginning to smoke before they are 18 or 19, the odds are that they won't become regular smokers.

But we have repeatedly said we are not banning these products. They remain legal for adults. And our farmers deserve a level playing field. Our trade policies are aimed at achieving that.

Our health policy is aimed at keeping kids from getting hooked, and that is what those proposals will accomplish.

Q: Your proposals have received a lot of criticism that they restrict the companies' First Amendment rights to advertise. How do you answer those critics?

A: First, let's remember that it's illegal to sell cigarettes and chewing tobacco to kids under 18. If it's illegal to sell these products to kids, what makes it right to appeal to kids?

Second, courts have consistently said that if there is a

substantial public interest at stake, the First Amendment permits some restrictions. We have 3,000 young people becoming regular smokers every day and nearly 1,000 of them will die prematurely from smoking-related diseases. That's a substantial public interest.

In fact, the Fourth Circuit Court of Appeals has recently upheld billboard restrictions -- even tougher than our proposal -- that the city of Baltimore wants to put in place for tobacco and alcohol ads.

Q: We haven't done a very good job of enforcing the state laws against underage smoking. Why is it going to be any different with these proposals?

A: These proposals, actually, will be very simple to enforce. It's very clear that you can't have billboards within 1,000 feet of schools and playgrounds, that you can't have vending machines, that you can't have self-service displays, that you can't sell cigarettes through the mail. These proposals actually make it easier for store owners and store clerks to do their job. State officials -- like Attorney General Hubert Humphrey III in Minnesota -- say our proposals will help them enforce their laws.

Q: The companies, ad agencies, some tobacco growers have sued the FDA to stop these proposals. Why not work out something with industry instead of tying this up in court?

A: We don't want to tie this up in court. There is a public comment period for this rule. If anyone has better ideas on how to keep kids from beginning to smoke or use chewing tobacco, we welcome them. People should be giving us better ideas, not suing us.

Q: Some members of Congress are talking about legislation to stop the FDA from regulating cigarettes. What is the administration going to do if Congress passes a bill to keep FDA from regulating tobacco?

A: We think every American shares our goal of keeping kids from smoking. We have proposed ways to make it harder for kids to buy cigarettes and smokeless tobacco products and ways to reduce the appeal of these products for children. That's going to be the test for any bill, and we just need to wait to see what happens at the end of the process, not at the beginning.

Q: This is just more Big Government, trying to tell me and my family what to do. We need less government interference in

our lives, not more.

A: This isn't Big Government. Other countries have banned advertising, for instance. We are tackling a real problem: kids smoking. Some 3,000 young people become regular smokers each and every day. By making it harder for kids to buy cigarettes, making them less appealing, we're trying to give parents, teachers, everyone who cares, the right environment in which to teach their kids the real risks about cigarettes and smokeless tobacco.

This is about giving parents a fighting chance against an industry that spends billions of dollars every year to promote and advertise their product.

Q: This is taking away my freedom to choose to do what I want. We're losing more and more of our freedoms.

A: Becoming addicted when you are 15 or 16 or 17 takes away your freedom to choose. These proposals don't limit or take away any adult's freedom to choose to smoke, or not to smoke.

Q: Isn't FDA going to have to ban cigarettes? They're not safe, are they?

A: FDA is not required to ban cigarettes and smokeless tobacco products, and will not. These products are dangerous to a smoker's health. But a ban will not work and is not an effective way of preventing the disease and death from tobacco.

Q: How can FDA regulate tobacco? It can't even do its job of approving drugs and devices.

A: FDA is reviewing and approving drugs faster than ever before, and is improving its performance in approving devices. The Vice President's National Performance Review has announced a number of initiatives to streamline drug and device processes while maintaining critical safeguards for the public health, and those initiatives are being implemented.

TOBACCO LEGISLATION

Q: Senator Ford/Representative Baesler introduced legislation on kids and smoking. Do you support it?

A: As the President said when he announced his initiative, the Administration welcomes any lawmaker's efforts to reduce children's use of cigarettes and chewing tobacco or other smokeless tobacco products. Our goal is to have a comprehensive and effective plan to make it harder for kids to buy these products, and to make the products less appealing to kids. We have 3,000 young people becoming regular smokers every day, and nearly 1,000 of them will eventually die from smoking-related diseases. We have to act, and we have proposed a way to do it. But that obviously leaves open the possibility for Congress taking action.

Q: But do you support this legislation?

A: The introduction of Senator Ford's/Representative Baesler's bill is a very important recognition that we have a serious problem that requires action. Children are becoming addicted at 14, 15, and 16 years of age. The average teenage smoker starts at 14 1/2 years old and becomes a daily smoker before age 18. More than 80 percent of all adult smokers has tried smoking by their 18th birthday and more than half of them had already become regular smokers by that age.

But introducing a bill is just the start of the process. Questions of support need to wait on committee and floor debate. In the meantime, we would be pleased to work with Senator Ford's/Representative Baesler's staff and provide technical support on the bill.

Q: This legislation seems to address access questions, but appears weak when it comes to advertising. It doesn't measure up to your proposal, does it?

A: The most effective strategy will require attention to both access and advertising questions. In addition to making it harder for kids to buy cigarettes and chewing tobacco, we need to make these products less appealing. The Centers for Disease Control has reported that 86 percent of underage smokers who buy their own cigarettes buy one of the three most heavily advertised brands: Marlboro, Newport and Camel.

As for the legislation itself, how it looks at the end of the congressional debate is the key issue, not how it looks when introduced.

Q: Would the President sign this bill as introduced?

A: That's a hypothetical question that's impossible to answer. No bill ever goes through the process unchanged.

Q: Will the Administration introduce legislation?

A: The Administration has a proposed rule that it fully supports and that process is going forward. The Administration routinely offers technical support to members of Congress and their staff in the legislative writing and debating process

Q: Senator Ford/Representative Baesler was pretty adamant about removing FDA from the process of regulating tobacco. Will the administration support some agency other than FDA regulating tobacco?

A: The President has always said that his concern is with getting the job done, not who does the job. It's premature to discuss what agency might have responsibility under a legislative approach.

TOBACCO PRODUCTS CONTROL ACT (S. 1262, Ford)

Advertising Restrictions

- ▶ Billboard advertisement must be more than 500 feet away from schools.
 - unless it is adjacent to an interstate highway and directed away from school;
 - unless it is part of a retail store's advertisement at street level.
- ▶ Publications that have more than 15 percent of their readership under 18 as determined annually by the FTC may not carry tobacco advertisements.
- ▶ Tobacco companies cannot pay for product placement in movies.
- ▶ Tobacco logos or names may not be used in a video or video game machine or on the premises of a "family amusement center" as defined in the bill.

Sale and Distribution Restrictions

- ▶ States must make it unlawful for any manufacturer, retailer or distributor of tobacco products to sell or distribute to anyone under 18.
- ▶ The enforcement mechanism is the stipulation that the Secretary may make a SAMHSA grant only to those states that comply with the requirement to make it unlawful to sell to anyone under 18.

[Note: all states are currently in compliance with this requirement.]

- ▶ Cigarette vending machines are allowed
 - if they are in view of the retailer;
 - if they are in places that do not permit anyone under 18, like a bar or club;
 - if they are in a place of employment inaccessible to the general public [i.e., an employee lounge]
 - if they are in another location permitted by state law.
- ▶ No free tobacco products or coupons may be distributed
 - in publications more than 15 percent of whose readership is under 18;
 - at retail stores unless the purchaser has a photo id proof of age;
 - except in locations that do not allow anyone under 18;
 - except as allowed by state law.

FDA Prohibition

- ▶ The FDA is expressly prohibited from regulating tobacco or tobacco products in any manner.

YOUTH SMOKING PREVENTION ACT (H.R. 2414, Baesler)

Advertising Restrictions

- ▶ Billboard advertisements may not be within the line of sight of those in a school or playground.
- ▶ Tobacco logos or brand names may not be used on any product marketed specifically to minors, including toys or video games.

Sale and Distribution Restrictions

- ▶ States must make it unlawful for anyone to sell or distribute tobacco products to anyone under 18; states must also make it unlawful for anyone under 18 to purchase tobacco products.
- ▶ States must issue licenses to retailers of tobacco products and such licenses can be revoked for repeated violations; states are required to conduct annual random unannounced inspections of license-holders.
- ▶ Those illegally selling or buying tobacco products shall be fined; the fines paid to the state pay for education programs related to the hazards of smoking.
- ▶ The Secretary may make a SAMHSA grant and preventative health services block grant only to the states that make underage buying or selling of tobacco products unlawful.
- ▶ Cigarette vending machines are allowed if they are:
 - in view of the retailer;
 - in places that do not permit anyone under 18, like a bar or club;
 - in a place of employment inaccessible to the general public;
 - have a device that controls the sale of tobacco products to anyone under 18
 - if they are in another location permitted by state law.
- ▶ The sale of individual cigarettes or of packages of cigarettes which contain less than 20 cigarettes is expressly prohibited.
- ▶ Free samples and tobacco products sent by mail are expressly prohibited to anyone under 18.

FDA Prohibition

- ▶ The FDA is expressly prohibited from regulating tobacco or tobacco products in any manner.

OTHER LEGISLATIVE PROPOSALS

In addition to Senator Ford's and Representative Baesler's bills, both of which are without co-sponsors, the following have introduced legislation:

- Rep. David Funderburk (R-NC) introduced the Motor Sports Protection Act (H.R. 2265) prohibiting federal regulation of advertising by the tobacco industry at NASCAR auto racing events and at any other race or event sponsored by any other professional motor sports association.
- Senator Helms (R-NC) introduced a companion bill (S. 1295) to the one introduced by Rep. Funderburk. Senators Faircloth (R-NC) and Warner (R-VA) are co-sponsors. The measure was referred to the Senate Commerce, Science and Transportation Committee, which is chaired by Senator Pressler (R-SD).
- Rep. L. F. Payne (D-VA) offered a bill (H.R. 2283) prohibiting the regulation of the sale or use of tobacco or tobacco products by the Secretary of Health and Human Services under the authority of the Federal Food, Drug and Cosmetic Act, the Federal Cigarette Labeling and Advertising Act or the Comprehensive Smokeless Tobacco Health Education Act. The bill has 21 co-sponsors (11 Democrats and 10 Republicans).

PRESIDENT'S INITIATIVE TO REDUCE UNDERAGE TOBACCO USE

Comparison of Legislative Proposals

	President's Initiative	Sen. Ford (S. 1262)	Rep. Baesler (HR 2414)	Rep. Payne (HR 2283)
RETAIL SALES	requires face-to-face sale w/ age verification	not permitted to those under 18; enforced by state laws	not permitted to those under 18; enforced by state laws	
VENDING MACHINES	not permitted	allowed in adult settings & in view of retailer; allows state exceptions	allowed in adult settings & in view of retailer; allows state exceptions.	
COUPONS	not permitted	only to those 18 or older; allows for state exceptions	only to those 18 or older	
SELF-SERVICE DISPLAYS	not permitted	no restriction	must be supervised by someone older than 18	
SINGLE CIGARETTES	not permitted	no restriction	not permitted	
PACKS W/ FEWER THAN 20 CIGARETTES	not permitted	no restriction	not permitted	
BILLBOARDS	must be more than 1000 ft. from school or playground; all others b/w text only	must be more than 500 feet from school [playgrounds not mentioned]; no text restrictions	not allowed w/in line of sight of school or playground; no text restriction	
PRINT ADS	B/w text only in publications 15% of whose readers are under 18	not permitted in publications 15% of whose readers are under 18	no restriction	
~NON-TOBACCO PRODUCT RESTRICTIONS	items w/ cigarette brand names and logos are prohibited	brand names & logos may not be used on video games in family amusement centers; allows for state exceptions	logos and brand names are not permitted on products marketed to children	
SPONSORSHIPS	prohibited using brand names	no restriction	no restriction	
FDA REGULATION		prohibited	prohibited	prohibited
PUBLIC EDUCATION FUND	\$150 million annually from the tobacco companies	not included	States may use fines collected for education programs	

**Remarks
by**

**David A. Kessler, M.D.
Commissioner of Food and Drugs**

GEORGETOWN UNIVERSITY

AUGUST 16, 1995

In every society there are moments that require us to define those choices that will shape our future. One of those moments came last week.

After reviewing FDA's evidence that nicotine is highly addictive, after considering FDA's evidence that nicotine addiction starts as a pediatric disease and our evidence about what the tobacco industry has known about nicotine over the past 30 years, President Clinton proposed a bold new policy to reduce tobacco use by children and teenagers in this country.

As a result, we now have an unprecedented opportunity to dramatically reduce death and disease from smoking and smokeless tobacco use.

It's easy to think of smoking as an adult problem. It is adults who die from tobacco-related diseases. We see adults light up in a restaurant or bar; we see a colleague step outside for a cigarette break, but this is a dangerously short-sighted view. It is as if we entered the theater in the third act, as if the plot has been set in motion, after the stage has been set. For while the epidemic of disease and death from smoking is played out in adulthood, it begins in childhood.

If there is one fact that I need to stress today, it is that a person who hasn't started smoking by age 18 is unlikely ever to become a smoker. Nicotine addiction begins when most tobacco users are teenagers. So let's call this what it really is, a pediatric disease.

More than 3 million American children currently smoke cigarettes, and an additional 1 million adolescent males use smokeless tobacco products. Every day of the year, another 3,000 of our kids become regular smokers, most of them will become addicted to nicotine before they are adults, and nearly 1,000 of them will eventually die from a smoking-related illness. Young people are the tobacco industry's primary source of new customers in this country, replacing adults who have either quit or died.

An internal document of a Canadian tobacco company, an affiliate of a tobacco company in the United States, states the case starkly: "If the last ten years have taught us anything, it is that the industry is dominated by the companies who respond most effectively to the needs of younger smokers."

If we could affect the smoking habits of just one generation, we could radically reduce the incidence of smoking-related death and disease. And a second unaddicted generation could see nicotine addiction go the way of smallpox and polio.

The tobacco industry has argued that the decision to smoke and continue to smoke is a free choice made by an adult. But ask a smoker when he or she began to smoke. Chances are you will hear the tale of a child. It's the age-old story, kids sneaking away to experiment with tobacco, trying to smoke without coughing, without getting dizzy, and staring at themselves in a mirror just to see how smooth and sophisticated they can look.

The child learns the ritual. It is a ritual born partly out of a children curiosity, partly out of a youthful need to rebel, partly out of a need to feel accepted, and wholly without regard for danger. It is a ritual that often, tragically, lasts a lifetime. And it is a ritual that can cut short that lifetime.

Are young people simply unaware of the dangers associated with smoking and nicotine addiction? No, not really. They just do not believe that these dangers apply to them.

For healthy young people, death and illness are nothing more than distant rumors. And until they experience the grip of nicotine addiction for themselves, they vastly underestimate its power over them. They are young, they are fearless, and they are confident that they will be able to quit smoking when they want to, and certainly well before any adverse health consequences occur. They are also wrong.

Quitting is not an easily available option for the juvenile smoker. Indeed, an internal document of one tobacco company, speaking of high school students, observes: "However, intriguing smoking was at 11, 12 or 13, by the age of 16 or 17 many regretted their use of cigarettes for health reasons and because they feel unable to stop smoking when they want to."

Unfortunately, youth smoking gives no sign of abating. While the prevalence of smoking among adults has steadily declined since 1964, the prevalence of smoking by young people has recently begun to rise. The past three years have seen a 30% increase in smoking by eighth-graders, and a 22 percent increase by tenth-graders. And young people's addiction to nicotine is not limited to smoking.

Children's use of smokeless tobacco, such as snuff and chewing tobacco, is also extensive. Today, of the seven million people in this country who use smokeless tobacco, as many as one in four is under the age of 19.

Nevertheless, the tobacco industry publicly insists that smoking is a choice freely made by adults. But listen to the words of one smoker on the subject of freedom and choice: Well, do you think I choose to smoke? Do you believe that I took a cigarette and said, "I think I'll smoke this one and then maybe four hundred thousand more?" She continues: Choice. That's a laugh. Within each day I make dozens —perhaps hundreds—of large and small choices. From morning until bedtime, I pick and choose. I look at options and decide. One thing I don't decide, however, is whether to smoke. For me, a forty-seven-year old woman, that decision was made nearly thirty years ago by a first-year college student. Belief in my power to choose, and denial of how totally nicotine has stripped me of that power, are my two greatest enemies.

This epidemic of youth addiction to nicotine has enormous public health consequences. A casual decision at a young age to use tobacco products can lead to addiction, serious disease, and premature death as an adult. More than 400,000 smokers die each year from

smoking-related illnesses. Smoking kills more people each year in the United States. than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides and fire combined. And the real tragedy is that these deaths from smoking are preventable.

We cannot adequately address this pediatric disease without recognizing the important influences on a young person's decision to smoke. One such influence is industry advertising and promotion. It is important to understand the effects of these practices on young people.

In the last two decades, the amount of money the cigarette industry has spent to advertise and promote its products has risen dramatically. Despite a long-standing ban on broadcast advertising, in 1993 alone the industry spent more than \$6 billion dollars.

Tobacco advertising appears in print media, on billboards, at point of sale, by direct mail, on an array of consumer items such as hats, t-shirts, jackets, and lighters, and at concerts and sporting events.

