Please deliver to
Elizabeth Bryce
Rm. 222.
Tdy

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 23, 1996

CHILDREN'S FUTURE AT RISK
FROM EPIDEMIC OF TOBACCO USE

President Clinton's initiative to reduce tobacco use by children is the result of an investigation by the Food and Drug Administration into industry practices and an extensive review of successful measures in preventing children from using tobacco products. After the proposed rule was published on August 11, 1995, the public was invited to comment until January 2, 1996. The Agency received more than 95,000 different comments, totaling more than 700,000 pieces of mail. The subsequent review and analysis of those comments, as well as the Agency's initial work, provide a solid base for the FDA's measures to reduce access and limit appeal of tobacco products for children.

Today, an estimated 4.5 million children and adolescents smoke in the United States, and another 1 million use smokeless tobacco. Each year, another 1 million young people join the ranks of regular smokers, and nearly one out of every three young people who smoke will have their lives shortened from the terrible diseases caused by smoking.

This public health crisis is worsening. Children are starting to smoke at younger and younger ages: Today, the average teenage smoker begins to smoke at 14 1/2 years old and becomes a daily smoker before age 18. And those children soon regret this loss of

freedom. The Gallup Poll in 1992 found that 70 percent of smokers between the ages of 12 and 17 regret beginning to smoke and 66 percent want to quit.

Children at Risk

Children are becoming addicted to nicotine. 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. 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. Of the almost 3,000 young people who become regular smokers each day, nearly 1,000 of them will have their lives shortened from tobacco-related diseases.

Costs of Smoking Staggering

Health care costs associated with tobacco use are rising. The Centers for Disease Control and Prevention estimated that in 1993 the health care costs associated with smoking totaled $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 lexpenditures. The Office of Technology Assessment calculated the social costs attributable to smoking in 1990 at $68 billion. The calculation was based on $20.8 billion in direct health care costs and $6.9 billion in lost productivity from

sickness and disabilities and $40.3 billion in lost productivity from premature deaths.

Benefits Outweigh Costs

Protecting the future health of our children provides a benefit that will continue to pay dividends for our society. The annual benefits from reduced disease caused by smoking are projected to be $28 to $43 billion. These benefits are achieved through annual net medical cost savings of $2.6 billion, annual morbidity-related productivity savings of $900 million, and annual benefits of reduced mortality of $24.6 to $39.7 billion. Under the final rule, manufacturers of tobacco products are projected to have one-time costs of $78 to $91 million and annual operating costs of $2 million. Retailers are projected to have one-time costs of $96 million and annual costs of $78 million, compared to the $45 billion to $50 billion spent annually on tobacco products at the retail level.

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Contact: Jim O'Hara
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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 23, 1996

LEGAL ISSUES RELATING TO FDA RULE ON CHILDREN AND TOBACCO

FDA Jurisdiction

FDA has concluded that cigarettes and smokeless tobacco are delivery devices for nicotine, a drug that causes addiction and other significant pharmacological effects. The Federal Food, Drug, and Cosmetic Act provides that a product is a drug or device if it is an article (other than food) "intended to affect the structure or any function of the body."

Nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body" because:

- nicotine in these products causes and sustains addiction;
- nicotine in these products causes other mood-altering effects, including tranquilization and stimulation;
- nicotine in these products controls body weight.

Manufacturers of cigarettes and smokeless tobacco "intend" these effects because:

- the addictive and pharmacological effects are so widely known and accepted, a reasonable manufacturer can foresee the products will be used by consumers for these effects;

- consumers use these products predominantly for pharmacological purposes;
- manufacturers know that nicotine in their products causes pharmacological effects and that consumers use their products primarily to obtain these effects;
- manufacturers of these products design the products to provide consumers with a pharmacologically active dose of nicotine; and
- an inevitable consequence of the design of these products to provide consumers with a pharmacologically active dose of nicotine is to sustain consumers' addiction to nicotine.

Rule Protects Appropriate Commercial Speech

The U.S. Supreme Court has upheld restrictions on commercial speech if certain standards are met. Given that selling cigarettes and smokeless tobacco to children under 18 is already illegal in every state, the rule is aimed at regulating commercial speech to ensure that an illegal activity is not promoted. Furthermore, the rule is narrowly tailored to meet the tests established by the U.S. Supreme Court in its opinions on commercial speech, including 44 Liquormart, Inc. v. Rhode Island.

- Protecting the health of children under 18 is a substantial government interest justifying restrictions on tobacco advertising that appeals to children;
- Advertising and promotion have been shown to play a

material role in children beginning and continuing to use tobacco products, and therefore the regulations directly advance the government's interest; and

- Permitting unrestricted advertising in publications primarily read by adults and permitting companies to sponsor events in the corporate name -- instead of the brand identifications so appealing to young people -- are examples of how the rule is narrowly tailored to advance the government's interest.

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Contact: Jim O'Hara
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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 23, 1996

REDUCING CHILDREN'S USE OF TOBACCO: A CHRONOLOGY

February 25, 1994: The Food and Drug Administration (FDA), responding to a petition asking FDA to regulate low-tar and low-nicotine cigarettes, writes a letter to the Coalition on Smoking or Health stating that the Agency will consider the question of whether it has jurisdiction over nicotine-containing tobacco products.

March 25, 1994: Food and Drug Commissioner David A. Kessler, M.D., testifies before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce on FDA's preliminary evidence -- including industry patents and analyses of nicotine-to-tar ratios -- that cigarette companies control the levels of nicotine in a manner that creates and sustains addiction in the vast majority of smokers.

April 14, 1994: The Subcommittee on Health and the Environment of the House Committee on Energy and Commerce hears testimony from the chief executives of seven tobacco companies on the industry's views on nicotine addiction and on industry practices with regard to nicotine, and each executive denies that nicotine in tobacco products is addictive.

April 28, 1994: The Subcommittee on Health and the Environment of the House Committee on Energy and Commerce hears testimony from two former Philip Morris scientists, Victor DeNoble and Paul Mele, on their company-sponsored research establishing the addictive properties of nicotine.

June 21, 1994: Food and Drug Commissioner David A. Kessler, M.D., testifies before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce on evidence developed by the FDA of the cigarette industry's manipulation of nicotine, specifically one company's breeding of high nicotine levels in one strain of tobacco and the use of chemical compounds in cigarettes to enhance nicotine delivery to smokers.

August 2, 1994: FDA's Drug Abuse Advisory Committee holds a public hearing on the addictiveness of nicotine-containing tobacco products and concludes that products currently marketed contain nicotine at levels sufficient to create and sustain addiction in consumers.

August 10, 1995: President Clinton announces the proposed FDA rule to reduce the access and appeal of tobacco products to children and adolescents and his goal of reducing children's use of tobacco products by 50 percent within seven years of final Agency action. The rule is published the next day in the Federal Register and a public comment period begins.

January 2, 1996: The public comment period for the proposed FDA rule closes, with a total of more than 95,000 different comments -- more than 700,000 pieces of mail -- received.

January 18, 1996: The Department of Health and Human Services and the Substance Abuse and Mental Health Services Administration issue the final Synar Rule designed to ensure that states and territories adopt and enforce laws prohibiting the sale or distribution of tobacco products to children.

March 18, 1996: FDA re-opens the public comment period for the limited purpose of seeking comments on the statements of three former Philip Morris employees about that company's manipulation of nicotine in the design and production of cigarettes and to seek comments on further explanations of certain provisions in the proposed rule.

April 19, 1996: The limited comment period closes.

August 23, 1996: President Clinton announces the publication of the final FDA rule to restrict access and reduce appeal of tobacco products for children and adolescents and FDA's proposal to mount a national mass-media campaign for young people on the dangers of tobacco use.

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Contact: Jim O'Hara
(301) 443-1130

PRESIDENT CLINTON ANNOUNCES NEW RULE ON RESTRICTING YOUTH ACCESS TO TOBACCO AND APPEAL OF TOBACCO TO CHILDREN

August 23, 1996

President Clinton today will announce that he has reviewed the final rule submitted to OMB by the Food and Drug Administration regarding measures to protect children from tobacco and has approved it as consistent with the goals he set out a little over a year ago -- to reduce the access and appeal of tobacco products to children and adolescents and to cut in half children's use of tobacco products within seven years.

In doing so, the President today will authorize the nation's first comprehensive program to prevent children and adolescents from smoking cigarettes or using smokeless tobacco and beginning a lifetime of nicotine addiction.

Every day, almost 3,000 young people become regular smokers and nearly 1,000 of them will ultimately die younger due to cancer, emphysema, heart disease and other diseases caused by smoking.

Extensive fact sheets on the final rule and on the Clinton Administration's efforts to find ways to protect children from the health consequences of tobacco use are attached.

History of the FDA Rule

On August 10, 1995, President Clinton announced the proposed FDA rule to reduce access and appeal of tobacco to children and adolescents and his goal of reducing children's use of tobacco products by 50 percent within seven years. After more than a year of reviewing and responding to more than 95,000 individual comments, the FDA transmitted its draft final regulation on children and tobacco to OMB on August 8, 1996. OMB had up to 90 days to review the draft rule and raise any questions to the Agency and on Thursday, August 22, OMB finished its review. Today, President Clinton will announce the completion of the FDA's process and unveil the final regulation.

Program for the President's Announcement

The speaking program will begin with remarks by the Vice President, who will introduce Mrs. Linda Crawford. Mrs. Crawford is the wife of the late Victor Crawford, a former tobacco lobbyist turned anti-smoking advocate, who died March 2 of lung cancer. Much of Mr. Crawford's estate helped to create the National Center for Tobacco Free Kids -- a D.C. based non-profit organization dedicated to reducing tobacco use by children.

Mrs. Crawford will speak and introduce the President for his remarks. Also

attending today's announcement will be Health and Human Services Secretary Donna Shalala, FDA Director David Kessler, HHS Assistant Secretary Phil Lee, USDA Undersecretary Mike Taylor, Rep. Meehan (D-MA), Rep. Durbin (D-IL) and the following state officials: Florida AG, Robert Butterworth, Mississippi AG, Michael Moore, Maryland AG, J. Joseph Curran, Jr. and New York City Public Advocate, Mark Green.

Also in the audience will be health advocates, members of the Campaign for Tobacco Free Kids and other activists working to protect children from tobacco, including former Surgeon General Dr. C. Everett Koop, and more than a dozen young people from Maryland and Virginia. The teens from Virginia are members of the Alliance on Smoking and Health, who participated in a youth tobacco purchase survey; the teens from Montgomery County, Maryland are participants in a project called Students Oppose Smoking.

Two young people will join the President on stage for the announcement: Neal Stewart McSpadden, 16, from Montgomery County, and Anna Santiago, 14, from Chicago. Anna is the recipient of the Campaign for Tobacco Free Kids Advocate of the Year award.

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
August 23, 1996

Contact: Jim O'Hara
(301) 443-1130

PRESIDENT CLINTON ANNOUNCES HISTORIC STEPS TO REDUCE CHILDREN'S USE OF TOBACCO

President Clinton today announced the nation's first comprehensive program to prevent children and adolescents from smoking cigarettes or using smokeless tobacco and beginning a lifetime of nicotine addiction. The President's announcement comes a little more than a year after the Food and Drug Administration (FDA) issued its proposed rule to reduce the access and appeal of tobacco products for children and adolescents.

The FDA rule-making on children and tobacco prompted the largest outpouring of public response in the Agency's history with more than 95,000 individual comments received, totaling more than 700,000 pieces of mail when form letters are counted. The final rule was put on display today at the Federal Register and will be published in the Federal Register next week.

Each day, almost 3,000 young people in the United States become regular smokers, and nearly 1,000 of them will die prematurely from diseases related to tobacco use. Each year, more than 400,000 Americans die from smoking-related diseases, more Americans than are killed each year by AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.

-More-

In the past four years, the United States has experienced dramatic increases in tobacco use by youngsters. Between 1991 and 1995, the percentage of eighth- and tenth-graders who smoke increased 34 percent. In 1995, more than a third of 12th-graders reported smoking in the past month, and daily smoking in that group was up to 21.6 percent. Among 10th-graders, current use was up to 27.9 percent, and daily use was up to 16.3 percent.

The President's goal is to cut in half tobacco use by children and adolescents over the next seven years.

"This is the most important public health initiative of our generation," said Health and Human Services Secretary Donna E. Shalala. "Our children's futures are at stake. President Clinton's action will ensure that children get their information about tobacco from their parents -- and not from Joe Camel."

The President's initiative to protect children is based on the final FDA rule that will make it harder for young people to buy cigarettes and smokeless tobacco and will reduce the appeal of tobacco products to children under 18. The rule is based on the Agency's finding that cigarettes and smokeless tobacco products are delivery devices for nicotine, an addictive drug. In addition to the rule, the FDA will propose to require tobacco companies to educate children and adolescents about the health risks of tobacco use as part of the President's initiative. This national mass media campaign would be monitored for its effectiveness.

Cigarettes and smokeless tobacco products remain legal products that can be marketed and sold to adults, 18 years and older.

"Nicotine addiction is a pediatric disease that often begins at 12, 13, and 14 only to manifest itself at 16 and 17 when these children find they cannot quit," said Commissioner of Food and Drugs David A. Kessler, M.D. "By then our children have lost their freedom and face the prospect of lives shortened by terrible diseases."

The President's initiative follows the recommendations of major medical and scientific organizations such as the American Medical Association and National Academy of Science's Institute of Medicine. It is a prevention strategy based on reducing children's access to tobacco products and limiting the appeal of these products to children. The tobacco industry spends more than $6 billion annually on advertising and promotion.

Besides the final rule, the FDA will propose to require tobacco companies to provide strong educational messages for children on the real dangers of smoking and using smokeless tobacco. This national multi-media campaign would include television spots, and it would be monitored for its effectiveness. FDA intends to begin consultations about this campaign with the nation's six tobacco companies with a significant share of sales to children. Under Section 518 of the Federal Food, Drug, and

Cosmetic Act, the FDA may require companies to inform consumers about the unreasonable health risks of their products.

"We have to tell our children the truth about the diseases caused by smoking," Kessler said. "For too long we have sent conflicting messages to our children and then have acted surprised when they begin to smoke."

In reviewing the public comments and developing a final rule, the FDA made a number of changes to more narrowly tailor provisions to children. For instance, there was little evidence presented that mail-order sales are used by children and adolescents, while they are used by adults in rural areas. Similarly, vending machines in facilities totally inaccessible to persons under 18 will accommodate adults while preventing easy access by young people.

The FDA rule reduces children's easy access to tobacco products by:

- Requiring age verification by photo ID for anyone under the age of 27 purchasing tobacco products;
- Banning vending machines and self-service displays except in "adult" facilities where children are not allowed, such as certain nightclubs totally inaccessible to anyone under 18; and
- Banning free samples, the sale of single cigarettes, and packages containing fewer than 20 cigarettes.

