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President Clinton Announces First Actions
Under FDA's Rule to Protect America's Children from Tobacco
February 28, 1997

Announcement

- o **President Clinton announced that today the Federal government is taking the first steps under the Food and Drug Administration's rule to restrict children's access to tobacco products.** Beginning today, provisions of FDA's rule:
 - o **Prohibit retailers from selling cigarettes and smokeless tobacco products to anyone under age 18 --** this age restriction becomes a Federally enforceable regulation, giving retailers a greater incentive to meet the requirement.
 - o **Require retailers to verify age by photo ID for anyone under the age of 27 purchasing these products.** Most state attorneys general, and even tobacco retailers, have indicated the need for checking IDs of customers significantly older than 18 so that retailers don't sell to mature-looking adolescents.

Background

- o **President Clinton announced the final FDA rule to protect children from tobacco on August 23, 1996.** The rule seeks to reduce children's tobacco use by 50% over seven years by restricting children's access to tobacco and by reducing the appeal of cigarettes and smokeless tobacco products to children. The first two provisions of the rule take effect today.
- o **Youth smoking is on the rise.** Each day about 3000 American children become regular smokers. Of these, 1,000 will die early from tobacco-related illness. In the past six years, the smoking rate among eighth graders has risen 50%. Today the average teenage smoker begins to smoke at 14 ½ years old and becomes a daily smoker before age 18.
- o **Youth have widespread access to tobacco products.** Although selling cigarettes to people under 18 is already against the law in all 50 states, studies show that young people easily obtain tobacco products. Most children and adolescents who smoke purchase their own cigarettes. National data from the 1995 Youth Risk Behavior Survey show that over three-quarters of high school students under age 18 who had purchased cigarettes in the previous month had not been asked by a clerk to show proof of age. Local studies have shown that enforcement of minors' access laws -- especially laws requiring the retailer to check for proof of age -- can significantly reduce the percentage of retailers who sell cigarettes to minors.

Additional Provisions to Restrict Access and Reduce Appeal Take Effect Later this Year

- o On August 28, 1997, additional provisions of FDA's rule become effective. They include: prohibiting billboards within 1,000 feet of schools and playgrounds and restricting other advertising to black-and-white text only except in locations only accessible to adults; permitting black-and-white text only advertising in publications with significant youth readership; prohibiting the sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos; and prohibiting vending machines and self-service displays except in places where people under 18 are never present.
- o On August 28, 1998, FDA's final rule will prohibit the brand-name sponsorship of sporting or entertainment events. The rule permits sponsorship in the corporate name.

KNOW THE RULES

Starting February 28, 1997

- ◆ No sales of cigarettes or smokeless tobacco to anyone under 18.*
- ◆ Photo ID check required for anyone under 27.

Starting August 28, 1997

- ◆ No vending machines or self-service displays except in places that never have anyone under 18 present. (Products sold only in a direct, face-to-face exchange.)
- ◆ No sales of single cigarettes ("loosies") or packs with fewer than 20 cigarettes ("kiddie packs").
- ◆ Coupons for cigarettes and smokeless tobacco redeemable only by adults in a store, not through the mail.
- ◆ No free samples of cigarettes or smokeless tobacco.
- ◆ No outdoor ads for cigarettes or smokeless tobacco (including on store windows) within 1,000 feet of a school or public playground.
- ◆ Tobacco ads generally must be in black text on a white background without pictures or colors. Color or picture ads are permitted only:
 - In any publication with a youth readership of 15% or less and fewer than 2 million youth readers; or
 - In places that never have anyone under 18 present.
- ◆ No give-away of any gift or item to anyone in exchange for a tobacco proof-of-purchase or as part of a sale of cigarettes or smokeless tobacco.
- ◆ No sale or give-away of hats, t-shirts, or other items identified with a tobacco brand.

Starting August 28, 1998

- ◆ No sponsorship of any sporting or other event, team, or entry identified with a tobacco brand. But, sponsorship in the corporate name is permitted.

* The age may be higher in your state.

1. Section 897.1—Scope

Proposed § 897.1(a) would state that part 897 is intended to establish conditions under which nicotine-containing cigarettes and smokeless tobacco products may be sold, distributed, or used. The proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act. FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products. Proposed § 897.1(b) would note that all references to regulatory sections in the Code of Federal Regulations are to Title 21 unless otherwise noted.

2. Section 897.2—Purpose

Proposed 897.2(a) would state that part 897 is intended to help prevent persons younger than 18 years of age from becoming addicted to nicotine, thereby avoiding the life-threatening consequences often associated with tobacco use. The proposed rule would accomplish this goal by reducing the appeal of and access to cigarettes and smokeless tobacco products by persons under 18 years of age; it would preserve access to cigarettes and smokeless tobacco products by persons 18 years of age and older. Proposed § 897.2(b) would add that the provisions are intended to provide important information about product use to users and potential users.

3. Section 897.3—Definitions

Proposed 897.3 would establish definitions of terms used in the proposed rule, such as "cigarette" (897.3(a)) and "distributor" (897.3(c)). In drafting the definitions, FDA examined existing definitions in Federal laws and regulations and paid special attention to existing definitions in other FDA regulations. These definitions are contained in the proposed codified language.

Proposed 897.3(e) contains the definition of "nicotine," which is based, in part, on the chemical name and formula for nicotine in the "Merck Index" (10th Edition). The agency also notes that, while the proposed rule defines "cigarette," in part, as a product that "contains or delivers nicotine," it is aware that some companies are trying to develop chemical substances that are pharmacologically active or are as addictive as nicotine or that would be used to enhance nicotine's

pharmacological qualities. The agency's investigation has focused primarily on cigarettes and smokeless tobacco products that contain nicotine, and FDA would therefore consider a cigarette-like product that contains a pharmacologically active or addictive substance in place of nicotine to be a "new" drug delivery device that would be outside the scope of this regulation. To be legally marketed, such a product would require premarket approval.

B. Subpart B—Sale and Distribution to Persons Under 18 Years of Age

Subpart B would establish certain conditions or requirements for the sale and distribution of cigarettes and smokeless tobacco pursuant to section 520(e) of the act. These provisions are intended to reduce access to cigarettes and smokeless tobacco products by children and adolescents. Studies show that it is easy for most young people to obtain tobacco products. The University of Michigan Monitoring the Future Study in 1993 reported that 75 percent of 8th graders and nearly 90 percent of 10th graders said it would be fairly easy or very easy to get cigarettes.¹ According to a 1990 survey of 9th graders, 67 percent of current smokers said they usually buy their own cigarettes.² Further, interviews conducted by the Department of Health and Human Services' (DHHS) Office of the Inspector General in 1986 found that 94 percent of junior and high school students said that "it was either never or only rarely difficult" to buy smokeless tobacco products.³

Most children and adolescents who smoke purchase their own cigarettes. A 1991 study showed that an estimated 516 million packs are consumed by young people every year; almost half of these packs are sold to minors.⁴ The 1994 Surgeon General's Report examined 13 studies of over-the-counter sales and determined that approximately 67 percent of minors are able to purchase tobacco illegally. Moreover, successful cigarette purchases by children and adolescents averaged 88 percent in studies of vending machines.⁵

A significant percentage of young people can also easily purchase smokeless tobacco products directly from retailers. Studies examining smokeless tobacco product purchases by young people suggest that direct successful underage purchases range from 30 percent (for junior high school students) to 62 percent (for senior high school students).⁶ Interviews conducted by the DHHS' Office of the Inspector General in 1986 found that 90 percent of smokeless tobacco users in junior and

senior high schools said they purchased their own smokeless tobacco products.⁷

Youth access restrictions have been found to be effective in reducing illegal sales and some studies have demonstrated that efforts to reduce access have led to a decrease in tobacco use by young people. In Woodridge, IL, for example, a comprehensive community intervention involving retailer licensing, regular compliance checks, and penalties for merchant violations significantly reduced illegal sales from 70 percent to less than 5 percent almost 2 years later. Further, rates of experimentation and regular smoking dropped by more than 50 percent among seventh and eighth graders.⁸