As the president said last Saturday, "These campaigns have one inevitable consequence—to start children on a lifetime habit of addiction to tobacco" The sheer magnitude of this advertising creates the impression among young people that smoking is much more ubiquitous and socially acceptable than it actually is. In studies, young smokers consistently overestimate the percentage of people who smoke. Make no mistake, all of this advertising and promotion is chillingly effective. The three most heavily advertised brands of cigarettes are Marlboro, Camel, and Newport. A recent study by the Centers for Disease Control found that 86 percent of underage smokers who purchase their own cigarettes buy one of those three most heavily advertised brands.

And young people who choose to smoke have easy access to those brands. Tobacco products are among the most widely available consumer products in America. On sale in virtually every gas station, convenience store, drug store, and grocery.

And though every single state in the country prohibits the sale of cigarettes to those who are underage, study after study has demonstrated that these laws are widely ignored. Teenagers can purchase tobacco products with little effort....and they know it.

We need to put in place a comprehensive and meaningful policy that will prevent future generations of youngsters from becoming addicted to nicotine in tobacco. And, President Clinton proposed last week that we do just that.

The policies that the President proposed cover two areas that experts agree must be part of any comprehensive program to reduce youth smoking: First, reducing easy access by children, and second, reducing the appeal of tobacco products to children.

Nationwide, sales of cigarettes and smokeless tobacco products would be prohibited to anyone under the age of 18, with photo identification required to verify age. Face to face sales would be required—vending machines and mail order sales would be eliminated. We would eliminate free samples, self-service displays, sales of single cigarettes and packs with less than 20 cigarettes.

With these steps, we will attempt to shut down many of the avenues by which cigarettes end up in children's hands.

The policy would also limit the appeal of cigarettes and smokeless tobacco. Today our children receive mixed messages when it comes to the hazards of tobacco use. As parents, we try to warn them about the risks, but our warnings about the dangers of tobacco use are hardly a match for an industry that spends billions of dollars a year to make its products look appealing. Listen to the words of one 18-year-old. "I figure if it's really so bad for you, they wouldn't be selling them everywhere. I mean, you walk into the Stop 'N' Go and there's a whole wall of them right up front at the cash register. If they were really that bad for you, they'd make them less accessible."

It isn't only a cartoon figure that appeals to kids. An enormous number of tobacco product advertisements play on themes of freedom and independence, glamour, fun, and sex appeal.

FDA's proposals would dramatically change the landscape. We would reduce the exposure of young people to these appealing images by: Banning outdoor advertising within 1,000 feet of playgrounds and schools. Restricting to black and white, text only: Outdoor advertising, in-store advertising and magazine ads in publications with a significant youth readership.

FDA's proposed rules would also eliminate brand promotions on non-tobacco items such as t-shirts, caps and sporting gear. The tobacco industry is increasingly turning to sponsorships that link specific brands with sporting events. This is the wrong message to send to children. Under FDA's policies, only corporate names could be used in sponsorship and advertising of events.

Already, tobacco companies and others are trying to block these proposals by claiming they violate the First Amendment. Let me point out that the Supreme Court has upheld advertising restrictions when there is a substantial public interest at stake. If 3,000 kids starting to smoke a day, and a thousand of them dying as a result, isn't a substantial public interest, then I don't know what is.

Let me mention one other element of The President's proposal. The tobacco industry would be required to spend 150 million dollars annually on an educational campaign, overseen by the Department of Health and Human Services, to counter the appeal created by the 6 million dollars the industry spends on advertising and promotion. This would include paid television advertisements. The last time anti-smoking messages appeared on

television was in the late 1960's, and they proved to be one of the most effective means of discouraging smoking.

If seven years from now, our goal of cutting teenage smoking in half is not met, we will put in place additional measures to prevent children from smoking.

We seek public comment on possible measures.

Let me emphasize one point. We have a very strong case. The evidence before the FDA supports the finding that nicotine in cigarettes and smokeless tobacco is a drug, and these products are nicotine delivery devices. But the agency invites public comment and further evidence on this matter, and will give them full and serious consideration.

To understand some of our evidence, just listen to the words of tobacco executives themselves: The general counsel of Brown and Williamson said, more than three decades ago: "We are, then, in the business of selling nicotine, an addictive drug." A top scientist of Philip Morris said: "Think of the cigarette pack as a storage container for a day's supply of nicotine.... Think of the cigarette as a dispenser for a dose unit of nicotine.... Think of a puff of smoke as the vehicle of nicotine.... Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke."

An R. J. Reynolds executive put it this way: "In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects."

Over the course of the last 17 months, we have learned that the tobacco industry has known about and extensively studied the pharmacological effects of nicotine for more than 30 years. And we have learned that the industry has gone to great lengths to ensure that tobacco products deliver an adequate dose of nicotine. Plus, we have discovered that some companies specifically designed marketing programs to attract young smokers.

This evidence is striking.

The President's decision to confront the single most preventable cause of death and disability sends a clear message: We will no longer passively cede to the tobacco industry the right to control the future health of so many of our children.

We owe it to our children to help them enter adulthood free from addiction. For addiction is freedom denied.

Our children are entitled to a lifetime of choices, not a lifelong addiction.

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 10, 1995

Contact: FDA Press Office
(301) 443-1130

CHILDREN AND TOBACCO: THE FACTS

The Clinton Administration is proposing a comprehensive and coordinated set of measures to significantly reduce the number of children and adolescents who become addicted to nicotine in cigarettes and smokeless tobacco (snuff and chewing tobacco). Children are becoming addicted to these products, with more than 80 percent of smokers beginning to smoke by age 18.

Smoking is the leading preventable cause of death in the United States, and health care costs associated with smoking soared to more than \$50 billion in 1993, according to the Centers for Disease Control. While the proposed measures will continue to maintain the legal status of cigarettes and smokeless tobacco products for adults, they will reduce the easy access and strong appeal for children.

Preventing children from smoking is key to reducing the deadly toll of smoking. The Clinton Administration's plan will help parents provide their children with an environment in which to grow up healthy.

A Pediatric Disease

Children are becoming addicted to nicotine. The average teenage smoker starts at 14 1/2 years old and becomes a daily smoker before age 18. More than 80 percent of all adult smokers had tried smoking by their 18th birthday and more than half of them had already become regular smokers by that age. Studies show that if people do not begin to smoke as teenagers or children, it is unlikely they will ever do so.

Each and every day, another 3,000 young people become regular smokers, and nearly 1,000 of them will eventually die as a result of their smoking. Currently, more than 3 million children and adolescents smoke cigarettes, and 1 million adolescent boys currently use smokeless tobacco. Smoking by young people is rising sharply. Between 1991 and 1994, the percentage of eighth graders who smoke increased 30 percent, and the percentage of tenth graders who smoke increased 22 percent.

Children tend to vastly underestimate the likelihood that they will become addicted to these products. Although only 5 percent of daily smokers surveyed in high school said they would definitely be smoking five years later, close to 75 percent were smoking 7 to 9 years later. A survey conducted in 1992 found that approximately two-thirds of adolescents who smoked said they wanted to quit and 70 percent said they would not start smoking if they could make that choice again.

Smoking: Leading Cause of Avoidable, Premature Death

Tobacco use takes enormous, deadly toll each year. Tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illness, heart disease, and other health problems. Cigarettes kill more Americans each year than AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined. Smokers who die as a result of smoking would have lived on average 12 to 15 years longer if they had not smoked.

The health care costs associated with tobacco use are rising. The Centers for Disease Control estimated that in 1993 the health care costs associated with smoking totalled \$50 billion: \$26.9 billion for hospital costs; \$15.5 billion for doctors; \$4.9 billion in nursing home costs; \$1.8 billion for prescription drugs and \$900 million for home-health care expenditures. The Office of Technology Assessment calculated the social costs attributable to smoking in 1990 at \$68 billion. That calculation was based on \$20.8 billion in direct health care costs and \$6.9 billion in lost productivity from disabilities and \$40.3 billion in lost productivity from premature deaths.

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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 10, 1995

Contact: FDA Press Office
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CHILDREN AND TOBACCO: THE PROBLEM

Easy Access

Despite state laws prohibiting the sale of tobacco to minors, children can easily buy these products. One study estimated that teenagers annually consume 516 million packs of cigarettes and 26 million containers of chewing tobacco. A review of 13 studies of over-the-counter sales found that on average, children and adolescents were able to successfully buy tobacco products 67 percent of the time.

- o **Vending machines** are a primary source of tobacco products for young smokers. A study by the vending machine industry found that 22 percent of 13-year-old smokers use vending machines compared with 2 percent of 17-year-old smokers. The 1994 Surgeon General's Report found that young people were able to buy cigarettes in vending machines an average of 88 percent of the time.
- o **Mail-order sales** provide no sure way of verifying age. Current industry practice only asks the consumer to provide a birth date or check box to verify age.
- o **Self-service displays** allow children to easily obtain tobacco products. The Institute of Medicine, in its landmark 1994 report, "Growing Up Tobacco Free," concluded that placing tobacco products "out of reach reinforces the message that tobacco products are not in the same class as candy or potato chips."
- o **Free samples** are obtained by children, including those in elementary school, despite industry code prohibiting distribution to anyone under 21. Free samples occur on street corners, at shopping malls and sporting events. A New Jersey survey found that one-third of high school students who were smokers or ex-smokers reported receiving free samples before age 16.

Appealing to Children

Advertising and promotional activities can greatly influence a young person's decision to smoke or use smokeless tobacco products. Awareness of tobacco products and messages is very high among even the youngest children. Studies show that 30 percent of 3-year-olds and 91 percent of 6-year-olds could identify "Joe Camel" as a symbol for smoking. The Centers for Disease Control recently reported that 86 percent of underage smokers who purchase their own cigarettes purchase one of the three most heavily advertised brands: Marlboro, Camel and Newport.

- o Tobacco products are among the most heavily advertised products in the United States. In 1993, the tobacco industry spent \$6.2 billion on advertising and promoting cigarettes and smokeless tobacco. Tobacco advertising expenditures have increased more than 1,500 percent between 1970 (the year before television and radio advertising was banned) and 1992.
- o Promotion of tobacco products through non-tobacco items such as t-shirts, hats and gym bags and through sponsorship of events is reaching children. A 1992 Gallup Survey found that half of adolescent smokers and one quarter of adolescents who do not smoke owned at least one tobacco promotional item such as a tee-shirt, cap, sporting good, or lighter. Another report found that one out of four 12- and 13-year-olds own one of these items. Used or worn by young people, these become "walking billboards," promoting these products in schools and other locations where tobacco advertising is usually prohibited. Sponsorship of events such as tennis tournaments, car races, and rodeos associate tobacco products with excitement and glamour, and provide a way for tobacco brands to be advertised on television despite the broadcast advertising ban.

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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 10, 1995

Contact: FDA Press Office
(301) 443-1130

CHILDREN AND TOBACCO: THE PROPOSAL

The Clinton Administration is proposing a comprehensive and coordinated plan to reduce smoking by children and adolescents by 50 percent. It builds on previous actions taken by Congress and others such as the ban on television advertising and state laws to prohibit the sale or use of tobacco by children. It follows recommendations by the American Medical Association and the Institute of Medicine. Experts have consistently recommended that the keys to achieving the goal are: reducing access and limiting the appeal for children. This ambitious initiative accomplishes that objective, while preserving the availability of tobacco products for adults. The proposals announced today include:

Reducing Easy Access by Children

- o Require age verification and face-to-face sale and eliminate mail order sales, vending machines, free samples, self-service displays, and sale of single cigarettes ("loosies") and packages with fewer than 20 cigarettes ("kiddie packs").

Reducing Appeal to Children

- o Ban outdoor advertising within 1,000 feet of schools and playgrounds. Permit black-and-white text only advertising for all other outdoor advertising, including billboards, signs inside and outside of buses, and all point-of-sale advertising.
- o Permit black-and-white text only advertising in publications with significant youth readership (under 18). (Significant readership means more than 15 percent or more than 2 million. No restrictions on print advertising below these thresholds).
- o Prohibit sale or giveaway of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos. Prohibit exchange of non-tobacco products for proof of purchase of tobacco products.

- o Prohibit brand name sponsorship of sporting or entertainment events, but permit it in the corporate name.
- o Require industry to fund (\$150 million annually) a public education campaign to prevent kids from smoking.

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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 10, 1995

Contact: FDA Press Office
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CHILDREN AND TOBACCO: WHAT OTHERS SAY

"I figure if it's really so bad for you, they wouldn't be selling them everywhere. I mean, you walk into the Stop 'N' Go, and there's a whole wall of them right up front at the cash register. If they were really that bad for you, they'd make them less accessible."

-- Brian Grindele, 18
The New York Times, July 30, 1995

"Given all that we know, the scientific case for protecting children from tobacco is indisputable. The moral imperative to act is imperative....This is not a Democratic or a Republican issue. It is a bipartisan, pro-child, pro-family, pro-health issue."

-- President Jimmy Carter
USA Today, August 3, 1995

"The tobacco industry continues to insist that smoking is a simple matter of individual rights and adult choice. If that were true, I would be on their side. But we're not talking about adults. We're talking about keeping an addictive and lethal substance out of the hands of children. Neither the FDA nor anyone else is talking about prohibiting adults from smoking."

-- Former U.S. Sen. Barry Goldwater
Wall Street Journal, August 8, 1995

"The American Medical Association reminds physicians, the public, and politicians that the damning evidence against tobacco makes opposition to its use a pressing, nonpartisan public health issue."

-- Editorial
Journal of the American Medical Association
July 19, 1995

"We believe that current tobacco regulations, limited primarily to a ban on television advertising and the promotion of warning labels on packages, are insufficient in protecting America's children. The FDA should have authority to control tobacco by placing new limits on tobacco advertising, creating stricter licensing regulations for vendors, and banning cigarette vending machines."

-- American Public Health Association
Letter to President Clinton from APHA
July 13, 1995

"What is most significant about teens and smoking, however, is that, from all indications, smoking is an addiction that is typically initiated during the teenage years or not at all. For the great majority of smokers, this addiction begins before they are old enough to purchase tobacco lawfully. In fact, 75 percent of all adult smokers report that they became addicted to tobacco before they were 18 years old. Very few smokers take up smoking for the first time as adults. If youth access can be controlled effectively, and the decision whether to smoke can be delayed until adulthood, then, over time, smoking will be greatly reduced as a major addiction in our society."

-- "No Sale: Youth, Tobacco and Responsible
Retailing"
Working Group of State Attorneys General
December, 1994

"The nation must commit itself to a vigorous public health initiative in tobacco control....The nation cannot reasonably expect to eliminate tobacco-related disease and death by 2010. However, by putting a youth-centered preventions strategy at the center of tobacco control efforts, and by implementing the initiatives proposed (to that end) in this report, the nation can take a firm and resolute step on that path."

-- "Growing Up Tobacco Free"
Institute of Medicine, September, 1994

"The concept -- pediatric disease -- qualifies as an epiphany, given the acknowledged authority of society over a minor. He/she has to go to school, has to wait until a certain age before being allowed to drive, to vote, to drink beer. It yields no substantial libertarian ground to add to the list enforcement mechanisms designed to dissuade the 15-year-old from taking up a habit that brings on premature and painful death."

-- William F. Buckley Jr.
Syndicated columnist, March, 1995

"... from a public-health standpoint, keeping kids away from cigarettes is the single most effective way to fight the nation's leading preventable cause of death."