- MORE -

The FDA rule limits the appeal of tobacco products to children by:

- Prohibiting billboards within 1,000 feet of schools and playgrounds. Other advertising is restricted to black-and-white text only; this includes all billboards, signs inside and outside of buses, and all advertising in stores. Advertising inside "adult only" facilities like nightclubs can have color and imagery.
- Permitting black-and-white text-only advertising in publications with significant youth readership (under 18). Significant youth readership means more than 15 percent or more than 2 million readers under 18; there are no restrictions on print advertising below these thresholds.
- Prohibiting sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos.
- Prohibiting brand-name sponsorship of sporting or entertainment events (including teams and entries), but permitting it in the corporate name.

These provisions will be phased in between six months and two years from the date of publication in the Federal Register to give businesses adequate time to comply.

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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 23, 1996

REDUCING YOUNG PEOPLE's ACCESS TO TOBACCO PRODUCTS

Proposed Rule	Final Rule
Minimum age of 18 to buy tobacco products	Same
Ban vending machines and self-service displays	Same EXCEPT in certain nightclubs and other "adult only" facilities totally inaccessible to persons under 18
Ban "kiddie" packs, "loosies," or free samples	Same
Ban mail-order sales	Mail-order sales permitted

REDUCING APPEAL OF TOBACCO PRODUCTS TO YOUNG PEOPLE

Proposed Rule	Final Rule
Ban billboards within 1,000 feet of schools and playgrounds	Same
Other billboards, outdoor and in-store advertising limited to black-and-white text only	Same EXCEPT color, imagery permitted in "adult only" facilities if not visible from outside and not removable
Advertising in publications with significant youth readership (more than 15% or 2 million) limited to black-and-white text only	Same
Ban brand-name sponsorship of sporting or other events; only corporate name sponsorship permitted	Same, INCLUDING cars and teams
Ban brand names on hats, t-shirts, gym bags, etc.	Same

EDUCATING YOUNG PEOPLE ABOUT HEALTH RISKS OF TOBACCO

The proposed rule called for a $150 million annual fund, paid by tobacco manufacturers, to conduct a national educational campaign.

The FDA will pursue the goals of the educational effort proposed in August 1995 by using Section 518 of the Federal Food, Drug, and Cosmetic Act. Under the authority of this provision, the FDA will propose to require the six tobacco companies with a significant share of sales to children to educate young people about the health risks of using their products. This national campaign, including television spots, would be monitored for its effectiveness.

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Contact: Jim O'Hara
(301) 443-1130

May 16, 1996

NOTE TO STEVE COHEN

FROM: Elizabeth Drye

SUBJECT: Background Materials on the President's Tobacco Initiative

Attached are brief background materials on the problem of teen smoking and the Administration's actions to address it. Specifically, I've attached:

1) A two-page fact sheet on the problem, the FDA proposed regulation, and the final Synar regulation.

2) Talking points for Mike McCurry on the legislative initiative Philip Morris announced and U.S. Tobacco (UST) endorsed yesterday.

3) A New York Times article on the Philip Morris proposal.

4) Four HHS fact sheets:

- "Children and Tobacco: the Facts,"
- "Children and Tobacco: the Problem,"
- "Children and Tobacco: the Proposal," and
- "Children and Tobacco: What Others Say."

I hope these materials are helpful. Please let me know if you need anything else.

FACT SHEET ON CLINTON TOBACCO INITIATIVES

The Problem: Public health data shows:

- 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 have tried smoking by 18, and more than half of them have 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.

- In 1993, the estimated health care costs from smoking-related disease and death was $50 billion.

- 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. Smokers who die as a result of smoking would have lived on average 12 to 15 years longer if they had not smoked.

- Children tend to vastly underestimate the likelihood that they will become addicted to tobacco. 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 is the leading cause of preventable death in the US. 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.

The Children's Tobacco Initiative

On August 10, 1995, President Clinton announced the nation's first comprehensive campaign to reduce children's use of tobacco products. Under the children's tobacco initiative, 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 plan goes into effect.

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 of events only in the corporate name.

Also proposed is 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 will be funded by the industry.

The Administration's initiative has been published as a proposed rule of the Food and Drug Administration, and the FDA is currently reviewing public comments on the proposal.

The Synar Regulation

On January 18, 1996, the Administration issued a final rule designed to ensure that states and territories adopt and enforce laws prohibiting the sale or distribution of tobacco products to children.

The Synar regulation provides guidance to the states on how to comply with the Synar Amendment, named for its author, the late Mike Synar, former Congressman from Oklahoma. The amendment was enacted in 1992 as part of the Public Health Service Act and requires states to have and to enforce laws banning the sale and distribution of tobacco products to people under 18.

The Synar regulation requires states and territories to enforce their youth access laws through such methods as random spot checks of retail establishments. It would also require states to designate an office or agency for coordinating compliance activities. States would be required to file annual progress reports and could suffer financial penalties through reductions in substance-abuse block grants for failing to achieve agreed-upon goals.

While all states currently have such laws, enforcement has been inconsistent; in 1991, an estimated 255 million cigarette packs were sold illegally to minors, according to the American Journal of Public Health. And in the 1995 Monitoring the Future Survey, more than 90 percent of high school tenth graders surveyed said it was "fairly easy" or "very easy" to obtain cigarettes.

Together, the Synar regulation and the proposed FDA regulations would work to achieve President Clinton's goal of reducing children's use of tobacco products by 50 percent within seven years.

Talking Points on Philip Morris Announcement

We are pleased that Philip Morris recognizes that action needs to be taken to protect our children from the pediatric disease of smoking.

From the day he announced the FDA's proposal, the President has said he would be open to a legislative solution to the crucial public health problem: how to keep kids from smoking and using chewing tobacco. But he made clear that any legislative approach that he would support would have to be as strong, and effective as the FDA's proposals. That's the bottom line, and the standard by which the President would evaluate any legislative proposals. The Philip Morris proposal falls short of that mark. We encourage Philip Morris to continue moving forward to meet the President's standard.

If asked whether Leon met with Philip Morris about the proposal:

Philip Morris asked for a meeting with the Chief of Staff to lay out its proposal. Mr. Panetta agreed to the meeting. He reiterated that any legislative approach that the President would support would have to be as strong and effective as the FDA's proposals. After reviewing their proposal, he told them that it wasn't as comprehensive and effective as the FDA's proposal. But he welcomed their effort to try to move forward on this issue.

N.Y.T. 5/16/96

2 Tobacco Giants Seek Anti-Smoking Laws

By GLENN COLLINS

Seeking an alternative to Federal regulation of the nicotine in tobacco as an addictive drug, two tobacco companies proposed yesterday that Congress adopt sweeping laws to reduce teen-age smoking by banning vending sales and restricting advertisements and promotions.

But the companies were rebuffed by Michael D. McCurry, the White House spokesman, who said the companies' unexpected proposal "falls a little bit short" of the President's call to curb teen-age smoking. And some anti-tobacco organizations dismissed the companies' proposal as a public-relations stunt.

The two companies — Philip Morris U.S.A., the tobacco unit of the Philip Morris Companies, the nation's largest cigarette maker, and the United States Tobacco Company, the nation's largest purveyor of chewing tobacco and snuff — proposed a ban on vending-machine cigarette sales, single-cigarette sales and promotional giveaways, as well as a ban on transit advertising of tobacco products and restrictions on billboard and stadium advertising and sports-event sponsorships.

Philip Morris and United States Tobacco also proposed a ban on the imprinting of tobacco-product logos on merchandise like hats, clothing and gym bags. They also proposed that the tobacco industry spend $250 million over the next five years to enforce restrictions on teen-age smoking. The companies' proposals would not affect their international business.

Steve Parrish, a spokesman for Philip Morris, termed the proposal "unprecedented and far-reaching," adding that the companies "want to make it impossible for anyone to obtain any tobacco product from a manufacturer or retailer without a face-to-face transaction where proof of age can be checked."

But Mr. Parrish said that the tobacco companies would support such legislation only if the Food and Drug Administration withdrew its proposals to regulate the sale of tobacco. He added that five tobacco companies would continue to sue the F.D.A. in Federal court to block the proposed regulations.

The R. J. Reynolds Tobacco Company and the Brown & Williamson Tobacco Corporation, said they would reserve comment on yesterday's proposal until they could give it further study. The Lorillard Tobacco Company, a unit of the Loews Corporation, said it supported many of the suggestions from Philip Morris and United States Tobacco.

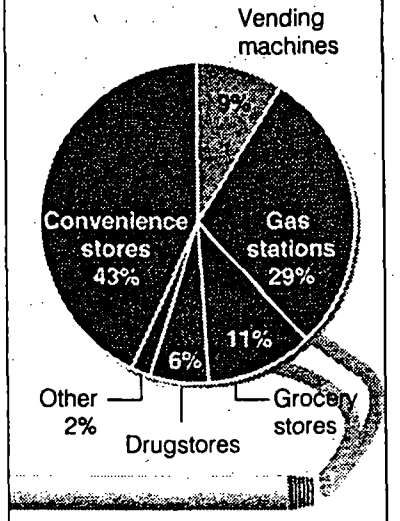
"This announcement is obviously a pre-emptive strike against the F.D.A.," said Richard A. Daynard, chairman of the Tobacco Products Liability Project at Northeastern University School of Law in Boston, a nonprofit anti-smoking group. "They want to make sure that the F.D.A. has nothing to do with regulating them."

Mr. Parrish denied that the companies were attempting to avoid more stringent anti-tobacco restrictions. But critics of the tobacco industry said that under the companies' proposal, cigarette brand images, such as Joe Camel and the Marlboro Man, would be unaffected.

THE NUMBERS

Buying Cigarettes

Where teen-agers, 13 to 17, buy cigarettes, according to a survey by the National Automatic Merchandising Association.



Of the 24.25 billion packs of cigarettes bought in 1994, about 915 million came from vending machines, according to Vending Times's annual survey. Some 400,000 machines carried cigarettes and the average machine sold 44 packs a week.

The New York Times

The tobacco industry makes an offer and promptly draws criticism.

A move that opponents call a pre-emptive strike against the F.D.A.

Under the Federal agency's plan, much advertising would be limited to black-and-white advertisements of text and not graphics. The tobacco companies have contended that such a limitation would infringe on their right of free speech.

The companies' proposal would also preclude any F.D.A. role in enforcement of tobacco regulations. And unlike the agency's proposal, the tobacco companies' proposal would not ban tobacco brand-name sponsorship in rodeos and motor sports.

Ellen Merlo, a spokeswoman for the Philip Morris Companies, said the company would continue its Marlboro Gear program, "offering gifts for points, but without the brand names," she said.

President Clinton said last summer that he welcomed a legislative solution to teen-age smoking that is as comprehensive and effective as the F.D.A.'s regulation plan.

"The Philip Morris proposal falls short of that mark," said Mitchell R. Zeller, F.D.A. Deputy Associate Commissioner of policy.

Supporters of the tobacco industry, like Representative Thomas J. Bliley Jr., Republican of Virginia, said that the companies' proposal had "little chance" of passage in Congress because Democrats had "already promised to filibuster any legislation that would preclude the F.D.A. from exercising jurisdiction over tobacco," he said.

But Henry A. Waxman, Democrat of California, one of the tobacco industry's leading opponents in Congress, said, "I commend Philip Morris for at least suggesting a legislative proposal," adding that he would "look forward to talking with them about enacting a bill this year."

About $2 billion worth of tobacco products were sold through 400,000 vending machines in 1994, or about 915 million packages of cigarettes, said Victor Lavay, publisher of Vending Times, a trade magazine.

Sheldon Silver, of the National Automatic Merchandising Association, said: "We oppose the ban on cigarette vending machines because it will not significantly reduce teen smoking." He cited a study showing that more than 72 percent of teenagers buy cigarettes in convenience stores and gas stations.

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.

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.

- **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.

- **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 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.

- **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.

- **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.

- **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."

- **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.

- 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 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
(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

- 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 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.

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
(301) 443-1130

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

DRAFT

ROLLOUT PLAN FOR STATE AND LOCAL GOVERNMENT REPRESENTATIVES

August 22 and 23, 1996

Early Alert - August 22 (evening)

Governors:

- Lawton Chiles, Florida
- Zell Miller, Georgia
- Paul Patton, Kentucky
- Jim Hunt, North Carolina

Attorneys General:

- Robert Butterworth, Florida
- Scott Harshbarger, Massachusetts
- Hubert H. Humphrey III, Minnesota
- Mike Moore, Mississippi
- Dan Morales, Texas
- Attorneys General of 6 other states that have filed lawsuits

Notification of Announcement - Friday, August 23

Governors:

- Howard Dean, Vermont
- John Kitzhaber, Oregon
- Mike Lowry, Washington

State Legislators:
(appropriate contacts being identified)

Other State Officials:
(appropriate contacts being identified)

Local Government Leaders:

- Mayors of America's largest 15 cities

State and Local Government Briefing - Friday, August 23, afternoon

HHS proposes to host a briefing for state and local government organizations and Washington representatives after the President's announcement. Invitees would include:

- State-Washington representatives
- National Governors' Association
- National Conference of State Legislatures
- American Public Welfare Association
- National Association of Attorneys General
- The Council of State Governments
- Association of State and Territorial Health Officials
- National Association of State Alcohol and Drug Abuse Directors
- County- and City-Washington representatives
- National Association of Counties
- National League of Cities
- U.S. Conference of Mayors
- National Association of Towns and Townships
- National Association of City and County Health Officials
- National Association of Local Boards of Health

Group 1

Senator Daschle	Rep. Gephardt
Senator Dodd (DNC)	Rep. Bonior
Senator Bob Kerrey (DSCC)	Rep. Fazio
Senator Mikulski	Rep. Frost (DCCC)

Group 2

Senator Lautenberg	Rep. Waxman
Senator Harkin	Rep. Durbin
Senator Kennedy	Rep. Meehan
Senator Boxer	Rep. Markey
Senator Bingaman	Rep. Schroeder
Senator Wellstone	Rep. Stark
Senator John Kerry	
Senator Simon	
Senator Bradley	

Group 2a

Senator Bennett	Rep. Hansen

Group 3

Senator Ford	Rep. L. F. Payne
Senator Robb	Rep. Baesler
Senator Hollings	Rep. Tanner
	Rep. Gordon
	Rep. Hefner

Group 4

Authorizing Committees:	
Senator Kassebaum (Chair, Labor & Human Resources)	Rep. Bliley (Chair, Commerce)
	Rep. Dingell (Ranking, Commerce)
Senator Lugar (Chair, Agriculture)	Rep. Bilirakis (Chair, Health & Environ. Subcom.)
Senator Leahy (Ranking, Agriculture)	Rep. Roberts (Chair, Agriculture)
	Rep. Ewing (Chair, Speciality Crops Subcom.)
	Rep. De La Garza (Ranking, Agriculture)
	Rep. Rose (Ranking, Speciality Crops Subcom.)

Appropriations Committees:

Senator Hatfield (Chair, Appropriations)
Senator Byrd (Ranking, Appropriations)
Senator Cochran (Chair, Ag. Approps. Subcom.)

Rep. Livingston (Chair, Appropriations)
Rep. Obey (Ranking, Appropriations)
Rep. Skeen (Chair, Ag. Approps. Subcom.)

