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THE WHITE HOUSE

WASHINGTON

March 6, 1996

MEMORANDUM FOR: LEON PANETTA

FROM: JENNIFER O'CONNOR
CHRIS CERF

RE: Tobacco Proposal

Attached is a detailed side-by-side comparison of the proposed FDA rule with the new proposal. The principal differences are summarized below.

I. ACCESS

Their proposal abandons the principle of no sales other than through a face-to-face transaction with an adult. Thus, they would permit (1) vending machines and free samples in areas where minors are denied access; and (2) mail order and coupons through the mail when accompanied by xeroxes of age identification.

II. ADVERTISING

The new proposal bans outdoor advertising within 500 feet of schools and playgrounds, while the FDA proposal would establish a 1000 foot perimeter.

With respect to outdoor advertising outside of the 500 -foot perimeter, the key differences are: (1) while the FDA would permit only black-and-white, text-only format (tombstone) ads, the new proposal would merely ban billboards of less than 225 square feet and on ads on taxis, busses and trains and their platforms and stands; and (2) while the FDA would require tombstone format for "point of sale" ads, the new proposal does not address point of sale at all.

For publications, the FDA requires tombstone advertising in all publications with youth readership above 15% or 2 million, whichever is smaller. The new proposal, in contrast, would ban advertising altogether in publications with greater than 75% youth readership (e.g., Weekly Reader). In addition, while the FDA requires tombstone format for all direct mail sent to the home, the new proposal does not address it at all.

With respect to merchandise giveaways (caps, etc.), the FDA bans them altogether, while the new proposal would permit them with appropriate age verification. For clothing, only adult sizes would be permitted.

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The new proposal would ban sponsorship of sporting events at baseball, football, hockey and basketball arenas unless the audience was expected to be 75% or more adults. Tennis and stockcar events are excluded altogether, unless played in such an arena. The FDA proposal banned corporate sponsorship of all such events.

III. EDUCATION CAMPAIGN

Unlike the FDA rule, the new proposal would not require any public education campaign, much less one funded by the industry.

IV. JURISDICTION AND ENFORCEMENT

Under the new proposal, the FDA is divested of jurisdiction. In its place, the FTC would enforce advertising provisions. Access provisions would be enforced pursuant to the SAMHSA/Synar scheme, e.g. conditioning federal funds on enforcement of state laws, including retail licensing.

Tobacco Side by Side
March 6, 1996

Us	Their Changes
1 Applies to cigarettes and smokeless tobacco products, not cigars or pipe tobacco.	1 Appears to apply to all tobacco products.
2 Prohibit sales to individuals under 18 years old, or the state age limit if higher (federalizing state law).	2 Prohibits sale to individuals under 18 (doesn't allow state to set higher limit) and also prohibits purchase by individuals under 18 (imposing penalties for using a fake id. to obtain cigarettes).
3 Access restrictions designed to limit sales to face-to-face transactions, <u>e.g.</u> , • Require retailers to verify age with a photo i.d. card • Ban everywhere: - vending machines, - free samples, - sale of "loosies" (single cigarettes), - sale of "kiddie packs" (fewer than 20 cigarettes per pack), - self-service displays, - coupons sent through the mail,	3 Access restrictions. • Require photo id. for anyone who appears under 21. • Ban except in areas where minors are denied access: - vending machines - free samples (levies fines where this particular provision is violated). • Ban everywhere: - sale of loosies - sale of kiddie packs is banned. • In locations except where minors are denied access, self service displays of single packs of cigarettes are allowed if in line of sight of cashier or under cashier's control (video monitoring is sufficient to satisfy this provision). • Bans coupons sent through mail for tobacco or products with tobacco trademarks to anyone who has not signed a certification that s/he is of legal age to purchase tobacco products and include a copy of proof of age such as drivers'

- mail order purchases.

license. (Graduated fines for companies not acting in good faith and persons submitting false certifications.)

- Tobacco products may be sent through mail only to persons certifying legal age as described above. Same requirements and fines as above.

4 Manufacturers are obliged to inspect (whenever they routinely visit a retail site) to ensure proper labeling, advertising and distribution of their products. When they see something that violates the rule, such as a self service display, they must remove it.

