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March 6, 1998

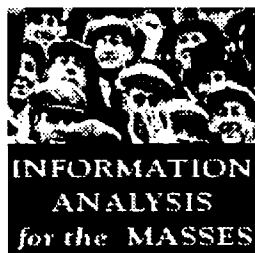
Senate Leaders Put McCain in Charge Of Crafting Bipartisan Tobacco Plan

By **JEFFREY TAYLOR**

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON -- The Senate leadership has placed the Commerce Committee and its chairman, John McCain, in charge of crafting bipartisan tobacco legislation.

The Arizona Republican is soliciting input from senators on the measure, which is expected to be substantially different from the proposed \$368.5 billion national tobacco settlement reached in June by the tobacco industry, states' attorneys general and public-health groups.



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Sen. McCain and the White House Seek a Bipartisan Deal on Tobacco (Mar. 4)

Congressional Leaders Are at Work on Bipartisan Bill for Tobacco Firms (Feb. 27)

The decision was made Wednesday, at a meeting that included Majority Whip Don Nickles of Oklahoma and Judiciary Committee Chairman Orrin Hatch of Utah. Mr. McCain agreed to postpone for at least two weeks a scheduled March 12 Commerce Committee meeting to formally consider tobacco legislation. In the meantime, his committee will hold at least two more hearings on the legislation.

Mr. McCain hopes to bring legislation to a committee vote before the April congressional recess, staff members said.

Sens. McCain and Hatch have drafted separate versions of tobacco legislation. Sen. McCain's bill largely replicates the proposed settlement, while Sen. Hatch's version makes a series of changes, including sharply increasing the amount the tobacco industry must pay to settle outstanding legal claims.

Mr. McCain is working with Senate Democrats, including John Breaux of Louisiana, Tom Harkin of Iowa and Bob Graham of Florida. Meanwhile, Democrat Kent Conrad of North Dakota has drafted a bill that is much tougher on the industry than the proposed settlement. Mr. McCain's main challenge may be to build bridges to antitobacco senators who have rallied around Mr. Conrad's bill.

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In the House, things are moving more slowly. Commerce Committee Chairman Thomas Bliley of Virginia hasn't proposed any legislation after a series of hearings on the settlement.

At a subcommittee hearing Thursday, Mr. Bliley attacked President Clinton's plan to speak publicly about tobacco in his weekly radio address Saturday. Rather than challenging Congress in public addresses, Mr. Bliley said, he should "work with Congress and don't leave town until together we have hammered out all the details."

Aides said Mr. Clinton is expected to deliver a tough message that a tobacco deal must get done and will call on Congress to adopt a timetable.

Mr. McCain is working with White House domestic-policy adviser Bruce Reed to try to reach a formula acceptable to both political parties.

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March 4, 1998

Sen. McCain and the White House Seek a Bipartisan Deal on Tobacco

By JEFFREY TAYLOR

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON -- Senate Commerce Committee Chairman John McCain has begun serious talks with the White House to hammer out the details of bipartisan tobacco legislation.

In an interview, the Arizona Republican said he met Monday with White House domestic-policy adviser Bruce Reed to discuss various aspects of the proposed \$368.5 billion national tobacco settlement and how Congress should change it. The two plan to meet again later this week and hold a series of meetings thereafter in an effort to reach agreement on a tobacco bill, Sen. McCain said.

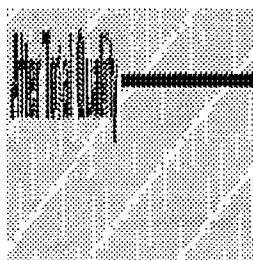
Also Tuesday, Federal Trade Commission Chairman Robert Pitofsky told Sen. McCain's committee that advertising restrictions in the proposed settlement aren't likely to withstand court challenges from advertisers. Congress should narrow the curbs, which would ban tobacco billboards and many in-store cigarette displays, before passing any tobacco bill, Mr. Pitofsky advised.

Effort to Keep Moving

Until this week, Sen. McCain had carried on a halting and largely unfruitful public correspondence with the White House. The senator fired off lists of bluntly worded questions, and the White House responded cautiously. The talks, Sen. McCain said, represent his

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"realization that the White House isn't going to get out front on this." He added: "You've got to keep everybody moving in the same direction."

Mr. Reed said the White House sees "growing interest on the Hill in getting this done," and added: "We're eager to resolve these issues."