In contrast, attempts to reduce sales to young people by relying exclusively on educational programs for retailers were not nearly as effective. For example, one study found that minors were able to buy cigarettes in 73 percent of stores receiving informational packages on preventing illegal sales to minors.⁹ After a comprehensive retailer education program was conducted, illegal sales to minors decreased to 68 percent of stores. However, after citations were issued to violative establishments, over-the-counter illegal sales dropped to 31 percent.¹⁰

The proposed rule would prohibit the sale and distribution of cigarettes and smokeless tobacco products to individuals younger than 18. This restriction parallels the age restrictions established by almost all States. Moreover, it is based on the fact that most people who become regular smokers do so at a young age. For instance, the IOM reported that the average age when people become "daily" smokers is 17.7 years.¹¹ According to the National Household Surveys on Drug Abuse (1991), 53 percent of people who ever smoked became regular smokers by the time they were 18 years old.¹² Further, 82 percent of those who had ever smoked daily first tried a cigarette before the age of 18.¹³

Available data documenting the course of a young person's ability to quit smoking after initiating smoking support the need for an age restriction. A study tracking students from grades 6 to 12 in six Minnesota communities noted a "striking pattern" that:

* * * once students become weekly smokers, they are unlikely to give up cigarettes. Of the students who were current smokers, an increasing percentage remained smokers over the years of follow-up; they were either unable or unwilling to quit smoking. Of the self-reported quitters, 13% to

46% returned to weekly smoking by the next year's measurement period.¹⁴

The study found that "students who smoke are increasingly unlikely to quit as they get older."¹⁵

Effectively prohibiting sales to people younger than 18 years of age will therefore help reduce the number of adolescents and youths who become daily smokers. FDA also selected the age limit of 18 to be consistent with the 1992 Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act¹⁶ that conditions receipt of substance abuse grants on States adopting laws prohibiting the sale and distribution of cigarette and smokeless tobacco products to minors under age 18, and because the majority of States have set 18 as the age of purchase of these products.

1. Section 897.10—General Responsibilities of Manufacturers, Distributors, and Retailers

Proposed 897.10 would describe the general responsibilities of manufacturers, distributors, and retailers, and would make manufacturers, distributors, and retailers responsible for ensuring that the cigarettes and smokeless tobacco products they manufacture, label, advertise, package, sell, distribute, or otherwise hold for sale comply with all the applicable regulations under proposed Part 897.

2. Section 897.12—Additional Responsibilities of Manufacturers

Proposed 897.12 would provide that, in addition to its other responsibilities, each manufacturer would be responsible for removing all self-service displays, violative advertising, labeling, and other manufacturer- or distributor-supplied items from each point of sale. Proposed § 897.12(b) would require each manufacturer to monitor, through visual inspection on each visit to a point of sale (carried out in the normal course of the manufacturer's business), to assure the proper labeling, advertising, and distribution of its products. This provision would not create a new responsibility or burden for companies (typically the smaller ones) who do not visit retail locations as part of their usual business practice. The obligation to inspect exists only for those companies (typically the larger ones) for whom visits are part of their usual business practice.

Further, because there are detailed contracts between the larger cigarette manufacturers and retailers, proposed 897.12 should not impose a significant burden on these manufacturers. For example, a Non-Self-Service Carton

Shelf Plan for the R.J. Reynolds Tobacco Co. specified that "[t]he height of the top shelf cannot exceed 72 inches and must have a height capacity of seven cartons * * *" and that the cigarette display or shelves " * * * must be in total view of the consumer * * *" and " * * * may not be placed more than 10 feet from point-of-purchase."¹⁷ Another plan, titled "R.J. Reynolds Tobacco USA Savings Center Display Plan," created six different pay scales for retailers; the retailers would receive more money if they sold a large volume of cigarettes. Under this plan, R.J. Reynolds would also provide a "merchandiser" to display its products, and the retailer would agree to stock the "designated RJR shelf rows" "no less than five cartons high," and not alter the shelves or reduce the amount allocated to R.J. Reynolds products.¹⁸ In both plans, the retailer also agreed to permit R.J. Reynolds representatives to "plan-o-gram, adjust, and divide its allocated space as deemed necessary" and to "make reasonable audits of performance and to inspect and rotate R.J.R.'s products in stores under contract."¹⁹

Former sales representatives and managers interviewed by FDA stated that manufacturers keep extremely detailed records about each retailer. Some records noted whether the retailer should be visited weekly, biweekly, monthly, etc.; other entries included the types of displays in the retailer's establishment. At least one company also gave portable computers to its representatives; the data entered into these computers were downloaded nightly and sent to company headquarters. These detailed contracts and records demonstrate that the manufacturers are heavily involved in establishing and maintaining retailers' displays and that the proposed rule's requirements that each manufacturer be responsible for removing violative advertising, labeling, and self-service displays, and for performing a visual inspection on each subsequent business call are both feasible and reasonable.

3. Section 897.14—Additional Responsibilities of Retailers

Proposed 897.14 would establish additional responsibilities for retailers. Proposed 897.14(a) would require the retailer or the retailer's employees to verify that people who intend to purchase cigarettes or smokeless tobacco products are legally entitled to do so. Verification would be by direct visual inspection of each prospective purchaser and, if necessary, would include the use of a photographic identification card with a birth date. Examples of documents that would be

acceptable are a driver's license or a college identification card. The proposal would require an identification card with a picture and a birth date because such identification cards are more reliable than other forms of identification. FDA invites comment on whether the final rule should contain more specific requirements concerning the types of identification that would comply with this provision.

The agency has found strong support for the additional retailer responsibilities that this section would impose. According to a recent report endorsed by 26 State attorneys general, industry training films and programs used by retailers regarding tobacco sales had little or no impact on preventing illegal sales to minors and, in some retail sectors, high employee turnover rates complicated training efforts. Moreover, determining a young customer's age through visual examination alone proved to be difficult. Thus, the attorneys general recommended requiring proof of age of anyone who does not appear to be at least 26 years old.²⁰

Additionally, studies indicate that minors who are able to purchase cigarettes and other tobacco products from stores are rarely asked to verify their age. For example, in one study, 67 percent of minors (mean age: 15 years) were asked no questions when they attempted to purchase cigarettes.²¹ Store cashiers tried discouraging the minors from buying cigarettes in only 7 percent of the spot checks conducted by the authors. In 14 percent of the cases, the cashiers actually "encouraged the minor's purchase by offering matches, suggesting a cheaper brand, or offering to make up the difference if the minor was 'short on cash'."²²

In another report, five minors between the ages of 13 and 16 were sent to various locations to buy cigarettes. Despite signs at some locations that prohibited entry by persons under the age of 21, the minors were able to buy cigarettes, even when they admitted they were under 21. For smokeless tobacco products, studies show that half of the stores examined were willing to sell smokeless tobacco products to minors.²³ In contrast, in Everett, WA, where a local ordinance required proof of age if the prospective buyer did not appear to be of legal age to purchase cigarettes, over 60 percent of students between the ages of 14 and 17 reported being asked for proof of age when they attempted to buy cigarettes, and tobacco use, among 14 to 17-year-olds, declined from 25.3 percent to 19.7 percent overall.²⁴

Proposed § 897.14(b) would prevent the retailer or an employee of the retailer from using any electronic or mechanical device in providing cigarettes or smokeless tobacco products to the purchaser. Requiring the retailer's employees to hand cigarettes or smokeless tobacco products to customers, after checking identification, has the practical effect of making access to such products more difficult for young people.