-- "Hooked on Tobacco: The Teen Epidemic"
Consumer Reports, March 1995

Further Reading:

"The Global Tobacco Epidemic"
Scientific American, May, 1995

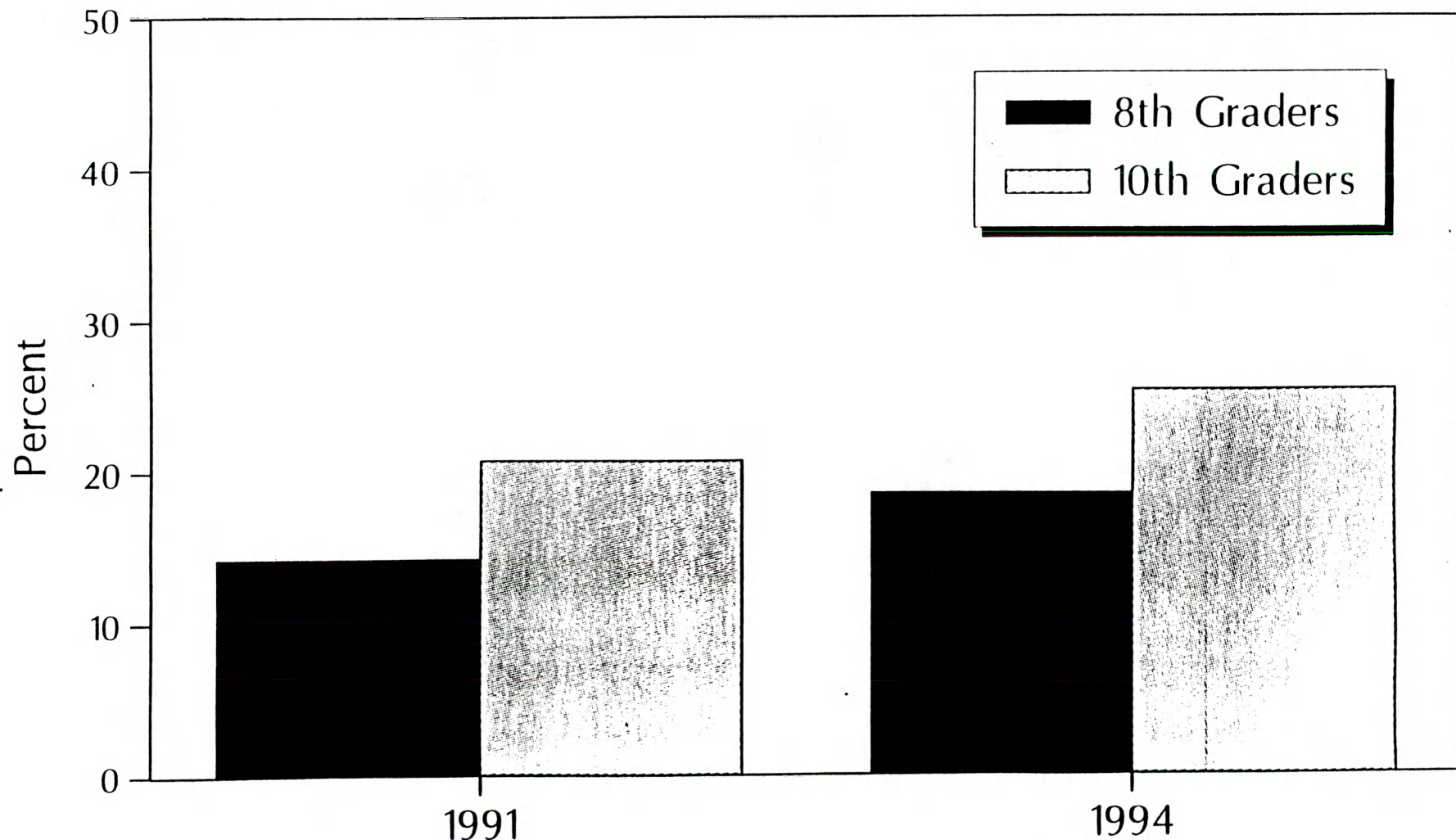
"The Nicotine Connection"
Chemical and Engineering News, November 28, 1995

"Hooked on Tobacco: The Teen Epidemic"
Consumer Reports, March, 1995

"Nicotine Addiction in Young People"
The New England Journal of Medicine, July 20, 1995

Smoking: A Pediatric Disease

Between 1991 and 1994, the prevalence of smoking by eighth graders rose 30%



Goal



To reduce smoking by children by **50%**
within seven years



Children



Access



Appeal

Smokers Get Hooked Early

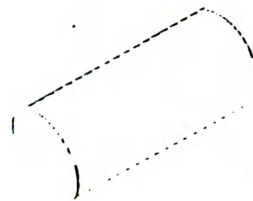
-  3,000 children start smoking **every day**
-  **82%** of adults who ever smoked had their first cigarette before age 18
-  **More than half** of adults who smoke had already become regular smokers by 18

By the Time Young People Become Regular Smokers:

-  70% regret their decision to smoke
-  66% want to quit

Access

75% of 8th graders and 90% of 10th graders said that it's fairly/very easy to get cigarettes.

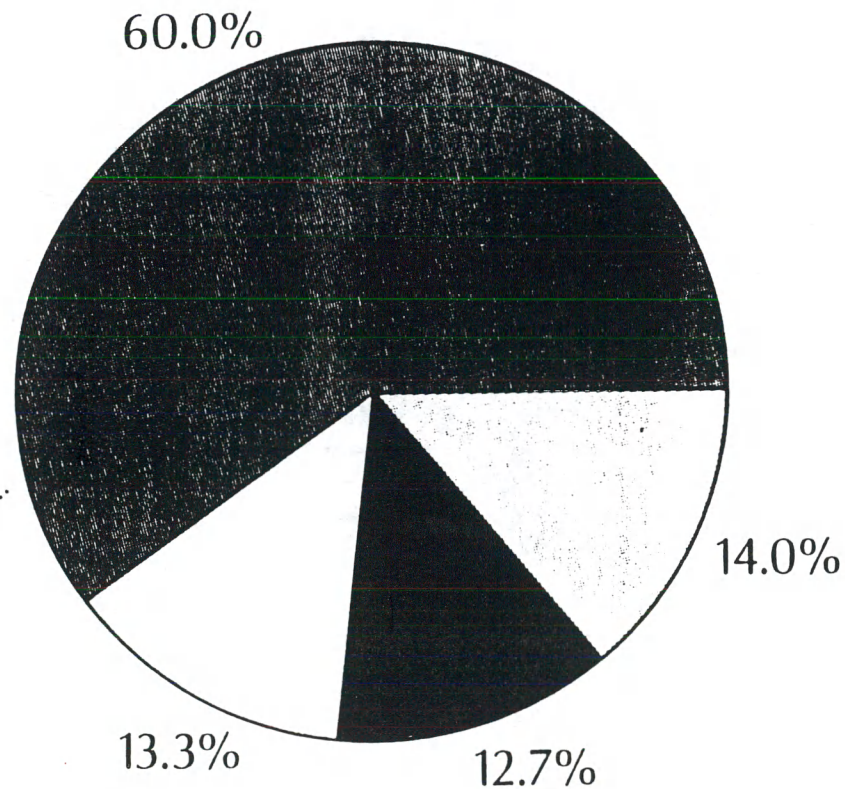


Advertising Clearly Increases Teen Smoking

- ❖ Teens (86%) are more than twice as likely as adults (35%) to smoke the three most advertised brands (Marlboro, Camel, and Newport).
- ❖ Extensive research shows that children are far more likely than adults to respond to images, cartoons, and photographs.
- ❖ Adolescents' brand preference for Camels, for example, was less than 3% before the "Joe Camel" campaign started in 1988. A year later, 8% of kids who smoked bought Camels and by 1993, 13% bought Camels.
- ❖ The images projected by the industry include independence (The Marlboro Man); fun and social prowess (Joe Camel); sexiness (Virginia Slims); and vigor (Newport is "Alive with Pleasure")

Advertising Clearly Increases Teen Smoking

Adolescent Brand Preference



Marlboro



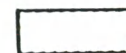
Camel



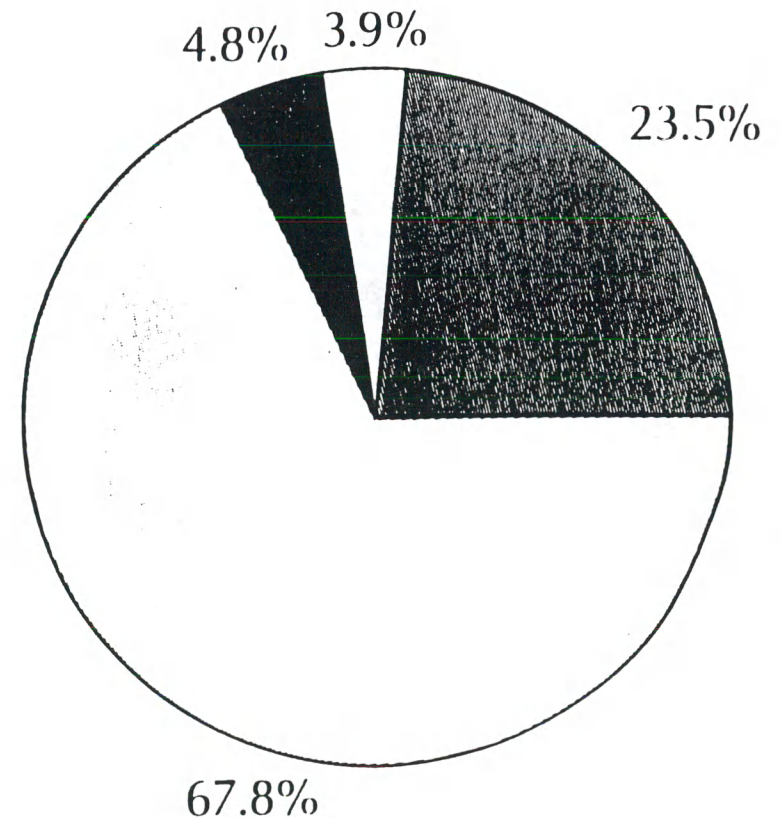
Newport



Other



Overall Market Share



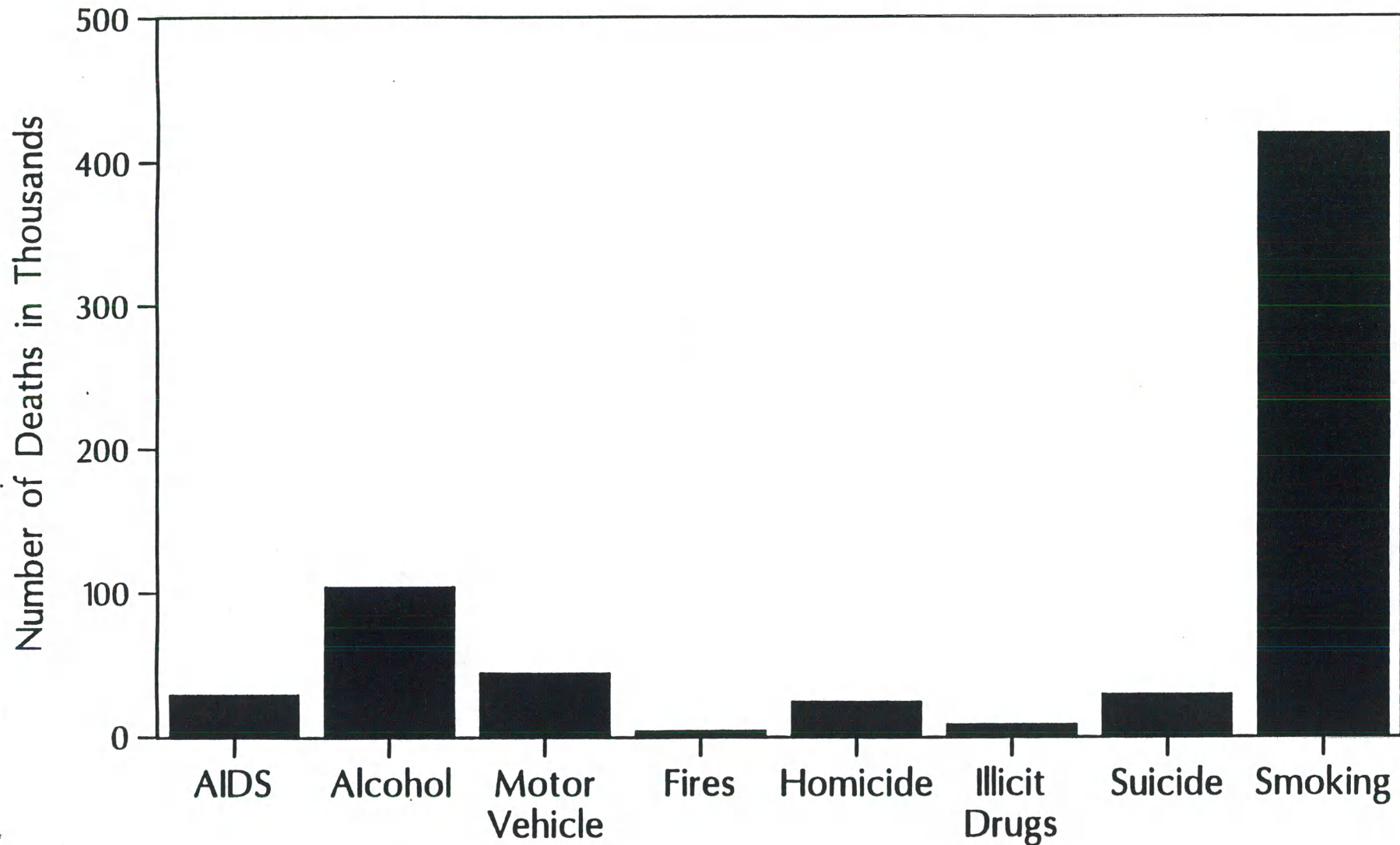
Reducing ACCESS to Children

-  Prohibit sale of tobacco products to anyone under 18
-  Require face-to-face sales - no vending machine or mail order sales.
-  Eliminate free samples, self-service displays, single cigarettes, and "kiddie packs"

Limiting the APPEAL of Smoking and Snuff to Children

- ❏ Ban outdoor advertising near schools and playgrounds
- ❏ Restrict to black-and-white, text-only:
 - ▶ outdoor ads
 - ▶ magazines, newspapers with significant youth readership
 - ▶ in-store ads
- ❏ Eliminate use of brand names and logos on tee shirts, caps and other trinkets
- ❏ Allow sponsorship of events in corporate name only
- ❏ Require industry-funded \$150 million/year educational campaign

Annual Deaths from Smoking and Other Preventable Causes



Secretary Shalala will open up by telling the President that these visitors are supporters of his tobacco initiative and have been taking actions that support it and they're here to tell him what they've been doing.

The President then makes an opening statement.

- I'm so pleased you could come to the White House to tell me about your efforts to stop and prevent kids from smoking. It's so important to have parents, teachers and children who are leaders -- heroes, really -- working in efforts to save the current and future generations of children from tobacco addiction.
- I understand today we are joined by Ginny Markel of the National PTA, who has already mobilized thousands of local PTA Chapters and millions of members in this fight. I salute you and the PTA for joining this vital effort.
- [Possibly other acknowledgements]
- Simply put, our goal is to make sure that we parents -- and not the advertising which is so attractive to kids -- are in control when it comes to educating young Americans about an addiction that could steal years of their lives.
- The fact is that teen smoking and use of spitting tobacco must be stopped. Every day, more than 3,000 young Americans become regular smokers. They light a slow-burning fire in their lungs that will lead to shortened lives and premature deaths for 1,000 of them. Smoking is the leading cause of preventable death in America -- more than 400,000 lived a year. And the vast majority of the people who smoke as adults started smoking as kids.
- But let me stop talking and hear what you've been doing to help in this effort.

Then there is a back and forth discussion where the guests will tell the President about their anti-tobacco activities. Some of the kids were out over the weekend identifying billboard in DC that advertise smoking and that are near schools. The PTA has launched an education campaign across the country. One of the students led a campaign to get cigarette vending machines removed in her local area, etc.

Secretary Shalala will "facilitate" by prompting the guests to tell stories or ask questions.

Some questions the President can ask of the group:

- Ginny, the PTA is so important in this effort because of your network -- what has the PTA been doing in this effort?
- I hear some of you went on an outing this weekend looking for tobacco billboards. Did you find any? Were they near schools or playgrounds?
- Is it easy or hard for people your age to get their hands on cigarettes? [The President will hear anecdotes about stores that don't check id and vending machines.] So you're saying that a kid can walk right up to a vending machine and buy a pack of cigarettes, unchallenged?
- What are some of the rest of you doing to stop all this?
- Do some of your friends and classmates think cigarettes are cool 'cause they're a grown-up thing? How can we get the message across that cigarettes aren't cool?
- You know when I was a kid, if a parent told us to do one thing, sometimes we'd do just the opposite. How do you get around that to keep kids from smoking?
- What kinds of things do you think can keep kids from smoking?

Then the President makes a closing statement:

- This discussion has been very instructive. I've learned a lot and I hope you all will keep working together and sharing ideas and strategies among yourselves, and with people from other communities all over the country.
- One of the things I've been talking about a lot lately is our need as a nation to come together and to find common ground. And I think we've got a lot of common ground on this one: I don't think there's a parent in this country who actually wants his or her child to start smoking -- to take that first step toward a lifelong addiction and terrible illness and premature death.
- We here in Washington are trying to give you some help and some tools in the fight against teen smoking. That's why my Administration has proposed some new regulations to make it harder for kids to buy cigarettes, and that lessen the impact of the advertising that is so appealing to kids. The FDA is currently looking over the comments it received on those proposals. And that's why we issued the Synar regulations just last month that make states step up their enforcement efforts too. But I know that our schools and communities are where the "rubber hits the road." So that's why what you're doing is so important.
- [We'll have a bullet about the fact that on Monday, Robert Wood Johnson is announcing a \$30 million effort to combat teen smoking -- the President will praise it.]

- But I can't stress enough how important it is for parents and local communities to continue to lead the way -- school by school -- and home by home -- to find local solutions that work and can be replicated across the country.
- Thank you for coming and keep fighting the good fight and we will be working with you, giving you the tools and resources you need to get the job done and same current and future generations of kids.

TALKING POINTS ON TOBACCO

- o Smoking among young people is a crucial public health issue. Every single day, 3000 young people become regular smokers and nearly 1,000 of them will die prematurely as a result.
- o For more than a decade, even as adult smoking was dropping, the smoking rate among high school seniors did not go down. That was bad enough, but since 1991, the percentage of teenage smokers has risen steadily and rapidly.
- o There's been a 30 percent increase in the number 8th graders who smoke, a 22 percent increase in the number of 10th graders who smoke, and by the age of 16 the average teenage smoker is smoking every day -- and will not stop.
- o The number of teenagers who believe smoking is dangerous is dropping dramatically. As the President has said, peer approval of smoking is a "recipe for disaster."
- o We have a responsibility to help parents keep cigarettes and chewing tobacco away from their kids. It's far too easy for children to buy and use tobacco products. There are things that can be done at the federal level to help in this area, and President Clinton is taking strong action today to address the problem of smoking among children.
- o The actions the President will unveil today will be, as he has said, tough and mandatory. They will focus on how to stop children from smoking, and how to stop them from starting.
- o We could change the dynamic of health care in America by saving these kids, because we will be paying years down the road for the health damage caused by smoking among today's children. Reducing teen smoking would be the cheapest, easiest, quickest thing we could do to reduce the cost of health care, help balance the budget over the long run, and improve the health of America.