4 Retailers are required to prominently display signage stating the minimum age requirement, that it is illegal to sell to minors, and that it is illegal for minors to buy cigarettes. Retailers are required to have or participate in employee training programs about minimum age laws, requiring employees to certify their awareness of the law.

States shall license retail stores to sell tobacco. Fees for license of sale of tobacco shall not exceed state's administrative costs in administering program, except that states that already license such establishments may maintain current fee schedule. Graduated penalties shall be imposed on retailers who sell to minors.

5 Prohibit manufacturers from using the trade name of a non-tobacco product for a cigarette or smokeless tobacco product, e.g., Harley Davidson, Cartier and Ritz cigarettes. These latter three names, along with any other brands already named after a non-tobacco product, will be exempted (grandfathered) from the rule.

5 Ban licensing payments by tobacco companies to non-tobacco companies to use brand names on new tobacco products. (It is unclear whether tobacco companies pay licensing fees at present; Harley Davidson, et al, may allow the use of their names for free.)

6 Permit sponsorship of events in corporate name only, e.g., the Phillip Morris, rather than the Virginia Slims,

6 Bans brand name advertising in amateur or professional baseball, football, basketball or hockey arenas,

Tennis Tournament. This provision does not include teams or entries in events. Any corporate names used for these purposes must have been in existence as of January 1, 1995.

except for signs at concession stands where tobacco is sold. (Note, this exempts tennis and stockcars.) Also bans brand name sponsorship of events held in such arenas, unless 75% or more of the audience is expected to be older than 18, as certified by arena authority.

- 7 Ban outdoor advertising within 1000 feet of schools and playgrounds. This includes outdoor but not indoor signs at buildings within 1000 feet of schools.
- 8 For all outdoor advertising that is more than 1000 feet from schools or playgrounds (including the inside and outside of buses, billboards at sports facilities, stockcars and their crews), permit only black and white, text-only (tombstone) ads. The same approach for all "point of sale" ads (e.g., clocks and exit signs in retail stores).
- 9 Black and white, text only tobacco advertising in publications with youth readership of 15% or more than 2 million, whichever is less, but no restrictions would be imposed on print advertising below that threshold (other than the warning labels described in #10 below). All direct mail ads to the home would be tombstone style.
- 10 All cigarette advertising (but not smokeless tobacco advertising) that is not on a package label, e.g., billboards, print ads, and direct mail, but not reminder ads such as those on stockcars and crews and other similar event participants, must include a statement that the product is a cigarette, that it is "a nicotine delivery device," and an additional warning.

- 7 Ban on outdoor advertising within 500 feet of a school, playground or youth recreation center. Grandfathers in current advertising contracts.
- 8 Ban on all outdoor billboards of less than 225 square feet. Ban transit ads, i.e., on busses, taxis, trains, and all stands and platforms for such vehicles. "Point of sale" ads are not covered.
- 9 Ban advertising of tobacco in periodicals with 75% or more youth readership, as determined by surveys. FTC is responsible for keeping a list of such periodicals. Direct mail is not covered.
- 10 No similar provision.

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The label must be readable, clear, conspicuous and prominently displayed and must be contiguous with the Surgeon General's warning. The FDA is soliciting comments on how best to meet these standards. An example of an appropriate warning is: "About one of three children who become smokers will die from their smoking."

- 11 Ban sale or giveaways of caps, shirts, gymbags and other "trinkets" which carry a tobacco brand name or other tobacco product identification. Ban lotteries or contests where the "entry fee" is a cigarette purchase. Ban the distribution of non-tobacco items in exchange for proof of purchase of tobacco products; this provision of the rule eliminates the "Camel Cash" and "Marlboro Miles" programs in which gifts are purchased using credits gained by buying tobacco products.
- 12 Create a \$150 million per year industry-funded educational program. Each company would pay the portion of \$150 million each year equal to its share of the total advertising and promotional expenditures of the industry.
- 13 Provide that if within seven years, youth smoking has not been reduced to 50% of its 1994 level, additional measures would be taken. The FDA will receive comments on what measures could be taken if youth smoking were not reduced by 50% within 7 years.
- 14 More restrictive state laws are not preempted by this rule. States and localities may request an advisory opinion from the FDA as to whether state or local requirements are

- 11 Ban all merchandise giveaways in person unless age can be verified. Clothing merchandise only permitted in adult sizes. Merchandise through the mail allowed only with age verification as described in #3 above. Doesn't specifically address lotteries and "Camel Cash" type programs. Trade to trade gifts are excluded from these rules.
- 12 No similar provision.
- 13 No similar provision.
- 14 No similar provision.

preempted.