Sen. McCain already has joined forces with Senate Judiciary Committee Chairman Orrin Hatch (R., Utah) to merge their rival tobacco bills. The Commerce Committee plans to take up the legislation next week. In another sign of serious progress on tobacco legislation, Mr. McCain said he had spoken with Majority Whip Don Nickles, who is now "interested in moving forward." The Oklahoma Republican has been pessimistic about the odds for a comprehensive tobacco bill.

Mr. McCain said he also intends to work closely with the Senate authors of another bipartisan tobacco bill. Republican John Chafee of Rhode Island has joined with Democrats Tom Harkin of Iowa and Bob Graham of Florida to write legislation that would cap the tobacco industry's annual legal payouts, but it provides little of the other relief the industry wants from a wave of lawsuits.

Class-Action Suits

Democrats on the Commerce Committee have said that at least one of the legal protections for the industry in the proposed national settlement -- a ban on class-action tobacco lawsuits -- must be eliminated. A variety of interests, from plaintiffs' lawyers to unions, have expressed strong opposition to this provision. "That's one piece of the puzzle I haven't figured out yet," Sen. McCain said. "The issue of limiting [tobacco-industry] liability is directly related to what you get in return."

In the proposed \$368.5 billion settlement, the industry has offered to sharply restrict its advertising and make a series of multibillion-dollar payments in exchange for legal protections. Scaling back those protections could prompt the industry to withdraw the voluntary ad limits. The FTC's Mr. Pitofsky testified Tuesday that regardless of the tobacco industry's position, other industries would likely sue to block the restrictions if they remain as broad as they are in the settlement.

That, he suggested, could leave Congress in the position of having approved legal relief for cigarette makers, only to see the concessions the industry offered in return struck down by a judge. Sen. McCain said he agreed that the ad restrictions in the settlement need to be narrowed.

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February 27, 1998

The Honorable John McCain
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

The Clinton Administration looks forward to working with you and others in Congress to reduce teen tobacco use. In addition to the enclosed responses to your questions, we are prepared to provide the appropriate staff to give the Committee the technical assistance you request. We also are providing you with a number of resource documents cited below that we hope will be of assistance as you work to develop comprehensive legislation to protect our nation's children from tobacco related disease and death. Your ongoing leadership on this issue will be critical to swift passage of comprehensive, bipartisan legislation.

As you know, the President has called on Congress to enact comprehensive, bipartisan legislation that raises the price of cigarettes by up to \$1.50 a pack over the next ten years, expressly confirms the FDA authority to regulate tobacco products, gets tobacco companies out of the business of marketing to children, furthers public health research and goals, and protects tobacco farmers and their communities. A piecemeal approach will not meet our overriding goal of dramatically reducing teen smoking.

As part of such a comprehensive effort, the Administration has long recognized the importance of restricting the advertising and marketing of tobacco products to young people. Two recent studies in The Journal of the American Medical Association underscore what we have said before -- that tobacco advertising aimed at young people is a significant factor in their decision to start smoking. Comprehensive tobacco legislation is an opportunity for Congress to reaffirm the FDA's efforts in this area.

Many of the provisions included in S.1415 would codify the comprehensive regulations on nicotine-containing tobacco products that the FDA adopted in its final Tobacco Rule issued August 28, 1996. The FDA restrictions were carefully crafted on the basis of a multi-year investigation, and resulted from the analysis of myriad studies and research on the effects of advertising, specifically tobacco advertising, on young people and the consideration and analysis of more than 700,000 comments submitted in response to the proposed FDA rule. As you know, the Administration believes strongly that the FDA has jurisdiction and authority to issue such advertising and access restrictions and that comprehensive tobacco legislation should provide express statutory confirmation of this power.

To assist the committee in developing legislation regulating tobacco products, including legislation restricting the advertising of tobacco products, we have provided with this response copies of the two documents that detail the analysis and findings on which the FDA regulations are based: the FDA's proposed rule and preamble published in 60 Fed. Reg. 41314 (August 11, 1995); and the FDA's final rule and preamble published in 61 Fed. Reg. 44396 (August 28, 1996). Our answers to your questions include citations to these documents where appropriate. In addition, the FDA's administrative record contains the studies described in those documents as well as public comments received by the agency. That record is contained on 5 CD's, which are also provided with this response.

We hope this material is helpful, and we look forward to providing you and the members of the Committee with any additional assistance that may be needed.

Sincerely,

Bruce N. Reed
Assistant to the President
for Domestic Policy

Enclosure

I. BAN ON OUTDOOR ADVERTISING, INCLUDING IN STADIA AND ARENAS

The agreement (bill page 15) bans outdoor tobacco product advertising, and tobacco advertising in stadia and arena.