CHILDREN AND TOBACCO: WHAT OTHERS SAY

"I figure if it's really so bad for you, they wouldn't be selling them everywhere. I mean, you walk into the Stop 'N' Go, and there's a whole wall of them right up front at the cash register. If they were really that bad for you, they'd make them less accessible."

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"What is most significant about teens and smoking, however, is that, from all indications, smoking is an addiction that is typically initiated during the teenage years or not at all. For the great majority of smokers, this addiction begins before they are old enough to purchase tobacco lawfully. In fact, 75 percent of all adult smokers report that they became addicted to tobacco before they were 18 years old. Very few

THE WHITE HOUSE
WASHINGTON

August 10, 1995

MEMORANDUM FOR LEON PANETTA
HAROLD ICKES
ERSKINE BOWLES
JACK QUINN
GEORGE STEPHANOPOULOS
MARCIA HALE
PAT GRIFFIN
CHRIS CERF

FROM: JENNIFER O'CONNOR
SUBJECT: TOBACCO MATERIALS

Attached are the following materials:

Two page talking points that summarize the danger of tobacco to kids, the elements of the rule, what is not in the rule, and the jurisdictional status. It serves as a two page summary of the most important material. It is the basic summary the President will have for his Oval Office discussion.

Six page questions and answers to be used by White House as well as HHS and FDA staff -- for internal use only.

One page Economic Impact statement -- for internal use only.

The FDA press packet which includes:

- One page general talking points

- One page summary of the rule (in six bullets)

- Two page fact sheet on dangers of tobacco to children

- Two page justification for each of our actions from banning vending machines to t-shirts and restricting advertising

- Two page sheet of quotes from health experts, Jimmy Carter, William F. Buckley, Jr., Barry Goldwater and others who support our approach in general.

Talking points

I. Kids-Oriented Regulation is Necessary

- * Although it is illegal in all 50 states to sell tobacco products to minors, smoking by both children and teenagers continues to rise.
- * On any given day, approximately 3000 young people become regular smokers, with total youth consumption of cigarettes exceeding 500 million packs per year.
- * Over 80% of adult smokers began as minors, beginning, on average, at age 14. If an individual does not become a smoker as a teen, it is unlikely that he or she ever will become one.
- * The consequences of these statistics are tragic. According to the CDC, of the two million Americans who will die in 1995, approximately 420,000 will die of conditions associated with tobacco.
- * This number is almost ten times the annual highway toll and more than the combined deaths last year from accidents, murders, suicides, AIDS, drugs, alcohol-related diseases and fire.

II. Principal Components of the Rule

- * Permits sale of tobacco products only through a face-to-face transaction with an adult. Under this principle, vending machines, self service displays, and mail order purchases would not be permitted.
- * Prohibits all outdoor advertising (e.g., billboards) within 1000 feet of schools and playgrounds.
- * For all other outdoor advertising, permits only black and white, text-only advertising.
- * For magazines with significant youth readership, limits advertising to black and white, text-only format; no restrictions on advertising in other publications.
- * Prohibits sale or giveaways of products (like caps or gymbags) that carry a tobacco brand name.
- * Prohibits brand-name sponsorship of sporting and entertainment events, but permits it in corporate name. (For example, the "Phillip Morris Tennis Tournament" would be permissible, but "The Virginia Slims Tournament" would not be.)

- * Requires the industry to fund (\$150 million per year) a public education campaign designed to prevent kids from smoking.

III. What the Rule Does Not Do

- * The rule does not in any way restrict adults' ability to purchase or consume tobacco products; it does not affect cigars or pipe tobacco at all.
- * The rule does not follow the course -- already adopted in 20 countries -- of simply banning all tobacco advertising. (Countries include France, Canada, and Norway.)

IV. Status of the Rulemaking Proceeding

- * The evidence before the FDA at this time supports the finding that nicotine in cigarettes and smokeless tobacco is a drug, but the agency is accepting further evidence and comment on that issue and will give them careful consideration.
- * Interested parties have 90 days to submit comments on the jurisdictional issue as well as the particulars of the proposed rule. Only after receipt and consideration of these comments will the FDA be in a position to issue its final rule.

TOBACCO QUESTIONS AND ANSWERS

Public Reaction

- Q: Won't Congress stop this? What's your strategy to fight an industry lawsuit?
- A: We hope Congress and the industry will agree with us. The President is firmly committed to the goals and has released his proposed regulation. However, he is open to other avenues to achieve the goal such as a statute which enacts the same measures as in the proposed regulation.

Voluntary Approaches

- Q: Why can't you just use a voluntary approach? Why are regulations needed?
- A: The tobacco industry has had a voluntary advertising code in place since 1964 to keep kids from beginning to smoke. And yet, 3,000 kids a day become smokers, and the numbers are getting worse, not better: smoking among eighth graders has risen 30 percent in the last three years. Either the code is insufficient or the code is not followed.
- Q: Isn't this a "big government" fix to a problem that should be addressed by the private sector?
- A: No. Other countries have taken much more extreme measures, such as banning all advertising. The Administration proposal is narrowly aimed at the real preventable problem: kids smoking. State laws prohibiting sales to or use by minors already exist in all 50 states. But we haven't done a good job -- in either the public or private sector: 3,000 kids become regular smokers each day.
- Q: What is the difference between what you are proposing and what the industry voluntarily has initiated so far?
- A: Tobacco industry programs consist primarily of awareness materials for retailers and educational materials for parents and teachers. The industry implies that these programs are all that is needed to reduce the sale of tobacco to minors. In recent weeks, the industry has suggested that it will take additional actions. (For example, Philip Morris indicated that it would add pack notices about underage sales; discontinue sampling and direct mail marketing; provide support to retailers; revise retailer incentive programs; and restrict use of company logos on children's products.)

Did the Industry Offer You a Deal?

Q: Did the industry offer you a deal?

A: No. We let them know what we were thinking about and they came back with a proposal we considered. It was similar in many respects to what the President outlined today. However in the important areas of advertising on billboards and at the point of sale, we didn't believe their proposal would be effective at reducing kids' smoking. And the President wouldn't accept that.

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Q: How will this be enforced?

A: The federal government will work with the States to enforce the prohibition on selling tobacco products to children under 18 years old. In addition, the FDA will be responsible for monitoring advertising and promotion to ensure that they comply with any final regulation. Any enforcement action would have to be initiated by the Department of Justice.

Won't FDA Ban Tobacco?

Q: If nicotine in tobacco is a drug, doesn't FDA have to ban it?

A: No. FDA is not required to and will not ban cigarettes and smokeless tobacco products.

Q: Even if FDA doesn't ban tobacco now, isn't that where this is leading?

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Q: What is the evidence that tobacco advertising actually influences teen smoking?

A: The proposed rule reviews in detail the evidence of how cigarette marketing practices affect teen smoking. Some of the most compelling data include:

- Teens (86%) are more than twice as likely as adults (35%) to smoke the three most advertised brands of cigarettes (Marlboro, Camel, and Newport).
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Q: Are the advertising restrictions in the proposed rules really geared to children? They look as though they will affect adults also.

A: During its investigation, the agency was struck by the evidence of the chilling effectiveness of tobacco advertising on young people's decision to use tobacco products. Also, we know that advertising is very successful with kids. 86% of kids smoke one of the three most heavily advertised brands.

Safety and Effectiveness

Q: How can FDA say these products are "safe and effective"?

A: FDA is saying these are dangerous products and people become addicted as kids. We are proposing a strategy to prevent this from happening.

Economic Impact

Growers

- Q: What is the economic impact on growers?
- A: The overall impact is both slight and gradual. The regulatory scheme is projected to reduce revenues from cigarette sales by 0.5 percent in the first year, 2.1 percent in the 5th year and 4.0 percent in the 10th year. Over this 10 year period, this would result in the loss of about 1,000 jobs annually among warehouses, manufacturers, tobacco growers and wholesalers.

Retail Stores

- Q: How will this proposal affect store owners?
- A: The major cost will be additional labor costs associated with verifying age, but those will be minimal. For instance, a typical small store will have a cost of \$320 in the first year, \$285 being the labor cost. If the store already verifies ages, the cost will be only \$35.

Vending Machines

- Q: What impact will FDA's proposal have on the vending machine industry?
- A: The impact on the vending machine industry will be minimal. The number of vending machines selling cigarettes has declined dramatically from 785,000 in 1983 to 480,000 in 1993. Cigarette vending machine yields about \$10 per day on average in sales, or less than 5 packs per day. In 1993, cigarette sales constituted only 3.4% of all vending machine sales. No new cigarette vending machines have been shipped in the United States since 1990.

Public Reaction

Q: What are the political implications of this action?

A: Health should not be a partisan political issue, and our children's health should come before all other considerations. In taking this action, the President has allied himself with every recognized major health and medical authority in this country including the American Medical Association, the American Academy of Pediatrics, the American Academy of Family Physicians, the American Heart Association, the American Cancer Society, the American Lung Association, as well as President Jimmy Carter, former Senator Barry Goldwater, Secretaries of Health and Human Services Otis Bowen and Louis Sullivan, Surgeons General Jesse Steinfeld, Paul Ehrlich, C. Everett Koop, and Antonia Novello, and many religious organizations of all faiths. The support for protecting the health of our children is found among those with a broad spectrum of political beliefs.

Q: Is there public support for these proposals, especially in tobacco-producing states?

A: The public overwhelmingly supports efforts to keep children from smoking and to impose reasonable restrictions on tobacco advertising. Almost 75 percent favored a ban of vending machine sales of cigarettes in a poll done for the Robert Wood Johnson Foundation, and 73 percent said text only advertising will make these products less appealing to children. This support cuts across party lines, this support is in every city and state. This is not a proposal aimed against any group or region. This proposal is for our children and our families. This is about helping kids grow up healthy.

Effectiveness of these proposed restrictions

Q: Do we have any evidence that restrictions on advertising will help keep kids from smoking?

A: Yes. A recent report looked at data from countries with laws on youth smoking and concluded that the most substantial and meaningful reductions in youth smoking occurred in countries with bans on advertising.

FDA PRESS PACKET

CHILDREN AND TOBACCO: THE PROPOSAL

The Clinton Administration is proposing a comprehensive and coordinated plan to reduce smoking by children and adolescents by 50 percent. It builds on previous actions taken by Congress and others such as the ban on television advertising and state laws to prohibit the sale or use of tobacco by children. It follows recommendations by the American Medical Association and the Institute of Medicine. Experts have consistently recommended that the keys to achieving the goal are: reducing access and limiting the appeal for children. This ambitious initiative accomplishes that objective, while preserving the availability of tobacco products for adults.

The proposals announced today include:

Reducing Easy Access by Children

- o Require age verification and face-to-face sale and eliminate mail order sales, vending machines, free samples, self-service displays, and sale of single cigarettes ("loosies") and packages with fewer than 20 cigarettes ("kiddie packs").

Reducing Appeal to Children

- o Ban outdoor advertising within 1,000 feet of schools and playgrounds. Permit black-and-white text only advertising for all other outdoor advertising, including billboards, signs inside and outside of buses, and all point-of-sale advertising.
- o Permit black-and-white text only advertising in publications with significant youth readership (under 18). (Significant readership means more than 15 percent or more than 2 million. No restrictions on print advertising below these thresholds).
- o Prohibit sale or giveaway of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos. Prohibit exchange of non-tobacco products for proof of purchase of tobacco products.
- o Prohibit brand name sponsorship of sporting or entertainment events, but permit it in the corporate name.
- o Require industry to fund (\$150 million annually) a public education campaign to prevent kids from smoking.

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CHILDREN AND TOBACCO: THE FACTS

The Clinton Administration is proposing a comprehensive and coordinated set of measures to significantly reduce the number of children and adolescents who become addicted to nicotine in cigarettes and smokeless tobacco (snuff and chewing tobacco). Children are becoming addicted to these products, with more than 80 percent of smokers beginning to smoke by age 18. Smoking is the leading preventable cause of death in the United States, and health care costs associated with smoking soared to more than \$50 billion in 1993, according to the Centers for Disease Control. While the proposed measures will continue to maintain the legal status of cigarettes and smokeless tobacco products for adults, they will reduce the easy access and strong appeal for children. Preventing children from smoking is key to reducing the deadly toll of smoking. The Clinton Administration's plan will help parents provide their children with an environment in which to grow up healthy.

* * *

A Pediatric Disease

Children are becoming addicted to nicotine. The average teenage smoker starts at 14 1/2 years old and becomes a daily smoker before age 18. More than 80 percent of all adult smokers had tried smoking by their 18th birthday and more than half of them had already become regular smokers by that age. Studies show that if people do not begin to smoke as teenagers or children, it is unlikely they will ever do so.

Each and every day, another 3,000 young people become regular smokers, and nearly 1,000 of them will eventually die as a result of their smoking. Currently, more than 3 million children and adolescents smoke cigarettes, and 1 million adolescent boys--currently use smokeless tobacco. Smoking by young people is rising sharply. Between 1991 and 1994, the percentage of eighth graders who smoke increased 30 percent, and the percentage of tenth graders who smoke increased 22 percent.

Children tend to vastly underestimate the likelihood that they will become addicted to these products. Although only 5 percent of daily smokers surveyed in high school said they would definitely be smoking five years later, close to 75 percent were smoking 7 to 9 years later. A survey conducted in 1992 found that approximately two-thirds of adolescents who smoked said they wanted to quit and 70 percent said they would not start smoking if they could make that choice again.

Smoking: Leading Cause of Avoidable, Premature Death

Tobacco use takes enormous, deadly toll each year. Tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illness, heart disease, and other health problems. Cigarettes kill more Americans each year than AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined. Smokers who die as a result of smoking would have lived on average 12 to 15 years longer if they had not smoked.

The health care costs associated with tobacco use are rising. The Centers for Disease Control estimated that in 1993 the health care costs associated with smoking totalled \$50 billion: \$26.9 billion for hospital costs; \$15.5 billion for doctors; \$4.9 billion in nursing home costs; \$1.8 billion for prescription drugs and \$900 million for home-health care expenditures. The Office of Technology Assessment calculated the social costs attributable to smoking in 1990 at \$68 billion. That calculation was based on \$20.8 billion in direct health care costs and \$6.9 billion in lost productivity from disabilities and \$40.3 billion in lost productivity from premature deaths.

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CHILDREN AND TOBACCO: THE PROBLEM

Easy Access

Despite state laws prohibiting the sale of tobacco to minors, children can easily buy these products. One study estimated that teenagers annually consume 516 million packs of cigarettes and 26 million containers of chewing tobacco. A review of 13 studies of over-the-counter sales found that on average, children and adolescents were able to successfully buy tobacco products 67 percent of the time.

- o **Vending machines** are a primary source of tobacco products for young smokers. A study by the vending machine industry found that 22 percent of 13-year-old smokers use vending machines compared with 2 percent of 17-year-old smokers. The 1994 Surgeon General's Report found that young people were able to buy cigarettes in vending machines an average of 88 percent of the time.
- o **Mail-order sales** provide no sure way of verifying age. Current industry practice only asks the consumer to provide a birth date or check box to verify age.
- o **Self-service displays** allow children to easily obtain tobacco products. The Institute of Medicine, in its landmark 1994 report, "Growing Up Tobacco Free," concluded that placing tobacco products "out of reach reinforces the message that tobacco products are not in the same class as candy or potato chips."
- o **Free samples** are obtained by children, including those in elementary school, despite industry code prohibiting distribution to anyone under 21. Free samples occur on street corners, at shopping malls and sporting events. A New Jersey survey found that one-third of high school students who were smokers or ex-smokers reported receiving free samples before age 16.

Appealing to Children

Advertising and promotional activities can greatly influence a young person's decision to smoke or use smokeless tobacco products. Awareness of tobacco products and messages is very high among even the youngest children. Studies show that 30 percent of 3-year-olds and 91 percent of 6-year-olds could identify "Joe Camel" as a symbol for smoking. The Centers for Disease Control recently reported that 86 percent of underage smokers who purchase their own cigarettes purchase one of the three most heavily advertised brands: Marlboro, Camel and Newport.

- o Tobacco products are among the most heavily advertised products in the United States. In 1993, the tobacco industry spent \$6.2 billion on advertising and promoting cigarettes and smokeless tobacco. Tobacco advertising expenditures have increased more than 1,500 percent between 1970 (the year before television and radio advertising was banned) and 1992.
- o Promotion of tobacco products through non-tobacco items such as t-shirts, hats and gym bags and through sponsorship of events is reaching children. A 1992 Gallup Survey found that half of adolescent smokers and one quarter of adolescents who do not smoke owned at least one tobacco promotional item such as a tee-shirt, cap, sporting good, or lighter. Another report found that one out of four 12- and 13-year-olds own one of these items. Used or worn by young people, these become "walking billboards," promoting these products in schools and other locations where tobacco advertising is usually prohibited. Sponsorship of events such as tennis tournaments, car races, and rodeos associate tobacco products with excitement and glamour, and provide a way for tobacco brands to be advertised on television despite the broadcast advertising ban.