15 General reporting such as sending copies of ads and labels to the FDA is required.

16 As with other drug delivery devices, advertising cannot be false or misleading.

17 Jurisdiction: FDA.

18 No similar provision.

19 No similar provision.

15 No similar provision.

16 No similar provision.

17 Jurisdiction: States would have jurisdiction over youth access provisions as a condition of receiving federal funds as is done under the Synar regulation. FTC would have jurisdiction over advertising provisions. FDA would be expressly divested of jurisdiction over tobacco products marketed without therapeutic claims.

18 No payment, direct or indirect, by any manufacturer or agent, for the placement of any tobacco product, package or advertisement as a prop in a movie or television program for viewing by the general public. (Doesn't affect use of products in movies/ tv shows where the tobacco company doesn't pay a fee.)

19 No tobacco product brand names or logos in video games or on video game machines, or on or within the premises of "family amusement centers."

TOBACCO

Q: Ford has introduced legislation that keeps FDA out of tobacco regulation. Is that OK?

A: Our concern has always been with getting the job done, not who does the job. 3,000 young people become regular smokers each day, and nearly 1,000 of them will die from smoking-related diseases. If we can reduce kids' smoking, we can make incredible public health gains: more than 80 percent of all adult smokers tried smoking by the time they were 18, and more than half of them became regular smokers by that age. We must address this -- and that's what my Administration's proposed regulation does and what any legislation that I would sign must do. It's premature, however, to discuss what agency might ultimately have responsibility under any legislation.

Q: Could the Administration support the Ford bill?

A: Senator Ford's bill is in itself an important recognition of the serious problem of kids' smoking. We have said from the start that we would welcome the opportunity to work with lawmakers to prevent this terrible public health tragedy we now face. It's too early to talk of support; the bill has just been introduced; there will have to be hearings; it's just too early in the process.

Q: The Administration proposals are getting beaten up on the NASCAR circuit. Does that worry you?

A: There has been a lot of confusion on this point. The tobacco companies can still sponsor NASCAR races under our proposal. What they will have to do is sponsor them in the corporate name, not in the brand name like they do now. Under our proposal, the tobacco companies can still sponsor teams -- such as cars in a race -- and they can even name their teams after cigarette brands if they want to.

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

Q: The proposals have also received a lot of criticism on First Amendment grounds, and Canada's high court just struck down that country's restrictions on tobacco advertising and promotions?

Copies of Mar 6 side by side
"1" - cert ~~#2~~ - O'Connor
bunnet

Principle diffs:

✓ (1) no verch wches

only not
for kids
premise of for to face

✓ (2) point of sale

✓ (3) bill boards

✓ (4) overheads

(5) jar /ent

✓ (6) sports

✓ (7) no edue fund /goals

- FDA investigators have
been out talking to
Wigand people

- breakthrough

- 2-3 ppl prepared
to sing

for RJR / PM

devastating

- comment per. - closed
raging debate

- let go

- reopen record, etc.