Proposed § 897.14(c) would prohibit the retailer or an employee of the retailer from opening a cigarette, cigarette tobacco, or smokeless tobacco product package to sell or distribute a cigarette, or cigarettes (often referred to as "singles" or "loosies") or any quantity of cigarette tobacco or of a smokeless tobacco product from that package. The agency is proposing this restriction because the primary market for "loosies" is children and adolescents. One California study found that 101 of 206 stores sold single cigarettes to minors and adults, and more stores sold single cigarettes to minors than to adults.²⁵ A survey in Nashville, TN, found that one-quarter of the stores sold single cigarettes.²⁶

Additionally, the IOM noted that the sale of single cigarettes is attractive to children due to the low costs, could make children more willing to experiment with tobacco products, and that single cigarettes may be easier for children to shoplift.²⁷ Consequently, the IOM advocated banning the sale of single cigarettes.²⁸ Several States, including Mississippi, Oklahoma, South Dakota, Tennessee, and Washington, already restrict the sale of unpackaged tobacco products, and a working group of State attorneys general recently recommended that single cigarette sales be prohibited.²⁹

4. Section 897.16—Conditions of Manufacture, Sale and Distribution

a. Restrictions on product names.

Proposed 897.16(a) would prohibit prospectively the use of a trade or brand name for a non-tobacco product as the trade or brand name for a cigarette or smokeless tobacco product. The agency is aware of three brands of cigarettes that have used this strategy: Harley-Davidson, Cartier, and Yves St. Laurent's Ritz cigarettes. In the final rule, the agency intends to exempt those brands that already use the trade or brand name of a non-tobacco product.

This provision would complement the requirements in proposed subpart D (regarding labeling and advertising) that would reduce the appeal of cigarettes and smokeless tobacco products to people younger than 18. FDA believes

that this provision is necessary to prevent manufacturers from circumventing the purpose of this proposed rule. As discussed elsewhere, the imagery associated with tobacco products is an important factor in why young people smoke. This provision would prevent tobacco manufacturers from capitalizing on the imagery of other consumer products by using the brand name of those products for tobacco products.

b. *Minimum package size.* Proposed § 897.16(b) would make 20 cigarettes the minimum package size for cigarettes. FDA selected 20 because the vast majority of cigarette packs in the United States contain 20 cigarettes. The proposal is intended to preclude firms from manufacturing packages that contain fewer than 20 cigarettes; these packs, sometimes referred to as "kiddie" packs, usually contain a small number of cigarettes, are easier to conceal, and are less expensive than full-size packs. (Young people, who generally have little disposable income, can be particularly sensitive to the price of cigarettes and may choose not to smoke as the price increases.³⁰) Further, FDA is aware that Lorillard Tobacco Company is offering a pack containing only 10 cigarettes of its Newport brand for sale and that another firm is experimenting with single cigarettes packed in individual tubes.³¹

One study showed that 56.3 percent of all 14 to 15 year old adolescent smokers surveyed in one urban area of Australia had purchased kiddie packs in the month prior to the survey, compared with only 8.8 percent of adult smokers. The study concluded, "If we fail to take strong action against the well targeted marketing methods of tobacco companies then the adolescent smoking rates recorded in this study are likely to remain high."³²

The Nova Scotia Council on Smoking and Health reported that 49 percent of tobacco users in the sixth grade purchased kiddie packs of 15 cigarettes.³³ Another study of Australian schoolchildren reported that 30 percent of the 12-year olds preferred packages containing 15 cigarettes compared to 11 percent of the 17-year olds.³⁴ The Australian study, however, also reported that older children preferred cigarette packages that contained 25 cigarettes. Consequently, even though FDA has no evidence that firms intend to market cigarette packages that contain more than 20 cigarettes, the agency invites comment as to whether proposed § 897.16(b) should also state the maximum package size for cigarettes.

c. *Impersonal modes of sale.* Proposed § 897.16(c) would permit cigarettes and smokeless tobacco products to be sold

only in a direct, face-to-face exchange between the retailer or the retailer's employees and the consumer. The proposal would prohibit specifically cigarette vending machines, self-service displays, mail-order sales, and mail-order redemption of coupons.

1. *Vending Machines.* Studies indicate that a significant percentage of adolescents are able to obtain their cigarettes from vending machines and that such purchases occur regardless of locks, warning signs, and other restrictions. In 1994, CDC examined 15 recent tobacco inspection surveys to investigate underage sales to minors. While 73 percent of over-the-counter outlets made illegal sales to children and adolescents, 96 percent of vending machine sales were successful.³⁵

A 1989 survey of 10th grade students in Minnesota indicated that 71 percent had purchased tobacco from vending machines.³⁶ Another 1989 report found that, in California, minors between the ages of 14 and 16 were able to purchase cigarettes from vending machines 100 percent of the time.³⁷ A 1992 study in Minnesota involving minors between the ages of 12 and 15 reported a 79 percent success rate in purchasing cigarettes from vending machines.³⁸ Children in the Washington, D.C. area, New York, Colorado, and New Jersey who were sent to purchase cigarettes from vending machines achieved 100 percent success rates.³⁹ The 1994 Surgeon General's Report examined nine studies on cigarette purchases from vending machines and found that underage persons were able to purchase cigarettes 82 to 100 percent of the time, with a weighted-average rate of 88 percent.⁴⁰

Moreover, younger children use vending machines to purchase cigarettes more often than older adolescents. A study commissioned by the vending machine industry revealed that 22 percent of 13-year olds who smoke reported purchasing cigarettes from vending machines "often" compared with only 2 percent of 17-year olds. Twenty-two percent of 13- to 17-year-olds who smoke report purchasing cigarettes from vending machines "often" or "occasionally."⁴¹

FDA is aware that some jurisdictions have attempted to place locks, post warning signs, or restrict placement of vending machines to curtail access by young people. These efforts have had only limited success. A 1992 report examining vending machines in St. Paul, MN, indicates the limitations of requiring locking devices on vending machines. Despite a 1990 city ordinance requiring locking devices on vending machines, the rate of noncompliance by

Each day, nearly 3,000 American youngsters become regular smokers. Of these, 1,000 will die early from tobacco-related diseases.

As a retailer, you can help protect kids from the dangers of tobacco and nicotine addiction.

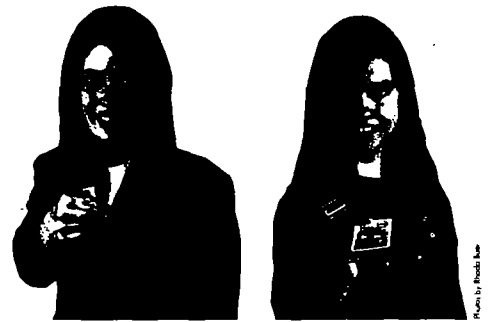
President Clinton recently announced new FDA rules to make it much harder for kids to get cigarettes and smokeless ("spit") tobacco. The rules also will help make these products less appealing to youngsters.

**BUT IT'S UP TO
YOU TO MAKE THESE
RULES WORK.**



FOOD AND DRUG ADMINISTRATION

WHICH ONE IS 16?



Melissa

Amy

*Can you tell?
If they walked into your
store, would you know
which one was under 18?
To eliminate the guesswork,
FDA requires you to card
anyone who is
under 27.*

Melissa is 16. Amy is 25.

RETAILERS YOU MAY BE WONDERING

Q: Who is responsible if one of my clerks sells to someone under 18?

A: If one of your employees sells to a minor, you are responsible. That is why it is important for you to make sure your employees know the rules.

Q: How will anyone know if I'm selling tobacco to youngsters?

A: Adolescents, accompanied by State or local officials, will visit stores across the country to try to buy cigarettes and smokeless tobacco. Also, people who observe an illegal sale can report the violation using FDA's toll-free hotline.

Q: Aren't the FDA rules just the first step toward stopping me from selling tobacco to anyone?

A: No. FDA's only purpose is to reduce young people's use of tobacco. Cigarettes and smokeless tobacco are and will remain legal products for sale to adults. The FDA rules do not change that in any way.

GAIN THE RESPECT OF YOUR COMMUNITY

Parents, teachers, doctors, and others who live in your neighborhood and shop in your store. Show store owners and their employees to take the rules seriously. Show them you put kids first. Follow the rules.



