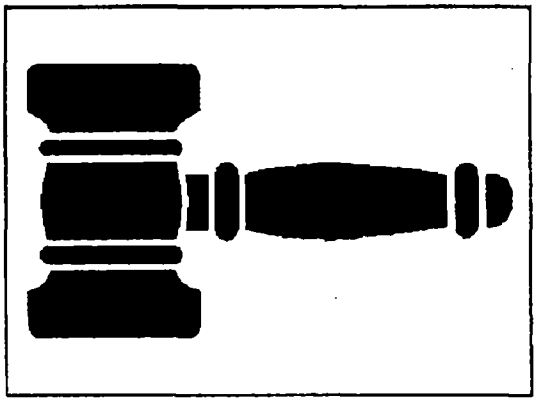
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL

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

DATE: February 12, 1997



TO: **ELIZABETH DRYE**
fax: 456-7028

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

COMMENTS: This is the draft I sent to Jen. I don't know what she did w/it or the extent to which she used it to kraft her exit memo on this issue.

No. of Pages (including cover): 6

DRAFT

November __, 1996

MEMORANDUM

TO:

FROM:

SUBJECT: **Status of Issues Related to the Children's Tobacco Initiative**

Immediately after the President's August 10, 1995 announcement that FDA was proposing regulations to protect children from tobacco, the Administration established a tobacco working group. The focus of this group has been to assure that the FDA regulatory process proceeds in an orderly manner and in full compliance with the law and to minimize the obstacles in the way of this objective. In doing so, the group has worked with Congress and monitored its activities, coordinated events for the President, the Vice President, Secretary Shalala, and other senior Administration officials, ensured that Administration officials delivered a consistent message, and reviewed all tobacco-related activities and speeches to assure their legal propriety.

The working group continues to manage the Administration's tobacco initiative, with its chief focus now being on the implementation of the FDA regulations, as well as helping to guide the Administration on other tobacco-related measures. This memorandum will briefly describe the status of the tobacco initiative as well as other significant tobacco-related issues that could effect it.

I. FDA REGULATIONS

After receiving over 700,000 public comments, FDA, on August 28, 1996, published in the Federal Register its final rule: "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." Apart from the rule, which is aimed at reducing access to and limiting the appeal of tobacco to children, FDA has proposed to require that the tobacco companies with significant youth sales fund a national mass media campaign to educate children about the

DRAFT

health risks of tobacco use.

A. Implementation

The majority of the provisions of the Regulations will become effective one year after the publication of the final, August 28, 1997. The prohibition on the sale of tobacco products to persons under age 18 and the requirement that retailers check photo identifications become effective six months after publication, February 28, 1997. The sponsorship prohibition becomes effective two years after publication, August 28, 1998.

FDA is currently working on an implementation plan and determining its budget needs to carry out that plan. With regard to the media campaign, FDA expects officially to inform the tobacco companies of the need for the notification program sometime in the spring of 1997.

B. Litigation

Immediately after FDA issued the proposed tobacco rule in August 1995, four sets of plaintiffs, including manufacturers of cigarettes and smokeless tobacco, the American Advertising Federation, and the National Association of Convenience Stores each sued to enjoin the FDA regulations from taking effect. The suits, which have been consolidated, are being heard by District Judge William Osteen in the United States District Court for the Middle District of North Carolina. In October, the government filed motions to dismiss primarily on the ground that there was no final agency action that was ripe for judicial review. The FDA final regulations were issued before Osteen was forced to decide whether to grant plaintiffs injunctive relief.

After the President announced that FDA was publishing the final rule, Judge Osteen set up a briefing schedule. Pursuant to this schedule, plaintiffs filed their motions for summary judgment on October 15. The motions are based on three principal grounds: (1) Congress has withheld from FDA the authority to regulate tobacco; (2) the Food, Drug, and Cosmetic Act does not authorize FDA to regulate tobacco; and (3) the First Amendment free speech protections prohibit the restrictions. The government's response is due on December 2, and oral argument, if needed, is scheduled for February 10, 1997 in Greensboro. Among others, the states of Kentucky, North Carolina, and Virginia have joined plaintiffs as *amicus curiae*.

We anticipate a ruling some time in March of 1997.