Group 5

Senator Pell
Senator Leahy
Senator Levin
Senator Glenn
Senator Feingold
Senator Bumpers
Senator Lieberman
Senator Pryor
Senator Moynihan
Senator Biden
Senator Snowe

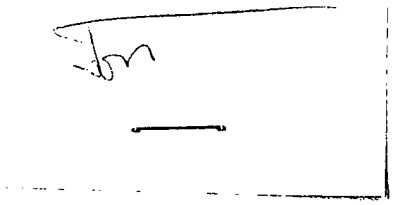
Senator Akaka
Senator Boxer
Senator Murray
Senator Kohl
Senator Sarbanes
Senator Feinstein
Senator Specter
Senator Chafee
Senator Rockefeller
Senator Jeffords

Group 6a

Senator Baucus
Senator Reid

Senator Bryan
Senator Dorgan

690-7755



NATIONAL NARCOTIC OFFICERS' ASSOCIATIONS COALITION

★ "You have given State and local law enforcement officers an opportunity to participate -- at the highest level -- in the development of national law enforcement policy -- and for that we thank you."

"In past Administrations, the opinions of State and local law enforcement officers were ignored by policy makers in Washington." [NNOAC letter to President Clinton, 7/12/96]

- **President Clinton has Matched his Words with Action.** President Clinton has been very active and outspoken on the issue of drugs. In his 1996 State of the Union, he challenged parents to talk openly and firmly to their children about the harm of drugs and announced General Barry McCaffrey as the Nation's New Drug Czar. He used international drug control policy as the centerpiece of an annual address to the United Nations. He convened a White House Leadership Conference that specifically addressed the issues of rising adolescent drug use and violence.

  ★ He is the **first** President to make the Director of National Drug Control Policy a Cabinet position.

  ★ He is the **first** President to refuse full certification to Andean source countries blocking them from receiving international loans and most U.S. foreign aid if they do not cooperate with U.S. anti-drug measures.

  ★ He is the **first** President to use international drug control policy as the centerpiece of an annual address to the U.N.

  ★ He is the **first** President to propose restricting youth access to tobacco products and reducing the advertising and promotional activities that make these products appealing to young persons.

  ★ He is the **first** President to convene a White House Conference that specifically addressed the issues of rising adolescent drug use and violence.

  ★ He is the **first** President to nominate a Drug Czar with drug interdiction background.

  ★ He is the **first** President to develop a comprehensive drug testing program for the Federal criminal justice system and he urged states and localities to adopt a similar program.

  ★ He is the **first** President to establish a National Methamphetamine Strategy that brings law enforcement, medical, environmental and treatment communities to attack this problem.

  ★ He is the **first** President to issue a Heroin Strategy to develop international cooperation against heroin.

- **Expanded Death Penalty.** Included the death penalty for drug kingpins and for a murder committed during a drug crime.

- **Three-Strikes-You're Out.** A tough "Three-Strikes-and-You're-Out" sentence to lock up the most dangerous career criminals for life.

- **Drug Courts and Drug Testing.** Provided for Drug Courts and drug testing and treatment for state prisoners to help break the cycle of crimes and drugs.

- **100,000 New Police.** 95% of all arrests occur at the State and local level. President Clinton's COPs program will hire 100,000 new state and local police officers -- increasing the number of cops on our streets by almost 20% -- and putting them where they count.

The President Has Introduced Even Tougher Measures -- But Congress Has Failed to Act. Earlier this year, President Clinton submitted to Congress legislation that would:

- **Tougher Penalties.** Increase the mandatory penalties for drug dealers who either sell drugs to children or use children to sell drugs. Announced May 13, 1996

- **First-Ever Meth Strategy.** Implement the legislative aspects of the President's Methamphetamine strategy by increasing the penalties for trafficking in this drug and expand the Attorney General's ability to control the chemicals used to make it. Announced April 29, 1996

- **Faster Response to New Drugs.** Give the Attorney General the emergency power to increase the penalties for emerging drugs that greatly impact adolescents, such as the "date-rape" drug -- Rohypnol.

- **Unprecedented International Drug-Fighting Efforts.** In addition, President Clinton has also continued to propose the largest drug budgets to Congress of any Administration while the Republican-led Congress has attempted to cut interdiction efforts. [Source: Office of National Drug Control Policy, The National Drug Control Strategy, April 1996; President's Veto Message Re: Commerce, Justice, State Appropriations, 12/19/95]

  * **Taking Down the Cali Cartel.** The Clinton Administration's assisted in the arrest of six of the top leaders of Colombian Cali Cartel -- the most powerful drug syndicate in the world. [Source: Office of National Drug Control Policy, The National Drug Control Strategy, April 1996]

  * **Fortifying our Borders.** The President has strengthened U.S. borders by increasing the number of Border Patrol Agents by nearly 40% on the Southwest Border. Seventy percent of the cocaine that enters the United States comes across the U.S.-Mexican border. And the Clinton Administration has provided more resources to the Southwest Border than any prior Administration. [Source: Office of National Drug Control Policy, The National Drug Control Strategy, April 1996; INS Budget Office, 7/96]

* **Stopping Drug Smugglers.** In 1995 the Clinton Administration implemented "Operation Hard Line" to stop drug smugglers from funneling their illicit drug cargo through U.S. ports. As a result, the number of port runners declined by 42 percent. Operation Hard Line also resulted in dismantling a major port-running organization in El Paso, Texas, which was reputed to have smuggled drugs in more than 2000 instances. The success against smuggling has continued with a 125% increase in narcotics seizures in commercial cargo along the Southwest Border in FY 1995. [Source: Office of National Drug Control Policy, The National Drug Control Strategy, April 1996]

* **Increasing Drug Seizures.** In the last three years, the Border Patrol has seized over $4.7 billion in drugs -- a 38% increase over the three prior years. The $4.7 billion represents nearly 20,000 drug seizures -- an increase of 22%. On the California border, alone, the Border Patrol has seized more than 110 tons of illegal drugs valued at $618 million. [Source: Department of Justice, U.S. Border Patrol, Total Drug Seizures; Narcotics; Dollar Value of Drugs seized, 1995

* **Proven Leadership.** President Clinton nominated Four-star General Barry McCaffrey -- a hero of the Persian Gulf War and U.S. military commander in South America -- to lead the country's efforts to reduce drug use.

★ *Joseph Califano, President of the National Center on Addiction and Substance Abuse at Columbia University and former Secretary of Health, Education and Welfare:* "The answer to recent increases in teen drug use is renewed prevention efforts that have at their core a no-use message; such programs cut drug use in half in the 1980s. We need expanded and more effective treatment and an investment in substance abuse research comparable to that in cancer, heart disease and AIDS. Retired general Barry McCaffrey's demonstrated leadership and familiarity with the Army's success in combatting soldiers' drug use after Vietnam make him just the man to coordinate America's anti-drug efforts." [Source: *The Washington Post,* May 26, 1996]

ANTI-DRUG PROGRAMS THAT WILL MAKE A DIFFERENCE:

* **Drug Testing for Federal Arrestees.** The President has developed a plan to drug test people arrested on federal criminal charges. These tests will help federal judges determine whether a defendant should be granted bail.

* **Drug testing for High School Athletes.** In January of 1995, the Clinton Administration supported high school athlete drug testing in an amicus brief to the Supreme Court, sending the message to parents and students that drug use will not be tolerated in our schools. [Vernonia School District 47J vs. Acton]

* **Getting Tough with Kids Who Drive Drunk.** He also signed the 1995 Highway Act, which requires States to adopt a "Zero Tolerance" standard for drivers under the age of 21. The result -- alcohol related crashes involving teenage drivers are down as much as 20 percent in those States which have a Zero Tolerance law on their books

* **Safe and Drug-Free Schools.** President Clinton expanded the Drug Free Schools Act into the Safe and Drug Free Schools Act in 1994, making violence prevention a key part of that program. The President has fought throughout his term for full funding of the program, fighting back a $266 million cut by the House in 1996. Forty million students in over 97% of the school districts in the country use these funds to keep violence and drugs away from students and our schools.

* **Combatting youth drug use.** President Clinton hosted first ever White House Conference on Youth, Drug Use and Violence in March 1996 and launched a national media literacy and drug deglamorization campaign aimed at youth.

* **Punishing Drug Pushers.** Drug prosecutions are up 13% from 1994 and federal prosecutors have achieved an 84% conviction rate in all drug cases in 1995. During the past three years, there has been a 9.4% increase in prosecutions of the toughest, most complex drug cases. There are now 48,000 convicted drug dealers in federal prisons -- the highest number in history. [Source: Department of Justice, U.S. Attorney's Office]

We Passed a Crime Bill with Tougher Penalties for Drug-Related Crimes. The 1994 Clinton Crime Bill, which was supported by every major law enforcement organization in America, provided for:

The Clinton Administration Anti-Drug Record

Overall drug use has declined by almost one-half since 1985 and since 1992 the number of cocaine users has dropped by 30%. The amount of money Americans spend on illicit drugs has declined by 23%. Every year, President Clinton has sought the largest drug budgets ever and his 1994 Crime Bill is the toughest and smartest Crime Bill in history -- it will put 100,000 new police officers on the streets, provide the death penalty for drug king pins and "Three-Strikes-and-You're-Out" for career criminals, break the cycle of crime and drugs through Drug Courts and Boot Camps. Internationally, he has helped dismantled the Cali Drug Cartel and on our borders he has provided more resources than ever before. He has developed a program to drug test federal arrestees and supported drug testing of high school athletes. And he has fought Republican efforts to eliminate prevention programs that address adolescent drug use, which has been on the rise since 1991.

★ **President Clinton has announced a 5-part strategy to combat drugs:**

THE NATIONAL DRUG CONTROL STRATEGY: 1996

1. Motivate America's youth to reject illegal drugs and substance abuse.
   => *President Clinton has expanded the **Safe and Drug-Free Schools** program.*
2. Enhance the safety of American's by substantially reducing drug-related crime and violence.
   => *President Clinton's 1994 Crime Bill is putting **100,000 new police** on the street.*
3. Reduce health, welfare and crime costs resulting from illegal drug use.
   => *The Administration has expanded **drug treatment** for hard-core users and developed a **drug testing** program for all federal arrestees to help end the cycle of violence and drug abuse.*
4. Shield America's air, land and sea frontiers from the drug threat.
   => *Initiatives such as U.S. Customs' "Operation Hard Line," and increasing the number of border patrols have helped to **close down the border to drug traffickers.***
5. Break foreign and domestic sources of supply.
   => *The Administration refused full certification to Andean source countries, pressure which resulted in the **arrest of six of the Cali Cartel's top leaders** and the dismantling of the cartel.*

- **Drug Use is Down.** Overall drug use is down by almost one-half since 1985. During this Administration the number of cocaine users have dropped by 30%. The amount of money Americans spend on illicit drugs has declined by 23%. [Source: Office of National Drug Control Policy, The National Drug Control Strategy, April 1996]

- **The Largest Anti-Drug Budgets Ever.** Year-in and Year-out, President Clinton has proposed the largest Anti-Drug Budgets of any President ever. Indeed, under the Clinton Budget now before Congress, the DEA would grow by 18% in one year and 116 new DEA agents would be added. [Source: Office of National Drug Control Policy, The National Drug Control Strategy, April 1996; Department of Justice, FY96 Budget Request]

EXECUTIVE OFFICE OF THE PRESIDE
N T EXECUTIVE OFFICE OF THE PRESIDE
N T

22-Aug-1996 10:34pm

TO: (See Below)

FROM: Kim B. Widdess
Office of the First Lady

SUBJECT: Final Layout for Tobacco event tomorrow

WHSO FINAL LAYOUT
a/o 8/22; K. Widdess

ANNOUNCEMENT OF FDA RULE ON CHILDREN AND TOBACCO
Friday, August 23, 1996
Rose Garden
Rain Site: OEOB 450
Max 180 guests/Open Press

Guest Invite: 1:00 p.m.
EV Gate Opens: 12:45 p.m.
PRINCIPAL: 1:30 p.m.

8:00 a.m. Rain Call is made.

12:30 p.m. IN PLACE TIME.

12:30 p.m. Mrs. Crawford arrives at the North West Gate and is escorted to the West Lobby.
Staff Contact: Barbara Woolley

12:45 p.m. East Visitor Entrance opens for guest arrival. Guests Hold in East Collonade until seated by Social Aides.
Staff Contact: Doug Matties

1:00 p.m. Children and Parents arrive to North West Gate and are escorted to the Palm Court.
Staff Contact: Brian Scott

1:00 p.m. Social Aides seat guests in the Rose Garden.

ROSE GARDEN SET UP (Per K. Engsklov) : Press risers behind seating; cutaway on east side; Stage (8 x 20) in Rose Garden on Oval Office side; steps on sides and front; Blue Goose; 6 chairs on stage; 180 chairs in audience; house flags; stanchions around

stage; press area roped off.

RESERVED SEATING:

Front Row

-Members of Congress: (4 - 2 confirmed)
-IGA: (4)
-Cabinet Officials: (Gen. McCaffrey, Ms. Rasco, others tbd)
-Dr. Koop
-WH Staff: (tbd)

Special Reserved Section (stage right)

-16 children

Other Reserved Seating

-TBD per Barbara Woolley (15)

1:15 p.m. THE PRESIDENT and THE VICE PRESIDENT arrive in the Oval Office for briefing.

Briefing Participants:
-Sec. Shalala
-Dr. Kessler
-Don Baer
-Jennifer O'Connor
-Greg Simon
-Michal Waldman/Jordan Tamagni

1:30 p.m. Upon conclusion of briefing the program begins.

Stage Participants
THE PRESIDENT
THE VICE PRESIDENT
Mrs. Linda Crawford
Sec. Shalala
Dr. Kessler
Dr. Lee

- The 16 Children are pre-positioned in special seating section on stage.

- THE PRESIDENT, THE VICE PRESIDENT, Mrs. Linda Crawford, Sec. Shalala, Dr. Kessler and Dr. Lee are announced from the Oval Office and proceed to their seats on stage.

- THE VICE PRESIDENT proceeds to the podium to make welcoming remarks and introduces Mrs. Linda Crawford.

- Mrs. Crawford makes remarks and introduces THE PRESIDENT.

- THE PRESIDENT makes remarks.

2:00 p.m. Following his remarks, THE PRESIDENT and THE VICE PRESIDENT work ropeline and then depart.

GUEST DEPARTURE: Guests depart South East Gate. Some guests may be escorted to North Grounds for press interviews. Those guests will depart NorthWest Gate.