1. What data does the Administration have to substantiate that a ban on outdoor advertising, including stadia and arenas, will reduce smoking and, in particular, youth smoking?

The FDA tobacco rule prohibits outdoor advertising within 1,000 feet of public playgrounds and elementary and secondary schools. All other outdoor advertising is restricted to black text on a white background, devoid of color and imagery. FDA's regulations are based on the agency's finding that children and adolescents spend a great deal of time in areas around schools and playgrounds and these areas, therefore, should be free of tobacco product advertising. All other outdoor advertising should be restricted to text information only, which generally is not as appealing to young people. (See response to question II.1, below.) Data supporting this conclusion are detailed at 61 Fed. Reg. 44501-08.

2. To what extent do you believe such restrictions be expected to reduce smoking?

FDA's advertising restrictions are based on quantitative and qualitative studies of cigarette advertising that show that a causal relationship exists between tobacco advertising and tobacco use by young people and that stringent advertising restrictions, when combined with a comprehensive program designed to reduce initiation and use among young people, will have a positive effect on reducing smoking rates and youth tobacco use.

FDA's findings regarding the ability of advertising restrictions to reduce youth tobacco use are summarized at 60 Fed. Reg. 41330-34 and 61 Fed. Reg. 44466-500.

3. Does the Administration support such a ban. If so, why? If not, why not?

As a preliminary matter, the Administration believes, as the Department of Justice has explained at length in the FDA litigation, that the FDA's regulations that restrict the advertising of tobacco products are consistent with the First Amendment, under the currently controlling framework for First Amendment review of restrictions on advertising, set out by the Supreme Court in Central Hudson Gas & Elec. Corp. V. Public Serv. Comm'n, 447 U.S. 557 (1980), and subsequent cases. The FDA restrictions would, if implemented, substantially advance the Government's wholly legitimate and compelling interest in curtailing minors' demand for and use of tobacco products by reducing minors' exposure to tobacco product advertising. Moreover, the FDA's regulations are tailored to serve this objective. For these reasons, we believe the advertising restrictions in S.1415 that track the FDA regulations are constitutional.

Other restrictions contained in S.1415 give rise to constitutional concerns that are not presented by the FDA regulations, such as whether such restrictions would be sufficiently

tailored to serve the governmental interest in reducing teenage smoking. Such limits on advertising nonetheless may be valuable in reducing youth smoking and protecting the public health, and the Administration would like to work with the Committee to minimize constitutional difficulties.

The Administration supports appropriate restrictions on outdoor advertising, as evidenced by the FDA tobacco rule (21 C.F.R. 897.30(b)) which prohibits outdoor advertising for cigarettes and smokeless tobacco, including billboards, posters, or placards, from being placed within 1,000 feet of the perimeter of any public playground or playground area in a public park, elementary or secondary school. All other outdoor advertising is limited to black text on a white background (21 C.F.R. 897.32(a)).

The prohibition set forth in Section 101(a)(1) of S. 1415, however, would prohibit "any form of outdoor tobacco product advertising, including billboards, posters, or placards." It does not contain the exception for tombstone advertising in certain locations that is included in the FDA regulation. Because that exception ensures that the FDA regulations are appropriately tailored to serve the government's substantial interest in reducing teenage smoking, Section 101(a)(1)'s broader restriction on all outdoor tobacco advertising raises significant constitutional concerns that are not presented by the FDA regulations. We look forward to working with the Committee to minimize these difficulties.

4. What specific changes, if any, in the legislative language implementing the ban would the Administration propose? Please provide specifics.

As discussed above, the Administration's efforts have been focused on supporting the restrictions now codified in FDA regulations. The Administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the outdoor advertising of tobacco products. The resources of the Administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

II. BAN ON HUMAN FIGURES AND CARTOON FIGURES IN ADVERTISING

The agreement (bill page 15) bans the use of human figures and cartoons in tobacco advertising.

1. What data does the Administration have to substantiate that barring the use of human figures and cartoon advertising will reduce smoking, in particular, youth smoking?

FDA's regulations restrict advertising, with certain exceptions, to black text on a white background. These restrictions encompass a prohibition of human figures and cartoon characters. FDA's findings in this area are summarized at 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44466-68, 44508-13. FDA's *Federal Register* documents contain specific evidence and summaries of studies. See 60 Fed. Reg. 41333-34 and 61 Fed. Reg. 44475-82. A new study, published in the February 18th edition of The Journal of the American Medical Association

(JAMA), found that tobacco industry advertising and promotional activities influence teens to start smoking and that 34 percent of teen smoking could be attributed to tobacco promotional activities.