II. OTHER ADMINISTRATION TOBACCO-RELATED INITIATIVES AND ISSUES

A. HHS

DRAFT

The Synar Regulation. In January 1996, HHS and its Substance Abuse and Mental Health Services Administration (SAMHSA) issued regulations to implement the 1992 Synar Amendment, named for its author the late Congressman Mike Synar. In addition to requiring states to have in effect laws prohibiting the sale of tobacco products to minors, the regulation requires the states to enforce those laws in a manner designed to achieve a sales violation target rate of no more than 20 percent. Failure to do so results in the states loss of their substance abuse block grants. Pursuant to the regulations, the states are currently working with HHS on establishing strategies to achieve their 20 percent goals.

B. Labor

OSHA Regulations. In 1994, the Occupational Safety and Health Administration proposed regulations that would require designated smoking areas in all workplaces and prohibit smoking elsewhere. Unlike the FDA regulations which are aimed at preventing children from ever smoking, the OSHA proposed regulations are designed to reduce secondhand smoke. OSHA, which has received more than 100,000 comments, is still reviewing the proposal. Several vocal tobacco control advocates have criticized the Administration for the delay, arguing that this would be the most effective tobacco control effort the government could take.

C. USTR

Tobacco trade policy. USTR and HHS are in the process of completing an HHS/USTR task force report that reconciles the Administration's free trade and public health policies. The *Washington Post* last week published a four part series highlighting the efforts of the federal government (primarily during the Reagan and Bush Administrations) to promote tobacco products abroad and, in doing so, to oppose foreign countries' public health initiatives that would keep U.S. tobacco out. USTR's current policy is that it will not raise any objections to foreign countries imposing health-related restrictions on tobacco, as long as the restrictions are applied equally to both domestic and foreign products.

III. LEGISLATION

Since FDA issued the proposed rule in August, 1995, certain members of Congress and, in one case, tobacco manufactures have proposed legislative compromises that they claim would reduce children's tobacco use. Invariably, these proposals have expressly prohibited FDA from having jurisdiction over tobacco. For example, Rep. Scotty Baesler (D-KY), Rep. Jon Fox (R-PA) and Sen. Wendell Ford (D-KY) introduced bills that would have

implemented some of the provisions found in FDA regulations, but would have expressly prohibited FDA from regulating tobacco products. Some bills dealt with narrow issues related to the FDA regulations. For example, Rep. Funderburk (R-NC) and Senator Helms (R-NC) introduced legislation to deny FDA authority to regulate sponsorship of NASCAR events; Senator Burns (R-MT) sponsored a bill to deny FDA authority to regulate rodeo sponsorships.

Other bills were proposed by private groups, but received significant attention. In May, 1996, Philip Morris and the U.S. Tobacco Company proposed legislation that contained numerous restrictions on tobacco advertising, but as written would not have significantly reduced the appeal of tobacco to children and would have taken jurisdiction away from FDA.

The week following the issuance of the final FDA rule, the *Wall Street Journal* reported that Trent Lott might support a plan whereby the provisions of the FDA rule would become law, the industry would settle all its litigation, and the FDA would relinquish jurisdiction.

No action was taken on these or any tobacco-related legislative proposal. In the Senate, the Chair of the Labor and Human Relations Committee, Senator Nancy Kassebaum (R-KS) felt that the Committee had more pressing business such as FDA reform, health insurance reform, and several other high profile issues. In the House, Rep. Thomas Bliley (R-VA), who chairs the Commerce Committee, decided not to hold hearings, choosing instead to wait for the court to resolve the issue. Although the President said he would prefer a legislative solution to the problem and, in some cases, he applauded the efforts made on behalf of the proposals, he consistently and publicly stated that all of these proposals fell short of what he would accept.

Some Members proposed legislation to enhance federal tobacco control efforts. For example, Rep. McHale (D-PA) and Senator Harkin (D-IA) introduced nearly identical bills that would have disallowed federal tax deductions for the advertising expenses of tobacco products; Rep. Meehan (D-MA) proposed legislation regulating permissible amounts of nicotine in tobacco products; Senator Lautenberg (D-NJ) offered a bill to allow states to retain a greater proportion of court awards from tobacco companies for Medicaid expenses.

Most of the legislative activity during the 104th Congress centered around different letters of support or opposition to the proposed FDA regulations. In December 1995, Senator Ford sponsored a letter strongly opposing the proposed regulations and some 30 Senators co-signed the letter. On the other side of the issue, Rep. Waxman (D-CA), Rep. Hansen (R-UT) and Rep. Durbin (D-IL) found nearly 100 fellow Members of the House to co-sign a

DRAFT

pledge of support for the FDA proposed regulations.