CONTACTS:

-Briefing Paper: Jennifer O'Connor
-Remarks: Michael Waldman/Jordan Tamagni
-Mrs. Crawford: Barbara Woolley
-Children: Brian Scott

-Members of Congress: Dan Tate, Ben Freeland
-Elected Officials: Megan Williams
-Stage Set up: Chris Engsklov
-Guest List: Kim Widdess

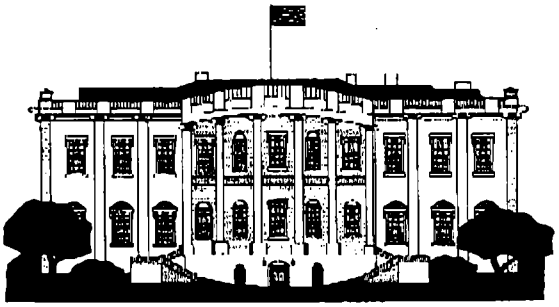
Distribution:

TO: Shana E. Tesler
TO: Kathy McKiernan
TO: Barry Toiv
TO: Robyn G. Dickey
TO: Kevin M. O'Keefe
TO: Elizabeth E. Drye
TO: Kinney Zalesne
TO: Julia Moffett
TO: Barbara D. Woolley
TO: Daniel Tate
TO: David Fein
TO: Jennifer M. O'Connor
TO: Julia R. Green
TO: David Wofford
TO: Loreen M. Keller
TO: Ben Freeland
TO: Anne E. McGuire
TO: Lisa Jordan Tamagni

CC: Kim B. Widdess

EXECUTIVE OFFICE OF THE PRESIDENT

Office of National Drug Control Policy
Washington, DC 20503



Office of National Drug Control Policy

FACSIMILE MESSAGE

TO: Elizabeth Drye

FAX: x67028

DATE: 08/23/96 **TIME: 9:00 am** **PAGES: 20 + Cover**

FROM: Janet Crist, Office of National Drug Control Policy

FAX NUMBER: 202/395-6708

OFFICE NO: 202/395-6705

COMMENTS: Packet left with Mr. Panetta last night. Also included in this fax, letter from Lloyd Johnston.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503
August 22, 1996

MEMORANDUM FOR LEON PANETTA

FROM: BARRY McCAFFREY

SUBJECT: Adolescent Tobacco and Illegal Drugs

Your decision to bring tobacco under the jurisdiction of the Food and Drug Administration is right on the mark. Nicotine and alcohol are gateway drugs. Nicotine has no mysterious property that compels tobacco smokers to go on to other addictive drugs. Evidence shows, however, that children who never drink or smoke are very unlikely to go on to use any illicit drug.

The 1988 law establishing the Office of National Drug Control Policy gives us the mandate to establish policy over the illegal use of alcohol and tobacco by adolescents.

While there is no scientific evidence of a causal relationship between gateway behavior and addictive behavior in later life, the statistical correlations are overwhelming. Children who smoke cigarettes are 5.9 times more likely to use any illegal substance; they are 12.1 times more likely to use marijuana; and they are 19.3 times more likely to use cocaine.

In sum, studies show that cigarette users are at high risk for illicit drug use. Parents must be aware that cigarette use places their children substantially at risk for the use of other drugs. Joe Califano's 1994 study demonstrated that 83 percent of all those who use cocaine included smoking cigarettes as a gateway behavior.

The Journal of 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.

and Substance Abuse
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Cigarettes, Alcohol, Marijuana: Gateways to Illicit Drug Use

October 1994

FOREWORD

This report of the Center on Addiction and Substance Abuse at Columbia University (CASA) addresses the controversial subject of the relationship of smoking cigarettes and drinking alcohol to the use of marijuana, cocaine, heroin and other illicit drugs. This report is the most comprehensive national analysis ever undertaken of all these relationships among children and adults, as experimenters and regular users. The report reveals remarkably consistent statistical relationships between the use of cigarettes and alcohol and the subsequent use of marijuana, and between the use of cigarettes, alcohol and marijuana and the subsequent use of illicit drugs like cocaine, regardless of the age, sex, ethnicity or race of the individuals involved.

For decades, public health professionals and social scientists have argued among themselves, and debated with tobacco and alcohol company representatives, about whether a relationship exists between children smoking cigarettes and drinking beer, wine coolers or other alcohol, and the subsequent use of drugs such as marijuana, cocaine and heroin. Those who argue for the decriminalization or legalization of marijuana have claimed that smoking marijuana is not related to experimentation with or addiction to other drugs, such as cocaine and heroin. The potent statistical relationships demonstrated in this report have profound implications for personal conduct and public policy. For the recent rise in the use of cigarettes, alcohol and marijuana by America's children and teenagers may be the harbinger of an increase in the use of illicit drugs like cocaine.

Chart 25

Paths to Cocaine Use

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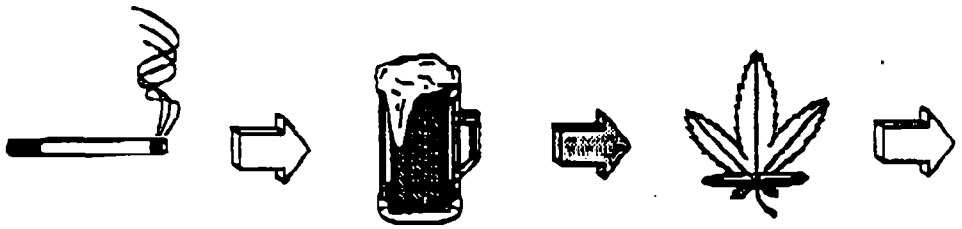

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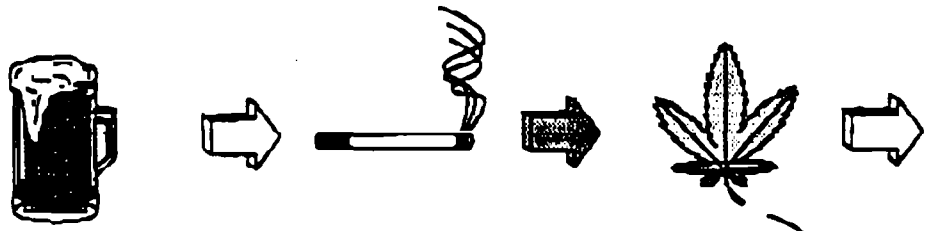

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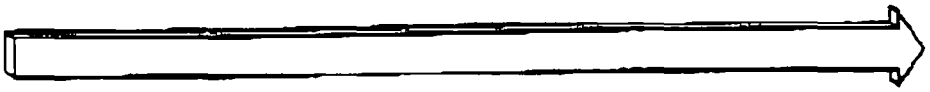

COCAINE

These percentages have been rounded to the nearest whole number.

Avram Goldstein, M.D.
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FAX TRANSMITTAL to Steve Donahoo

at FAX No. 202-395-6708 Total pages: 2 Date: August 22, 1996

1. Nicotine is an addictive drug in every sense of the word "addictive":

(a) Most current smokers find it extremely difficult to give up cigarettes -- they are addicted to the nicotine. In the USA today, large numbers have been able to quit -- just as it is possible, no matter how difficult, for any addict to quit using an addictive drug. But there is a hard core of 48 million who have not quit, who relapse repeatedly when they try; and 70% of this hard core say they wish they could quit.

(b) It stimulates receptors in the brain reward system, just as do other addictive drugs like cocaine and heroin.

(c) Laboratory animals will self-administer nicotine into their veins, just as they do cocaine and heroin; and other tests of addiction in laboratory animals also give positive results with nicotine.

(d) In "blind" experiments, where smokers are not told whether or not the experimental cigarettes contain nicotine, most reject nicotine-free cigarettes. In other "blind" experiments, if smokers are given nicotine by injection, they reduce their cigarette smoking -- the more injected nicotine, the less they smoke; this means they smoke primarily for the nicotine.

(e) The evidence is reviewed in detail (as of eight years ago) in the 1988 Surgeon General's Report, "The Health Consequences of Smoking: Nicotine Addiction" (DHHS Publication No. (CDC) 88-8406).

2. Tobacco (nicotine) and alcohol are by far the worst addictive drugs from the standpoint of health risks and the consequent cost to society, as well as the huge number of individual users. In terms of the numbers of lives destroyed, tobacco dwarfs all the illicit drugs.

3. Nicotine addiction starts early. In general, people who are not already smokers in adolescence never become smokers. Therefore, prevention of this addiction means making nicotine (tobacco) less readily available to children, not targeting children in advertising, banning cigarette machines, making it a federal offense (it is already illegal in many states) to sell or distribute cigarettes to minors. That is good policy in its own right, because of the intrinsic health dangers of tobacco.

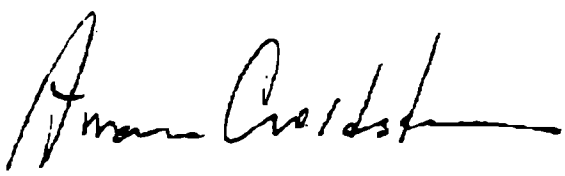
4. In addition, nicotine and alcohol are "gateway" drugs. Of course, nicotine has no mysterious property that compels tobacco smokers to go on to other addictive drugs; and most do not. However, it is true that users of the illicit drugs -- including marijuana, cocaine, and heroin -- have almost always launched their drug abuse careers with nicotine and alcohol. Children who never drink or smoke are very unlikely to go on to use any illicit drug. Nicotine is a gateway drug in two other senses:

(a) The adolescent new users learn that changing one's mood and behavior by self-administering a psychoactive drug is acceptable behavior, and thus becomes more accepting of the self-administration of other drugs.

(b) Adolescent users, in the many states where sale to minors is illegal, have to break the law in order to obtain cigarettes, and thus become more accepting of the use of illicit drugs -- first marijuana, then cocaine and other psychostimulants (e.g., methamphetamine) or heroin.

(c) The route of administration -- smoking -- has become socially acceptable and therefore offers no barrier to use. With the widespread availability of crack cocaine, a young person who already smokes can readily become a crack user. Learning the new and bizarre technique of injecting into one's own veins comes later in the sequence.

5. Policy recommendations concerning nicotine, and the evidence on which they are based, are discussed in my book (A. Goldstein, ADDICTION: From Biology to Drug Policy, WH Freeman, New York, 1994), especially chapters 8 and 19.



"The investigators also point out that cigarette smoking is strongly correlated with the use of marijuana and suggest that the upturn in cigarette smoking during the past four to five years may well have contributed to the increase in marijuana use over the same period. Because cigarette smoking usually precedes marijuana use and teaches youngsters how to take smoke into their lungs to secure a drug-induced effect, it provides an excellent training ground for learning how to smoke marijuana."

Lloyd D. Johnston, Ph. D.
Principal Investigator,
Monitoring the Future Study
December 15, 1995

The University of Michigan

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August 22, 1996

General Barry McCaffrey, Director
Office of National Drug Control Policy
Executive Office of the President
The White House
750 17th. Street, NW
Washington, DC 20503

Dear General McCaffrey:

You asked for my thoughts on the connection between cigarette smoking among young people and their use of other drugs. I offer the following observations:

1. Without question there is a strong statistical association between adolescents' use of cigarettes and their use of alcohol, their use of illicit drugs in general, and each of the individual classes of illicit drugs. Based on a set of analyses of nationally representative samples of eighth, tenth and twelfth grade students in 1994— a part of the Monitoring the Future Study—we know the following (see Table 9 enclosed):

   •As Table 9 shows, the probability of using marijuana rises directly as a function of degree of experience with cigarettes. Among eighth graders who never smoked, only 3% had ever tried marijuana. Among eighth graders who were current pack-a-day smokers, 73% had tried marijuana. Among pack-a-day smokers in tenth grade, 84% have experience with marijuana, and in twelfth grade, 86%. At all grade levels the relationship is ordinal and very strong.

   •As Table 9 also illustrates, a very strong and ordinal relationship also exists between youngsters' cigarette smoking experience and the use of all the illicit drugs other than marijuana including crack, powdered cocaine, heroin, amphetamine stimulants, LSD, tranquilizers, and inhalants.

   •The use of alcohol and smokeless tobacco correlates with the youngsters' degree of involvement with cigarettes, as well. (Table 9).

•Heavy or daily use of the illicit drugs is very strongly related to smoking (Table 12).

2. The sequence of events involved in these associations tends to be one in which cigarette smoking *precedes* the initiation of the use of the other drugs.

•When eighth graders were asked when they first used each drug, extremely few said they used marijuana before cigarettes. (See Table 16). For example, of those who said that their first experience with cigarettes occurred in sixth grade (see 3rd column of data in Table 16) only 1.5% said they had previously used marijuana, but 28% said they had begun marijuana use in seventh or eighth grade. (Another 6% said they had begun marijuana use in sixth grade.) The same pattern shows up among the eighth graders who began to smoke in fifth and seventh grades, as well. (See other columns in Table 16.)

•When twelfth graders are asked similar questions, the same results emerge (see Table 18.) For example, of the twelfth graders who said they first used cigarettes back when they were in seventh grade, only 1.6% reported *previously* using marijuana vs. 53.9% who said they used marijuana *subsequent* to the seventh grade. (Some 6.7% began both in the same year.)

3. The strength and consistency of the cross-time association between cigarette smoking and the subsequent use of marijuana and other drugs, in combination with the fact that highly plausible intervening mechanisms can be offered, leads me to the conclusion that cigarette smoking is a contributing factor to the use of illicit drugs. The intervening mechanisms which I hypothize are two. First, learning to smoke cigarettes is excellent training for learning to smoke marijuana. A child learns to do something which is abnormal behavior for all species—to take smoke into the lungs. Secondly, this drug-taking behavior is positively reinforced (eventually) with pleasurable changes in mood—a learned association which can be generalized to the taking of other chemicals by inhalation, and even to the taking of psychoactive chemicals by other means.

4. Also note in Tables 16 and 18, by looking across the last row of statistics, that the *earlier* that cigarette smoking is initiated, the more likely the youngster is to try marijuana. For example, among eighth graders who have not smoked at all by the time they reach the eighth grade, less that 2% (1.7%) have used marijuana; but among their peers who started to smoke by fourth grade, 43% already have gone on to use in marijuana, even by the end of eighth grade!

I hope this information proves helpful to you in your very important work.