2. To what extent do you believe such restrictions can be counted on to reduce youth smoking?

See response to I.2., above.

3. What entity would you propose to determine what constitutes a human image or cartoon character?

4. What penalty do you believe is appropriate and should accrue for a violation of the prohibition on material containing figures determined to be human or cartoon?

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Food, Drug, and Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

5. Does the Administration support this ban? If so, why? If not, why not?

The Administration supports appropriate advertising restrictions, as evidenced by the FDA tobacco rule. The Administration also supports enactment of legislation confirming the existing authority of the FDA to regulate the use of images in the advertising of tobacco products. This regulatory approach would ensure that the FDA would be authorized, based on existing and future research, to develop necessary and appropriately tailored supplements to its current restrictions, if and when such supplements are needed.

Section 101(b) of S.1415 provides that "[n]o manufacturer, distributor, or retailer may use a human image or a cartoon character or cartoon-type character in its advertising, labeling, or promotional material with respect to a tobacco product." This restriction would go beyond the FDA regulation restricting the use of images in the advertising of tobacco products, which provides that, in general, tobacco advertising must take the form of tombstone advertising but permits images to be used without restriction in certain circumstances, for example, in an "adult publication," one whose readership is at least 85 percent adult and includes less than two million children. 21 C.F.R. § 897.32(a)(2)(I)-(ii). The provision's broader restriction on the use of images in the advertising of tobacco products would raise significant constitutional concerns that the FDA regulation does not present. Such limits on advertising nonetheless may be valuable in reducing youth smoking and protecting the public health, and the Administration would like to work with the Committee to minimize constitutional difficulties.

6. What specific changes, if any, in the legislative language implementing the ban would the Administration propose? Please provide specifics.

As discussed above, the Administration's efforts have been focused on the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in discussing how these restrictions will be implemented and the associated penalties, and whether further restrictions are constitutional and otherwise appropriate.

III. BAN ON INTERNET ADVERTISING

The agreement (bill page 16) bans tobacco advertising on the Internet.

- 1. Does the Administration support such a ban? If so, why? If not, why not?**
- 2. How can and should a ban on Internet advertising of cigarettes be enforced?**
- 3. What, if any, concerns does the Administration have regarding the constitutional free speech issues raised by any such ban?**
- 4. What specific changes, if any, in the legislative language implementing the ban would the Administration propose?**

In response to III.1-III.4, the Administration notes that, insofar as S.1415's proposed complete ban on Internet advertising of tobacco products would be for the purpose of diminishing minors' exposure to such advertising, it would raise significant constitutional concerns, because there might be more narrowly tailored means of achieving such a governmental objective. Cf. Reno v. ACLU, 117 S.Ct. 2329, 2346-48 (1997) (discussing less restrictive alternatives to a ban on Internet transmission of indecency in a manner available to minors).

In order to ensure that the government retains necessary flexibility to regulate the advertising of tobacco products on the Internet, we recommend that the Congress provide express statutory confirmation of the FDA's existing authority to regulate such advertising. This would ensure that any future regulatory restrictions are targeted at appropriate forms of Internet advertising and are fashioned in a manner that is appropriately sensitive to First Amendment concerns. We also would be prepared to work with Congress to fashion a more narrowly focused Internet restriction.

IV. BAN ON POINT-OF-SALE ADVERTISING

The agreement (bill page 16) bans point-of-sale tobacco except for advertisements which comply with that certain restriction.

1. What data does the Administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?

See responses to I.2. and II.1. above. In its tobacco rulemaking, FDA found that young people get their information and product imagery from all types of advertising, including at the point of sale. See 61 Fed. Reg. 44509-44510. Point-of-sale advertising presents children and adolescents with an enticement at the time when purchase is immediately available.

2. Does the Administration support such a ban? If so, why? If not, why not?

Section 101(d) of S.1415 would, in general, limit each manufacturer of tobacco products to the display of not more than two separate point-of-sale advertisements in any location at which tobacco products are sold, and would limit each retailer to the display of one point-of-sale advertisement relating to the retailer's own or its wholesaler's contracted retailer or private label brand product. The bill also would require that these point-of-sale advertisements consist only of black letters on a white background, and not be larger than a prescribed size. However, the bill would include a significant exception to these limitations for "adult-only stores and tobacco outlets." Sec. 101(d)(2).