If your employees want more information, call the toll-free (1-888-FDA-4KIDS) or visit the website (www.fda.gov/).

February 28, 1997

QUESTIONS AND ANSWERS

THE REGULATION

- Q. What are the provisions of the final rule?
- A. Broadly, there are two types of restrictions: those dealing with youth access and those dealing with advertising.

Access:

Prohibits sale of tobacco products -- cigarettes and smokeless tobacco -- to persons under age 18.

Requires age verification by photo ID for anyone under the age of 27 purchasing these tobacco products.

Bans vending machines and self-service displays except in locations that are totally inaccessible to anyone under 18.

Bans free samples, sales of single cigarettes, and packages containing fewer than 20 cigarettes.

Advertising:

Permits 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.

Bans billboards within 1,000 feet of schools and playgrounds. Other advertising -- billboards, signs in and on buses, and in-store advertising -- is restricted to black and white text-only. Advertising in "adult only" facilities, such as nightclubs, can have color and imagery.

Prohibits brand-name sponsorship of sporting or entertainment events (including teams and entries), but permits sponsorship in the corporate name.

Bans brand identified non-tobacco items (e.g., tee shirts).

- Q: What parts of the rule take effect today?
- A: As of today, Federal law prohibits retailers from selling cigarettes and smokeless tobacco to persons under age 18 and requires retailers to request photo IDs from customers who are under age 27.

Q: Why are you insisting that retailers card people as old as 26?

A: We received recommendations from more than half the state attorneys general that the carding age be significantly higher so that retailers will be sure not to sell tobacco products to mature-looking adolescents. Even tobacco manufacturers and retailers of tobacco products have recognized the need to set the carding age higher than 18.

THE BURDEN ON RETAILERS

Q: Isn't this really going to burden retailers?

A: These are common sense rules to make sure that tobacco products are kept out of the hands of our kids and doesn't overly burden businesses. It's about doing what everyone agrees should be done. Nobody wants our kids to smoke, including the people who sell tobacco products.

ENFORCEMENT

Q: How will the Administration enforce the FDA regulation?

A: The most important part of enforcement is informing the retailers and the general public of what the regulations require. FDA has conducted an outreach program to inform retailers, as well as parents, health professionals, community groups, state and local officials, about the FDA's tobacco regulations.

In addition, the President included \$34 million in his FY 98 budget for the implementation and enforcement of the FDA regulations. The bulk of these funds will be used to contract with state governments to inspect the estimated 400,000 retail outlets that sell tobacco products.

These steps are critical because, unfortunately, the majority of retail outlets continue to sell tobacco products to children, reinforcing the need for an aggressive and visible enforcement program.

Q: Will there be penalties exacted against retailers who sell to minors?

A: FDA will first send a warning letter to any retailer who sells tobacco products to minors. Any retailer who does this a second time will be subject to civil money penalties.

Q: When will FDA start exacting these penalties?

A: We don't anticipate bringing any specific enforcement action until after the Court's ruling. If that ruling should be delayed for an extended time, we would certainly notify the Court of our intention to bring such an action before doing so.

VIRGINIA

Q: According to news reports, Virginia officials had said they were not going to enforce the FDA rule on tobacco and children. Although Virginia ultimately repudiated this position, what will FDA do if another state refuses to enforce the rule?

A: First, the initial provisions of the FDA rule become effective Friday, February 28, and they are the law everywhere. Second, obviously the principal responsibility for enforcing a federal law or rule is with the federal government. In the area of protecting the public health in food and drug law, the FDA has traditionally worked with states. (Examples are mammography standards, dairy regulations and food sanitation inspections.) We commission, train, and frequently pay state officials to do inspections for us. We intend to work with states to protect our children from tobacco products and the diseases related to tobacco use. We would hope that everyone -- state officials, local officials -- would agree that protecting our children is a very important public health priority.

Q: But what if a state won't work with the FDA?

A: The FDA is prepared to ensure that retailers comply with the law, and the Agency will use its own resources if necessary.

EDUCATIONAL CAMPAIGN

Q: Are tobacco companies required to pay for an educational campaign?

A: The Agency has not yet begun the consultation process with the companies on a national multi media campaign to provide educational messages to children.

FDA REGULATION AND SYNAR REGULATION

Q: Is the FDA rule really needed, given the existence of the Federal Synar statute?

A: Because of the magnitude of the problem, both efforts are needed. The Synar rule focuses on providing incentives to states to enforce their existing state laws to prohibit the sale of tobacco products to children. It is complemented by the FDA regulation that, in addition, reduces the allure of tobacco products. We need to reduce both the supply (access) and demand (appeal) for tobacco products and these two Federal actions work in concert to do so.

SETTLEMENT

Q: Is the President negotiating with the tobacco companies on a settlement?

A: While we are aware of discussions among some of the parties, we are not involved in any negotiations.

Q: Would the President support such a settlement?

A: We have always stated that if the tobacco industry or others propose ideas that meet our Public Health objectives of protecting children from tobacco products and are as strong and comprehensive as the FDA rules, we would certainly consider those proposals.

REPLACEMENT FOR DR. KESSLER

Q: Do you have a replacement for Dr. Kessler yet? When will that be announced?

A: No. Dr. Michael Friedman is the lead Deputy who will work in close consultation with the other deputies during this transition.

We are conducting a nationwide search for the best person to replace Dr. Kessler.

LITIGATION

Q: When is Judge Osteen going to rule?

- A: Judge Osteen said that he hoped to rule within five to ten weeks of the February 10th hearing. If you take the longer estimate, that would mean the decision may not be issued until the end of April. The issues are complicated, so it is hard to know when the Judge will actually issue his ruling.
- Q: How will the Administration respond if the Judge rules against FDA.
- A: We are confident in our legal position and believe and certainly hope that the Court will rule in the government's favor. But, it is premature to speculate about a hypothetical decision until we actually have one. As in every case, if the court rules against us, the Department of Justice and the FDA will have to examine the scope and basis of that ruling to determine whether an appeal, or some other action, is appropriate.
- Q: What do you think are the chances of your winning this case?
- A: We are confident that we stand on firm legal ground and that we will prevail. We think these steps are absolutely essential if we are to reduce the numbers of our kids who become addicted to tobacco products and who will eventually die because of this addiction. The decision is now in Judge Osteen's hands and it is simply impossible to guess what he might do. We are content to wait for his ruling.

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Q: What parts of the rule take effect today?

A: As of today, Federal law prohibits retailers from selling cigarettes and smokeless tobacco to persons under age 18 and requires retailers to request photo IDs from customers who are under age 27.

Q: Why are you insisting that retailers card people as old as 26?

A: We received recommendations from more than half the state attorneys general that the carding age be significantly higher so that retailers will be sure not to sell tobacco products to mature-looking adolescents. Even tobacco manufacturers and retailers of tobacco products have recognized the need to set the carding age higher than 18.

THE BURDEN ON RETAILERS

Q: Isn't this really going to burden retailers?

A: These are common sense rules to make sure that tobacco products are kept out of the hands of our kids and doesn't overly burden businesses. It's about doing what everyone agrees should be done. Nobody wants our kids to smoke, including the people who sell tobacco products.

ENFORCEMENT

Q: How will the Administration enforce the FDA regulation?

A: The most important part of enforcement is informing the retailers and the general public of what the regulations require. FDA has conducted an outreach program to inform retailers, as well as parents, health professionals, community groups, state and local officials, about the FDA's tobacco regulations.

In addition, the President included \$34 million in his FY 98 budget for the implementation and enforcement of the FDA regulations. The bulk of these funds will be used to contract with state governments to inspect the estimated 400,000 retail outlets that sell tobacco products.

These steps are critical because, unfortunately, the majority of retail outlets continue to sell tobacco products to children, reinforcing the need for an aggressive and visible enforcement program.

Q: Will there be penalties exacted against retailers who sell to minors?

A: FDA will first send a warning letter to any retailer who sells tobacco products to minors. Any retailer who does this a second time will be subject to civil money penalties.