IV. GRASSROOTS ACTIVITIES

When the President announced the FDA's proposed rule in August 1995, more than one hundred organizations, led by the American Medical Association, the American Heart Association, the American Cancer Society, and the American Lung Association and funded primarily by the Robert Wood Johnson Foundation, created the Campaign for Tobacco-Free Kids, to galvanize grassroots support specifically for the FDA regulation. Last spring these same groups established the National Center for Tobacco-Free Kids as a permanent, non-partisan, national organization. The Campaign continues to exist as the "public action arm" of the Center. The Center works with health, education, and community organizations and private industry to: disseminate information and develop media campaigns and events; provide assistance to state and community-level tobacco control programs; conduct outreach to broaden the base of organizations involved; coordinate with federal, state and local governments; and engage in public policy advocacy.

HHS and White House officials recently met the heads of the Center to discuss next steps. Their primary message was that the Administration not lose the momentum it had gained as a result of issuing the FDA regulations and that it not support legislation that would take jurisdiction over tobacco away from FDA.

V. STATE LAWSUITS

To date, 17 states (16 by the states' attorneys general and one, Alabama, by the Lt. Governor) have filed suits against the tobacco industry to recover Medicaid costs related for treatment of tobacco-related illnesses. These states include: Alabama, Arizona, Connecticut, Florida, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, Oklahoma, Texas, Utah, Washington, and West Virginia. Iowa's Attorney General and Governor will announce on Wednesday, November 27 that they will bring a suit. Two counties in California, Los Angeles and California, have brought suits for non-Medicaid costs for treating indigent patients.

Elizabeth Drye
Env. Policy Consult.

Post-it® Fax Note 7671 | Date | # of pages ▶
To Nikki | From Gail
Co./Dept. | Co.
Phone # | Phone #
Fax # | Fax #

Winston-Salem Journal 3/7/97

N.C. panel OKs tougher rules on selling cigarettes to teens

By David Rice
JOURNAL RALEIGH BUREAU

RALEIGH — In an effort to beat federal officials at their own game, a panel of state senators endorsed a proposal yesterday that carries harsher penalties than the U.S. Food and Drug Administration has enacted for selling tobacco products to teen-agers.

But some senators objected, saying that the rules would make unfair demands on low-paid store clerks to make sure that every buyer of cigarettes is 18. Others questioned whether the exercise is a charade because police are unlikely to enforce laws on the sale of cigarettes when they have homicides, gangs and drugs to worry about.

GENERAL ASSEMBLY

The proposal from N.C. Attorney General Mike Easley would remove the word "knowingly" from a state law that forbids knowingly selling cigarettes to someone under 18. It would require store clerks to ask for photo identification before selling to-

See PROPOSAL, Page A8

■ *More from the General Assembly, Page B7.*

PROPOSAL

Continued From Page A1

bacco products, and it would forbid cigarette-vending machines in places frequented by minors.

Under Easley's proposal, it would remain a misdemeanor for a store clerk to sell tobacco to someone under 18 or to not ask for identification from someone under 18. A minor who buys tobacco would continue to be guilty of an infraction — a level of offense less severe than a misdemeanor, the same as a traffic ticket — but the penalty for using a fake ID would be raised to a misdemeanor.

Under the FDA rules, by contrast, a clerk who sells cigarettes to a minor would receive only a warning for the first offense. Subsequent offenses would bring escalating fines that would range from $250 to $15,000 for each offense.

Several senators complained that the penalties are too severe for store clerks, who already work under less-than-ideal conditions.

"If you work in a convenience store, you face being robbed three times a week," said Sen. David Hoyle, D-Gaston. "It seems to me it's a little harsh, a little punitive."

Sen. Bob Shaw, R-Guilford, said that some clerks won't be able to handle the task of checking IDs.

"In Greensboro we're under 3 percent unemployed. Half the winos are working, and the other half are trying to find a job because you can get a better grade of wine," he said. "I've got six grandchildren. I'd smack one if I found him with a cigarette in his mouth. But we're bombing the wrong people."

But Sen. Tony Rand, D-Cumberland, the bill's sponsor in the Senate, said that the task just isn't that hard.

"All you have to do is check an ID. You don't even have to take your shoes off and add it up," Rand said.

The state and tobacco companies are fighting in federal court against the FDA's new regulations on tobacco sales and advertising.

Easley noted that his proposal is backed by cigarette manufacturers, as well as the state's heart, lung, cancer and medical societies. And he said that if it passes, the lawyers fighting the federal regulations would be able to argue that the state law is stronger and more effective. "Consequently, we are more able to enforce this on the state level than on the federal level."