The FDA regulations contain restrictions that are targeted at point-of-sale advertising similar to those proposed in S. 1415. They are not quite as broad as those set forth in S.1415 in that there is no numerical limitation and no size limitation. See 21 C.F.R. §§ 897.32, 897.16. Moreover, unlike S.1415, the FDA regulations do not include an exemption for certain manufacturers with a substantial market share.

Under both the FDA regulation and the S.1415 proposal, manufacturers and retailers limited to text-only advertising at the point of sale would not be prohibited from promoting products at retail. Adult consumers looking for price and product information will be able to find that information even without imagery and colors, which are particularly attractive to children. While text-only advertising can still be effective with adults, it will have less allure and be less appealing to minors. Children and adolescents, who are less likely than adults to process print information in a leisurely setting (such as reading a magazine), will find textual material even less appealing in the few moments spent at the retail counter.

The Administration supports appropriate restrictions on point-of-sale advertising, as evidenced by the FDA tobacco rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

3. Is the exemption of point-of-sale advertisement for adult stores and tobacco outlets appropriate?

The Administration's focus has been on preventing children and adolescents from using tobacco products. Restrictions on the advertising that makes these products appealing to young people is a vital component of these efforts. FDA's regulations exempt adult-only locations because there is little reason to believe that advertising in such locations would have a significant adverse effect on efforts to reduce youth tobacco use.

- 4. Is it appropriate to grant companies with greater cigarette market share additional point-of-sale advertising rights? If so, why? If not, why not?**
- 5. Does such a privilege constitute a statutorily granted competitive advantage? Please discuss.**
- 6. Does the Administration support this grant? If so, why? If not, why not?**
- 7. What specific changes, if any, in the legislative language implementing the ban would the Administration propose? Please provide specifics.**

In response to IV.4 - IV.7, the Administration notes that Section 101(d)'s exception permitting manufacturers with a greater market share to engage in more point-of-sale advertising than their competitors appears inconsistent with the government's asserted interest in restricting such advertising. Granting manufacturers point-of-sale advertising opportunities consonant with market share is unrelated to the objective of reducing youth tobacco use; indeed it may run counter to that goal. Moreover, the proposal presents constitutional and anti-competitive concerns that should be addressed. The resources of the Administration are available to assist the Committee in exploring those concerns.

V. LIMITATIONS ON POINT-OF-SALE ADVERTISING

The agreement (bill page 17) specifies the size and design of permissible point-of-sale advertising.

- 1. What data does the Administration possess to suggest that such limitations will reduce smoking, particularly among youth?**

See responses to IV.1 and IV.2, above.

- 2. Does the Administration support this provision? If so, why? If not, why not?**
- 3. If so, what is the justification for statutorily determining a particular size limitation and for the particular size and restrictions proposed?**

4. What specific changes in legislative language, if any, does the Administration propose? Please provide specifics.

In response to V.2 - V.4, the Administration supports appropriate restrictions on point-of-sale advertising, as evidenced by the FDA Tobacco Rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in determining whether further restrictions -- such as those limiting the size of point-of-sale advertisements -- are constitutional and otherwise appropriate.

VI. BAN ON ADVERTISING RESTRICTION AGREEMENTS

The agreement (bill page 17) includes a prohibition on arrangements to limit the ability of a retailer to display permissible point-of-sale advertisement or promotional material originating with another manufacturer or distributor.

1. Are such agreements currently against federal or state law? If so, is such a provision necessary?

Ordinarily, under the free market system, retailers are permitted to decide from whom and to whom they will buy and sell, and on what terms. While an agreement of the sort described -- between a manufacturer and a retailer to limit the ability of a competing manufacturer to display advertising on the retailer's premises -- might be anticompetitive under certain circumstances, such agreements are usually not condemned under the federal antitrust laws. The Administration has not undertaken a review of state laws to determine whether such an arrangement would violate the law of any state.

2. Does the Administration support such a provision? If so, why? If not, why not?

The Administration's primary concern is not the relationship of retailers, manufacturers, and distributors between or among one another with respect to advertising. Rather, the Administration wants to ensure that point-of-sale advertising and promotional material, whatever their source, consist only of black text on a white background, except in adult-only facilities.

3. Does the Administration support the limitation. If so, why? If not, why not?

See answer to question VI.2 above.

4. What specific changes, if any, in the legislative language implement the ban would the Administration propose? Please provide specifics.

See answer to question VI.2 above.

VII. GLAMORIZATION OF TOBACCO

The agreement (bill page 20) prohibits payments to glamorize or promote the image or use of tobacco through print, films, or live performances that appeals to individuals under 18 years of age.