Q: When will FDA start exacting these penalties?

A: We don't anticipate bringing any specific enforcement action until after the Court's ruling. If that ruling should be delayed for an extended time, we would certainly notify the Court of our intention to bring such an action before doing so.

VIRGINIA

Q: According to news reports, Virginia officials had said they were not going to enforce the FDA rule on tobacco and children. Although Virginia ultimately repudiated this position, what will FDA do if another state refuses to enforce the rule?

A: First, the initial provisions of the FDA rule become effective Friday, February 28, and they are the law everywhere. Second, obviously the principal responsibility for enforcing a federal law or rule is with the federal government. In the area of protecting the public health in food and drug law, the FDA has traditionally worked with states. (Examples are mammography standards, dairy regulations and food sanitation inspections.) We commission, train, and frequently pay state officials to do inspections for us. We intend to work with states to protect our children from tobacco products and the diseases related to tobacco use. We would hope that everyone -- state officials, local officials -- would agree that protecting our children is a very important public health priority.

Q: But what if a state won't work with the FDA?

A: The FDA is prepared to ensure that retailers comply with the law, and the Agency will use its own resources if necessary.

EDUCATIONAL CAMPAIGN

Q: Are tobacco companies required to pay for an educational campaign?

A: The Agency has not yet begun the consultation process with the companies on a national multi media campaign to provide educational messages to children.

FDA REGULATION AND SYNAR REGULATION

Q: Is the FDA rule really needed, given the existence of the Federal Synar statute?

A: Because of the magnitude of the problem, both efforts are needed. The Synar rule focuses on providing incentives to states to enforce their existing state laws to prohibit the sale of tobacco products to children. It is complemented by the FDA regulation that, in addition, reduces the allure of tobacco products. We need to reduce both the supply (access) and demand (appeal) for tobacco products and these two Federal actions work in concert to do so.

SETTLEMENT

Q: Is the President negotiating with the tobacco companies on a settlement?

A: While we are aware of discussions among some of the parties, we are not involved in any negotiations.

Q: Would the President support such a settlement?

A: We have always stated that if the tobacco industry or others propose ideas that meet our Public Health objectives of protecting children from tobacco products and are as strong and comprehensive as the FDA rules, we would certainly consider those proposals.

REPLACEMENT FOR DR. KESSLER

Q: Do you have a replacement for Dr. Kessler yet? When will that be announced?

A: No. Dr. Michael Friedman is the lead Deputy who will work in close consultation with the other deputies during this transition.

We are conducting a nationwide search for the best person to replace Dr. Kessler.

LITIGATION

Q: When is Judge Osteen going to rule?

A: Judge Osteen said that he hoped to rule within five to ten weeks of the February 10th hearing. If you take the longer estimate, that would mean the decision may not be issued until the end of April. The issues are complicated, so it is hard to know when the Judge will actually issue his ruling.

Q: How will the Administration respond if the Judge rules against FDA.

A: We are confident in our legal position and believe and certainly hope that the Court will rule in the government's favor. But, it is premature to speculate about a hypothetical decision until we actually have one. As in every case, if the court rules against us, the Department of Justice and the FDA will have to examine the scope and basis of that ruling to determine whether an appeal, or some other action, is appropriate.

Q: What do you think are the chances of your winning this case?

A: We are confident that we stand on firm legal ground and that we will prevail. We think these steps are absolutely essential if we are to reduce the numbers of our kids who become addicted to tobacco products and who will eventually die because of this addiction. The decision is now in Judge Osteen's hands and it is simply impossible to guess what he might do. We are content to wait for his ruling.

§ 897.16 to permit certain modes of sale, such as vending machines and self-service displays (merchandisers only), in facilities where young people are not present, or permitted to enter, at any time. These modes of sale do not involve hand-to-hand transactions between the retailer and the purchaser. Consequently, FDA has made a corresponding amendment to § 897.14(c) to require retailers to personally provide cigarettes or smokeless tobacco to purchasers "[e]xcept as otherwise provided in § 897.16(c)(2)(ii) and revised the text to correspond more closely with the language in § 897.16(c)(1)." The amendments to § 897.16 are discussed in greater detail below.

(40) A few comments questioned the need for proposed § 897.14(b) (now renumbered as § 897.14(c)). These comments said that the rule would not prompt retailers to verify a prospective purchaser's age because retailers who sell cigarettes and smokeless tobacco to minors are already in violation of State laws.

FDA disagrees with the comments' assertion. FDA's enforcement authority and the range of sanctions under the act should give retailers additional incentives to verify proof of age. Hence, FDA believes that the weight of Federal law and these regulations will prompt retailers to pay more attention to the consumer's age. By way of analogy, the United States enjoys a very high rate of compliance with prescription drug restrictions in part because a violation of the prescription requirement is actionable under Federal law. Similarly, section 1926 of the PHS Act gives States, as a condition for receiving a block grant for the prevention and treatment of substance abuse, further incentive to ensure that illegal tobacco sales to young people do not occur and that the illegal sales rate steadily decreases from 50 percent in fiscal year 1994 (or fiscal year 1995 for some States) to 20 percent 4 years later. States must also conduct annually a reasonable number of random, unannounced inspections to ensure compliance with State law (see 61 FR 1492 at 1508, January 19, 1996). Section 1926 of the PHS Act and its implementing regulations should also prompt States to devote more attention to compliance efforts to prevent illegal sales to young people and, through the requirement for random, unannounced inspections, make retailers more aware of the need to verify the consumer's age.

4. Restrictions Against the Sale of Individual Cigarettes

Proposed § 897.14(c) (now renumbered as § 897.14(d)) would have prohibited the retailer or an employee of the retailer from breaking or otherwise opening any cigarette package or smokeless tobacco product to sell or distribute individual cigarettes or any quantity of cigarette tobacco or of a smokeless tobacco that is smaller than the quantity in the unopened product. In response to comments and for other reasons discussed below, the agency has amended § 897.14(d) to prohibit retailers from breaking or otherwise opening "any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use."

Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to "an employee of the retailer" because the retailer is generally responsible for its employee's actions.

(41) Several comments opposed proposed § 897.14(c) (now renumbered as § 897.14(d)) in conjunction with proposed § 897.10 (which would establish general responsibilities for manufacturers, distributors, and retailers). The comments said it would be unreasonable to expect retailers to inspect all packages to assure compliance with minimum package requirement, as well as other requirements, and yet retailers would face significant penalties if they failed to comply. Other comments asked whether retailers would be held liable for opening shipping packages consisting of individual cigarette packages or cartons and selling the individual packages or cartons.

The comments misinterpreted the proposed provision. Section 897.14(d) does not require retailers to police minimum package requirements, but rather expressly states that the retailer shall not break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or number of cigarettes or any quantity of cigarettes or smokeless tobacco that is smaller than the quantity in the unopened package. The confusion may have stemmed from the definition of "package." Section 897.3(f) defines "package" as a "pack, box, carton, or other container * * * in which

cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers." The provision, therefore, focuses on two distinct actions: (1) The retailer breaks or opens a cigarette package or smokeless tobacco product; and (2) the retailer sells or distributes a portion of the cigarette package or smokeless tobacco product to a consumer.

A literal reading of proposed §§ 897.3(f) and 897.14(d) together would prohibit a retailer from opening a carton of cigarettes to sell a single package of 20 cigarettes. The agency did not intend to prohibit retailers from opening shipped quantities or bundles of cigarette packages or cartons or smokeless tobacco in order to break the shipment down into ordinary packages, cartons, or other standard product units. The agency has amended § 897.14(d), to eliminate this unintended effect. The new language clarifies that retailers may open shipping boxes or cigarette cartons to sell a pack of cigarettes or a smokeless tobacco package. Additionally, FDA has modified the introduction to § 897.14(d), changing "the retailer shall not" break or open any cigarette or smokeless tobacco package to "no retailer may" break or open any package. This change is intended to simplify the text and does not alter a retailer's obligations under § 897.14(d).