Sincerely,

LDJ:ec

Lloyd D. Johnston, Ph.D.
Program Director and Research Scientist

cc: Peter Edelman, DHHS
Alan Leshner, NIDA

Table 9
Lifetime Use of Drugs by Five Categories of Smoking Behavior by Grade, 1994

	A	B	C	D	E	
	Never Smoked	Smoked 1-2 Times in Lifetime	Smoked 3+ Times, Not Current Daily	Current Daily Smoking, Less than Pack-a-Day	Current Daily Smoking, Pack-a-Day or More	Risk Ratio E/A
Any Illicit Drug[3]						
8th Grade	8.9[a]	29.0	53.1	75.7	79.1	8.9
10th Grade	12.0[a]	38.3	60.0	81.9	88.7	7.4
12th Grade	17.7[a]	41.6	65.5	83.5	90.2	5.1
Any Illicit Drug[3] Other than Marijuana						
8th Grade	6.9	17.4	36.8	53.6	64.2	9.3
10th Grade	7.0	18.7	32.4	52.6	69.0	9.9
12th Grade	10.1	21.1	37.6	54.1	71.8	7.1
Marijuana						
8th Grade	2.8	18.2	38.5	64.1	73.0	26.1
10th Grade	6.6	29.1	50.7	77.0	84.1	12.7
12th Grade	11.0	33.3	57.2	76.9	85.5	7.8
Inhalants[4]						
8th Grade	8.8	23.7	39.0	47.6	55.6	6.3
10th Grade	6.4	15.6	30.6	38.0	50.2	7.8
12th Grade	5.1	14.0	25.9	34.3	50.9	10.0
Hallucinogens[4]						
8th Grade	0.5	2.3	9.3	22.1	39.5	79.0
10th Grade	1.2	4.7	11.3	26.1	44.0	36.7
12th Grade	1.9	5.9	15.2	28.6	43.9	23.1
LSD						
8th Grade	0.4	1.8	7.7	19.3	36.8	92.0
10th Grade	1.0	4.2	9.7	23.6	40.3	40.3
12th Grade	1.7	5.4	13.7	26.9	41.8	24.6
Cocaine						
8th Grade	0.4	2.6	7.6	17.1	32.6	81.5
10th Grade	0.7	2.3	6.3	12.6	25.4	36.3
12th Grade	0.8	2.5	7.9	14.4	28.7	35.9
Crack						
8th Grade	0.2	1.7	4.7	12.1	23.5	117.5
10th Grade	0.4	1.1	3.4	5.7	13.5	33.8
12th Grade	0.5	1.1	3.7	7.1	15.9	31.8

Table 9 (cont.)
Lifetime Use of Drugs by Five Categories of Smoking Behavior by Grade, 1994

	A Never Smoked	B Smoked 1-2 Times in Lifetime	C Smoked 3+ Times, Not Current Daily	D Current Daily Smoking, Less than Pack-a-Day	E Current Daily Smoking, Pack-a-Day or More	Risk Ratio E/A
Other Cocaine[e]						
8th Grade	0.3	2.1	6.3	14.3	25.4	84.7
10th Grade	0.5	2.2	5.5	10.6	22.9	45.8
12th Grade	0.8	2.0	6.8	12.3	25.5	31.9
Heroin						
8th Grade	0.3	1.0	3.9	10.2	21.0	70.0
10th Grade	0.3	1.1	2.0	3.5	10.9	36.3
12th Grade	0.3	0.5	1.3	2.2	7.2	24.0
Other Opiates[f]						
8th Grade	NA	NA	NA	NA	NA	—
10th Grade	NA	NA	NA	NA	NA	—
12th Grade	2.2	3.9	7.7	13.3	28.0	12.7
Stimulants[g]						
8th Grade	4.8	12.7	25.2	35.5	42.3	8.8
10th Grade	4.8	13.1	22.7	36.9	47.1	9.8
12th Grade	4.8	11.2	22.2	31.2	48.2	10.0
Barbiturates[h]						
8th Grade	NA	NA	NA	NA	NA	—
10th Grade	NA	NA	NA	NA	NA	—
12th Grade	2.3	4.0	9.2	13.5	29.3	12.7
Tranquilizers[i]						
8th Grade	1.9	3.6	9.4	12.8	25.3	13.3
10th Grade	1.6	4.0	7.6	13.7	24.4	15.3
12th Grade	2.5	4.7	8.6	12.0	23.7	9.5
Alcohol						
8th Grade	32.3	77.1	90.8	93.5	94.2	2.9
10th Grade	44.7	85.2	94.0	96.6	98.4	2.2
12th Grade	57.4	90.0	97.3	97.8	98.8	1.7
Smokeless Tobacco[j]						
8th Grade	6.5	25.6	39.6	51.5	70.6	10.9
10th Grade	10.6	32.2	45.8	53.6	72.8	6.9
12th Grade	7.5	35.8	47.4	45.3	71.5	9.5

Table 9 (cont.)
Lifetime Use of Drugs by Five Categories of Smoking Behavior by Grade, 1994

[1]This means that 8.9 percent of 8th graders who ever smoked have used some illicit drug in their lifetime (at least once), 12.0% of 10th graders who never smoked have used some illicit drug in their lifetime (at least once), and 17.7% of 12th graders who never smoked have used some illicit drug in their lifetime (at least once).

[2]For 12th graders: Use of "any illicit drug" includes any use of marijuana, hallucinogens, cocaine, heroin, or any use of other opiates, stimulants, barbiturates, or tranquilizers not under a doctor's orders. For 8th and 10th graders: The use of other opiates and barbiturates has been excluded, because these younger respondents appear to misreport use (perhaps because they include the use of nonprescription drugs in their answers).

[3]Inhalants are unadjusted for underreporting of amyl and butyl nitrites. For 12th graders: Data based on five of six questionnaire forms. N is five-sixths of N indicated.

[4]Hallucinogens are unadjusted for underreporting of PCP.

[5]For 12th graders: Data based on four of six questionnaire forms. N is two-thirds of N indicated.

[6]Only drug use which was not under a doctor's orders is included here.

[7]Data based on a single questionnaire form. N for 12th graders is one-sixth of N indicated. N for 8th and 10th graders is one-half of N indicated.

Table 12
Daily Use of Drugs by Five Categories of Smoking Behavior by Grade, 1994

	A Never Smoked	B Smoked 1-2 Times in Lifetime	C Smoked 3+ Times, Not Current Daily	D Current Daily Smoking, Less than Pack-a-Day	E Current Daily Smoking Pack-a-Day or More	Risk Ratio E/A
Any Illicit Drug[a]						
8th Grade	NA	NA	NA	NA	NA	—
10th Grade	NA	NA	NA	NA	NA	—
12th Grade	NA	NA	NA	NA	NA	—
Any Illicit Drug[a] Other than Marijuana						
8th Grade	NA	NA	NA	NA	NA	—
10th Grade	NA	NA	NA	NA	NA	—
12th Grade	NA	NA	NA	NA	NA	—
Marijuana						
8th Grade	0.1[e]	0.3	0.5	4.6	12.9	129.0
10th Grade	0.2[e]	0.9	1.5	9.0	17.4	87.0
12th Grade	0.7[e]	1.1	3.3	8.9	21.6	30.9
Inhalants[c]						
8th Grade	0.0	0.2	0.5	1.3	1.7	0.0
10th Grade	0.0	0.1	0.1	0.3	0.5	0.0
12th Grade	0.0	0.1	0.0	0.1	0.6	0.0
Hallucinogens[d]						
8th Grade	0.0	0.0	0.1	0.2	0.2	0.0
10th Grade	0.0	0.0	0.1	0.1	0.1	0.0
12th Grade	0.0	0.0	0.2	0.0	0.6	0.0
LSD						
8th Grade	0.0	0.0	0.1	0.1	0.0	0.0
10th Grade	0.0	0.0	0.0	0.1	0.0	0.0
12th Grade	0.0	0.0	0.2	0.0	0.4	0.0
Cocaine						
8th Grade	0.0	0.1	0.1	0.3	2.2	0.0
10th Grade	0.0	0.0	0.1	0.2	1.1	0.0
12th Grade	0.1	0.0	0.1	0.2	0.3	3.0
Crack						
8th Grade	0.0	0.0	0.0	0.3	1.1	0.0
10th Grade	0.0	0.0	0.0	0.2	0.0	0.0
12th Grade	0.0	0.1	0.2	0.1	0.8	0.0

Table 12 (cont.)
Daily Use of Drugs by Five Categories of Smoking Behavior by Grade, 1994

	A Never Smoked	B Smoked 1-2 Times in Lifetime	C Smoked 3+ Times, Not Current Daily	D Current Daily Smoking, Less than Pack-a-Day	E Current Daily Smoking Pack-a-Day or More	Risk Ratio E/A
Other Cocaine[e]						
8th Grade	0.0	0.1	0.0	0.0	0.3	0.0
10th Grade	0.0	0.0	0.0	0.0	0.7	0.0
12th Grade	0.0	0.1	0.0	0.1	0.0	0.0
Heroin						
8th Grade	0.0	0.1	0.0	0.4	0.3	0.0
10th Grade	0.0	0.0	0.0	0.0	0.1	0.0
12th Grade	0.0	0.0	0.0	0.0	0.1	0.0
Other Opiates[f]						
8th Grade	NA	NA	NA	NA	NA	–
10th Grade	NA	NA	NA	NA	NA	–
12th Grade	0.0	0.0	0.0	0.1	0.8	0.0
Stimulants[g]						
8th Grade	0.1	0.0	0.2	0.8	1.1	11.0
10th Grade	0.0	0.2	0.1	0.2	0.4	0.0
12th Grade	0.0	0.1	0.2	0.4	1.1	0.0
Barbiturates[h]						
8th Grade	NA	NA	NA	NA	NA	–
10th Grade	NA	NA	NA	NA	NA	–
12th Grade	0.1	0.0	0.0	0.1	0.1	1.0
Tranquilizers[i]						
8th Grade	0.0	0.1	0.0	0.1	1.1	0.0
10th Grade	0.0	0.0	0.0	0.1	0.4	0.0
12th Grade	0.1	0.1	0.0	0.0	0.5	5.0

Table 12 (cont.)
Daily Use of Drugs by Five Categories of Smoking Behavior by Grade, 1994

	A Never Smoked	B Smoked 1-2 Times in Lifetime	C Smoked 3+ Times, Not Current Daily	D Current Daily Smoking, Less than Pack-a-Day	E Current Daily Smoking Pack-a-Day or More	Risk Ratio E/A
Alcohol						
8th Grade	0.2	0.7	1.4	3.5	15.7	78.5
10th Grade	0.4	1.0	2.4	4.3	10.1	25.3
12th Grade	0.9	1.8	4.3	4.8	12.1	13.4
5+ drinks in a row in last 2 weeks						
8th Grade	4.0	15.1	28.2	53.5	70.1	17.5
10th Grade	7.0	21.3	37.3	56.9	69.2	9.9
12th Grade	10.2	25.4	39.6	54.5	61.8	6.1
Smokeless Tobacco[g]						
8th Grade	0.5	1.3	3.1	8.2	16.8	33.6
10th Grade	0.6	2.0	6.7	6.7	8.8	14.7
12th Grade	1.5	3.6	5.2	6.5	11.3	7.5

cigarettes are current daily users ... [illegible]

[a]This means that 0.1 percent of 8th graders who never smoked cigarettes are current daily users, have used marijuana in their lifetime (at least once), 0.2% of 10th graders who never smoked have used marijuana in their lifetime (at least once), and 0.7% of 12th graders who never smoked have used marijuana in their lifetime (at least once).

[b]For 12th graders: Use of "any illicit drug" includes any use of marijuana, hallucinogens, cocaine, heroin, or any use of other opiates, stimulants, barbiturates, or tranquilizers not under a doctor's orders. For 8th and 10th graders: The use of other opiates and barbiturates has been excluded, because these younger respondents appear to overreport use (perhaps because they include the use of nonprescription drugs in their answers).

[c]Inhalants are unadjusted for underreporting of amyl and butyl nitrites. For 12th graders: Data based on five of six questionnaire forms. N is five-sixths of N indicated.

[d]Hallucinogens are unadjusted for underreporting of PCP.

[e]For 12th graders: Data based on four of six questionnaire forms; N is two-thirds of N indicated.

[f]Only drug use which was not under a doctor's orders is included here.

[g]Data based on a single questionnaire form. N for 12th graders is one-sixth of N indicated. N for 8th and 10th graders is one-half of N indicated.

Table 16
Age of First Use of Cigarettes by Age of First Use of Marijuana
Eighth Graders, 1994

8th Grade	Age of First Use of Cigarettes: 4th Grade or Earlier	5th Grade	6th Grade	7th Grade	8th Grade	Never Smoked
Age of First Use of Marijuana						
4th Grade or Earlier	6.7*	1.7	0.5	0.4	0.2	0.1
5th Grade	5.1	5.2	1.0	0.1	0.0	0.1
6th Grade	8.5	7.1	4.1	1.5	0.4	0.2
7th Grade	10.6	17.0	13.7	10.4	2.2	0.5
8th Grade	11.9	10.8	14.3	11.9	6.4	0.8
Never Used Marijuana	57.2	59.2	64.5	75.3	82.7	98.3
Total (Any Marijuana Use)	42.8	40.8	35.5	24.7	17.3	1.7
Weighted N:	*1355*	*1157*	*1617*	*1668*	*779*	*8019*

*This means 6.7 percent of eighth graders who had smoked cigarettes by 4th grade had used marijuana by 4th grade.

Table 18
Age of First Use of Cigarettes by Age of First Use of Marijuana
Twelfth Graders, 1994

	Age of First Use of Cigarettes							
12th Grade	6th Grade or Earlier	7th Grade	8th Grade	9th Grade	10th Grade	11th Grade	12th Grade	Never Smoked
Age of First Use of Marijuana								
6th Grade or Earlier	[illegible]	1.6	0.9	0.4	0.2	0.3	1.1	0.4
7th Grade	7.8	[illegible]	2.8	0.6	0.0	0.0	0.5	0.4
8th Grade	8.9	10.4	[illegible]	2.8	1.5	0.2	0.6	0.7
9th Grade	11.5	14.0	12.7	[illegible]	3.9	2.1	0.4	1.0
10th Grade	11.1	14.7	14.9	16.4	[illegible]	3.9	4.2	2.0
11th Grade	11.0	7.0	12.0	13.8	20.5	[illegible]	6.1	2.3
12th Grade	6.1	7.8	10.0	10.4	12.0	13.2	[illegible]	2.2
Never Used Marijuana	35.8	37.9	38.4	44.5	46.6	59.0	67.7	[illegible]
Total (Any Marijuana Use)	64.2	62.1	61.6	55.5	53.4	41.0	32.3	8.9
Weighted N:	*1090*	*620*	*606*	*561*	*452*	*372*	*199*	*2612*

Note: Data based on three of six forms.
*This means 7.8 percent of twelfth graders who had smoked cigarettes by 6th grade had used marijuana by 6th grade.

Smoking/marijuana relat.

The University of Michigan

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FROM: Lloyd D. Johnston, PhD

PAGES:

DATE: August 10, 1995

SAMPLE STATEMENTS WHICH COULD BE MADE

Table 9: 1st line of data:

Among 8th graders, those who are pack-a-day smokers are 9 times as likely to have used some illicit drug (like marijuana or cocaine) than those who have never smoked. In fact, 79% of them have tried an illicit drug by 8th grade (versus 9% of those who never smoked).

Table 9: 2nd line of data:

By 10th grade, 89% [or nearly 90%] of the current pack-a-day smokers have tried an illicit drug.

Table 9: Marijuana: 1st line of data:

The probability of smoking marijuana increases sharply with experience at smoking cigarettes.

Hardly any of the 8th graders who have NOT smoked cigarettes have ever tried marijuana (2.8%); whereas nearly three-quarters (73%) of the 8th grade pack-a- / smol s have. Th current pack-a-day smokers are 26 tir likely to

Table 9: Crack: 1st line of data:

The use of illicit drugs other than marijuana—like LSD, cocaine, crack, and heroin—is also strongly associated with cigarette smoking. For example, among 8th graders, nearly a quarter (23.5%) of the current pack-a-day smokers have tried crack. This is 118 times higher than among the 8th graders who never smoked cigarettes, only 0.2% of whom have tried crack. The fact that both involve inhaling fumes may well account for this extremely strong association.

Table 12: Current Daily Use of Marijuana

: first 3 lines of data:

Daily marijuana use is particularly strongly associated with being a current smoker, especially with being a current heavy smoker.

Hardly any 8th graders who have ~~never~~ NOT smoked cigarettes are current daily marijuana users (0.1%), but one-in-every eight of the current pack-a-day cigarette smokers are (12.9%).

Table 16: Age of First Use for 8th Graders

The use of cigarettes is far more likely to come before the use of marijuana than after.