- 1. What data does the Administration possess to indicate whether and to what extent this provision will reduce smoking, particularly among youth?**

A number of studies (Tye 1990; Terre, Drabman, and Speer 1991; Hazan, Lipton, and Glantz 1994; Thumbs Up! Thumbs Down! 1997) show that depictions of tobacco use in the entertainment media, particularly feature films, are on the increase and exaggerate greatly the actual prevalence of tobacco use in the U.S. population. Research also suggests that adolescents are highly susceptible to pro-smoking messages and images conveyed in entertainment media (Signorielli 1993; Davies 1993; Basil 1997). Focus group research found that young people are able to recall virtually no anti-smoking messages on TV or in the movies, yet they are able quite readily to recall specific movies that portray smoking and to identify actors and actresses who smoke in their entertainment roles (Mermelstein 1997). Deglamorizing tobacco use in the entertainment media can be achieved both by decreasing pro-smoking cues and by increasing anti-smoking cues. A study by researchers at the University of California at Irvine suggests that anti-smoking ads before movies can help inoculate young people against the positive images of smoking that appear in movies. Ninth graders who watched the movie "Reality Bites" (in which the cast smokes in about one-third of the scenes) preceded by a California Department of Health Services anti-smoking ad were much less likely to find smoking exciting compared with teens who watched the movie without the counter-advertisement (Pechmann, 1996).

- 2. What entity does the Administration propose will determine what activity constitutes promoting the image or use of a tobacco product?**
- 3. How does the Administration envision such a ban will be enforced?**
- 4. Does the Administration support such limitations?**
- 5. What specific changes, if any, in the legislative language would the Administration propose? Please provide specifics.**

In response to Questions VII.2 - VII.5, the Administration believes that the scope of the restriction on glamorization in S.1415 is unclear. For example, is the provision intended only to restrict attempts to promote certain brand names of tobacco products or is it intended to restrict the promotion of smoking generally? If the latter were the case, then the provision would appear to reach some noncommercial speech, raising significant constitutional concerns. It is also not clear what is meant by the use of the word "promoting." Finally, the phrase "appeals to individuals under 18 years of age" could be subject to challenge on vagueness grounds.

Alternatively, no such constitutional concerns would be raised if Congress enacted legislation that would confirm the authority of the FDA to regulate the advertising of tobacco products through such indirect means as the use of product placement agreements.

VIII. RESTRICTIONS ON COLOR ADVERTISEMENTS

The agreement (bill page 21) prohibits the use of color advertising except in adult publications.

- 1. What data does the Administration have to substantiate that a ban on color ads, except in publications with limited youth readership, will reduce smoking particularly youth smoking?**

See response to II.1., above.

- 2. Does the Administration believe that the threshold for the restriction of two million readers is the appropriate threshold?**

FDA's tobacco rule requires that advertising be restricted to black and white text, except in publications that are read primarily by adults or in adult-only facilities. The text-only requirement is intended to reduce the appeal of cigarettes and smokeless tobacco advertising on young people without unduly affecting the informational messages conveyed to adults. Therefore, FDA proposed in its rulemaking that advertising in so-called "adult" publications should be allowed to use imagery and color because the effect of such advertising on young people should be nominal. The agency set the definition of adult publication as those whose readers age 18 or older constitute 85 percent or more of the publication's total readership, or those which are read by two million or fewer people under age 18, whichever method results in the lower number of young people. (Magazines with small readership numbers but which appeal to young people may not attract two million young readers but may still be primarily youth oriented; that is, 15 percent or more of their readers are under 18.) In addition, the agency noted that at some point, the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless of the percentage of the readership. For example, a magazine with a large total readership base may attract as many as 5 million young people, or more, but those numbers would still not be 15 percent of the magazine's readership. See 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44513-19.

- 3. How does the Administration envision readership demographics being determined?**

In its tobacco rulemaking, FDA explained that readership demographics would be determined by measuring the total number of people that read any given copy of a publication. Readership demographics would be measured according to industry standards and, at a minimum, would be based on a nationally projectable survey of people. Two examples of

currently available surveys are Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK. FDA also indicated that it would be willing to work with industry on this issue. See 61 Fed. Reg. 44516-19.

4. How would this restriction be enforced?

The restriction would be enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Federal Food, Drug and Cosmetic Act which provides for the imposition of civil money penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

5. Does the Administration support this restriction? If so, why? If not, why not?

The Administration supports the regulation in the FDA rule based upon the findings of the Food and Drug Administration regarding the role and attractiveness of images and color in advertising to young people. See, e.g., 61 Fed. Reg. 44467-68, 44509 (1996).