(42) One comment from a company opposed a restriction on the sale of single cigarettes because it had made a substantial investment developing a vending machine that would sell single cigarettes that complied with applicable labeling and tax laws. The comment added that its machines are located in areas that are frequented by or limited to adults and that there is a market for adults who wish to smoke only occasionally.

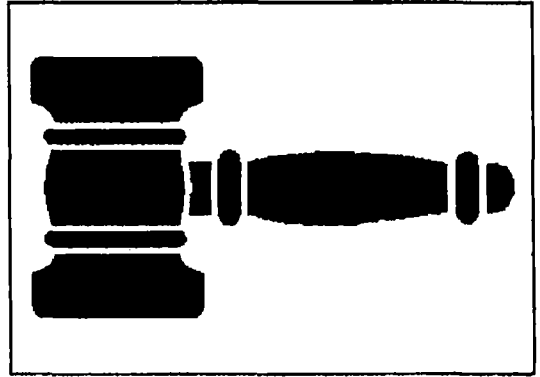
The restriction against the sale of single cigarettes pertained to single cigarettes that are removed from cigarette packages or cartons and sold on an individual basis. Thus, the product described by the comment, a prepackaged single cigarette that complies with all applicable labeling and tax laws, does not appear to correspond to what is commonly known as a "loose." As for selling a package single cigarette in a vending machine, the final rule permits vending machines to be used in certain locations that are entirely inaccessible to young people. This comment, and corresponding amendments to the rule, are discussed in greater detail in section IV.E.4.a. of this document.

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

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FAX: (202) 690-7998

DATE: February 26, 1997

TO: ANN McGUIRE
fax: 456-2525

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: Draft Qs and As

Elizabeth Dye
Julie Green
Gin Attie
Barbara Woolley

No. of Pages (including cover): 5

FYI anne

✓

DRAFT

DRAFT

February 26, 1997

QUESTIONS AND ANSWERS

THE REGULATION

Q. What are the provisions of the final rule?

A. Broadly, there are two types of restrictions: those dealing with youth access and those dealing with advertising.

Access:

Prohibits sale of tobacco to persons under age 18.

Requires age verification by photo ID for anyone under the age of 27 purchasing tobacco products.

Ban vending machines and self-service displays except in locations that are totally inaccessible to anyone under 18.

Bans free samples, sales of single cigarettes, and packages containing fewer than 20 cigarettes.

Advertising:

Permits 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.

Ban~~s~~ billboards within 1,000 feet of schools and playgrounds. ✓
Other advertising -- billboards, signs in and on buses, and in-store advertising -- is restricted to black and white text-only. Advertising in "adult only" facilities, such as nightclubs, can have color and imagery.

Prohibits brand-name sponsorship of sporting or entertainment events (including teams and entries), but permits sponsorship in the corporate name.

Bans brand identified non-tobacco items (e.g., tee shirts).

Q: What parts of the rule take effect today?

A: As of today, Federal law prohibits retailers from selling cigarettes and smokeless tobacco to persons under age 18 and requires retailers to request photo IDs from customers who are under age 27.

DRAFT

EDUCATIONAL CAMPAIGN

- Q: Are tobacco companies required to pay for an educational campaign?
- A: The Agency has not yet begun the consultation process with the companies on a national multi media campaign to provide educational messages to children.

THE BURDEN ON RETAILERS

- Q: Isn't this really going to burden retailers?
- A: These are common sense rules to make sure that tobacco products are kept out of the hands of our kids and doesn't overly burden businesses. It's about doing what everyone agrees should be done. Nobody wants our kids to smoke, including the the people who sell ~~them~~ tobacco products. ✓

ENFORCEMENT

- Q: How will the Administration enforce the FDA regulation?
- A: The most important part of enforcement is informing the retailers and the general public of what the regulations require. FDA has conducted an outreach program to inform retailers, as well as parents, health professionals, community groups, state and local officials, about the FDA's tobacco regulations.
- In addition, the President included \$34 million in his FY 98 budget for the implementation and enforcement of the FDA regulations. The bulk of these funds will be used to contract with state governments to inspect the estimated 400,000 retail outlets which sell tobacco products. This is critical because, unfortunately, the majority of retail outlets continue to sell tobacco products to children, reinforcing the need for an aggressive and visible enforcement program.
- Q: Will there be penalties exacted against retailers who sell to minors?
- A: FDA will first send a warning letter to any retailer who sells tobacco products to minors. Any retailer who does this a second time will be subject to civil money penalties.

DRAFT

We are conducting a nationwide search for the best person to replace Dr. Kessler.

LITIGATION

Q: When is Judge Osteen going to rule?

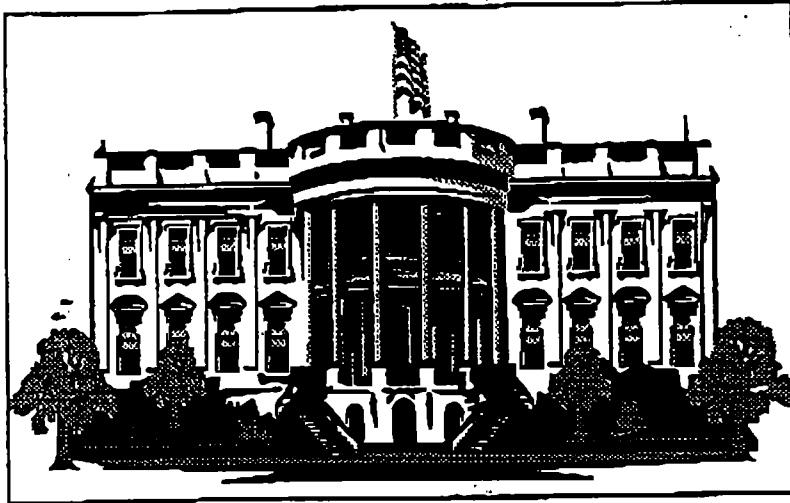
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Q: What do you think are the chances of your winning this case?

A: We are confident that we stand on firm legal ground and that we will prevail. We think these steps are absolutely essential if we are to reduce the numbers of our kids who become addicted to tobacco products and who will eventually die because of this addiction. The decision is now in Judge Osteen's hands and it is simply impossible to guess what he might do. We are content to wait for his ruling.



THE WHITE HOUSE
OFFICE OF CABINET AFFAIRS
Room 160, Old Executive Office Building
Washington, D.C. 20500
Tel. 202-456-2572
Fax. 202-456-6704

FAX COVER SHEET

DATE:

2/24/97

TO:

Andy Hyman, Jim O'Hara
Jerry Mann, Barbara Woolley, Elizabeth Dye

PHONE:

202-456-2572

FAX:

456-6704

FROM:

Anne McGuire

NO. OF PAGES:

3

PRIORITY: ☒ Y ☐ N

MESSAGE:

Attached is a list of
suggested invitees for Friday's
event. Please get me your comments
tomorrow morning so we can start
inviting. Thanks Anne

GROUPS***

American Cancer Society
American Lung Association
National PTA
National Association of Secondary School Principals
American Nurses Association
Students Opposing Smoking

*** These groups have been identified as needing a representative. Suggestions welcome.

The following are suggested invitees:

Mr. Scott Ballin
Vice President, American Heart Association

Mr. John Banzhaf
Executive Director, Action on Smoking and Health

Ms. Felicia Bloom
Tobacco Control Project, American Medical Women's Association

Mr. Roy Branson
Interreligious Coalition on Smoking Or Health

Dr. Jan Breslow
President, American Heart Association

Dr. Lonnie Bristow
President, American Medical Association

Rev. Jesse Brown
Chairman, Uptown Coalition for Tobacco Control and Public Health

Ms. Brenda Caffee
African Americans Against Tobacco

Mr. Joe Califano
President and CEO, Center for Alcohol and Substance Abuse

Mr. Gregory Connolly
Director, Tobacco Control, Massachusetts Department of Health

Ms. Linda Crawford
Regional Director, PMA

Dr. Jane L. Delgado
President, National Coalition of Hispanic Health and Human Services Organization

Ms. Carmen Delgado-Votaw
Director, Girl Scouts of the USA

Mr. Andrew Halpert
President, Student Coalition Against Tobacco

Mr. Matthew Hardman
Coordinator, Tobacco Free, Inc.