11th Cir

- will preempt state tort actions under medical device act
- will kill the P's

Wigand w/o baggage -

PM - saying Wigand,
but more credible

docs/stmts w/ FDA

in a week
they 'll announce
they 'll expand
revenue

^{to}
open comment
period

for 30 days

they would say impact
on timing

(1) A - drafts & research articles w/
no copy ghs
(release)

(2) B - transcripts
(not released)

- statements
by witnesses
(released)

id'd as confid does
repping transcript.

will be unrecorded but

7 rely on these
fessler principle - but's (FDA)
abn. to do invest's

If we release statements & not
transcripts - they'll say
how can we comment
if I have all ev

Choice - do nothing -
we can win w/o
etc

better to respond comment
per look we're on side
of angels - better to be
open - if it gets out
we're wise, it will be
criticized

this old cause
up again on opening up
period - which would
enjoy rule

Chris says ok b/c
group for judge to
need in camera
& decide to release

Draft Proposal

FDA's Proposed Rule

I. LEGISLATION

A. Youth Access

Minimum age Establish minimum age of 18 for the sale and purchase of tobacco products. States not precluded from establishing higher minimum age requirement.	Same, but does not expressly allow states to set a higher minimum age requirement, although proposed rule's preemption provisions would effectively allow states to do so.
Identification Require picture identification for the purchase and sale of tobacco products for any individual appearing to be under the age of 21.	Same, but proposed rule itself does not limit requirements to individuals appearing to be under the age of 21 (although discussion of proposed rule notes state attorney's general recommendation that proof-of-age requirement should apply to those who do not appear to be at least 26 years old).
Signage Retailers required to prominently display signage clearly stating: 1) minimum age requirement; 2) illegal to sell tobacco products to minors; and 3) illegal for minors to purchase.	No comparable provision. (Proposed rule, however, imposes general responsibility on distributors to ensure that tobacco products comply with FDA's rules.)
Vending Tobacco products only sold through vending machines located in age restricted establishments.	Ban vending machine sales.
Sampling Sampling of product permitted only in areas or establishments where minors are denied access. Graduated system of fines for violations.	Ban sampling, either in person or through the mails.
Single Cigarettes Prohibit the sale of single cigarettes.	Same. (Specifically, ban sales other than from unopened packages.)
Packs of Less Than 20 Ban packs containing fewer than 20 cigarettes.	Same.

Draft Proposal**FDA's Proposed Rule**

Training Require retail employee training programs about minimum age laws, requiring employees to certify their awareness and commitment to observing law. (Should contain phase-in period for compliance.)	No comparable provision.
Merchandise Giveaways In Person Ban all merchandise giveaways in person unless age can be verified. Clothing merchandise only permitted in adult sizes. Trade to trade gifts excluded from these rules.	Ban gifts or lotteries based on proof-of-purchase of tobacco products or redeemable coupons. Ban use of tobacco product brand names or logos on all nontobacco (utilitarian) items and services.
Purchase By Minors Prohibit purchase of tobacco products by minors and provide enhanced penalties for use of false I.D. to obtain tobacco products.	No comparable provision. (As noted above, prohibit the sale and distribution to minors; but doesn't address purchase by minors or provide penalties for use of false identification.)
Licensing Under SAMSHA-like scheme, every state shall adopt a licensing scheme on a per store-site basis permitting the retail sale of tobacco products. Fees for such license, and their renewals, on a per store-site basis, may not exceed the administrative costs incurred by the state in issuing and/or renewing such licenses. This limitation on fees would only apply to states that do not already have licensing schemes in place by the effective date of this Act. Graduated penalties would be imposed on retail outlets that sells cigarettes to minors.	No comparable provision

Draft Proposal

FDA's Proposed Rule

Retailer Line of Site It is unlawful for a retail establishment to display single packages of tobacco products in any place that is not within the line of sight, or under direct control of a cashier or other employee of retailer during regular business hours. For purposes of this subsection, a location monitored by electronic means in a manner that enables the cashier or other employee to view the location shall be deemed to be within the line of sight. The display restriction would not apply to tobacco products offered for sale in any place of business to which persons under 18 are not admitted or to which such persons are not admitted unless accompanied by parent or other adult.	No identical provision. (But FDA's proposed rule would ban self-service displays; require retailers to ensure that all sales are "direct, face-to-face" transactions; and require manufacturers to conduct visual inspections to ensure retailers' compliance with the FDA's rules. And, manufacturer must remove from retail outlets all self-service displays, advertising, labeling and other manufacturer-owned items that do not comply with the proposed rules.)
Jurisdiction Would give states jurisdiction over Youth Access provisions as a condition of receiving federal funds as is currently done with SAMHSA. Must expressly divest FDA of jurisdiction over tobacco products marketed without therapeutic claims.	Manufacturers, distributors and retailers would have to comply with more stringent state and local requirements as long as they do not conflict with FDA requirements.