6. What specific changes, if any, in the legislative language implementing the restriction does the Administration propose? Please provide specifics.

As discussed above, the Administration supports effective restrictions on the use of color and imagery in tobacco advertising. The Administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the advertising of tobacco products.

IX. GENERAL QUESTION REGARDING MARKETING/ADVERTISING BAN

1. Can the marketing and advertising restrictions envisioned in the settlement be constitutionally imposed, with or without the industry's consent? Please discuss.

The answers to questions in Parts I-VIII above address the government's authority to impose restrictions on advertising and marketing without the industry's consent. As noted, we believe that certain of those restrictions raise significant constitutional concerns. We address here the degree to which "the industry's consent" may affect the constitutional analysis of the advertising restrictions.

Voluntary commitments to restrict advertising are of course constitutional. For this reason, we believe that the inclusion of such restrictions in state court consent decrees between states and tobacco manufacturers -- rather than in federal legislation -- would significantly increase the likelihood that the restrictions would be upheld if challenged in the future. However, the inclusion of such restrictions in a federal statute that made adherence to such restrictions a condition of the receipt of certain federal benefits would continue to raise

substantial constitutional questions. Such a statute, depending on how it were framed, could be subject to substantial challenge under the unconstitutional conditions doctrine. The resources of the Administration are available to assist the Committee in crafting legislation designed to minimize this potential problem.

X. WARNING LABELS

The agreement (bill page 26-28) authorizes a variety of new warning labels for tobacco products.

1. Does the Administration believe that these are appropriate warning labels?

The Administration supports the concept of strengthening warning label statement requirements. Several recent studies (Health Canada 1996; Borland, Cappiello, and Hill 1996; Robinson and Killen 1997) and literature reviews (USDHHS 1994; IOM 1994) are available concerning the effectiveness of warning labels in conveying information to consumers. The Administration's resources are available to help the Committee evaluate possible improvements to warning label requirements.

2. Does the Administration possess data suggesting that these warnings will effectively reduce smoking, particularly youth smoking?

See response to X.1., above.

3. What data suggests that the various new warnings will be as or more effective than the current warning requirements?

See response to X.1., above.

4. Does the Administration support the provisions authorizing specific new labels? If so, why? If not, why not?

5. What specific changes, if any, in the legislative language implementing this provision would the Administration propose? Please provide specifics?

As stated above, the Administration is available to work with the Committee in determining whether changes to the warning statement requirements are appropriate.

XI. WARNING LABEL SIZE AND LOCATION REQUIREMENTS

The agreement (page 28-29) specifies the size, placement, and print type of the various tobacco warning labels.

- 1. What data does the Administration have to suggest that these specifications will reduce smoking, particularly youth smoking?**

See response to X.1., above.

- 2. Does the Administration support these particular specification? If so, why? If not, why not?**
- 3. Does the Administration support the exception (page 29) provided for flip-top cigarette packages? If so, why? If not, why not?**
- 4. What specific changes, if any, in the legislative language to implement these restrictions would the Administration propose? Please provide specifics.**

The Administration, as discussed above, has focused its efforts on supporting the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in determining whether further restrictions are appropriate.

XII. SMOKELESS TOBACCO ALTERNATIVE LABELS

The agreement (bill page 34) provides for various new warning label options for smokeless tobacco.

- 1. What data does the Administration have to suggest that the various new warning labels will effectively reduce the use of smokeless tobacco, particularly among youth?**

See response to X.1., above.

- 2. Does the Administration support the use of these alternative labels?**
- 3. What changes, if any, to the legislative language implementing this provision would the Administration propose? Please provide specifics.**

The Administration, as discussed above, has focused its efforts on supporting the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in determining whether further restrictions are appropriate.

XIII. ENFORCEMENT OF ADVERTISING, MARKETING AND LABELING RESTRICTIONS

The agreement (bill page 36-37) provides for the enforcement of advertising, marketing, and labeling restrictions.

- 1. Does the Administration support the enforcement provisions regarding advertising, marketing and labeling? If so why? If not, why not?**

Section 114 of S.1415 provides FTC with the authority to enforce sections 111 and 112, the provisions relating to warning statement requirements. Section 114 also contains a penalty provision for violations of section 113, the requirement that companies provide ingredient information to the Secretary of HHS pursuant to a new provision of the Federal Food, Drug, and Cosmetic Act, and authorizes the FTC to bring actions to enforce that provision. With respect to sections 111 and 112, section 114 appears to maintain the status quo with respect to warning label enforcement issues. Some other proposed bills would shift that authority to FDA. The Administration is available to assist in the Committee in considering these differing approaches. With regard to section 113, which relates to a provision of FDA law, the Administration would be pleased to assist the Committee in evaluating whether enforcement authority for the ingredient disclosure requirements may be more appropriately vested entirely in FDA.