Dr. Richard Heyman
American Academy of Pediatrics

Mr. Andrew Kaufman
RWJ Foundation

Ms. Patricia Moreis-Stiles
Manager of Public Advocacy Communications, Smoke Free Class of 2000

Mr. Matthew Myers
General Counsel, Campaign for Tobacco-Free Kids

Mr. William Novelli
Director, Campaign for Tobacco-Free Kids

J.B. Pratt
???????????

Mrs. Janet Sachman and Mr. Joseph Sachman
Former Lucky Strike/Chesterfield Model

Ms. Judy Sopenski
Executive Director, Stop Teenage Addiction to Tobacco

Frank Hunger
U.S. Department of Justice

WHITE HOUSE STAFFING MEMORANDUM

4:30 p.m.

DATE: 2/27/97ACTION/CONCURRENCE/COMMENT DUE BY: 2/27/97SUBJECT: Remarks — Tobacco Regulations Announcement

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☒	☐	McCURRY	☐	☒
BOWLES	☒	☐	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☐	☐
PODESTA	☒	☐	RUFF	☒	☐
MATHEWS	☒	☐	SMITH	☐	☐
RAINES	☐	☐	REED	☒	☐
BAER	☒	☐	SOSNIK	☒	☐
ECHAVESTE	☒	☐	LEWIS	☒	☐
EMANUEL	☒	☐	YELLEN	☐	☐
GIBBONS	☐	☐	STREETT	☐	☐
HALE	☐	☐	SPERLING	☐	☐
HERMAN	☐	☐	HAWLEY	☐	☐
HIGGINS	☐	☐	WILLIAMS	☐	☐
HILLEY	☐	☐	RADD	☐	☐
KLAIN	☒	☐	<u>Waldman</u>	☒	☐
BERGER	☐	☐	<u>E. Drye</u>	☒	☐
LINDSEY	☐	☐		☐	☐

REMARKS:

Comments to Terry Edmonds.

RESPONSE:

DRAFT

PRESIDENT WILLIAM J. CLINTON
TOBACCO REGULATIONS ANNOUNCEMENT
THE WHITE HOUSE
FEBRUARY 28, 1997

Thank you, Anna Santiago for the power of your example and for that warm introduction. I also want to thank the Vice President and Secretary Shalala for their outstanding commitment to this effort. And I want to offer a special word of thanks to David Kessler, the finest FDA Commissioner we have ever had, for your outstanding service to our nation, and especially for your leadership in this effort to protect our young people from the dangers of tobacco. Because of your actions over the last six years, more AIDS and cancer patients are getting better drugs faster. More people are getting better information on their food labels. And every American can go to bed knowing that the food on their tables and the medicines in their cabinets are safe. You have left a great legacy of progress and all Americans should be grateful for your service.

We are all here today to help ensure that Anna Santiago and every young person in this country has a chance to live out their dreams. They can only do that if they choose to live positive and healthy lifestyles, and if we give them the support they need to make that choice. Most of us have an instinctive urge to protect our young people from danger. We teach them to look both ways before crossing the street. We tell them not to touch a hot stove. We make sure they bundle up before going out into the cold. We should wrap that same protective arm around them when it comes to smoking.

More Americans die every year from smoking related diseases than from AIDS, car accidents, murders, suicides and fires combined. Today, it is estimated that 4.5 million of our children and adolescents smoke, and another 1 million use smokeless tobacco. And the problem is getting worse. Smoking rates among eighth graders have risen 50 percent in the last six years. One out of every three young persons who picks up this deadly habit will have their lives shortened from the terrible diseases caused by smoking. We, as parents, as leaders and as citizens have a moral obligation to do what we can to protect those precious young lives.

That is why last August, the FDA took bold action to protect our children from the dangers of tobacco. We set a goal of reducing tobacco use by children and adolescents by 50 percent in seven years. To do that, we initiated the nation's first-ever comprehensive effort to restrict access and limit the appeal of tobacco to children.

Today is the first day that some of these rules take effect. First, we are making the law of the land what already is the law in every state -- no sale of tobacco products to anyone under the age of 18. Second, we are now requiring age verification by photo ID for anyone under the age of 27 before the purchase of tobacco products. From now on, in every store in America, our children will be told "no ID, no sale." By requiring ID checks for anyone under 27, store clerks and managers will no longer have to guess the age of those seeking to buy cigarettes. Studies show that minors succeed in buying cigarettes over-the-counter nearly 70 percent of the time. That simply must stop. With this new requirement to check IDs, we will help keep cigarettes out of reach of our young people while giving

store clerks and managers a tool to make sure they are not violating the law by selling to minors.

Over the last three weeks, we have conducted a massive nationwide education campaign to let retailers know how they can comply with these new rules. We have even prepared this new guide [hold up brochure] and made it available to 500,000 retailers across the country. **I call on every retailer in every community across this country to join with us in this important effort to protect our children. Parents must continue to be the first line of defense. But it is up to all of us to make these rules work.** Let me be clear -- cigarettes are a legal product for adults. If they want to smoke, they can still do so. But, we must draw the line at our children.

Thank you.

*to protect minors
children Ann
Abner
begin to take
effect*

President Clinton Announces First Actions
under FDA's Rule to Protect Children from Tobacco
February 28, 1997 -- THIS DRAFT NOT FOR DISTRIBUTION

Announcement -- *Tougher new measures begin to take effect.*

- o **President Clinton announced that today the Federal government is taking the first steps under the Food and Drug Administration's rule to restrict children's access to tobacco products.** Beginning today, provisions of FDA's rule:
 - o **Prohibit retailers from selling cigarettes and smokeless tobacco products to anyone under age 18** -- this age restriction becomes a Federally enforceable regulation, giving retailers a greater incentive to meet the requirement.
 - o **Require retailers to verify age by photo ID for anyone under the age of 27 purchasing these products.** Most state attorneys general, and even tobacco retailers, have indicated the need for checking IDs of customers significantly older than 18 so that retailers don't sell to mature-looking adolescents.

Background

- o **President Clinton announced the final FDA rule to protect children from tobacco on August 23, 1996.** The rule seeks to reduce children's tobacco use by 50% over seven years by restricting children's access to tobacco and by reducing the appeal of cigarettes and smokeless tobacco products to children. The first two provisions of the rule take effect today.
- o **Youth smoking is on the rise.** Each day about 3000 American children become regular smokers. Of these, 1,000 will die early from tobacco-related illness. In the past six years, the smoking rate among eighth graders has risen 50%. Today the average teenage smoker begins to smoke at 14 ½ years old and becomes a daily smoker before age 18.
- o **Youth have widespread access to tobacco products.** Although selling cigarettes to people under 18 is already against the law in all 50 states, studies show that young people easily obtain tobacco products. Most children and adolescents who smoke purchase their own cigarettes. National data from the 1995 Youth Risk Behavior Survey show that over three-quarters of high school students under age 18 who had purchased cigarettes in the previous month had not been asked by a clerk to show proof of age. Local studies have shown that enforcement of minors' access laws -- especially laws requiring the retailer to check for proof of age -- can significantly reduce the percentage of retailers who sell cigarettes to minors.

Additional Provisions to Restrict Access and Reduce Appeal Take Effect Later this Year

- o On August 28, 1997, additional provisions of FDA's rule become effective. They include: prohibiting billboards within 1,000 feet of schools and playgrounds and restricting other advertising to black-and-white text only except in locations only accessible to adults; permitting black-and-white text only advertising in publications with significant youth readership; prohibiting the sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos; and prohibiting vending machines and self-service displays except in places where people under 18 are never present.
- o On August 28, 1998, FDA's final rule will prohibit the brand-name sponsorship of sporting or entertainment events. The rule permits sponsorship in the corporate name.