Some legislators questioned how well the law would be enforced by police who often have more pressing issues at hand.

The proposal would allow only police and sheriff's departments to use minors in "sting" operations.

Sen. Don East, R-Surry, a retired police officer, said yesterday that police will put little or no emphasis on the tobacco rules.

"Police officers have serious business to take care of," East said. "Snooping around service stations and convenience stores, I don't think, will be high on their priorities."

Easley said agencies that enforce laws on alcohol sales, such as Alcohol Law Enforcement, would be in a perfect position to enforce the tobacco-sale law. "When they go in and ask for beer, they can ask for beer and a pack of cigarettes," he said.

But he also said that it would be up to local authorities to set their priorities. "Local law enforcement will be as committed as the local community is. If the local community isn't interested in protecting their children, they won't ask law enforcement to do it," Easley said.

In Forsyth County, Assistant Sheriff Alan G. Gentry said yesterday that the proposed law would be hard to enforce and that local officials haven't discussed using teen-agers in undercover operations. Authorities would investigate, though, if a parent called to say that a 14-year-old has cigarettes, Gentry said.

Sen. Ham Horton, the only member of the Senate Judiciary Committee from Forsyth County, voted against the proposal yesterday. Horton suggested later that he wants to amend Easley's proposal to include regulation of cholesterol.

"If the government's going to become a universal nanny, it might as well do a good job," he said.

■ Journal *reporter Christopher Quinn contributed to this report.*

Tobacco-regulation fight brings another solution to senators' minds: secession

JOURNAL STAFF REPORT

With all the furor over federal attempts to regulate tobacco, state senators briefly considered a response yesterday that hadn't been considered in a long while.

"We could secede from the Union," said Sen. Frank Ballance, a Democrat from Warren County.

"We tried that," said Sen. Tony Rand, a Democrat from Fayetteville who is sponsoring a proposal to make it tougher for teen-agers to buy tobacco. "It didn't work too well."

But Sen. John Kerr, a Democrat from Goldsboro, wasn't so sure that a new secession would meet the same fate as the last, in 1861.

"I think we're in a little better position now because we've got Fort Bragg and Seymour Johnson Air Force Base," Kerr told the Senate Judiciary Committee. "And we've got a battleship ready to go."

The attached contains:

1) Talking Points for external distribution to surrogates or others

2) Questions & Answers for internal use only

3) Internal Fact Sheets for internal use only

3) HHS fact sheets, publicly available after 11:00am, for public distribution

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.

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.

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

State of the Union Proposal	Current Status	Internal Action Needed	Legislative Process	Deadlines
"[W]e must also protect our children by standing firm in our determination to ban the advertising and marketing of cigarettes that endanger their lives."	• Supervision: Reed-DPC Working Group. • Issued ~~public~~ Final rule last year. • Continue work with FDA and HHS to implement FDA measures to reduce advertising and sales to children. 2/28/97: First requirement takes effect prohibiting sales to minors and requiring i.d. checks 8/28/97 Additional provisions, ~~targeting, those prohibiting~~ help 8/28/98 Sponsorship of sporting events, take effect. • ~~Federal~~ Judge heard oral arguments challenging rule 2/10; should rule on motion for summary judgment in 5-10 weeks	• Implement rule. • Win litigation or appeal. • ~~If win litigation, will have to~~ push for FDA budget increase to ~~help~~ implement ~~the~~ rule. FY98 • Next Oct. report on Synar rule could be prepared. • Issue new ~~set~~ of challenges to billboard and magazine industries • ~~Continue~~ initiative through principal and cabinet events • 2/28 POTUS event on first effective date of rule. • Outreach to family and children's organizations, governors, others • Support grass roots efforts to replicate FDA rule at local level and to motivate parents to demand that companies 'stop hooking our kids!'	• ~~Discuss legislative options with the Hill~~ ~~and tobacco budget requests, and FY98 request to increase to implement rule~~ • Pass appropriations request • Watch for blocking legislation • Support legislative efforts that codify FDA provisions	

Tobacco Rule Requirements.

2/28/97:

Subpart B -- Prohibition on sales and distribution to those under 18
897.14 (a). Prohibition on sales to any person under 18.

897.14 (b). Verify age by i.d.

8/28/97:

Subpart B -- Prohibition on sales and distribution to those under 18
897.12. Manufacturers remove from each point of sale all self service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the requirements under this part.

897.14 (c) Except as under 897.16(c)(2)(ii), retailer may sell only in face-to-face exchange; (d) no sale smaller than minimum package size; (e) shall ensure that self-service displays, advertising, etc. not complying w/rule are removed.