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int use only

Internal use only

CHILDREN AND TOBACCO: THE PROPOSAL'S ECONOMIC IMPACT

Each year, an estimated 1 million children and adolescents begin to smoke. The goal of this ambitious proposal to prevent children from becoming addicted to cigarettes and smokeless tobacco products (snuff and chewing tobacco) is to reduce that number by 500,000.

- o Meeting this goal will prevent well over 60,000 premature deaths.
- o The benefits to the U.S. economy from meeting this goal would be a savings of more than \$2.6 billion in reduced medical costs. In total, there are potential savings ranging from \$28 billion to \$43 billion in avoiding disabilities or premature deaths from tobacco use.
- o These benefits are repeated each year for each group of children not beginning to smoke or use smokeless tobacco products.

The economic costs associated with this proposal are gradual and slight. It is projected that it will reduce revenues from cigarettes sales by 0.5 percent in the first year, 2.1 percent in the fifth year, and 4 percent in the 10th year. Over this 10-year period, this would result in the loss of about 1,000 jobs annually among warehouses, manufacturers, tobacco growers and wholesalers.

- o Tobacco manufacturers will have costs of about \$177 million annually (about one-half of 1 percent of current sales), and this will mainly be the result of the educational campaign they fund.
- o Retailers will have an annual estimated cost of \$53 million, mainly for activities related to verifying age. The impact on a typical small retail store is estimated -- to be \$320 in the first year, with the largest single cost, \$285, being the labor cost for checking identification. Small stores already verifying ages of young customers would have an additional cost of only \$35.
- o Vending machine sales of cigarettes are already falling, down 25 percent from 1992 to 1993. Currently, cigarettes only account for 3.4 percent of total vending machine sales. No new cigarette vending machine has been shipped in the United States since 1990.
- o Of the \$6.2 billion spent by the tobacco industry on advertising and promotion, the proposal affects \$1.9 billion (less than 1.5 percent of total U.S. media advertising).

###

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

10-Aug-1995 09:48am

TO: Jennifer M. O'Connor

FROM: Carol H. Rasco
 Economic and Domestic Policy

SUBJECT: Congratulations on a fine packet

of briefing materials on tobacco! It is terrific!

THE WHITE HOUSE
WASHINGTON

August 10, 1995

MEMORANDUM FOR LEON PANETTA

HAROLD ICKES
ERSKINE BOWLES
JACK QUINN
GEORGE STEPHANOPOULOS
MARCIA HALE
PAT GRIFFIN
CHRIS CERF

FROM: JENNIFER O'CONNOR

SUBJECT: TOBACCO MATERIALS

Attached are the following materials:

Two page talking points that summarize the danger of tobacco to kids, the elements of the rule, what is not in the rule, and the jurisdictional status. It serves as a two page summary of the most important material. It is the basic summary the President will have for his Oval Office summary.

Six page questions and answers to be used by White House as well as HHS and FDA staff -- for internal use only.

One page Economic Impact statement -- for internal use only.

The FDA press packet which includes:

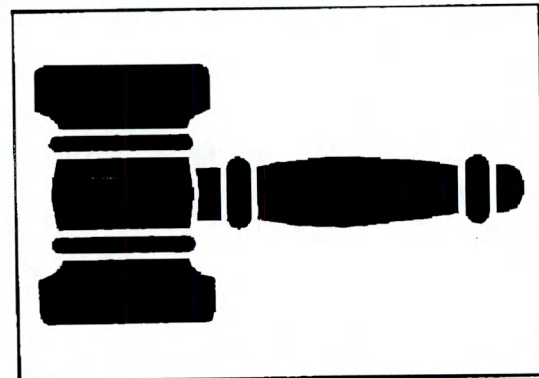
- One page general talking points
- One page summary of the rule (in six bullets)
- Two page fact sheet on dangers of tobacco to children
- Two page justification for each of our actions from banning vending machines to t-shirts and restricting advertising
- Two page sheet of quotes from health experts, Jimmy Carter, William F. Buckley, Jr., Barry Goldwater and others who support our approach in general.

DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL

PHONE: (202) 690-6318
FAX: (202) 690-7998

DATE: August 5, 1996

TO: JEN O'CONNOR



FROM: ANDREW D. HYMAN
Special Assistant to the General Counsel
Office of the General Counsel, Room 707F
Department of Health and Human Services
200 Independence Ave., SW
Washington D.C. 20201

COMMENTS: I thought you may want a copy of this resolution by the National Association of Counties. Could you forward a copy to Kevin O'Keefe? Thanks.

No. of Pages (including cover): 3

CC ✓
Kevin
O'Keefe

CAMPAIGN for TOBACCO-FREE Kids

July 29, 1996

Andy Hyman
Office of the General Counsel
707-F Hubert H. Humphrey Building
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Andy:

I thought you would find of interest the resolution passed by the Health Steering Committee of the National Association of Counties. We worked closely with the author of the resolution and were pleased to see the National Association of Counties go on record in support of each of the basic components of the plan announced by the President and the Food and Drug Administration last August.

Sincerely,



Matthew L. Myers
Executive Vice President and General Counsel

cc: Bill Novelli
Charlotte Blount

NATIONAL CENTER FOR TOBACCO-FREE KIDS
1707 L STREET, NW • SUITE 800 • WASHINGTON, DC 20036
PHONE (202) 296-5469 • FAX (202) 296-5427

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HEALTH STEERING COMMITTEE

RESOLUTION ON TOBACCO USE BY MINORS

WHEREAS, tobacco use among minors has increased during each of the last four years and is higher today than at any time in the last fifteen years; and

WHEREAS, the average age at which minors are starting to use tobacco is younger today than at any time in our nation's history; and

WHEREAS, despite state laws prohibiting the sale of tobacco products to minors, underage customers purchase over half a billion packs of cigarettes and twenty-six million containers of chewing tobacco each year; and

WHEREAS, given that the tobacco industry spends over six billion dollars a year marketing its products, more needs to be done to reduce the appeal of tobacco products to minors and to better educate them about the reasons not to use tobacco; and

WHEREAS, tobacco use among minors is a concern not just because it is illegal, but because tobacco use is an addiction which is almost always begun during the teenage years and which leads to premature death from a variety of illnesses; and

WHEREAS, NACo has long supported strong efforts to reduce tobacco use by minors and to make tobacco less accessible to minors;

THEREFORE, BE IT RESOLVED that the National Association of Counties (NACo) reaffirms existing NACo policy which urges that more must be done to reduce tobacco use among minors, including:

1. strengthening regulation and enforcement of policies to make tobacco products less accessible to minors no matter where they live in the United States;
2. curtailing activities which make tobacco products appealing to minors; and
3. expanding educational programs which target young people and pregnant women.

Motion to waive the 30 day requirement for introducing resolutions. Approved 22-0.

Adopted by Health Steering Committee
(unanimous)
July 13, 1996

Adopted by NACo Board of Directors
July 14, 1996

BYLINE: Scott Andron

file

BODY:

Half of North Carolinians now think the state's farmers should 'find some crops to replace tobacco, because tobacco has been criticized as a health hazard,' according to a new poll by UNC researchers.

That's up by 17 percentage points from the last time pollsters asked this question, in 1983.

Forty-two percent thought farmers should stick with tobacco because 'tobacco has always been important to North Carolina.' That's a drop of 20 percentage points from 13 years ago.

Reduced support for tobacco was one of the findings of the most recent Carolina Poll, a semi-annual survey of state residents conducted by the Institute for Research in Social Science and the School of Journalism and Mass Communication at UNC-Chapel Hill.

In February, pollsters interviewed 662 adult North Carolinians from all parts of the state. The survey's margin of error is plus or minus 4 percentage points.

In response to a new poll question, 44 percent of respondents favored government regulation of nicotine, while 46 percent opposed such regulation.

Native North Carolinians, smokers, and people who described themselves as Southerners were more likely to support tobacco farming.

More educated and higher-paid respondents were more likely to favor seeking other crops.

UNC faculty and students have been administering the Carolina Poll twice a year since 1976. The February poll included 72 questions on matters ranging from politics to vacation habits.

LOAD-DATE: May 31, 1996

TOBACCO QUESTIONS AND ANSWERS

Public Reaction

- Q: Won't Congress stop this? What's your strategy to fight an industry lawsuit?
- A: We hope Congress and the industry will agree with us. The President is firmly committed to the goals and has released his proposed regulation. However, he is open to other avenues to achieve the goal such as a statute which enacts the same measures as in the proposed regulation.

Voluntary Approaches

- Q: Why can't you just use a voluntary approach? Why are regulations needed?
- A: The tobacco industry has had a voluntary advertising code in place since 1964 to keep kids from beginning to smoke. And yet, 3,000 kids a day become smokers, and the numbers are getting worse, not better: smoking among eighth graders has risen 30 percent in the last three years. Either the code is insufficient or the code is not followed.
- Q: Isn't this a "big government" fix to a problem that should be addressed by the private sector?
- A: No. Other countries have taken much more extreme measures, such as banning all advertising. The Administration proposal is narrowly aimed at the real preventable problem: kids smoking. State laws prohibiting sales to or use by minors already exist in all 50 states. But we haven't done a good job -- in either the public or private sector: 3,000 kids become regular smokers each day.
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Safety and Effectiveness

Q: How can FDA say these products are "safe and effective"?

A: FDA is saying these are dangerous products and people become addicted as kids. We are proposing a strategy to prevent this from happening.

Free choice for adults

Q: Isn't this proposal a threat to personal, free choice?

A: No. Adults can still smoke or use what will continue to be legal products. But these products are unique -- no other legal product is as deadly or addictive when used as intended. The scientific and medical evidence is overwhelming: cigarettes contain nicotine in sufficient amounts to create and sustain an addiction and our kids are becoming regular smokers at a rate of 3,000 a day.

Message to kids

Q: Won't these measures just make cigarettes more attractive to kids by making them "forbidden"?

A: No. We have already said kids shouldn't smoke, but we haven't done a good job of telling our kids that. We have continued to let these products be easily available and the industry promotions have told kids it's cool and glamorous to use them. Kids believe you if your actions match your words. For the first time, we're going to do that.

What Other Countries Do

Q: Aren't the measures you are proposing today more severe than those that exist anywhere else in the world?

A: No. In fact, approximately 20 countries have in place a total ban on advertising and promotion of tobacco products, including Canada and France. Others require that much larger portions of the pack contain much stronger warnings than in this country.

White House Review

Q: Why did the President review the rule? Isn't that unusual? Is it appropriate?

A: This is one of the most important public health issues that the country is facing. It is completely appropriate that the President review the proposed rule.

Effective Date

Q: When is the initiative likely to become effective?

A: The agency has allowed 90 days for the public to comment on the proposed rule. When the agency publishes a final rule, it will specify effective dates, which are likely to vary depending on the particular portion of the rule.

Public Reaction

Q: What are the political implications of this action?

A: Health should not be a partisan political issue, and our children's health should come before all other considerations. In taking this action, the President has allied himself with every recognized major health and medical authority in this country including the American Medical Association, the American Academy of Pediatrics, the American Academy of Family Physicians, the American Heart Association, the American Cancer Society, the American Lung Association, as well as President Jimmy Carter, former Senator Barry Goldwater, Secretaries of Health and Human Services Otis Bowen and Louis Sullivan, Surgeons General Jesse Steinfeld, Paul Ehrlich, C. Everett Koop, and Antonia Novello, and many religious organizations of all faiths. The support for protecting the health of our children is found among those with a broad spectrum of political beliefs.

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A: The major cost will be additional labor costs associated with verifying age, but those will be minimal. For instance, a typical small store will have a cost of \$320 in the first year, \$285 being the labor cost. If the store already verifies ages, the cost will be only \$35.

Vending Machines

Q: What impact will FDA's proposal have on the vending machine industry?

A: The impact on the vending machine industry will be minimal. The number of vending machines selling cigarettes has declined dramatically from 785,000 in 1983 to 480,000 in 1993. Cigarette vending machine yields about \$10 per day on average in sales, or less than 5 packs per day. In 1993, cigarette sales constituted only 3.4% of all vending machine sales. No new cigarette vending machines have been shipped in the United States since 1990.

August 9, 1995

NOTE TO ALISON WILKE:

Enclosed are the documents for tomorrow's tobacco release. They're labelled on the disk as follows:

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Children and Tobacco: What Others Say -- SMOSUP

Children and Tobacco: The Proposal's Economic Impact --- SMOECON

Talking points -- TPS

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As always, if you guys need anything, please call me at work (690-6853) or home

(625-0548.) Jim O'Hara of FDA can be reached through my office, or at home tonight at 301-585-9408, or through SKYPAGE with Pin number 8372057.

Thanks -- Melissa

TALKING POINTS ON TOBACCO

- o Smoking among young people is a crucial public health issue. Every single day, 3000 young people become regular smokers and nearly 1,000 of them will die prematurely as a result.
- o For more than a decade, even as adult smoking was dropping, the smoking rate among high school seniors did not go down. That was bad enough, but since 1991, the percentage of teenage smokers has risen steadily and rapidly.
- o There's been a 30 percent increase in the number 8th graders who smoke, a 22 percent increase in the number of 10th graders who smoke, and by the age of 16 the average teenage smoker is smoking every day -- and will not stop.
- o The number of teenagers who believe smoking is dangerous is dropping dramatically. As the President has said, peer approval of smoking is a "recipe for disaster."
- o We have a responsibility to help parents keep cigarettes and chewing tobacco away from their kids. It's far too easy for children to buy and use tobacco products. There are things that can be done at the federal level to help in this area, and President Clinton is taking strong action today to address the problem of smoking among children.
- o The actions the President will unveil today will be, as he has said, tough and mandatory. They will focus on how to stop children from smoking, and how to stop them from starting.
- o We could change the dynamic of health care in America by saving these kids, because we will be paying years down the road for the health damage caused by smoking among today's children. Reducing teen smoking would be the cheapest, easiest, quickest thing we could do to reduce the cost of health care, help balance the budget over the long run, and improve the health of America.

int use only

CHILDREN AND TOBACCO: THE PROPOSAL'S ECONOMIC IMPACT

Each year, an estimated 1 million children and adolescents begin to smoke. The goal of this ambitious proposal to prevent children from becoming addicted to cigarettes and smokeless tobacco products (snuff and chewing tobacco) is to reduce that number by 500,000.

- o Meeting this goal will prevent well over 60,000 premature deaths.
- o The benefits to the U.S. economy from meeting this goal would be a savings of more than \$2.6 billion in reduced medical costs. In total, there are potential savings ranging from \$28 billion to \$43 billion in avoiding disabilities or premature deaths from tobacco use.
- o These benefits are repeated each year for each group of children not beginning to smoke or use smokeless tobacco products.

* * *

The economic costs associated with this proposal are gradual and slight. It is projected that it will reduce revenues from cigarettes sales by 0.5 percent in the first year, 2.1 percent in the fifth year, and 4 percent in the 10th year. Over this 10-year period, this would result in the loss of about 1,000 jobs annually among warehouses, manufacturers, tobacco growers and wholesalers.

- o Tobacco manufacturers will have costs of about \$177 million annually (about one-half of 1 percent of current sales), and this will mainly be the result of the educational campaign they fund.
- o Retailers will have an annual estimated cost of \$53 million, mainly for activities related to verifying age. The impact on a typical small retail store is estimated to be \$320 in the first year, with the largest single cost, \$285, being the labor cost for checking identification. Small stores already verifying ages of young customers would have an additional cost of only \$35.
- o Vending machine sales of cigarettes are already falling, down 25 percent from 1992 to 1993. Currently, cigarettes only account for 3.4 percent of total vending machine sales. No new cigarette vending machine has been shipped in the United States since 1990.
- o Of the \$6.2 billion spent by the tobacco industry on advertising and promotion, the proposal affects \$1.9 billion (less than 1.5 percent of total U.S. media advertising).

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Suggested Cover Sheet

President Clinton today announced the nation's first comprehensive campaign to reduce children's use of tobacco products. Under the new plan, children will not be able to buy cigarettes, and smokeless tobacco products and promotional and advertising gimmicks appealing to children will be limited.

The President's goal is to reduce smoking by children by 50 percent within seven years after the Administration's plan goes into effect.

The Administration's actions are based on the overwhelming public health data showing that children are becoming addicted to nicotine and that one out of every three will eventually die from their tobacco use. Smoking by young people is rising sharply. Between 1991 and 1994, the percentage of eighth graders who smoke increased 30 percent. More than 80 percent of adult smokers had tried smoking by 18, and more than half of them had already become regular smokers by that age. In 1993 the estimated health care costs from smoking-related disease and death was \$50 billion.

The measures are aimed at assuring that only adults have access to tobacco products, as under current law, and to limit the reach of advertisements and promotions that have encouraged children to begin using cigarettes and smokeless tobacco products. The ambitious initiative will allow parents who are already trying to teach their children the risks of smoking a better chance for success.

The proposals to reduce access by children include: prohibiting the sale of tobacco products to anyone under age 18; requiring face to face sales; requiring age verification with photo identification; and eliminating free samples and impersonal sales like vending machines, mail order sales and self-service displays.