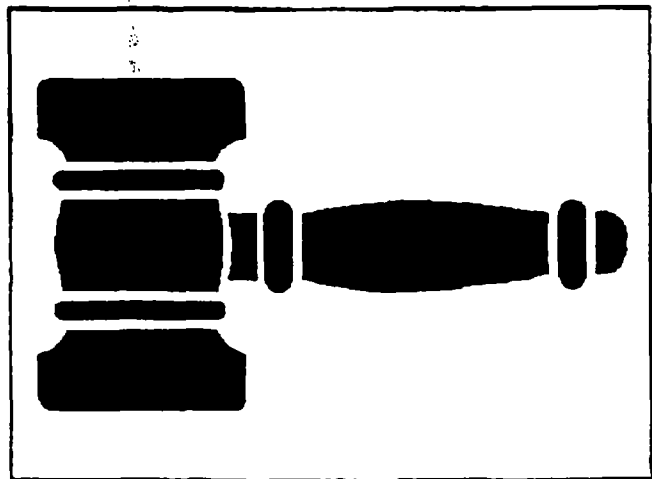
FACSIMILE TRANSMISSION

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 713-F H.H. Humphrey Building
Washington, DC 20201

TO: *Elizabeth Drye*
486-5581
7028

FROM: Andrew D. Hyman
Office of the General Counsel
Telephone: 202/690-6318
Facsimile: 202/690-7998

FAX:



No. of pages:

3

MESSAGE:

draft
2/25/97
8 a.m.

10

**PROTECTIONS FOR CHILDREN FROM TOBACCO
TAKE EFFECT TODAY**

The Clinton Administration's plan to reduce children's use of tobacco products kicks off today with the first provisions of the Food and Drug Administration's final rule on youth and tobacco taking effect. These provisions make 18 the age for the purchase of tobacco products nationwide and require photo IDs for anyone under 27.

The Administration's efforts come in the face of grim statistics: 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. In the past four years, the United States has experienced a startling rise in tobacco use by youngsters. Between 1991 and 1995, the percentage of eighth- and tenth-graders who smoke increased 34 percent. Today, the average teenage smoker begins to smoke at 14 1/2 years old and becomes a daily smoker before age 18.

President Clinton announced the final FDA rule to protect children from tobacco on August 23, 1996, slightly more than a year after the Agency proposed a number of ways to reduce adolescents' use of tobacco products. During that year, the FDA reviewed and analyzed

more than 700,000 comments from the public -- the largest outpouring in the Agency's history -- before making its final decisions. The rule was then published in the Federal Register on August 28, 1996, with the first provisions -- dealing with children's access to tobacco -- becoming effective in 6 months.

On August 28, 1997, additional provisions -- those aimed at reducing the appeal of tobacco products to children -- will become effective. They include: prohibiting billboards within 1,000 feet of schools and playgrounds and restricting other advertising to black-and-white text only; permitting black-and-white text only advertising in publications with significant youth readership; prohibiting the sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos. On August 28, 1998, the final rule will prohibit the brand-name sponsorship of sporting or entertainment events.

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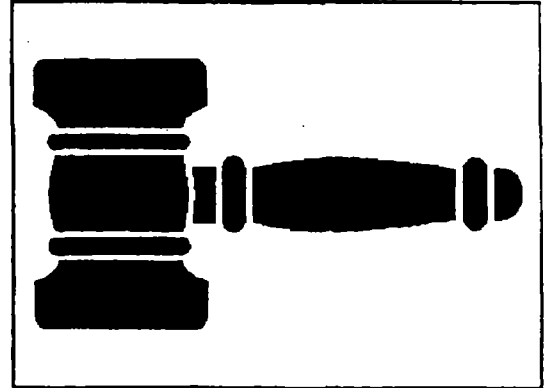
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL

PHONE: (202) 690-6318

FAX: (202) 690-7998

DATE: February 25, 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: Youth access info:

Widespread youth access to tobacco remains a serious problem in our country. National data from the 1995 Youth Risk Behavior Survey show that over three-quarters of high school students under age 18 who had purchased cigarettes in the previous month had not been asked by the clerk to show proof of age. In this same survey, students reported that their most common source of cigarettes was purchasing them from stores. Other national data from the 1993 Teenage Attitudes and Practices Survey found that 62% of smokers aged 12-17 years usually bought their own cigarettes.

Numerous local studies in which underage minors attempted to buy cigarettes have documented the ease with which minors are able to purchase cigarettes from both vending machines and over-the-counter retail outlets. Minors were usually able to purchase cigarettes in over half of attempts from over-the-counter outlets and over 90% of the time from vending machines. Other local studies have shown that enforcement of minors' access laws, especially laws requiring the retailer to check for proof of age, can significantly reduce the percentage of retailers who sell cigarettes to minors.

No. of Pages (including cover): 1

FACSIMILE TRANSMISSION

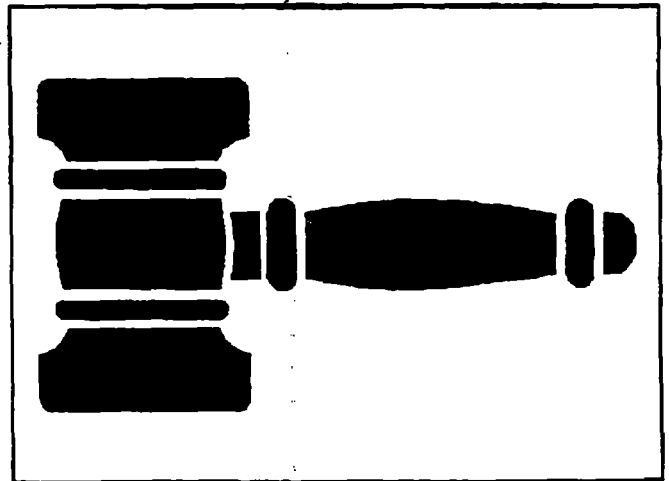
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 713-F H.H. Humphrey Building
Washington, DC 20201

TO: *Elizabeth Dye*

FROM: Andrew D. Hyman
Office of the General Counsel
Telephone: 202/690-6318
Facsimile: 202/690-7998

FAX:

456 7028



No. of pages: *3*

MESSAGE:

As requested.

6:00 AM
6/20/99

T 5:00 Conference Call. —

Shalala
VP

KID

President

→ Anna Santiago — Nat Center
for tobacco-free kids
advocate the year

40

8th grade
people
props

Leg Affairs

5

Kids w/ T-shirt

10-15

Other. —

20

4 color brochures. — 300,000. —

1-800 — line —

— Retailers can call

— ~~Other~~ violations. —

— Kids —

— Parent —

— Pratt. —

10:30 am Friday —

Anne — will follow up w/ ~~PR~~

Get From FDA — latest sell Data

— 1-800-number

Tobacco Event

Roosevelt Room — as back up to
Rose Garden —

Tony Edmunds speechwriter.

— J. B. Pratt. —

Memo COB tomorrow —

Tobacco 4/18 4:00

- Mrs. Gore?
- Conf call?
- Julia - w/Dan - 17/10/11 is coming to POTUS -
 - ↳ but video
 - Conf call
 - Mrs. Gore OK

US Women's soccer team - finals of tournament
in DC

May 18th -

NJR - Shareholders mts - LeBaron & the State of Directors.
if Liggett succeeds in getting majority shareholders
of last week - Liggett already started
paying states under settlement.

Hill staff mts -

- positive staff -
- Concerns about NACAR 1st Amendment -
bills in on that.

Campaign For Tobacco Free Kids

- 50-30-1 plans 50

Kleuger / Phil Hiltz -

Vanity Fair - profile of Wiggand -

Producers end of campaign period to on deposition -

Pending
news

Focus on 94 names

Jim O'Hara
Victor HAS has seen.
301 443-1130
U.S.T.

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.