B. Advertising

Tobacco Free Advertising Zone No exterior brand advertising of tobacco products would be permitted, including in a window of a commercial establishment facing out toward a public space, within 500 feet of any public, church-affiliated, or accredited private elementary school, junior high school or high school, or any public youth playground or public youth recreation center under any contract entered into after (insert date). All contracts for above described advertising after effective date would include clauses implementing prohibitions.	Ban outdoor ads within 1,000 feet of any playground, elementary or secondary school (including signs on retail stores).
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Brand Name Advertising and Sponsorship at Sporting Events Ban on permanent brand name advertising in arenas or stadia where either sanctioned amateur or professional baseball, football, basketball or hockey events are regularly conducted. Exception made for signage at concession stands where tobacco products are offered for sale. In addition, ban on brand name sponsorship of any event held in said arena or stadia and related signage unless the arena or stadia authority certifies that it expects 75% or more of the attendees to be 18 years of age or older.	Ban sponsorship of athletic, municipal, artistic or other social or cultural event in tobacco product brand name; allow only corporate sponsorships (if tobacco company name was in existence on 1/1/95). Also limit logos and brand names on entries and teams in sponsored events to a black-on-white format.
Periodicals Advertising of tobacco products would only be permitted in periodicals for which at least 75% of the subscribers are 18 or older, as determined on the basis of surveys of the type currently conducted for periodicals to determine subscribership. The FTC would be responsible for maintaining and keeping current a list of all periodicals described above. If subscriber data is unavailable, purchaser data to be used.	Allow only "tombstone" ads, except for advertising in certain "adult" periodicals, defined as a publication whose readers age 18 or older constitute 85% or more of total readers and that is read by fewer than 2 million persons under age 18.
Product Placement No payment, direct or indirect, by any manufacturer or any agent thereof for the placement of any tobacco product, package or advertisement as a prop in any movie or television program produced for viewing by the general public.	No comparable provision (although it is not clear that FDA's rules defining permissible outlets for advertising would include product placement).

Draft Proposal

FDA's Proposed Rule

Coupons/Utilitarian Items by Mail No coupons for free or discounted tobacco products or utilitarian items (consider adopting definition of "utilitarian" item from Smokeless Act) bearing tobacco trademarks may be sent through the mail to any person who has not signed a certification that the person is of legal age to purchase tobacco products under state law, is a tobacco product consumer, and desires to receive free items and offers and who has been verified to be of legal age to purchase tobacco products under state law by the receipt of a copy of a person's drivers license or other proof of age documentation. Effective date for collection of proof of age within 12 months of date of enactment. Graduated system of fines for violations by tobacco companies not acting in good faith and by persons submitting false certifications.	Ban mail-order redemption of coupons and coupons that are used as proof-of-purchase for a nontobacco gift. Ban gifts or lotteries based on proof-of-purchase of tobacco products or redeemable coupons.
Video Games/Amusement Centers No tobacco product brand names or logos in video games or on video game machines, and no tobacco product brand names or logos on or within the premises of family amusement centers.	No comparable provision.
Transit Ads Ban transit ads -- i.e., all subway, bus, taxi and train ads, as well as ads in bus, taxi, train and subway shelters, platforms and stations.	No comparable provision. (As noted above, however, ban outdoor ads within 1,000 feet of any elementary or secondary schools. And, all ads, including transit, must be in tombstone format, except for those in "adult" publications, as discussed above.)
Non-Tobacco Product Brand Name Ban Ban licensing payments by tobacco companies to non-tobacco companies to use their brand names on new tobacco products.	Same (except that ban is couched in terms of <u>use of</u> non-tobacco brand name on tobacco product, rather than on licensing payments, and brand names in use on 1/1/95 are excluded).