The proposals to limit the appeal of cigarettes and smokeless tobacco include: banning outdoor advertising within 1,000 feet of schools and playgrounds; restricting all other outdoor advertising to black-and-white text only; restricting advertising in publications with significant children readership to black-and-white text only; banning non-tobacco products such as t-shirts and caps that have cigarette or smokeless tobacco product brand names, logos, or symbols, and eliminating the exchange of non-tobacco products for proof of purchase of tobacco products; and allowing sponsorship and advertising of events only in the corporate name.

Bolstering these actions will be a new educational campaign aimed at countering the industry's multi-billion dollar annual promotional and advertising expenditures and at teaching children the real health risks of these products. This campaign, including paid television ads, will be funded by the industry.

The Administration's initiative is being published today as a proposed rule of the Food and Drug Administration. Public comment on the proposal will be accepted for 90 days, and a final rule will be issued at a later date.

CHILDREN AND TOBACCO: THE FACTS

The Clinton Administration is proposing a comprehensive and coordinated set of measures to significantly reduce the number of children and adolescents who become addicted to nicotine in cigarettes and smokeless tobacco (snuff and chewing tobacco). Children are becoming addicted to these products, with more than 80 percent of smokers beginning to smoke by age 18. Smoking is the leading preventable cause of death in the United States, and health care costs associated with smoking soared to more than \$50 billion in 1993, according to the Centers for Disease Control. While the proposed measures will continue to maintain the legal status of cigarettes and smokeless tobacco products for adults, they will reduce the easy access and strong appeal for children. Preventing children from smoking is key to reducing the deadly toll of smoking. The Clinton Administration's plan will help parents provide their children with an environment in which to grow up healthy.

* * *

A Pediatric Disease

Children are becoming addicted to nicotine. The average teenage smoker starts at 14 1/2 years old and becomes a daily smoker before age 18. More than 80 percent of all adult smokers had tried smoking by their 18th birthday and more than half of them had already become regular smokers by that age. Studies show that if people do not begin to smoke as teenagers or children, it is unlikely they will ever do so.

Each and every day, another 3,000 young people become regular smokers, and nearly 1,000 of them will eventually die as a result of their smoking. Currently, more than 3 million children and adolescents smoke cigarettes, and 1 million adolescent boys currently use smokeless tobacco. Smoking by young people is rising sharply. Between 1991 and 1994, the percentage of eighth graders who smoke increased 30 percent, and the percentage of tenth graders who smoke increased 22 percent.

Children tend to vastly underestimate the likelihood that they will become addicted to these products. Although only 5 percent of daily smokers surveyed in high school said they would definitely be smoking five years later, close to 75 percent were smoking 7 to 9 years later. A survey conducted in 1992 found that approximately two-thirds of adolescents who smoked said they wanted to quit and 70 percent said they would not start smoking if they could make that choice again.

Smoking: Leading Cause of Avoidable, Premature Death

Tobacco use takes enormous, deadly toll each year. Tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illness, heart disease, and other health problems. Cigarettes kill more Americans each year than AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined. Smokers who die as a result of smoking would have lived on average 12 to 15 years longer if they had not smoked.

The health care costs associated with tobacco use are rising. The Centers for Disease Control estimated that in 1993 the health care costs associated with smoking totalled \$50 billion: \$26.9 billion for hospital costs; \$15.5 billion for doctors; \$4.9 billion in nursing home costs; \$1.8 billion for prescription drugs and \$900 million for home-health care expenditures. The Office of Technology Assessment calculated the social costs attributable to smoking in 1990 at \$68 billion. That calculation was based on \$20.8 billion in direct health care costs and \$6.9 billion in lost productivity from disabilities and \$40.3 billion in lost productivity from premature deaths.

###

CHILDREN AND TOBACCO: THE PROBLEM

Easy Access

Despite state laws prohibiting the sale of tobacco to minors, children can easily buy these products. One study estimated that teenagers annually consume 516 million packs of cigarettes and 26 million containers of chewing tobacco. A review of 13 studies of over-the-counter sales found that on average, children and adolescents were able to successfully buy tobacco products 67 percent of the time.

- o **Vending machines** are a primary source of tobacco products for young smokers. A study by the vending machine industry found that 22 percent of 13-year-old smokers use vending machines compared with 2 percent of 17-year-old smokers. The 1994 Surgeon General's Report found that young people were able to buy cigarettes in vending machines an average of 88 percent of the time.
- o **Mail-order sales** provide no sure way of verifying age. Current industry practice only asks the consumer to provide a birth date or check box to verify age.
- o **Self-service displays** allow children to easily obtain tobacco products. The Institute of Medicine, in its landmark 1994 report, "Growing Up Tobacco Free," concluded that placing tobacco products "out of reach reinforces the message that tobacco products are not in the same class as candy or potato chips."
- o **Free samples** are obtained by children, including those in elementary school, despite industry code prohibiting distribution to anyone under 21. Free samples occur on street corners, at shopping malls and sporting events. A New Jersey survey found that one-third of high school students who were smokers or ex-smokers reported receiving free samples before age 16.

Appealing to Children

Advertising and promotional activities can greatly influence a young person's decision to smoke or use smokeless tobacco products. Awareness of tobacco products and messages is very high among even the youngest children. Studies show that 30 percent of 3-year-olds and 91 percent of 6-year-olds could identify "Joe Camel" as a symbol for smoking. The Centers for Disease Control recently reported that 86 percent of underage smokers who purchase their own cigarettes purchase one of the three most heavily advertised brands: Marlboro, Camel and Newport.

- o **Tobacco products are among the most heavily advertised products in the United States.** In 1993, the tobacco industry spent \$6.2 billion on advertising and promoting cigarettes and smokeless tobacco. Tobacco advertising expenditures have increased more than 1,500 percent between 1970 (the year before television and radio advertising was banned) and 1992.
- o **Promotion of tobacco products through non-tobacco items such as t-shirts, hats and gym bags and through sponsorship of events is reaching children.** A 1992 Gallup Survey found that half of adolescent smokers and one quarter of adolescents who do not smoke owned at least one tobacco promotional item such as a tee-shirt, cap, sporting good, or lighter. Another report found that one out of four 12- and 13-year-olds own one of these items. Used or worn by young people, these become "walking billboards," promoting these products in schools and other locations where tobacco advertising is usually prohibited. Sponsorship of events such as tennis tournaments, car races, and rodeos associate tobacco products with excitement and glamour, and provide a way for tobacco brands to be advertised on television despite the broadcast advertising ban.

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CHILDREN AND TOBACCO: WHAT OTHERS SAY

"I figure if it's really so bad for you, they wouldn't be selling them everywhere. I mean, you walk into the Stop 'N' Go, and there's a whole wall of them right up front at the cash register. If they were really that bad for you, they'd make them less accessible."

- Brian Grindele, 18

The New York Times, July 30, 1995

"Given all that we know, the scientific case for protecting children from tobacco is indisputable. The moral imperative to act is imperative....This is not a Democratic or a Republican issue. It is a bipartisan, pro-child, pro-family, pro-health issue."

- President Jimmy Carter

USA Today, August 3, 1995

"The tobacco industry continues to insist that smoking is a simple matter of individual rights and adult choice. If that were true, I would be on their side. But we're not talking about adults. We're talking about keeping an addictive and lethal substance out of the hands of children. Neither the FDA nor anyone else is talking about prohibiting adults from smoking."

- Former U.S. Sen. Barry Goldwater

Wall Street Journal, August 8, 1995

"The American Medical Association reminds physicians, the public, and politicians that the damning evidence against tobacco makes opposition to its use a pressing, nonpartisan public health issue."

- Editorial

Journal of the American Medical Association, July 19, 1995

"We believe that current tobacco regulations, limited primarily to a ban on television advertising and the promotion of warning labels on packages, are insufficient in protecting America's children. The FDA should have authority to control tobacco by placing new limits on tobacco advertising, creating stricter licensing regulations for vendors, and banning cigarette vending machines."

- American Public Health Association

Letter to President Clinton from APHA, July 13, 1995

"What is most significant about teens and smoking, however, is that, from all indications, smoking is an addiction that is typically initiated during the teenage years or not at all. For the great majority of smokers, this addiction begins before they are old enough to purchase tobacco lawfully. In fact, 75 percent of all adult smokers report that they became addicted to tobacco before they were 18 years old. Very few

smokers take up smoking for the first time as adults. If youth access can be controlled effectively, and the decision whether to smoke can be delayed until adulthood, then, over time, smoking will be greatly reduced as a major addiction in our society."

- "No Sale: Youth, Tobacco and Responsible Retailing"

Working Group of State Attorneys General, December, 1994

"The nation must commit itself to a vigorous public health initiative in tobacco control....The nation cannot reasonably expect to eliminate tobacco-related disease and death by 2010. However, by putting a youth-centered preventions strategy at the center of tobacco control efforts, and by implementing the initiatives proposed (to that end) in this report, the nation can take a firm and resolute step on that path."

- "Growing Up Tobacco Free"

Institute of Medicine, September, 1994

"The concept -- pediatric disease -- qualifies as an epiphany, given the acknowledged authority of society over a minor. He/she has to go to school, has to wait until a certain age before being allowed to drive, to vote, to drink beer. It yields no substantial libertarian ground to add to the list enforcement mechanisms designed to dissuade the 15-year-old from taking up a habit that brings on premature and painful death."

- William F. Buckley Jr.

Syndicated columnist, March, 1995

"... from a public-health standpoint, keeping kids away from cigarettes is the single most effective way to fight the nation's leading preventable cause of death."

- "Hooked on Tobacco: The Teen Epidemic"

Consumer Reports, March 1995

Further Reading:

"The Global Tobacco Epidemic"

Scientific American, May, 1995

"The Nicotine Connection"

Chemical and Engineering News, November 28, 1995

"Hooked on Tobacco: The Teen Epidemic"

Consumer Reports, March, 1995

"Nicotine Addiction in Young People"

The New England Journal of Medicine, July 20, 1995

August 9, 1995

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Thanks -- Melissa

The Food and Drug Administration [FDA] has conducted an extensive investigation and has engaged in comprehensive legal analysis regarding the agency's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. Based on the record before the agency, nicotine in cigarettes and smokeless tobacco products is a drug, and these products are drug delivery devices within the meaning of the Food, Drug and Cosmetic Act.

Elsewhere in this issue of the Federal Register, the agency is issuing a proposed regulation of nicotine-containing cigarettes and smokeless tobacco products under the restricted device provisions of the Act. Because the agency recognizes the unique importance of the jurisdictional issue underlying this regulation, the record remains open for comment on jurisdiction. Comments should be sent to the docket specified in brackets in the heading of this document. Comments should be submitted by the date identified in the proposed rule regarding cigarettes and smokeless tobacco products published elsewhere in this issue of the Federal Register.

The agency will not initiate any enforcement action regarding cigarettes or smokeless tobacco products covered by the proposed rule until it has completed the rulemaking proceeding.

hats), and see tobacco industry-sponsored events⁸ in person or on television.

o Advertising images are extremely powerful. Eighty-six percent of underage smokers purchased only Marlboro, Camel, or Newport, the three most heavily advertised brands.⁹ By contrast, the most popular "brand" of cigarette among adult smokers were generic cigarettes, which typically rely on little or no advertising and are much cheaper than brandname products.¹⁰

o A recent advertising and promotion campaign with particular appeal to children increased the children's share of a product's market from 3-4 percent to 13 percent in just four years.

o Owning the promotional items is significantly linked with using the tobacco product. A 1992 Gallup survey found that 50 percent of adolescent smokers but only 25 percent of adolescent non-smokers owned at least one tobacco promotional item.¹¹

Alternatively, restrictions on advertising and promotion have a significant effect on smoking rates and smoking initiation. One large study, that examined consumption trends in 33 countries found that the greater a government's restrictions on tobacco promotion, the greater the average fall in the rate of decrease of smoking among children.¹² In those countries with the most stringent advertising restrictions (either an

⁸ In Australia, cigarette brand purchases by 12 and 14 year olds mirrored the brands that had sponsored sporting events in their respective States. For example, more than 44 percent of children in New South Wales and Queensland smoke Winfield, the sponsor of the Queensland Rugby League, whereas, in South Australia, about 44 percent of children smoke Escort, which sponsors the South Australia's Australian Rules Escort Cup. This study demonstrates the effectiveness of sports sponsorship in influencing children's choice of cigarettes. (Memorandum from Gray, N., to All Members of the Federal Parliament, Anti-Cancer Council of Victoria, December 15, 1989.)

⁹ "Changes in the Cigarette Brand Preferences of Adolescent Smokers - United States, 1989-1993," in "MMWR," CDC, DHHS, vol. 43, No. 32, pp. 577-581, 1994.

¹⁰ Teinowitz, I., "Add RJR to List of Cigarette Price Cuts," Advertising Age, pp. 3, 46, April 26, 1993.

¹¹ "Teen-Age Attitudes and Behavior Concerning Tobacco - Report of the Findings," The George H. Gallup International Institute, Princeton, N.J., p. 17, September 1992.

¹² "Health or Tobacco - An End to Tobacco Advertising and Promotion," Toxic Substances Board, Wellington, New Zealand, May 1989.

advertising ban or severe ad strictures), fewer children began to smoke than in those countries with laxer advertising practices.¹³

The IOM and the AMA have strongly endorsed all of the above provisions. The AMA went even further and recommended that "[a]ll tobacco advertising should be eliminated, and a vigorous counter advertising campaign should be instituted."¹⁴ The IOM recommended either a ban on tobacco advertising or restricting ads to a text-only format. In fact, the IOM stated that restrictions on advertising, banning non-tobacco promotional items such as hats and tee-shirts, and prohibiting sponsorship in the brand name represent "essential components" of a regulatory plan to reduce children's use of tobacco. The IOM further stated that the promotional items "become walking advertisement capable of penetrating areas of a child's world that might be off-limits to other forms of advertising. The ubiquity of such specialty items conveys the impression that tobacco use is the norm."¹⁵

#6. Industry-funded educational program. Tobacco companies would be required to finance a national public educational program that relies heavily on youth-oriented messages to discourage children from using tobacco products.

Such a program would be very effective in reducing children's use of tobacco products and in reinforcing parental efforts to discourage children from smoking. From 1967 to 1970, the Federal Communications Commission, in applying its Fairness Doctrine, required broadcasters to air one anti-smoking message for every 3 or 4 tobacco advertisements. During this period, per capita cigarette consumption showed one of the largest declines ever recorded.¹⁶ When the anti-smoking messages on TV and radio ended, per capita cigarette consumption began to rise.¹⁷

¹³ Id.

¹⁴ Journal of the American Medical Association, July 19, 1995, vol. 274, no. 3.

¹⁵ Institute of Medicine, 1994 Report, p. 110.

¹⁶ Additionally, a study of nearly 7000 adolescents found that adolescent smoking rates declined during this period. Lewit, E.M., D. Coate, and M. Grossman, "The Effects of Government Regulation on Teenage Smoking," Journal of Law and Economics, vol. XXIV, No. 3, pp. 545-573, 1981.

¹⁷ Hamilton, J.L., "The Demand for Cigarettes: Advertising, the Health Scare, and the Cigarette Advertising Ban," Rev Econ Stat, vol. 54, pp. 401-411, 1972. Recent experience in Vermont, California and other states is consistent with the finding two decades ago and confirms that mass-media campaigns can help prevent teens from starting to smoke. Flynn.

RATIONALE FOR A YOUTH-ORIENTED APPROACH

The provisions described above represent a child-centered regulatory approach that, nonetheless, has some effect on the nation's forty million adult smokers.¹⁸ This approach is significantly less restrictive than those advocated by the AMA or IOM. It also stops far short of the action in 27 countries, including France, Canada, and Australia, that have banned tobacco advertising altogether.

Advertising claims will not be affected (e.g. tar and nicotine claims, price claims, taste and flavor claims) and sponsored events can continue in the corporate name. Although adults and children will be unable to purchase or receive promotional items bearing brand identification, in most cases, these items are of more interest to children and not in any respect central to adults' need for continuing access to tobacco products. Finally, the industry-funded educational messages are directed to and designed for young people.

One caveat is appropriate. If we take an approach that is not comprehensive, the tobacco companies can be expected to shift their considerable resources to areas not meaningfully regulated, thereby significantly undermining the initiative. The history of the early 1970's, during the TV ad ban, is instructive. Prior to the ban, the industry spent approximately 80 percent of its advertising dollars in traditional media such as television, newspapers, and billboards. Following the advertising ban, the industry moved the bulk of its money out of traditional

B.S., et al, "Prevention of Cigarette Smoking Through Mass Media Intervention and School Programs," American Journal of Public Health, vol. 82, pp. 827-834, 1992; Flynn, B.S., et al., "Mass Media and School Interventions for Cigarette Smoking Prevention: Effects Two years After Completion," American Journal of Public Health, vol. 84, pp. 1148-1150, 1994. The California media program may have contributed to stopping the rise in teen smoking that had been occurring in California prior to the campaign. Hu, T.W., et al., "The State Antismoking Campaign and the Industry Response: The Effects of Advertising on Cigarette Consumption in California," AEA Papers and Proceedings, vol. 85, no. 2, pp. 88-89, May 1995. The FDA proposal provides that if tobacco use among young people is not cut roughly in half by the year 2000, the agency would require that either the industry expend more money on the educational messages, or alternatively, that products must be sold in plain packaging (white packaging with only black lettering).