897.16 (a) Prohibits using trade name of nontobacco product; (b) minimum package size of 20 cigarettes; (c) prohibits "impersonal" modes of sale except: i) mail-order sales, excluding coupon redemption and free samples; ii) vending machines and self service displays that are located in facilities where the retailer ensures that no person under 18 is present or permitted at any time; (d) prohibits free samples; (e) prohibits distribution of cigarettes or smokeless tobacco not labeled in compliance with Subparts C and D.

Subpart C -- Labels
897.24 Standard names; .25 statement"Nicotine-Delivery Device for Persons 18 or Older."

Subpart D -- Labeling and Advertising
897.30. (a)(1) advertising allowed in certain media w/restrictions; (2) notify FDA for media not listed; (b) no outdoor advertising within 1,000 feet of any public playground or any primary or secondary school.

897.32. (a) Only black text on white background, except: (1) where vending machines permitted, not visible to outside, and affixed to a wall or fixture; or (2) appearing in any publication that the manufacturer, distributor, or retailer demonstrates is an adult publication.

> "adult publication" is defined as (i) readers younger than 18 are 15%or less of total readership as measured by survey evidence; (ii) read by fewer than 2 million persons under 18;

(b)(1) audio format should be limited to words only with no music or sound effects; (2) video formats static black text only on a white background w/no music or sound effects;
(c) shall include "Cigarettes -- A Nicotine-Delivery Device for Persons 18 or Older.

897.34(a). No sale of item which bears the name, motto, logo, indicia of tobacco product.
(b) no gifts, credits, proofs-of-purchase with cigarette sales;

8/28/98

897.34(c) no brand name sponsorship of athletic, music, artistic, or other social events, teams.

April 14, 1997

POTENTIAL TOBACCO ACTIVITIES

Enforcement of broadcast advertising ban. Request the Department of Justice to investigate whether there are other situations similar to that addressed in its consent order with Philip Morris (the Marlboro logo placed in a position at Madison Square Garden so that it appeared frequently during telecasts of New York Knicks games) and encourage the Department to continue its efforts to enforce the ban of broadcast advertising of tobacco products. Enforcement would prevent the broadcast of tobacco brand logos during televised events, particularly sporting events. Sporting events, including auto races, are increasingly popular events with families and are therefore seen by large numbers of young people either in person or on television.

Treatment of adolescent nicotine addiction. Direct DHHS to develop and carry out a federal research plan focusing on the prevention and treatment of adolescent addiction to nicotine. To date, virtually all research that has been conducted on nicotine addiction has focused on adults. It is not known whether currently available prevention strategies and treatments are effective with children and adolescents or whether different approaches are necessary for this group.

State assistance. Direct DHHS to provide technical assistance to states to help develop individual action plans focused on preventing and treating adolescent nicotine addiction. This initiative could build on the results of the federal research in this area described above and could include publication and distribution of guides for states - such as smoking cessation materials aimed at adolescents. It could also involve creating or highlighting public-private partnerships with schools or non-profit groups.

Improved teen surveys. Direct the Office on Smoking and Health, Centers for Disease Control and Prevention, DHHS, to expand its research efforts, especially teen surveys, to include more questions concerning teens' tobacco brand preference and advertising awareness. Further direct the Office of Management and Budget (OMB) to expedite the clearance of the questionnaires used in these surveys. Information on teen preference and awareness is essential to the development of more effective addiction prevention and treatment approaches for adolescents. In the past, OMB has refused to allow certain questions concerning teens' tobacco brand preference and awareness of marketing strategies and slogans to be asked, or if asked, to be publicly reported.

State interventions. Fully fund tobacco intervention programs in all 50 states. This would require a minimum budget increase of $25 million over the President's 1998 budget. Currently, only 17 states participate in NCI's ASSIST program through which each state receives annual awards that range from $650,000 a year to $1.8 million. The remaining 33 states receive annual grants ranging from $75,000 to $210,000 through CDC's IMPACT program.

[redacted]

April 14, 1997

OTHER POTENTIAL TOBACCO ACTIVITIES

Synar regulations. After consulting with the Department of Justice, direct SAMSHA to revisit its Synar regulations and consider making changes that would tighten the standards that States are required to meet in order to qualify for substance abuse block grants.

Smoke-free federal facilities. Issue an Executive Order making all federal facilities smoke-free. GSA could be involved in implementing the Order.

Smoking in the workplace. Encourage the Department of Labor to issue final regulations addressing smoking in the workplace.