Draft Proposal**FDA's Proposed Rule**

Products Sent Through Mail Tobacco products may be sent through the mail only to persons who have signed a certification that the person is of legal age to purchase tobacco products under state law , is a tobacco product consumer, and desires to receive tobacco products and who has been verified to be of legal age to purchase tobacco products under state law by the receipt of a copy of the person's drivers license or other proof of age documentation . Effective date for collection of proof-of-age within 12 months of date of enactment. Graduated fines for violations by tobacco companies not acting in good faith and by persons submitting false certifications .	Ban sale and distribution of tobacco products through the mail
Billboards Ban on outdoor billboards of less than 225 square feet .	As noted above, ban billboards within 1,000 feet of any playground, elementary or secondary school (including signs on retail stores). In addition, billboards are restricted to black text on white background ("tombstone" format only).
Jurisdiction Items in Advertising section would be under the jurisdiction of the FTC.	FDA would have jurisdiction over advertising restrictions in the proposed rule.

FACSIMILE TRANSMISSION

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FROM:

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Department of Health &
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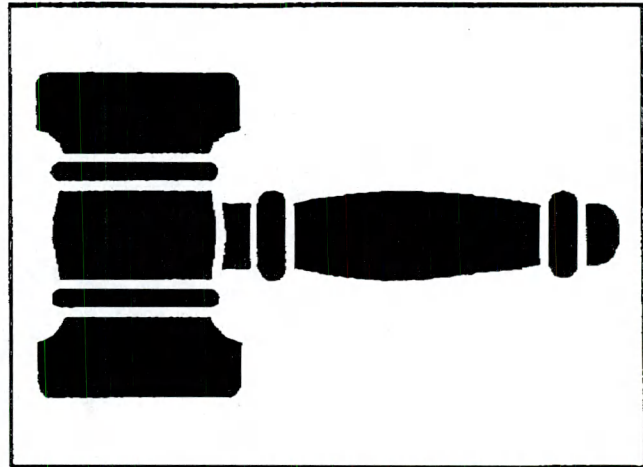
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01-18-96 12:27PM FROM SENATOR WENDELL FORD TO 61063

P002/007

NEWS RELEASE

WENDELL H. FORD of KENTUCKY

UNITED STATES SENATE

**173-A Russell Senate Office Building
Washington, D.C. - 202/224-4343**

**FOR IMMEDIATE RELEASE
January 18, 1995**

**Contact: Mark L. Day
(202) 224-1156**

FORD: SAMHSA PROPOSALS REPRESENT PROPER ROLE FOR GOVERNMENT IN TEEN SMOKING BATTLE

WASHINGTON-- U.S. Senator Wendell Ford (D-KY) today said that the Substance Abuse and Mental Health Services Administration's (SAMHSA) proposed regulations addressing teenage tobacco use "is a proper role for government in the fight against teen smoking."

SAMHSA -- part of the U.S. Department of Health and Human Services (HHS) -- outlined their final regulations today on a 1992 law passed by Congress at the behest of anti-smoking legislators to prohibit the sale of tobacco products to those under 18 years of age.

"These regulations show just how misguided the Food and Drug Administration's proposals on teen smoking really are," Ford said. "What a contrast it is to see an agency following Congressional authority in a responsible manner, compared to another agency determined to offer outlandish and overburdensome proposals designed just to put tobacco farmers out of business."

The new SAMHSA proposals include requiring States to set up enforcement programs to prevent sales to teens and punishing States that don't meet their enforcement targets. HHS is directed to periodically evaluate the performance of each state in restricting teen tobacco sales. Under the 1992 law, complete authority in this area was given to SAMHSA.

"As I've said all along, I'm not opposed to government action to address this issue," Ford said. "These new proposals today from SAMHSA represent proper governmental action in this area. What I am opposed to is power grabbing bureaucrats at the Food and Drug Administration trying to trample adult citizens' rights to use a legal product."

He continued, "While I don't agree with every aspect of these final regulations, I do believe SAMHSA has the proper authority over this issue. Congress clearly set out for SAMHSA to work with the States, and I believe these proposals will help us more effectively fight teen smoking."

Ford said those who want to work with him in reducing teen smoking should support proposals such as SAMHSA's and work with the States. "Let's work with SAMHSA and the States to enforce the laws that are already on the books preventing the sale or

distribution of tobacco products to anyone under the legal age."