¹⁸ The restriction on vending machine sales provides a useful example of that effect. Only 1.2 to 3 percent of all cigarettes are currently purchased from vending machines so while the adults who use those machines now will be inconvenienced, the balance of considerations weighs heavily in favor of protecting children.

advertising and into other types of promotion such as hats, tee-shirts, and sponsorship of sporting events. By 1993, more than 80 percent of advertising dollars went into non-traditional media. At the same time and over the years since the early 1970's, the industry evaded the TV ad ban itself by sponsoring televised events, e.g., sporting events, and then arranging for the cameras to broadcast the images of tobacco billboard ads that were positioned in the stadiums and other venues where those events occurred.

The experience with the ban on TV advertising underscores the importance of a comprehensive approach to reduce youth smoking. The full array of proposals in this initiative should significantly reduce the number of children who become addicted to cigarettes and other tobacco products.

Questions Presented

1. Can FDA publish an NPRM on access and advertising, ultimately adopt an appropriate rule on access and refer all advertising questions to a Federal Advisory Committee for review and advice to the Secretary of HHS?
2. What are the requirements and constraints controlling the creation of such an advisory committee?

Discussion

Issue 1 The President can sign an Executive Order creating an advisory committee to the Secretary of Health and Human Services, assigning to that committee, through its charter, advice and recommendation authority with regard to specified tobacco product advertising issues. The advisory committee could gather facts, hold meetings and hearings, receive information in written form and deliberate, offering advice as and when appropriate to the Secretary for her decision.

This process could be set in motion at the start of, during or at the conclusion of the publication of an FDA NPRM on nicotine containing tobacco products.

Alternatively, the Secretary, rather than the President, could create an advisory committee with the same authority and functions, reporting to her, but without the need for Presidential engagement. In this event, no Executive Order would be required.

Once created, the committee could function into the future, advising on any issues within its charter, including any left open at the conclusion of the rulemaking.

Issue 2 Appointees to a committee must be "balanced" (typically by gender, race, geography - but not on the substantive matters that come before the committee, see, Food Chemical News v. HHS). Conflicts of interest that are disqualifying without a waiver are employment based or financial interest based.

DRAFT RESOLUTION

Whereas more children alive today will die from tobacco use than from any other single cause including AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined.

Whereas child smoking rates are rising, with the number of eighth-graders who smoke increasing 30% between 1991 and 1994.

Whereas every day another 3,000 American children start to smoke, nearly 1,000 of whom will become addicted to nicotine and ultimately die from lung cancer, heart disease, or other tobacco-related causes.

Whereas the tobacco industry spends over \$6 billion a year on advertisements and promotions that, whether intentional or not, have the effect of encouraging children to use tobacco products.

Whereas the three most heavily advertised cigarette brands (Marlboro, Camel, and Newport) are the brands chosen by five out of every six child smokers.

Whereas state and local laws restricting tobacco sales to minors are routinely ignored.

Therefore, this Body resolves to support President Clinton's common-sense goal and corresponding regulatory proposal to decrease tobacco use by children by reducing the access and appeal of tobacco products to children.

CHILDREN AND TOBACCO: THE CLINTON PROPOSAL

The Clinton Administration is proposing a comprehensive and coordinated plan to reduce smoking by children and adolescents by 50 percent. The proposal builds on previous actions taken by Congress, state and local governments such as the ban on television advertising and state and local laws to prohibit the sale or use of tobacco by children. It follows the recommendations of the American Medical Association and the Institute of Medicine. Experts have consistently recommended that the keys to achieving the goal of reducing smoking by children are: reducing access and limiting the appeal for children. This ambitious initiative accomplishes that objective, while preserving the availability of tobacco products for adults.

The Administration's proposals include:

Reducing Easy Access by Children

Require age verification and face-to-face sale and eliminate mail order sales, vending machines, free samples, self service displays, and sale of single cigarettes ("loosies") and packages with fewer than 20 cigarettes ("Kiddie packs").

Reducing Appeal to Children

Ban outdoor advertising within 1,000 feet of schools and playgrounds. Permit black-and-white text only advertising for all other outdoor advertising, including billboards, signs inside and outside of buses, and all point-of-sale advertising.

Permit black-and-white text only advertising in publications with significant youth readership (under 18). (Significant readership means more than 15 percent or more than 2 million. No restrictions on print advertising below these thresholds.)

Prohibit sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos. Prohibit exchange of non-tobacco products for proof of purchase of tobacco products.

Prohibit brand name sponsorship of sporting or entertainment events, but permit it in the corporate name.

Require industry to fund (\$150 million annually) a public education campaign to permit kids from smoking.

The President has recently made a major policy proposal on the issue of smoking by children and adolescents. In states, counties and cities there has been a concerted effort to reduce smoking by children including the passage of laws prohibiting the sale and possession of cigarettes by minors. Despite these efforts, smoking by children continues to increase at an alarming rate. To address this issue, the President has authorized the Food and Drug Administration to develop a plan to reduce smoking by children and adolescents by 50%. The proposal has two central elements: (1) to further reduce minor's easy access to cigarettes and (2) to limit advertising and promotions that have the effect of enhancing the appeal of tobacco products to children. The President's proposals make common sense, and he will need your support if we are truly going to reduce the number of children who use tobacco products.

We are enclosing a copy of the Administration's proposal on Children and Smoking, a draft resolution supporting the proposal, and series of backgrounders on the facts, the problem, and the proposal's economic impact. If there is any further information you need please advise.

Talking points

I. Kids-Oriented Regulation is Necessary

- * Although it is illegal in all 50 states to sell tobacco products to minors, smoking by both children and teenagers continues to rise.
- * On any given day, approximately 3000 young people become regular smokers, with total youth consumption of cigarettes exceeding 500 million packs per year.
- * Over 80% of adult smokers began as minors, beginning, on average, at age 14. If an individual does not become a smoker as a teen, it is unlikely that he or she ever will become one.
- * The consequences of these statistics are tragic. According to the CDC, of the two million Americans who will die in 1995, approximately 420,000 will die of conditions associated with tobacco.
- * This number is almost ten times the annual highway toll and more than the combined deaths last year from accidents, murders, suicides, AIDS, drugs, alcohol-related diseases and fire.

II. Principal Components of the Rule

- * Permits sale of tobacco products only through a face-to-face transaction with an adult. Under this principle, vending machines, self service displays, and mail order purchases would not be permitted.
- * Prohibits all outdoor advertising (e.g., billboards) within 1000 feet of schools and playgrounds.
- * For all other outdoor advertising, permits only black and white, text-only advertising.
- * For magazines with significant youth readership, limits advertising to black and white, text-only format; no restrictions on advertising in other publications.
- * Prohibits sale or giveaways of products (like caps or gymbags) that carry a tobacco brand name.
- * Prohibits brand-name sponsorship of sporting and entertainment events, but permits it in corporate name. (For example, the "Phillip Morris Tennis Tournament" would be permissible, but "The Virginia Slims Tournament" would not be.)

- * Requires the industry to fund (\$150 million per year) a public education campaign designed to prevent kids from smoking.

III. What the Rule Does Not Do

- * The rule does not in any way restrict adults' ability to purchase or consume tobacco products; it does not affect cigars or pipe tobacco at all.
- * The rule does not follow the course -- already adopted in 20 countries -- of simply banning all tobacco advertising. (Countries include France, Canada, and Norway.)

IV. Status of the Rulemaking Proceeding

- * The evidence before the FDA at this time supports the finding that nicotine in cigarettes and smokeless tobacco is a drug, but the agency is accepting further evidence and comment on that issue and will give them careful consideration.
- * Interested parties have 90 days to submit comments on the jurisdictional issue as well as the particulars of the proposed rule. Only after receipt and consideration of these comments will the FDA be in a position to issue its final rule.

TOBACCO QUESTIONS AND ANSWERS

Public Reaction

- Q: Won't Congress stop this? What's your strategy to fight an industry lawsuit?
- A: We hope Congress and the industry will agree with us. The President is firmly committed to the goals and has released his proposed regulation. However, he is open to other avenues to achieve the goal such as a statute which enacts the same measures as in the proposed regulation.

Voluntary Approaches

- Q: Why can't you just use a voluntary approach? Why are regulations needed?
- A: The tobacco industry has had a voluntary advertising code in place since 1964 to keep kids from beginning to smoke. And yet, 3,000 kids a day become smokers, and the numbers are getting worse, not better: smoking among eighth graders has risen 30 percent in the last three years. Either the code is insufficient or the code is not followed.
- Q: Isn't this a "big government" fix to a problem that should be addressed by the private sector?
- A: No. Other countries have taken much more extreme measures, such as banning all advertising. The Administration proposal is narrowly aimed at the real preventable problem: kids smoking. State laws prohibiting sales to or use by minors already exist in all 50 states. But we haven't done a good job -- in either the public or private sector: 3,000 kids become regular smokers each day.
- Q: What is the difference between what you are proposing and what the industry voluntarily has initiated so far?
- A: Tobacco industry programs consist primarily of awareness materials for retailers and educational materials for parents and teachers. The industry implies that these programs are all that is needed to reduce the sale of tobacco to minors. In recent weeks, the industry has suggested that it will take additional actions. (For example, Philip Morris indicated that it would add pack notices about underage sales; discontinue sampling and direct mail marketing; provide support to retailers; revise retailer incentive programs; and restrict use of company logos on children's products.)

Did the Industry Offer You a Deal?

- Q: Did the industry offer you a deal?
- A: No. We let them know what we were thinking about and they came back with a proposal we considered. It was similar in many respects to what the President outlined today. However in the important areas of advertising on billboards and at the point of sale, we didn't believe their proposal would be effective at reducing kids' smoking. And the President wouldn't accept that.

Jurisdiction

- Q: Are you today declaring nicotine a drug or asserting FDA jurisdiction?
- A: The evidence before the FDA supports the finding that nicotine in cigarettes and smokeless tobacco products is a drug, but the agency is accepting further evidence and comment on that issue and will give them careful consideration.

This is a legal issue that is up to the FDA and does not require the President to act.

Enforcement

- Q: How will this be enforced?
- A: The federal government will work with the States to enforce the prohibition on selling tobacco products to children under 18 years old. In addition, the FDA will be responsible for monitoring advertising and promotion to ensure that they comply with any final regulation. Any enforcement action would have to be initiated by the Department of Justice.

Won't FDA Ban Tobacco?

- Q: If nicotine in tobacco is a drug, doesn't FDA have to ban it?
- A: No. FDA is not required to and will not ban cigarettes and smokeless tobacco products.
- Q: Even if FDA doesn't ban tobacco now, isn't that where this is leading?
- A: FDA does not believe that a ban would be an effective means of reducing the toll of death and disease from tobacco, because a ban would not be effective in stopping the 40 million currently addicted tobacco users from gaining access to tobacco.

Advertising

Q: What is the evidence that tobacco advertising actually influences teen smoking?

A: The proposed rule reviews in detail the evidence of how cigarette marketing practices affect teen smoking. Some of the most compelling data include:

- Teens (86%) are more than twice as likely as adults (35%) to smoke the three most advertised brands of cigarettes (Marlboro, Camel, and Newport).
- Teen preference for Camel cigarettes, approximately 3% before the Joe Camel campaign was launched in 1988, increased to 13% by 1993. During this same time period, the percentage of adult sales was unchanged.
- From 1985-1989, adult smoking prevalence rates dropped and the affordability of cigarettes for teens also decreased. During this same period, teen smoking initiation rates increased and cigarette promotional expenditures quadrupled.

Educational Program

Q: Isn't the educational program really a tax on the tobacco industry?

A: No. The money does not go to the federal government. It goes to the combat the past tobacco industry advertising that has hooked kids. When misleading or new safety information is discovered about a drug product, FDA routinely uses its authority to require drug companies to inform, at their own expense, the health care community and consumers of the new and correct information.

Adults

Q: Are the advertising restrictions in the proposed rules really geared to children? They look as though they will affect adults also.

A: During its investigation, the agency was struck by the evidence of the chilling effectiveness of tobacco advertising on young people's decision to use tobacco products. Also, we know that advertising is very successful with kids. 86% of kids smoke one of the three most heavily advertised brands.

Safety and Effectiveness

Q: How can FDA say these products are "safe and effective"?

A: FDA is saying these are dangerous products and people become addicted as kids. We are proposing a strategy to prevent this from happening.

Economic Impact

Growers

Q: What is the economic impact on growers?

A: The overall impact is both slight and gradual. The regulatory scheme is projected to reduce revenues from cigarette sales by 0.5 percent in the first year, 2.1 percent in the 5th year and 4.0 percent in the 10th year. Over this 10 year period, this would result in the loss of about 1,000 jobs annually among warehouses, manufacturers, tobacco growers and wholesalers.

Retail Stores

Q: How will this proposal affect store owners?

A: The major cost will be additional labor costs associated with verifying age, but those will be minimal. For instance, a typical small store will have a cost of \$320 in the first year, \$285 being the labor cost. If the store already verifies ages, the cost will be only \$35.

Vending Machines

Q: What impact will FDA's proposal have on the vending machine industry?

A: The impact on the vending machine industry will be minimal. The number of vending machines selling cigarettes has declined dramatically from 785,000 in 1983 to 480,000 in 1993. Cigarette vending machine yields about \$10 per day on average in sales, or less than 5 packs per day. In 1993, cigarette sales constituted only 3.4% of all vending machine sales. No new cigarette vending machines have been shipped in the United States since 1990.

Public Reaction

Q: What are the political implications of this action?

A: Health should not be a partisan political issue, and our children's health should come before all other considerations. In taking this action, the President has allied himself with every recognized major health and medical authority in this country including the American Medical Association, the American Academy of Pediatrics, the American Academy of Family Physicians, the American Heart Association, the American Cancer Society, the American Lung Association, as well as President Jimmy Carter, former Senator Barry Goldwater, Secretaries of Health and Human Services Otis Bowen and Louis Sullivan, Surgeons General Jesse Steinfeld, Paul Ehrlich, C. Everett Koop, and Antonia Novello, and many religious organizations of all faiths. The support for protecting the health of our children is found among those with a broad spectrum of political beliefs.

Q: Is there public support for these proposals, especially in tobacco-producing states?

A: The public overwhelmingly supports efforts to keep children from smoking and to impose reasonable restrictions on tobacco advertising. Almost 75 percent favored a ban of vending machine sales of cigarettes in a poll done for the Robert Wood Johnson Foundation, and 73 percent said text only advertising will make these products less appealing to children. This support cuts across party lines, this support is in every city and state. This is not a proposal aimed against any group or region. This proposal is for our children and our families. This is about helping kids grow up healthy.

Effectiveness of these proposed restrictions

Q: Do we have any evidence that restrictions on advertising will help keep kids from smoking?

A: Yes. A recent report looked at data from countries with laws on youth smoking and concluded that the most substantial and meaningful reductions in youth smoking occurred in countries with bans on advertising.

CHILDREN AND TOBACCO: THE FACTS

The Clinton Administration is proposing a comprehensive and coordinated set of measures to significantly reduce the number of children and adolescents who become addicted to nicotine in cigarettes and smokeless tobacco (snuff and chewing tobacco). Children are becoming addicted to these products, with more than 80 percent of smokers beginning to smoke by age 18. Smoking is the leading preventable cause of death in the United States, and health care costs associated with smoking soared to more than \$50 billion in 1993, according to the Centers for Disease Control. While the proposed measures will continue to maintain the legal status of cigarettes and smokeless tobacco products for adults, they will reduce the easy access and strong appeal for children. Preventing children from smoking is key to reducing the deadly toll of smoking. The Clinton Administration's plan will help parents provide their children with an environment in which to grow up healthy.

A Pediatric Disease

Children are becoming addicted to nicotine. The average teenage smoker starts at 14 1/2 years old and becomes a daily smoker before age 18. More than 80 percent of all adult smokers had tried smoking by their 18th birthday and more than half of them had already become regular smokers by that age. Studies show that if people do not begin to smoke as teenagers or children, it is unlikely they will ever do so.

Each and every day, another 3,000 young people become regular smokers, and nearly 1,000 of them will eventually die as a result of their smoking. Currently, more than 3 million children and adolescents smoke cigarettes, and 1 million adolescent boys-- currently use smokeless tobacco. Smoking by young people is rising sharply. Between 1991 and 1994, the percentage of eighth graders who smoke increased 30 percent, and the percentage of tenth graders who smoke increased 22 percent.

Children tend to vastly underestimate the likelihood that they will become addicted to these products. Although only 5 percent of daily smokers surveyed in high school said they would definitely be smoking five years later, close to 75 percent were smoking 7 to 9 years later. A survey conducted in 1992 found that approximately two-thirds of adolescents who smoked said they wanted to quit and 70 percent said they would not start smoking if they could make that choice again.

Smoking: Leading Cause of Avoidable, Premature Death

Tobacco use takes enormous, deadly toll each year. Tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illness, heart disease, and other health problems. Cigarettes kill more Americans each year than AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined. Smokers who die as a result of smoking would have lived on average 12 to 15 years longer if they had not smoked.

The health care costs associated with tobacco use are rising. The Centers for Disease Control estimated that in 1993 the health care costs associated with smoking totalled \$50 billion: \$26.9 billion for hospital costs; \$15.5 billion for doctors; \$4.9 billion in nursing home costs; \$1.8 billion for prescription drugs and \$900 million for home-health care expenditures. The Office of Technology Assessment calculated the social costs attributable to smoking in 1990 at \$68 billion. That calculation was based on \$20.8 billion in direct health care costs and \$6.9 billion in lost productivity from disabilities and \$40.3 billion in lost productivity from premature deaths.