: 3rd and 4th data columns:

When 8th graders are asked when they first used each drug, extremely few say they used marijuana first, some say they began both in the same year, and many say they used marijuana after starting cigarette use.

For example, of those who said they first used cigarettes in the 6th grade, only 1.5% said they had previously used marijuana, 6% said they also began marijuana use in 6th grade, and 28% said they began to use marijuana in 7th or 8th grade.

Table 18: Age of First Use for 12th Graders: 4th column:

To take another example, this time using high school seniors, of those who said that they initiated cigarette smoking back when they were in 9th grade, only 3.3% had already tried marijuana up to that point, but 41.2% initiated use in 9th grade or later (11.7% in 9th grade and 29.5% in grades 10 to 12).

THE WHITE HOUSE

WASHINGTON

August 23, 1996

MEMORANDUM FOR LEON PANETTA
HAROLD ICKES
EVELYN LIEBERMAN
DON BAER
GEORGE STEPHANOPOULOS
MIKE MCCURRY
CAROL RASCO
RON KLAIN
MARCIA HALE
JOHN HILLEY
ALEXIS HERMAN

FROM: JENNIFER O'CONNOR

SUBJECT: TOBACCO ANNOUNCEMENT MATERIALS

Attached are:

1) Talking Points (for distribution to surrogates, etc.)

2) Fact sheets including:

-- Key Elements of the Rule

-- Comparison of the Proposed Rule and Final Rule

-- Changes From Proposed Rule to Final Rule

-- Legal Issues Relating to the Rule

-- A Chronology of the Rule

3) Questions and Answers (for internal use only)

PRESIDENT CLINTON TAKES HISTORIC STEP TO REDUCE CHILDREN'S USE OF TOBACCO

August 23, 1996

Today President Clinton announced a new initiative to reduce tobacco use by children. The cornerstone of the initiative is a comprehensive regulation designed to stop sales of cigarettes and smokeless tobacco to children and to prevent tobacco companies from appealing to children in their advertisements. As part of the initiative, FDA will also start a process to require tobacco companies to educate children about the dangers of tobacco use.

The Threat to Our Children. Tobacco use by children is an enormous health problem that is getting worse.

- Approximately 4.5 million children under 18 smoke cigarettes or use smokeless tobacco in the United States. Every day, almost 3,000 more children become regular smokers, and nearly 1,000 of these will have their lives shortened by tobacco-related disease.

- Despite a decline in adult smoking, youth smoking is on the rise. In 1995, more than a third of high-school seniors smoked cigarettes -- more than at any time since the 1970s.

- The threat to children's health is tremendous. Tobacco is the leading cause of premature death in the U.S., killing over 400,000 Americans each years -- more than AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.

Nicotine Addiction is a Pediatric Disease. The strength of the President's initiative is that it recognizes that preventing children from becoming addicted to nicotine is the key to reducing tobacco use in the United States. The vast majority of smokers (over 80%) start smoking before age 18. Those who don't become addicted to nicotine in childhood won't use tobacco products as adults. The President's initiative is the first comprehensive plan designed to prevent the cycle of tobacco dependency, disease, and death from taking root in our children.

Reducing Children's Access to Tobacco Products. It is far too easy for children to buy cigarettes and smokeless tobacco. The 1994 Surgeon's General Report found that approximately 67% of minors are able to buy cigarettes illegally. To restrict youth access to tobacco, the new Food and Drug Administration rule will:

- Require retailers to verify age by photo ID before selling cigarettes or smokeless tobacco to anyone 26 and under.
- Ban vending machines and self-service displays in areas accessible to children.
- Eliminate free samples and the sale of loose single cigarettes and kiddie packs.

Eliminating Tobacco Advertising that Appeals to Children. The new sales restrictions cannot

work unless tobacco advertising that appeals to children is also restricted. The tobacco industry spends more than $6 billion for advertising and promotions that often appeal to children. This advertising is so pervasive that over 90% of 6-year-olds can identify "Joe Camel" as a symbol of smoking. To prevent tobacco companies from marketing their products to children, the FDA rule will:

- Ban outdoor billboards within 1,000 feet of schools and playgrounds.
- Require most other tobacco advertising to use a black-and-white text-only format, eliminating the use of images and colors that appeal to children. Advertising in adult-only settings and primarily adult magazines will be unrestricted.
- Prohibit the sale or giveaways of products like caps and T-shirts that carry tobacco product brand names.
- Prevent tobacco companies from sponsoring sporting or entertainment events in tobacco product brand names, but permit sponsorship in the companies' names.

Educating Our Children about the Hazards of Tobacco Use. FDA will also use public education to deter tobacco use by proposing to require tobacco companies to educate children about the dangers of smoking and using smokeless tobacco. Working in combination, the access restrictions, the advertising limitations, and the mass media program are expected to meet the President's goal of cutting tobacco use by children in half over the next seven years.

Everyone -- families, teachers, community leaders, clergy and government have an important role in combating kids' smoking. Families need help protecting their children from tobacco. It's hard for a parent to discourage a child from smoking while the tobacco companies remain free to spend billions of dollars on marketing campaigns that portray smoking as fun and glamorous. The FDA rule will help parents fight back by outlawing vending machines and banning "Joe Camel" and the "Marlboro Man" from magazines teenagers read.

Focusing On Children, While Preserving Adults' Right to Choose. The President's initiative recognizes that cigarettes are a legal product. Adults have the maturity to decide whether to smoke. Many good people farm tobacco and have the right to make a living. Cigarette companies have the right to market their products to adults. But the President's initiative draws the line on children because we have an obligation to protect them from influences that are stronger than they are. The initiative is narrowly tailored to limit only advertising that appeals to children. For example, color advertisements with images continue to be allowed in magazines that have only a limited youth readership.

Cigarettes and Smokeless Tobacco Are Nicotine Delivery Devices. The legal authority for the tobacco rule comes from FDA's determination that nicotine in cigarettes and smokeless tobacco is a "drug" and that cigarettes and smokeless tobacco are nicotine delivery "devices" under the Federal Food, Drug, and Cosmetic Act. An extensive FDA investigating found evidence from internal company documents that showed that the tobacco industry considers their products to be vehicles for delivering the addictive drug nicotine to consumers and that they "intend" to addict consumers.

KEY ELEMENTS OF RULE

Reducing Easy Access by Children

Children and adolescents continue to have easy access to tobacco products. In 13 studies reviewed by the Surgeon General, minors were successfully able to buy cigarettes 67 percent of the time. The FDA rule will:

- Require age verification and face-to-face sale (except for mail orders), and eliminate free samples, and the sale of single cigarettes and packages with fewer than 20 cigarettes.

- Ban vending machines and self-service displays except in facilities where only adults are permitted, such as certain nightclubs totally inaccessible to persons under 18.

Reducing Appeal to Children

The tobacco industry spending more than $6 billion annually on advertising. Children and adolescents are influenced by this advertising and promotion. One study found that 30 percent of 3-year-olds and 91 percent of 6-year-olds could identify "Joe Camel" as a symbol of smoking. Another study found that 86 percent of underage smokers who buy their own cigarettes purchase one of the three most heavily advertised brands. The FDA rule will:

- Ban outdoor advertising within 1,000 feet of schools and publicly-owned 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. Advertising inside "adult only" facilities like nightclubs can use color and imagery.

- 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. There are no restrictions on print advertising below these thresholds.

- Prohibit sale or giveaway of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos.

- Prohibit brand-name sponsorship of sporting (including teams and entries) or entertainment events, **but** permit it in the corporate name.

Educating Children About Real Dangers of Smoking

In addition to the rule and its provisions aimed at reducing access and appeal, the FDA will propose to require each of the six tobacco companies with significant sales to children to educate young people about the real health dangers associated with the use of tobacco products. This national multi-media campaign would be monitored for its effectiveness. The FDA will initiate the process under Section 518 of the Federal Food, Drug, and Cosmetic Act, which allows the FDA to require companies to notify consumers about the unreasonable health risks of their products. As part of this process, FDA will first consult with companies about the necessity and manner of the media campaign.

COMPARISON OF PROPOSED AND FINAL RULE

KEEPING TOBACCO AWAY FROM YOUNG PEOPLE

Proposed Rule	Final Rule
Minimum age of 18 to buy tobacco products	Same
Ban vending machines and self-service displays	Same EXCEPT in certain nightclubs and other "adult only" facilities totally inaccessible to persons under 18
Ban "kiddie" packs, "loosies," or free samples	Same
Ban mail-order sales	Mail-order sales permitted

REDUCING APPEAL OF TOBACCO PRODUCTS TO YOUNG PEOPLE

Proposed Rule	**Final Rule**
Ban billboards within 1,000 feet of schools and playgrounds	Same
Other billboards, outdoor and in-store advertising limited to black-and-white text only	Same EXCEPT color, imagery permitted in "adult only" facilities if not visible from outside and not removable
Advertising in publications with significant youth readership (more than 15% or 2 million) limited to black-and-white text only	Same
Ban brand-name sponsorship of sporting or other events; only corporate name sponsorship permitted	Same, but includes cars and teams
Ban brand names on hats, t-shirts, gym bags, etc.	Same

EDUCATING YOUNG PEOPLE ABOUT HEALTH RISKS OF TOBACCO

The proposed rule called for a $150 million annual fund, paid by tobacco manufacturers, to conduct a national educational campaign.

The FDA will pursue the goals of the educational effort proposed in August 1995 by using Section 518 of the Federal Food, Drug, and Cosmetic Act. Under the authority of this provision, the FDA will propose to require the six tobacco companies with a significant share of sales to children to educate young people about the health risks of using their products. This national campaign, including television spots, would be monitored for its effectiveness.

CHANGES FROM PROPOSED TO FINAL RULE -- FOCUSING ON CHILDREN

In reviewing the more than 95,000 individual comments received from the public during the comment period, the FDA made a number of changes aimed at more narrowly targeting the rule to its goal: reducing the use of tobacco products among children and adolescents under 18. Changes include:

- Vending machines and self-service displays will be allowed in facilities where only adults are permitted. By removing vending machines and self-service displays from sites accessible to children, the rule's goal will still be achieved, and the Agency will closely monitor the effectiveness of this provision for two years to determine if additional restrictions are necessary.

- Mail-order sales will be permitted. This provision will allow adults in rural or isolated areas to have access to these products. There was little evidence presented that children use mail order at the present time, but the Agency will monitor future trends.

- Advertising using color and imagery will be permitted in "adult only" facilities totally inaccessible to persons under 18, provided that the advertising is not visible from the outside and is not removeable.

Other changes were responsive to comments and aimed to more closeley tailor the rule to statutory provisions. These changes include:

- Some state and local laws that are different from, or in addition to, this rule will be preempted under this rule. However, the Agency is establishing an expedited process for state and local government to apply for waivers for more stringent laws or regulations. The FDA believes the requirements it is establishing set an appropriate floor but as a matter of policy, the Agency should leave open the possibility for state or local governments to adopt more restrictive requirements. State laws not related to the rule -- such as local bans on smoking in restaurants -- will not be affected.

- The final rule does not require that tobacco advertising include a brief statement of warnings. The agency has determined that the current Surgeon General's warnings serve the same function as the brief statements would have.

- The final rule expands the ban on brand name sponsorship of events to include a ban on brand name sponsorship of teams or other participants, such as placing the brand name on the car or driver's jacket.

- Rather than including an educational campaign in the regulation itself, the agency will propose to require manufacturers to carry out a notification program under section 518 of the act that would warn those under 18 of the unreasonable risk of substantial harm presented by these products. As part of this process, FDA will offer tobacco companies an opportunity to consult about the necessity and form of notification before it issues any notification orders.

LEGAL ISSUES RELATING TO FDA RULE

FDA Jurisdiction

FDA has concluded that cigarettes and smokeless tobacco are delivery devices for nicotine, a drug that causes addiction and other significant pharmacological effects. The Federal Food, Drug, and Cosmetic Act provides that a product is a drug or device if it is an article (other than food) "intended to affect the structure or any function of the body."

Nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body" because:
- nicotine in these products causes and sustains addiction;
- nicotine in these products causes other mood-altering effects, including tranquilization and stimulation;
- nicotine in these products controls body weight.

Manufacturers of cigarettes and smokeless tobacco "intend" these effects because:
- the addictive and pharmacological effects are so widely known and accepted. a reasonable manufacturer can foresee the products will be used by consumers for these effects:
- consumers use these products predominantly for pharmacological purposes;
- manufacturers know that nicotine in their products causes pharmacological effects and that consumers use their products primarily to obtain these effects;
- manufacturers of these products design the products to provide consumers with a pharmacologically active dose of nicotine; and
- an inevitable consequence of the design of these products to provide consumers with a pharmacologically active dose of nicotine is to sustain consumers' addiction to nicotine.

Rule Protects Appropriate Commercial Speech

The U.S. Supreme Court has upheld restrictions on commercial speech if certain standards are met. Given that selling cigarettes and smokeless tobacco to children under 18 is already illegal in every state, the rule is aimed at regulating commercial speech to ensure that an illegal activity is not promoted. Furthermore, the rule is narrowly tailored to meet the tests established by the U.S. Supreme Court.

- Protecting the health of children under 18 is a substantial government interest justifying restrictions on tobacco advertising that appeals to children;
- Advertising and promotion have been shown to play a material role in children beginning and continuing to use tobacco products, and therefore the regulations directly advance the government's interest; and
- Permitting unrestricted advertising in publications primarily read by adults and permitting companies to sponsor events in the corporate name -- instead of the brand identifications so appealing to young people -- are examples of how the rule is narrowly tailored to advance the government's interest.

A CHRONOLOGY OF THE RULE

February 25, 1994: The Food and Drug Administration (FDA), responding to a petition asking FDA to regulate low-tar and low-nicotine cigarettes, writes a letter to the Coalition on Smoking or Health stating that the Agency will consider the question of whether it has jurisdiction over nicotine-containing tobacco products.

March 25, 1994: Food and Drug Commissioner David A. Kessler, M.D., testifies before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce on FDA's preliminary evidence -- including industry patents and analyses of nicotine-to-tar ratios -- that cigarette companies control the levels of nicotine in a manner that creates and sustains addiction in the vast majority of smokers.

April 14, 1994: The Subcommittee on Health and the Environment of the House Committee on Energy and Commerce hears testimony from the chief executives of seven tobacco companies on the industry's views on nicotine addiction and on industry practices with regard to nicotine, and each executive denies that nicotine in tobacco products is addictive.

April 28, 1994: The Subcommittee on Health and the Environment of the House Committee on Energy and Commerce hears testimony from two former Philip Morris scientists, Victor DeNoble and Paul Mele, on their company-sponsored research establishing the addictive properties of nicotine.

June 21, 1994: Food and Drug Commissioner David A. Kessler, M.D., testifies before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce on evidence developed by the FDA of the cigarette industry's manipulation of nicotine, specifically one company's breeding of high nicotine levels in one strain of tobacco and the use of chemical compounds in cigarettes to enhance nicotine delivery to smokers.

August 2, 1994: FDA's Drug Abuse Advisory Committee holds a public hearing on the addictiveness of nicotine-containing tobacco products and concludes that products currently marketed contain nicotine at levels sufficient to create and sustain addiction in consumers.