Reimbursement for nicotine addiction treatment. Direct DHHS to reimburse for the treatment of nicotine addiction for Federally-funded health care programs and to encourage private sector coverage as well.

Health-focused foreign policy. Direct the U.S. Trade Representative and the State Department to develop trade and foreign policy that emphasizes the Administration's concerns about the health consequences of tobacco use.

Smoke-free transportation facilities. Direct the Department of Transportation to issue regulations making airports (and other transportation facilities under its jurisdiction) smoke-free. Direct the Department to also begin negotiating with foreign governments to obtain an agreement that international flights to the U.S. be made smoke-free.

Conversion of tobacco crop. Announce a program designed to end the tobacco states' dependence on the tobacco economy. Assist and provide incentives to farmers to convert from tobacco crops to other agricultural products, as well as non-agricultural alternatives.

April 14, 1997

POTENTIAL TOBACCO ACTIVITIES

Enforcement of broadcast advertising ban. Request the Department of Justice to investigate whether there are other situations similar to that addressed in its consent order with Philip Morris (the Marlboro logo placed in a position at Madison Square Garden so that it appeared frequently during telecasts of New York Knicks games) and encourage the Department to continue its efforts to enforce the ban of broadcast advertising of tobacco products. Enforcement would prevent the broadcast of tobacco brand logos during televised events, particularly sporting events. Sporting events, including auto races, are increasingly popular events with families and are therefore seen by large numbers of young people either in person or on television.

Treatment of adolescent nicotine addiction. Direct DHHS to develop and carry out a federal research plan focusing on the prevention and treatment of adolescent addiction to nicotine. To date, virtually all research that has been conducted on nicotine addiction has focused on adults. It is not known whether currently available prevention strategies and treatments are effective with children and adolescents or whether different approaches are necessary for this group.

99 budget

State assistance. Direct DHHS to provide technical assistance to states to help develop individual action plans focused on preventing and treating adolescent nicotine addiction. This initiative could build on the results of the federal research in this area described above and could include publication and distribution of guides for states - such as smoking cessation materials aimed at adolescents. It could also involve creating or highlighting public-private partnerships with schools or non-profit groups.

Improved teen surveys. Direct the Office on Smoking and Health, Centers for Disease Control and Prevention, DHHS, to expand its research efforts, especially teen surveys, to include more questions concerning teens' tobacco brand preference and advertising awareness. Further direct the Office of Management and Budget (OMB) to expedite the clearance of the questionnaires used in these surveys. Information on teen preference and awareness is essential to the development of more effective addiction prevention and treatment approaches for adolescents. In the past, OMB has refused to allow certain questions concerning teens' tobacco brand preference and awareness of marketing strategies and slogans to be asked, or if asked, to be publicly reported.

99 budget

State interventions. Fully fund tobacco intervention programs in all 50 states. This would require a minimum budget increase of $25 million over the President's 1998 budget. Currently, only 17 states participate in NCI's ASSIST program through which each state receives annual awards that range from $650,000 a year to $1.8 million. The remaining 33 states receive annual grants ranging from $75,000 to $210,000 through CDC's IMPACT program.

[redacted]

April 14, 1997

OTHER POTENTIAL TOBACCO ACTIVITIES

Synar regulations. After consulting with the Department of Justice, direct SAMSHA to revisit its Synar regulations and consider making changes that would tighten the standards that States are required to meet in order to qualify for substance abuse block grants.

Smoke-free federal facilities. Issue an Executive Order making all federal facilities smoke-free. GSA could be involved in implementing the Order.

Smoking in the workplace. Encourage the Department of Labor to issue final regulations addressing smoking in the workplace.

Reimbursement for nicotine addiction treatment. Direct DHHS to reimburse for the treatment of nicotine addiction for Federally-funded health care programs and to encourage private sector coverage as well.

Health-focused foreign policy. Direct the U.S. Trade Representative and the State Department to develop trade and foreign policy that emphasizes the Administration's concerns about the health consequences of tobacco use.

Smoke-free transportation facilities. Direct the Department of Transportation to issue regulations making airports (and other transportation facilities under its jurisdiction) smoke-free. Direct the Department to also begin negotiating with foreign governments to obtain an agreement that international flights to the U.S. be made smoke-free.

Conversion of tobacco crop. Announce a program designed to end the tobacco states' dependence on the tobacco economy. Assist and provide incentives to farmers to convert from tobacco crops to other agricultural products, as well as non-agricultural alternatives.