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CHILDREN AND TOBACCO: THE PROBLEM

Easy Access

Despite state laws prohibiting the sale of tobacco to minors, children can easily buy these products. One study estimated that teenagers annually consume 516 million packs of cigarettes and 26 million containers of chewing tobacco. A review of 13 studies of over-the-counter sales found that on average, children and adolescents were able to successfully buy tobacco products 67 percent of the time.

- o Vending machines are a primary source of tobacco products for young smokers. A study by the vending machine industry found that 22 percent of 13-year-old smokers use vending machines compared with 2 percent of 17-year-old smokers. The 1994 Surgeon General's Report found that young people were able to buy cigarettes in vending machines an average of 88 percent of the time.
- o Mail-order sales provide no sure way of verifying age. Current industry practice only asks the consumer to provide a birth date or check box to verify age.
- o Self-service displays allow children to easily obtain tobacco products. The Institute of Medicine, in its landmark 1994 report, "Growing Up Tobacco Free," concluded that placing tobacco products "out of reach reinforces the message that tobacco products are not in the same class as candy or potato chips."
- o Free samples are obtained by children, including those in elementary school, despite industry code prohibiting distribution to anyone under 21. Free samples occur on street corners, at shopping malls and sporting events. A New Jersey survey found that one-third of high school students who were smokers ~~or ex-~~ smokers reported receiving free samples before age 16.

Appealing to Children

Advertising and promotional activities can greatly influence a young person's decision to smoke or use smokeless tobacco products. Awareness of tobacco products and messages is very high among even the youngest children. Studies show that 30 percent of 3-year-olds and 91 percent of 6-year-olds could identify "Joe Camel" as a symbol for smoking. The Centers for Disease Control recently reported that 86 percent of underage smokers who purchase their own cigarettes purchase one of the three most heavily advertised brands: Marlboro, Camel and Newport.

- o Tobacco products are among the most heavily advertised products in the United States. In 1993, the tobacco industry spent \$6.2 billion on advertising and promoting cigarettes and smokeless tobacco. Tobacco advertising expenditures have increased more than 1,500 percent between 1970 (the year before television and radio advertising was banned) and 1992.
- o Promotion of tobacco products through non-tobacco items such as t-shirts, hats and gym bags and through sponsorship of events is reaching children. A 1992 Gallup Survey found that half of adolescent smokers and one quarter of adolescents who do not smoke owned at least one tobacco promotional item such as a tee-shirt, cap, sporting good, or lighter. Another report found that one out of four 12- and 13-year-olds own one of these items. Used or worn by young people, these become "walking billboards," promoting these products in schools and other locations where tobacco advertising is usually prohibited. Sponsorship of events such as tennis tournaments, car races, and rodeos associate tobacco products with excitement and glamour, and provide a way for tobacco brands to be advertised on television despite the broadcast advertising ban.

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CHILDREN AND TOBACCO: WHAT OTHERS SAY

"I figure if it's really so bad for you, they wouldn't be selling them everywhere. I mean, you walk into the Stop 'N' Go, and there's a whole wall of them right up front at the cash register. If they were really that bad for you, they'd make them less accessible."

- Brian Grindele, 18

The New York Times, July 30, 1995

"Given all that we know, the scientific case for protecting children from tobacco is indisputable. The moral imperative to act is imperative.... This is not a Democratic or a Republican issue. It is a bipartisan, pro-child, pro-family, pro-health issue."

- President Jimmy Carter

USA Today, August 3, 1995

"The tobacco industry continues to insist that smoking is a simple matter of individual rights and adult choice. If that were true, I would be on their side. But we're not talking about adults. We're talking about keeping an addictive and lethal substance out of the hands of children. Neither the FDA nor anyone else is talking about prohibiting adults from smoking."

- Former U.S. Sen. Barry Goldwater

Wall Street Journal, August 8, 1995

"The American Medical Association reminds physicians, the public, and politicians that the damning evidence against tobacco makes opposition to its use a pressing, nonpartisan public health issue."

- Editorial

Journal of the American Medical Association, July 19, 1995

"We believe that current tobacco regulations, limited primarily to a ban on television advertising and the promotion of warning labels on packages, are insufficient in protecting America's children. The FDA should have authority to control tobacco by placing new limits on tobacco advertising, creating stricter licensing regulations for vendors, and banning cigarette vending machines."

- American Public Health Association

Letter to President Clinton from APHA, July 13, 1995

"What is most significant about teens and smoking, however, is that, from all indications, smoking is an addiction that is typically initiated during the teenage years or not at all. For the great majority of smokers, this addiction begins before they are old enough to purchase tobacco lawfully. In fact, 75 percent of all adult smokers report that they became addicted to tobacco before they were 18 years old. Very few

int use only

CHILDREN AND TOBACCO: THE PROPOSAL'S ECONOMIC IMPACT

Each year, an estimated 1 million children and adolescents begin to smoke. The goal of this ambitious proposal to prevent children from becoming addicted to cigarettes and smokeless tobacco products (snuff and chewing tobacco) is to reduce that number by 500,000.

- o Meeting this goal will prevent well over 60,000 premature deaths.
- o The benefits to the U.S. economy from meeting this goal would be a savings of more than \$2.6 billion in reduced medical costs. In total, there are potential savings ranging from \$28 billion to \$43 billion in avoiding disabilities or premature deaths from tobacco use.
- o These benefits are repeated each year for each group of children not beginning to smoke or use smokeless tobacco products.

The economic costs associated with this proposal are gradual and slight. It is projected that it will reduce revenues from cigarettes sales by 0.5 percent in the first year, 2.1 percent in the fifth year, and 4 percent in the 10th year. Over this 10-year period, this would result in the loss of about 1,000 jobs annually among warehouses, manufacturers, tobacco growers and wholesalers.

- o Tobacco manufacturers will have costs of about \$177 million annually (about one-half of 1 percent of current sales), and this will mainly be the result of the educational campaign they fund.
- o Retailers will have an annual estimated cost of \$53 million, mainly for activities related to verifying age. The impact on a typical small retail store is estimated -- to be \$320 in the first year, with the largest single cost, \$285, being the labor cost for checking identification. Small stores already verifying ages of young customers would have an additional cost of only \$35.
- o Vending machine sales of cigarettes are already falling, down 25 percent from 1992 to 1993. Currently, cigarettes only account for 3.4 percent of total vending machine sales. No new cigarette vending machine has been shipped in the United States since 1990.
- o Of the \$6.2 billion spent by the tobacco industry on advertising and promotion, the proposal affects \$1.9 billion (less than 1.5 percent of total U.S. media advertising).

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TALKING POINTS ON TOBACCO

- o Smoking among young people is a crucial public health issue. Every single day, 3000 young people become regular smokers and nearly 1,000 of them will die prematurely as a result.
- o For more than a decade, even as adult smoking was dropping, the smoking rate among high school seniors did not go down. That was bad enough, but since 1991, the percentage of teenage smokers has risen steadily and rapidly.
- o There's been a 30 percent increase in the number 8th graders who smoke, a 22 percent increase in the number of 10th graders who smoke, and by the age of 16 the average teenage smoker is smoking every day -- and will not stop.
- o The number of teenagers who believe smoking is dangerous is dropping dramatically. As the President has said, peer approval of smoking is a "recipe for disaster."
- o We have a responsibility to help parents keep cigarettes and chewing tobacco away from their kids. It's far too easy for children to buy and use tobacco products. There are things that can be done at the federal level to help in this area, and President Clinton is taking strong action today to address the problem of smoking among children.
- o The actions the President will unveil today will be, as he has said, tough and mandatory. They will focus on how to stop children from smoking, and how to stop them from starting.
- o We could change the dynamic of health care in America by saving these kids, -- because we will be paying years down the road for the health damage caused by smoking among today's children. Reducing teen smoking would be the cheapest, easiest, quickest thing we could do to reduce the cost of health care, help balance the budget over the long run, and improve the health of America.

**STATEMENT OF ATTORNEYS GENERAL
IN SUPPORT OF THE PRESIDENT'S ANNOUNCEMENT
ON RESTRICTING TOBACCO SALES TO YOUTH**

"As the chief law enforcement officers of our respective states, we applaud President Clinton's proposals to help prevent another generation of American kids from dying of tobacco-related diseases. Since about 90 percent of smokers begin smoking illegally as teenagers, the President's focus on kids is right on target. Cracking down on illegal sales to kids, controlling marketing aimed at youngsters and improving public education are all key to helping break the cycle of tobacco addiction. It's a problem that kills more Americans than homicides, illegal drugs, car accidents, suicides and AIDS, combined."

HUBERT H. HUMPHREY III
Attorney General
State of Minnesota

JEFFREY B. PINE
Attorney General
State of Rhode Island

RICHARD BLUMENTHAL
Attorney General
State of Connecticut

ROBERT A. BUTTERWORTH
Attorney General
State of Florida

TOM MILLER
Attorney General
State of Iowa

J. JOSEPH CURRAN, JR.
Attorney General
State of Maryland

SCOTT HARSHBARGER
Attorney General
State of Massachusetts

MIKE MOORE
Attorney General
State of Mississippi

DREW EDMONDSON
Attorney General
State of Oklahoma

JAN GRAHAM
Attorney General
State of Utah

JAMES DOYLE
Attorney General
State of Wisconsin

WINSTON BRYANT
Attorney General
State of Arkansas

GRANT WOODS
Attorney General
State of Arizona

House of Representatives

Washington, DC 20515

September 28, 1995

The Honorable William J. Clinton
President of the United States
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mr. President:

As Republican Members of Congress, we are writing to inform you of our support for common-sense tobacco regulations aimed at curbing youth access. Some have tried to paint this as a partisan issue, which is clearly not true. We are cautious in our support of government regulations. However, reasonable regulations aimed at preventing our youth from smoking or using other tobacco products are a matter of national health.

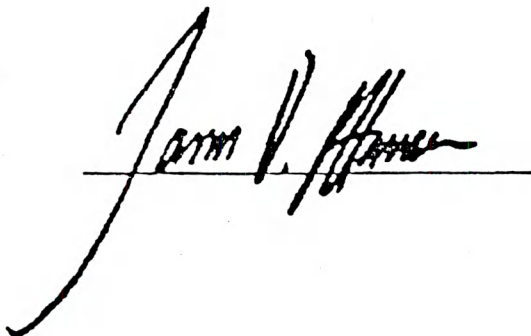
This nation can no longer close its eyes to a product that kills 400,000 Americans each year and brings into its deathly fold 3,000 children every day. Given the increase in smoking among youth and the fact that 90 percent of adult smokers started before 19, it is time to take the necessary steps to prevent another generation from becoming addicted to this deadly product.

Furthermore, we know that young people overwhelmingly smoke the three most-advertised brands. We are also aware of attempts by the tobacco industry to replenish their fold of smokers by spending billions of dollars in advertising targeting children.

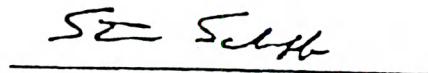
Every independent scientific body that has reviewed the evidence now holds that tobacco products are addictive. These include the Institute of Medicine, U.S. Department of Health and Human Services, the World Health Organization, the American Psychiatric Association, and the American Medical Association. It is time for the nicotine in tobacco products to be treated like the highly addictive substance it is.

Teenage smoking is a national health issue and we support your worthwhile efforts to improve the health of future generations through reasonable regulations.

Sincerely,



Jim V. Hansen



SE Sch

Louise Murrell

Frank Rys

Miss Cottle

Linda A Smith

JDox

Erin G. Walldorf

Hans W. Javel

Mary Rouhana

A COMMITMENT TO OUR CHILDREN

Whereas more children alive today will die from tobacco use than from any other single cause -- including AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.

Whereas child smoking rates are rising, with the number of eighth-graders who smoke increasing 30% between 1991 and 1994.

Whereas every day, another 3,000 American children start to smoke, nearly 1,000 of whom will die from lung cancer and other diseases caused by smoking.

Whereas the tobacco industry spends over \$6 billion a year on advertisements and promotions that, whether intentional or not, have the effect of encouraging children to use tobacco products.

Whereas over 85% of the children who smoke use one of the three most heavily advertised cigarette brands (Marlboro, Camel, or Newport).

Whereas state and local laws restricting tobacco sales to minors have been largely ineffective.

Therefore, I commit:

1. To support the common-sense goal of decreasing tobacco use by children by reducing the access and appeal of tobacco products to children; and
2. To oppose efforts to enact legislation that would weaken or delay the President's proposal to decrease tobacco use by children.

Signed:

James V. Hansen (R. Utah)
Michael N. Castle (R. Del.)
Robert K. Dornan (R. Cal.)
Jon D. Fox (R. Penn.)
Constance A. Morella (R. Md.)
Ron Packard (R. Cal.)
Frank Riggs (R. Cal.)
Marge Roukema (R. N.J.)
Linda Smith (R. Wash.)
Enid G. Waldholtz (R. Utah)

Henry A. Waxman (D. Cal.)
John Bryant (D. Tex.)
Richard J. Durbin (D. Ill.)
Anna G. Eshou (D. Cal.)
Elizabeth Furse (D. Or.)
John Lewis (D. Ga.)
Martin T. Meehan (D. Mass.)
George Miller (D. Cal.)
Peter J. Visclosky (D. Ind.)
Ron Wyden (D. Or.)

Date: September 29, 1995

THE WHITE HOUSE
WASHINGTON

26 September 1995

MEMORANDUM FOR CHRIS CERF

FROM: JENNIFER O'CONNOR

SUBJECT: TOBACCO

This is what Kevin O'Keefe is planning to fax out to state and local officials. What do you think?

Ab,

Based on ~~my~~ OUR DISCUSSION
yesterday, I ASSUME it's OK to
go forward with this

Please let me know

Chris

yes

to limit advertising and
promotions that have the
effect of enhancing the
appeal of tobacco products to children

authorized the Food and Drug Administration
to ~~prop~~ develop

The President has recently made a major policy proposal on the issue of smoking by children and adolescents. In states, counties and cities there has been a concerted effort to reduce smoking by children including the passage of laws prohibiting the sale and possession of cigarettes by minors. Despite these efforts, smoking by children continues to increase at an alarming rate. To address this issue, the President has undertaken a plan to reduce smoking by children and adolescents by 50% by further reducing the ^{easy} access to cigarettes and ^{by} reducing the appeal to children. The President's proposals make common sense, and he will need your support if we are truly going to attempt to reduce the number of children who use tobacco products. (2)

ADMINISTRATION'S

We are enclosing a copy of the President's proposal on Children and Smoking, a draft resolution supporting the proposal, and series of backgrounders on the facts, the problem, and the proposal's economic impact. If there is any further information you need please advise.

The proposal has two central elements: (1) to

DRAFT RESOLUTION

Whereas more children alive today will die from tobacco use than from any other single cause-including AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined.

Whereas child smoking rates are rising, with the number of eighth-graders who smoke increasing 30% between 1991 and 1994.

Whereas ⁴everyday another 3,000 American children start to smoke, nearly 1,000 of whom will become addicted to nicotine and ultimately die from lung cancer, heart disease, or other tobacco-related causes.

Whereas the tobacco industry spends over \$6 billion a year on advertisements and promotions that, whether intentional or not, have the effect of encouraging children to use tobacco products.

Whereas the three most heavily advertised cigarette brands (Marlboro, Camel, and Newport) are the brands chosen by five out of every six child smokers.

Whereas state and local laws restricting tobacco sales to minors are routinely ignored.

Therefore, this Body resolves to support President Clinton's common-sense goal and corresponding regulatory proposal to decrease tobacco use by children by reducing the access and appeal of tobacco products to children.

Clinton

CHILDREN AND TOBACCO: THE CLINTON PROPOSAL

~~The Forward Drug Administration~~ +0
President Clinton is proposing a comprehensive and coordinated plan to reduce smoking by children and adolescents by 50 percent. The President's proposal builds on previous actions taken by Congress, state and local governments such as the ban on television advertising and state and local laws to prohibit the sale or use of tobacco by children. It follows the recommendations of the American Medical Association and the Institute of Medicine. Experts have consistently recommended that the keys to achieving the goal of reducing smoking by children are: reducing access and limiting the appeal for children. This ambitious initiative accomplishes that objective, while preserving the availability of tobacco products for adults.

~~ADMINISTRATIONS~~
The President's proposals include:

Reducing Easy Access by Children

Require age verification and face-to-face sale and eliminate mail order sales, vending machines, free samples, self service displays, and sale of single cigarettes ("loosies") and packages with fewer than 20 cigarettes ("Kiddie packs").

Reducing Appeal to Children

Ban outdoor advertising within 1,000 feet of schools and playgrounds. Permit black-and-white text only advertising for all other outdoor advertising, including billboards, signs inside and outside of buses, and all point-of-sale advertising.

Permit black-and-white text only advertising in publications with significant youth readership (under 18). (Significant readership means more than 15 percent or more than 2 million. No restrictions on print advertising below these thresholds.)

Prohibit sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos. Prohibit exchange of non-tobacco products for proof of purchase of tobacco products.

Prohibit brand name sponsorship of sporting or entertainment events, but permit it in the corporate name.

Require industry to fund (\$150 million annually) a public education campaign to permit kids from smoking.