August 10, 1995: President Clinton announces the proposed FDA rule to reduce the access and appeal of tobacco products to children and adolescents and his goal of reducing children's use of tobacco products by 50 percent within seven years of final Agency action. The rule is published the next day in the Federal Register and a public comment period begins.

January 2, 1996: The public comment period for the proposed FDA rule closes, with a total of more than 95,000 different comments -- more than 700,000 pieces of mail -- received.

January 18, 1996: The Department of Health and Human Services and the Substance Abuse and Mental Health Services Administration issue the final Synar Rule designed to ensure that states and territories adopt and enforce laws prohibiting the sale or distribution of tobacco products to children.

March 18, 1996: FDA re-opens the public comment period for the limited purpose of seeking comments on the statements of three former Philip Morris employees about that company's

manipulation of nicotine in the design and production of cigarettes and to seek comments on further explanations of certain provisions in the proposed rule.

April 19, 1996: The limited comment period closes.

August 23, 1996: The President unveils the final FDA rule to restrict access and reduce appeal of tobacco products for children and adolescents and FDA's proposal to mount a national mass-media campaign for young people on the dangers of tobacco use.

TOBACCO

Q: Why regulate tobacco?

A: Nicotine addiction is a pediatric disease. Every day, almost 3,000 young people become regular smokers; nearly 1,000 of them will ultimately die younger due to cancer, emphysema, heart disease and other diseases caused by smoking. Smoking kills more than 400,000 Americans per year -- more than AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined. More than 80% of adult smokers start smoking before their 18th birthdays. In fact, smokers almost always become addicted during their teenage years. And youth smoking is on the rise. In 1995, more than a third of high school seniors smoked cigarettes -- more than at any time since the 70s -- and close to 28% of tenth graders smoked as well.

Q: What is being announced Friday?

A: Friday, you will announce the culmination of over two and a half years' work by the FDA to complete a final rule to combat children's smoking. First, FDA investigated and studied for 18 months to develop a proposed rule. In August, 1995, you announced the promulgation of that proposed rule to curb access and appeal of tobacco to young people. Over the last year, the FDA reviewed comments, including more than 95,000 different comments totalling more than 700,000 pieces of mail, and considered various changes to the original proposal. FDA revised the rule in response to public comments and in an effort to make it more closely targeted to kids. Then OMB reviewed the rule for compliance with your priorities and various regulatory policies. Upon OMB's sign-off, the rule will be placed on display at the Federal Register on Friday and will be published next week.

Q: What does the final rule do?

The FDA rule reduces children's easy access to tobacco products by: requiring age verification by photo ID for anyone under 26 for anyone purchasing tobacco products; banning vending machines and self-service displays except in "adult" facilities where children are absolutely not allowed, such as certain nightclubs; banning free samples; banning the sale of single cigarettes and "kiddie packs" -- packs with fewer than 20 cigarettes.

The FDA rule limits the appeal of tobacco products to children by:

Prohibiting billboards within 1000 feet of schools and playgrounds. Other advertising is restricted to black-and-white text only; this includes all billboards, signs inside and outside of buses, and all ads in stores or at other points of sale. Ads inside "adult only" facilities like nightclubs are unrestricted if they cannot be seen from outside and are not removable.

Permitting only black-and-white text ads in publications with 15% or more, or 2 million or more, readers under 18. No restrictions on ads in other magazines.

Banning sale or giveaways of products like caps or gymbags that carry cigarette or smokeless tobacco product brand names or logos.

Banning brand-name sponsorship of sporting or entertainment events but permitting it in the corporate name.

Q: When does this rule go into effect?

A: The provisions will be phased in between six months and two years from the date of publication in the Federal Register in order to give businesses time to comply.

Q: What are the differences between the proposed rule and the final rule?

A: In reviewing the more than 95,000 different comments received from the public, the FDA made a number of changes aimed at more narrowly targeting the rule to the goal of reducing the use of tobacco by kids. Changes include:

Allowing vending machines and self-service displays and unrestricted advertising in facilities where only adults are permitted. By removing vending machines from places where kids can get to them, the rule's goal will be achieved without hindering adults in adult-only settings like certain nightclubs.

Mail orders will be permitted because there was little evidence presented that children use mail order at the present time, yet some adults in rural or isolated areas rely on mail order to have access to cigarettes.

Q: Didn't the proposal also have a requirement that the industry fund an education campaign and didn't you remove it from the final rule?

A: A different provision of FDA's statute, section 518(a), provides explicit authority to the FDA to require device manufacturers,which now include tobacco manufacturers, to notify people about a risk presented by use or misuse of their devices, when notification is needed to eliminate an unreasonable risk of harm. The FDA decided this is a more appropriate provision for it to use to achieve the goals of the educational campaign. Therefore, in addition to the rule that is going on display on Friday, the FDA also will propose to require tobacco companies to provide strong messages for children on the real dangers of smoking and using smokeless tobacco. This national media campaign could include television spots. The companies will be given an opportunity to consult with FDA about the necessity and form of the education campaign before the FDA issues any directives.

Q: What are the health benefits of the rule?

A: Health care costs associated with smoking are rising. The CDC 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 in home health care expenditures.

Q: In taking this action are you or the FDA declaring tobacco to be a drug?

A: FDA's regulation is based on its conclusion that cigarettes and smokeless tobacco are drug delivery devices for the highly addictive drug nicotine.

Q: Is the FDA saying the tobacco companies are trying to addict people?

A: FDA found that nicotine is addictive, and that manufacturers legally intend this effect because they design these products to provide a pharmacologically active dose of nicotine and an clear consequence is to sustain consumers' addiction to nicotine.

Q: Is the FDA saying that the tobacco companies intentionally target children?

A: The FDA did not go into the question of whether the companies intentionally target children. They did, however, find significant evidence that advertising plays an important role in young people's decisions to use tobacco. For example, almost 90% of young smokers choose the three most heavily advertised brands.

Q: Isn't this censorship in violation of the First Amendment?

A: The Department of Justice is confident that this rule is consistent with recent Supreme Court rulings. The sale of tobacco to children is illegal, so if the advertising is related to illegal sales to children, it is constitutional to limit it. Plus, the FDA put the rule together so it is very narrowly tailored to get just at kids smoking -- that's why vending machines are only banned in places kids can get to, but not in places like certain bars where you can't get in without an ID card that says you're 18.

Q: If tobacco is so bad for people, why not just ban it altogether?

A: A prevention strategy aimed at kids is the most effective approach. The regulation will reduce the tobacco available to kids, while allowing it to be available to adults users, who typically are already addicted. We have learned from the alcohol prohibition experience, that a ban will not eliminate the tobacco use of addicted adults; it will lead to a black market, with perhaps even higher health risks for people.

Q: Now that the rule is out, will you support legislation?

A: For over a year, I've said that I'd support legislation as comprehensive as the FDA's proposals -- it would be better than the prospect of a lot of litigation. I still believe that and would welcome Congressional action to enact what we've been able to do through executive action with the FDA rule.

Q: What is the impact on tobacco growers?

A: The effect on tobacco farmers is expected to be extremely gradual, at most a 4% change in tobacco sales in 10 years. Tobacco will remain a legal crop and millions of adults will continue to use these products. Many tobacco farmers are looking at diversifying and several states have programs aimed at helping them do this. We can all surely agree that no one wants to make money from smoking by our kids.

Q: The FDA has been criticized for being slow on getting new drugs on the market. Will this new initiative take away even more of its resources and make the drug approval process slower?

A: FDA is actually a world leader in both the speed and quality of drug approvals. Much of the regulation, such as review of tobacco advertising, can be done with current agency resources. There may be some small resource needs, but they are justified by the fact that every year another million young people become regular smokers, and a third of them will die because of it.

Q: How will the FDA enforce these regulations?

A: The regulations set some bright line standards. These provisions are virtually self-enforcing because it is clear where vending machines are allowed and where billboards are prohibited. We will work in partnership with states and localities. And, a violation of these rules is a violation of the Food Drug and Cosmetic Act and will be enforced accordingly.

Q: Did the White House have a lot of changes to the FDA's proposed draft final rule?

A: No. There were a handful of technical changes suggested by the regulatory review staff at OMB. But basically, Dr. Kessler and the FDA are the experts and spent over a year reading and responding to comments, and making changes to tighten the rule and make it more targeted to kids, and I think they hit it right on.

Q: How could the rule be finished so fast...did you rush it because of the Convention coming up?

A: There was nothing fast about it. The FDA took 18 months to develop the proposed rule that I announced a year ago, based on intense investigation and study. Then they took another year to read through the 95,000 different comments totaling more than 700,000 pieces of mail, and to respond to those comments and make changes based on them. And, as you can see, they gave those comments serious attention and tightened up the rule to make it more targeted to kids. With 3000 young people taking up smoking every day, it was important that the FDA make this a high priority -- but they certainly gave the rule thorough consideration.

Q: Will anything really happen here? Aren't you going to be tied up in lawsuits for years?

A: Well, that depends on the tobacco industry. And they've filed the suits last year. But I would hope they might come around and we have reason to believe they will since they have acknowledged the problem. This is all about our kids and their futures, and whether another million kids each year are going to become hooked and a third of them will have their lives shortened.

Q: You announced this rule on the eve of this Convention...and various receptions at your Convention will be underwritten by tobacco companies? How is that consistent with your policies?

A: The real question is who is doing the right thing when it comes to our kids. My administration was the first to seriously take on the issue of children smoking. Every day nearly 3,000 of our young people start smoking and that will shorten the lives of almost 1,000 of them. Everyone from parents to teachers to community leaders to the federal government needs to do their part to end this tragedy. What I've been critical of is the apparent impact the tobacco industry's contributions have had on the Republican's policy decisions. We have had real opposition by Senator Dole to this initiative. The Washington Post reported recently that 85% of tobacco industry money has gone to the Republicans. You can judge for yourself whether contributions have had anything to do with our opposing policy positions.

Q: How does your trade policy mesh with this tobacco rule?

A: My administration changed the trade policy process so that HHS is now involved in cigarette trade policy discussions. And, because of that, we have a policy where if another country wants to enact legitimate health measures to protect its citizens -- like measures to keep tobacco away from kids -- we respect that. In fact,. we applaud other nations' efforts and we are working with them to address kids' smoking and would support stronger efforts around the world to protect kids from tobacco addiction.

So, while in general, our policy is to insist that U.S. products not be discriminated against, my administration is the first to say this should not undermine other countries legitimate health policies.

Q. What is the relationship between smoking and illicit drug use?

A. Studies show that underage smokers are more likely than non-smokers to use illicit drugs, although most young smokers do not use illegal substances. A causal link between smoking and illicit drug use has not been established.

We are very concerned too many young Americans are engaged in a whole range of risky behaviors, including the use of tobacco and illicit drugs. We have powerful, comprehensive strategies for preventing each of these behaviors.

Q. But a lot of people are calling tobacco a "gateway drug." They're citing studies that say if you've smoked cigarettes as a child, you're much more likely to develop an addictive problem later in life. Do you believe that tobacco use by children is a gateway to illicit drugs?

A. Scientific evidence has not established that tobacco is a gateway drug. We do know that a significant portion of young people who use tobacco also use illicit drugs. That's why we're working aggressively to educate youth about why they should not use tobacco or illicit drugs.

Q. Why is the Administration focusing on nicotine when illegal drug use is causing more serious problems in this country?

A. This Administration has been fighting hard against illegal drug use. At the same time, we cannot ignore the fact that smoking is the leading cause of preventable death in this country, that 3000 children become regular smokers each day, and that 1000 lives will be shortened as a result. We must focus on both. This is not an either/or situation.

Q: Earlier this week your Administration announced that illegal drug use among teens is rising. Is this initiative the Administration's answer to rising drug use among teenagers? Is this announcement politically timed to deflect criticism about rising illegal drug use?

A: No. The reason for this initiative is the public health tragedy of children's tobacco use. The Administration proposed the tobacco rule a year ago. The final rule just completed the OMB review process and is ready, so we are announcing it today. Remember, 3,000 young people a day become regular smokers. We can't afford to waste even one day in addressing this tragedy.

But make no mistake, we are deeply concerned about the rise in youth drug use. That's why the top priority of the National Drug Control Strategy is to reduce drug

and substance abuse among youth. Over the last four years the we have expanded youth drug prevention programs and fought Republican efforts to gut these programs. In the1996 State of the Union address, I challenged parents to talk openly and firmly to their children about the harm of drugs. Our drug control strategy is comprehensive: we're working with parents, schools, communities, religious organizations, businesses, the media and entertainment industries, state and local government, and young people themselves to make sure that America's youth hear a powerful and consistent anti-drug message.

NASCAR

Q: What will be the impact on NASCAR?

A: The tobacco industry accounts for an estimated 8 percent of NASCAR's sponsorship revenues and about 1.5 percent of their total revenue. Most industry observers believe that major events, such as the Winston Cup, will have no trouble attracting replacement sponsors. In recent years, auto racing has expanded beyond its traditional motor oil, beer, and tobacco sponsorship base and acquired mainstream consumer product sponsors such as Tide, Kellogg's, and McDonald's. Smaller or lower profile events will experience some shortfalls, but this impact will be mitigated by the rapidly expanding popularity of motor sports.

Q: Why has FDA decided to expand its ban on brand name sponsored events to include teams and entries?

A: The agency is persuaded that sponsored teams and entries, such as cars and race car drivers, create the same problems for young people as do tobacco sponsored events. Specifically, the use of brand imagery on cars and race drivers creates the same association between tobacco and sports figures and heroes, and it creates the same linkage between an enjoyable event and tobacco use. Moreover, the cars and race drivers are seen for an extended period of time during the event and can even leave the event and be seen at fairs and malls.

Q: What evidence is there that race cars, sporting and other events sponsored by tobacco companies in the name of one of their brands cause kids to start using tobacco?

A: Studies found that these types of event are attended by, and seen on TV by, large numbers of young people and that their effect is to increase brand awareness, to create an association between the product and the event, and to create a sense of "friendly familiarity" about tobacco and tobacco use. The events associate tobacco products with exciting and risky events, and with sports heros, for example. Even the tobacco industry in its Advertising Code recognized the problems of hero worship and emulation caused by sports figures' endorsements and banned them. The same concerns exist with the emblazoning of brand names and logos over sports uniforms and race cars.

Q: What will be the economic impact of your regulation?

A: This nation spends about $50 billion annually on health care costs associated with smoking-related diseases and this rule will work to diminish that toll. Conservative estimates of the economic consequences of achieving the FDA goal of cutting the rate of teenage smoking by one-half generate health benefits valued at from $28 to $43 billion per year. Moreover, even if the rule were to halt the onset of smoking for just 5 percent of new smokers, the annual benefits measure about $3 to $4 billion.

The total cost of achieving this goal is about $180 million in one-time costs and $165 million in annual operating costs. Manufacturers and retailers of tobacco products will incur most of the burden. Manufacturers will incur one-time compliance costs of about $85 million, primarily for removing prohibited retail promotional items and self service displays and for changing package labels. Retailers face one-time costs of about $96 million and annual costs of about $78 million for removing self-service displays, checking customer I.D.s, and training sales employees.

The effect on individual retail establishments will be small. For small retail convenience stores not currently complying with the provisions of the final regulation, the additional first year costs total about $400. For those stores that already verify the age of young customers, the costs fall to $137. Consumer expenditures on tobacco products will decline over time, but dollars not spent on tobacco-related items will be spent on other goods or services. Thus, the overall employment impact on the national economy will be small. In sum, the health-related benefits of the rule far outweigh its potential costs.

Q: What is the expected effect on tobacco prices?

A: The near-term effect of the regulation on tobacco prices will not be perceptible, only about one-half cent per pack of cigarettes.

Q: Will your rule have exemptions for small business?

A: Specific exemptions based solely on business size are not provided because children could use such opportunities to obtain tobacco products.

Q: What will be the impact on tobacco growers?

A: The effect on tobacco farmers will be gradual, because the rule is expected to reduce tobacco consumption by only about one-half of a percent after the first year, two percent by the fifth year, and four percent by the tenth year. Employment losses for tobacco growers are projected to total less than 2,500 by the tenth year, or an average of 250 jobs per year over the 10-year period.

Q: What will be the impact on advertisers?

A: Tobacco manufacturers reported 1993 promotional/advertising expenditures of over $6 billion. Over 43 percent went to consumers as financial incentives to induce further sales (e.g., coupons, cents-off, buy-one-get-one free, free samples), and over 26 percent to retailers to promote the sale of their products. The remaining 31 percent was directed to the consumer advertising activities that will be affected by the "text only" restrictions. FDA cannot project the ultimate industry response to these restrictions, as some tobacco advertising outlays will fall and others rise. For example, publications with a large youth readership may lose advertising revenues, while publications without a large youth readership may gain revenues. Past performance, however, indicates that the tobacco

industry is unlikely to curtail creative promotional activities.

Q: Isn't FDA duplicating state efforts to limit youth access with these restrictions?

A: No. Although the sale of tobacco products to minors is illegal in 50 States, and some States and localities have adopted a variety of other restrictions, the tobacco industry engages in extensive marketing campaigns which appeal to children and adolescents. This rule puts restrictions in place that would both complement the existing state restrictions on access and reduce demand by preventing tobacco companies from marketing their products to children and adolescents.

TOBACCO

Q: Why regulate tobacco?

A: Nicotine addiction is a pediatric disease. Every day, almost 3,000 young people become regular smokers; nearly 1,000 of them will ultimately die younger due to cancer, emphysema, heart disease and other diseases caused by smoking. Smoking kills more than 400,000 Americans per year -- more than AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined. More than 80% of adult smokers start smoking before their 18th birthdays. In fact, smokers almost always become addicted during their teenage years. And youth smoking is on the rise. In 1995, more than a third of high school seniors smoked cigarettes -- more than at any time since the 70s -- and close to 28% of tenth graders smoked as well.

Q: What is being announced Friday?

A: Friday, you will announce the culmination of over two and a half years' work by the FDA to complete a final rule to combat children's smoking. First, FDA investigated and studied for 18 months to develop a proposed rule. In August, 1995, you announced the promulgation of that proposed rule to curb access and appeal of tobacco to young people. Over the last year, the FDA reviewed comments, including more than 95,000 different comments totalling more than 700,000 pieces of mail, and considered various changes to the original proposal. FDA revised the rule in response to public comments and in an effort to make it more closely targeted to kids. Then OMB reviewed the rule for compliance with your priorities and various regulatory policies. Upon OMB's sign-off, the rule will be placed on display at the Federal Register on Friday and will be published next week.

Q: What does the final rule do?

The FDA rule reduces children's easy access to tobacco products by: requiring age verification by photo ID for anyone under 26 for anyone purchasing tobacco products; banning vending machines and self-service displays except in "adult" facilities where children are absolutely not allowed, such as certain nightclubs; banning free samples; banning the sale of single cigarettes and "kiddie packs" -- packs with fewer than 20 cigarettes.

The FDA rule limits the appeal of tobacco products to children by:

Prohibiting billboards within 1000 feet of schools and playgrounds. Other advertising is restricted to black-and-white text only; this includes all billboards, signs inside and outside of buses, and all ads in stores or at other points of sale. Ads inside "adult only" facilities like nightclubs are unrestricted if they cannot be seen from outside and are not removable.

Permitting only black-and-white text ads in publications with 15% or more, or 2 million or more, readers under 18. No restrictions on ads in other magazines.

Banning sale or giveaways of products like caps or gymbags that carry cigarette or smokeless tobacco product brand names or logos.

Banning brand-name sponsorship of sporting or entertainment events but permitting it in the corporate name.

Q: When does this rule go into effect?

A: The provisions will be phased in between six months and two years from the date of publication in the Federal Register in order to give businesses time to comply.

Q: What are the differences between the proposed rule and the final rule?

A: In reviewing the more than 95,000 different comments received from the public, the FDA made a number of changes aimed at more narrowly targeting the rule to the goal of reducing the use of tobacco by kids. Changes include:

Allowing vending machines and self-service displays and unrestricted advertising in facilities where only adults are permitted. By removing vending machines from places where kids can get to them, the rule's goal will be achieved without hindering adults in adult-only settings like certain nightclubs.

Mail orders will be permitted because there was little evidence presented that children use mail order at the present time, yet some adults in rural or isolated areas rely on mail order to have access to cigarettes.

Q: Didn't the proposal also have a requirement that the industry fund an education campaign and didn't you remove it from the final rule?

A: A different provision of FDA's statute, section 518(a), provides explicit authority to the FDA to require device manufacturers,which now include tobacco manufacturers, to notify people about a risk presented by use or misuse of their devices, when notification is needed to eliminate an unreasonable risk of harm. The FDA decided this is a more appropriate provision for it to use to achieve the goals of the educational campaign. Therefore, in addition to the rule that is going on display on Friday, the FDA also will propose to require tobacco companies to provide strong messages for children on the real dangers of smoking and using smokeless tobacco. This national media campaign could include television spots. The companies will be given an opportunity to consult with FDA about the necessity and form of the education campaign before the FDA issues any directives.

Q: What are the health benefits of the rule?

A: Health care costs associated with smoking are rising. The CDC 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 in home health care expenditures.

Q: In taking this action are you or the FDA declaring tobacco to be a drug?

A: FDA's regulation is based on its conclusion that cigarettes and smokeless tobacco are drug delivery devices for the highly addictive drug nicotine.

Q: Is the FDA saying the tobacco companies are trying to addict people?

A: FDA found that nicotine is addictive, and that manufacturers legally intend this effect because they design these products to provide a pharmacologically active dose of nicotine and an clear consequence is to sustain consumers' addiction to nicotine.

Q: Is the FDA saying that the tobacco companies intentionally target children?

A: The FDA did not go into the question of whether the companies intentionally target children. They did, however, find significant evidence that advertising plays an important role in young people's decisions to use tobacco. For example, almost 90% of young smokers choose the three most heavily advertised brands.

Q: Isn't this censorship in violation of the First Amendment?

A: The Department of Justice is confident that this rule is consistent with recent Supreme Court rulings. The sale of tobacco to children is illegal, so if the advertising is related to illegal sales to children, it is constitutional to limit it. Plus, the FDA put the rule together so it is very narrowly tailored to get just at kids smoking -- that's why vending machines are only banned in places kids can get to, but not in places like certain bars where you can't get in without an ID card that says you're 18.

Q: If tobacco is so bad for people, why not just ban it altogether?

A: A prevention strategy aimed at kids is the most effective approach. The regulation will reduce the tobacco available to kids, while allowing it to be available to adults users, who typically are already addicted. We have learned from the alcohol prohibition experience, that a ban will not eliminate the tobacco use of addicted adults; it will lead to a black market, with perhaps even higher health risks for people.

Q: Now that the rule is out, will you support legislation?

A: For over a year, I've said that I'd support legislation as comprehensive as the FDA's proposals -- it would be better than the prospect of a lot of litigation. I still believe that and would welcome Congressional action to enact what we've been able to do through executive action with the FDA rule.

Q: What is the impact on tobacco growers?

A: The effect on tobacco farmers is expected to be extremely gradual, at most a 4% change in tobacco sales in 10 years. Tobacco will remain a legal crop and millions of adults will continue to use these products. Many tobacco farmers are looking at diversifying and several states have programs aimed at helping them do this. We can all surely agree that no one wants to make money from smoking by our kids.

Q: The FDA has been criticized for being slow on getting new drugs on the market. Will this new initiative take away even more of its resources and make the drug approval process slower?

A: FDA is actually a world leader in both the speed and quality of drug approvals. Much of the regulation, such as review of tobacco advertising, can be done with current agency resources. There may be some small resource needs, but they are justified by the fact that every year another million young people become regular smokers, and a third of them will die because of it.

Q: How will the FDA enforce these regulations?

A: The regulations set some bright line standards. These provisions are virtually self-enforcing because it is clear where vending machines are allowed and where billboards are prohibited. We will work in partnership with states and localities. And, a violation of these rules is a violation of the Food Drug and Cosmetic Act and will be enforced accordingly.

Q: Did the White House have a lot of changes to the FDA's proposed draft final rule?

A: No. There were a handful of technical changes suggested by the regulatory review staff at OMB. But basically, Dr. Kessler and the FDA are the experts and spent over a year reading and responding to comments, and making changes to tighten the rule and make it more targeted to kids, and I think they hit it right on.

Q: How could the rule be finished so fast...did you rush it because of the Convention coming up?

A: There was nothing fast about it. The FDA took 18 months to develop the proposed rule that I announced a year ago, based on intense investigation and study. Then they took another year to read through the 95,000 different comments totaling more than 700,000 pieces of mail, and to respond to those comments and make changes based on them. And, as you can see, they gave those comments serious attention and tightened up the rule to make it more targeted to kids. With 3000 young people taking up smoking every day, it was important that the FDA make this a high priority -- but they certainly gave the rule thorough consideration.

Q: Will anything really happen here? Aren't you going to be tied up in lawsuits for years?

A: Well, that depends on the tobacco industry. And they've filed the suits last year. But I would hope they might come around and we have reason to believe they will since they have acknowledged the problem. This is all about our kids and their futures, and whether another million kids each year are going to become hooked and a third of them will have their lives shortened.

Q: You announced this rule on the eve of this Convention...and various receptions at your Convention will be underwritten by tobacco companies? How is that consistent with your policies?

A: The real question is who is doing the right thing when it comes to our kids. My administration was the first to seriously take on the issue of children smoking. Every day nearly 3,000 of our young people start smoking and that will shorten the lives of almost 1,000 of them. Everyone from parents to teachers to community leaders to the federal government needs to do their part to end this tragedy. What I've been critical of is the apparent impact the tobacco industry's contributions have had on the Republican's policy decisions. We have had real opposition by Senator Dole to this initiative. The Washington Post reported recently that 85% of tobacco industry money has gone to the Republicans. You can judge for yourself whether contributions have had anything to do with our opposing policy positions.

Q: How does your trade policy mesh with this tobacco rule?

A: My administration changed the trade policy process so that HHS is now involved in cigarette trade policy discussions. And, because of that, we have a policy where if another country wants to enact legitimate health measures to protect its citizens -- like measures to keep tobacco away from kids -- we respect that. In fact,. we applaud other nations' efforts and we are working with them to address kids' smoking and would support stronger efforts around the world to protect kids from tobacco addiction.

So, while in general, our policy is to insist that U.S. products not be discriminated against, my administration is the first to say this should not undermine other countries legitimate health policies.

Q. What is the relationship between smoking and illicit drug use?

A. Studies show that underage smokers are more likely than non-smokers to use illicit drugs, although most young smokers do not use illegal substances. A causal link between smoking and illicit drug use has not been established.

We are very concerned too many young Americans are engaged in a whole range of risky behaviors, including the use of tobacco and illicit drugs. We have powerful, comprehensive strategies for preventing each of these behaviors.

Q. But a lot of people are calling tobacco a "gateway drug." They're citing studies that say if you've smoked cigarettes as a child, you're much more likely to develop an addictive problem later in life. Do you believe that tobacco use by children is a gateway to illicit drugs?

A. Scientific evidence has not established that tobacco is a gateway drug. We do know that a significant portion of young people who use tobacco also use illicit drugs. That's why we're working aggressively to educate youth about why they should not use tobacco or illicit drugs.

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and substance abuse among youth. Over the last four years the we have expanded youth drug prevention programs and fought Republican efforts to gut these programs. In the1996 State of the Union address, I challenged parents to talk openly and firmly to their children about the harm of drugs. Our drug control strategy is comprehensive: we're working with parents, schools, communities, religious organizations, businesses, the media and entertainment industries, state and local government, and young people themselves to make sure that America's youth hear a powerful and consistent anti-drug message.

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

August 23, 1996

CHILDREN'S FUTURE AT RISK
FROM EPIDEMIC OF TOBACCO USE

President Clinton's initiative to reduce tobacco use by children is the result of an investigation by the Food and Drug Administration into industry practices and an extensive review of successful measures in preventing children from using tobacco products. After the proposed rule was published on August 11, 1995, the public was invited to comment until January 2, 1996. The Agency received more than 95,000 different comments, totaling more than 700,000 pieces of mail. The subsequent review and analysis of those comments, as well as the Agency's initial work, provide a solid base for the FDA's measures to reduce access and limit appeal of tobacco products for children.

Today, an estimated 4.5 million children and adolescents smoke in the United States, and another 1 million use smokeless tobacco. Each year, another 1 million young people join the ranks of regular smokers, and nearly one out of every three young people who smoke will have their lives shortened from the terrible diseases caused by smoking.

This public health crisis is worsening. Children are starting to smoke at younger and younger ages: Today, the average teenage smoker begins to smoke at 14 1/2 years old and becomes a daily smoker before age 18. And those children soon regret this loss of

freedom. The Gallup Poll in 1992 found that 70 percent of smokers between the ages of 12 and 17 regret beginning to smoke and 66 percent want to quit.

Children at Risk

Children are becoming addicted to nicotine. 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. 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. Of the almost 3,000 young people who become regular smokers each day, nearly 1,000 of them will have their lives shortened from tobacco-related diseases.

Costs of Smoking Staggering

Health care costs associated with tobacco use are rising. The Centers for Disease Control and Prevention estimated that in 1993 the health care costs associated with smoking totaled $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 1expenditures. The Office of Technology Assessment calculated the social costs attributable to smoking in 1990 at $68 billion. The calculation was based on $20.8 billion in direct health care costs and $6.9 billion in lost productivity from

sickness and disabilities and $40.3 billion in lost productivity from premature deaths.

Benefits Outweigh Costs

Protecting the future health of our children provides a benefit that will continue to pay dividends for our society. The annual benefits from reduced disease caused by smoking are projected to be $28 to $43 billion. These benefits are achieved through annual net medical cost savings of $2.6 billion, annual morbidity-related productivity savings of $900 million, and annual benefits of reduced mortality of $24.6 to $39.7 billion. Under the final rule, manufacturers of tobacco products are projected to have one-time costs of $78 to $91 million and annual operating costs of $2 million. Retailers are projected to have one-time costs of $96 million and annual costs of $78 million, compared to the $45 billion to $50 billion spent annually on tobacco products at the retail level.

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