- 2. What changes in legislative language, if any, does the Administration recommend regarding these provisions? Please provide specific language.**

As discussed above, the Administration would be pleased to assist the Committee in evaluating issues related to the enforcement of advertising, marketing, and labeling restrictions, and in developing modifications, if appropriate, to legislative language.

XIV. PREEMPTION OF STATE AND LOCAL ACTION

The agreement (bill page 38) prohibits state and local requirements related to the packaging or advertising of cigarettes or smokeless tobacco.

- 1. Does the Administration support such preemption? If so, why? If not, why not?**
- 2. What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specific language.**

The Administration generally supports the limited preemption of state and local requirements related to the packaging of cigarettes or smokeless tobacco, but does not support the preemption of state and local restrictions on advertising. FDA's recently promulgated regulations address advertising. Although the regulations are preemptive, the Federal Food,

Drug and Cosmetic Act allows states and localities to apply for waivers to be exempted from federal thresholds. This would allow states and localities to enact or retain existing advertising restrictions that would be more stringent.

The Administration is available to work with the Committee with respect to the broader issues of preemption raised by other provisions of the bill. The Administration is committed to allowing states and localities the maximum flexibility practicable to develop strong public health policies to prevent and reduce youth tobacco use.

XV. EXEMPTION OF EXPORTS

The agreement (bill page 40) exempts exports from the packaging, labeling, and advertising requirements.

1. Does the Administration support this exemption? If so, why? If not, why not?

The Administration strongly believes that one of the elements of any comprehensive bipartisan tobacco legislation must be the strengthening of international efforts to control tobacco. Just this month the Administration issued guidance to its diplomatic posts that prohibits them from promoting the sale or export of tobacco or tobacco products, and encourages them to assist and promote tobacco-control efforts in host countries. The Administration also supports efforts to address the health risks associated with tobacco use at an international level by funding multilateral and bilateral efforts. The Administration is currently reviewing other provisions on international tobacco control in light of the U.S.'s foreign policy and trade interests. The Administration looks forward to working with members of Congress of both parties in crafting comprehensive tobacco legislation that contains international tobacco-control provisions.

2. What ramifications does this provision have in the area of foreign relations?

See response to XV.1. above.

3. What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.

See response to XV.1. above.

XVI. RESTRICTIONS ON ACCESS TO TOBACCO PRODUCTS

The agreement (bill page 40-41) prohibits the sale of tobacco products to individuals under 18 years of age; requires that retailers verify the age of individuals purchasing tobacco; and exempts individuals 27 years of age or older from the photo identification requirement.

1. Does the Administration support these provisions? If so, why? If not, why not?

The Administration supports access restrictions based upon FDA's findings regarding the ability of persons under 18 to purchase tobacco products in the absence of a photo identification requirement. See, e.g., 61 Fed. Reg. 44437-39 (1996).

2. How does the Administration envision that this provision will be enforced, and can it be enforced effectively?

3. What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.

FDA currently is enforcing aspects of its restrictions on youth access to tobacco products embodied in the FDA tobacco rule (21 C.F.R. §§ 897.14, 897.16). FDA is enforcing the age and photo ID provisions cooperatively with state and local officials. Because of the enormous number of retailers that sell tobacco, FDA has adopted a cooperative model. By way of comparison, this is how FDA regulations are enforced for dairy farm and retail food inspections in communities across the country—by commissioning the services of state and local officials.

In its initial enforcement efforts, FDA contracted with 10 states. Under these contracts, states are conducting between 200 and 330 unannounced retail compliance checks each month over a period of eight months. Information about the compliance checks is sent to FDA, which issues a warning for the first violation to retailers found selling to the adolescents. These retailers will be subject to repeat inspections. FDA will seek a fine of \$250 for the second violation and greater fines for subsequent violations. FDA is in the process of contracting with additional states.

FDA anticipates that state and local contracts will provide effective mechanisms to check compliance with other access restrictions, such as the requirement that all transactions be face-to-face, without the assistance of any electronic device. Commissioned state and local officials will be able to determine compliance with these and similar provisions by visiting facilities, and appropriately documenting observations.

XVII. PROHIBITION ON SALE OF LESS THAN A FULL PACK OF CIGARETTES

The agreement (bill page 41) prohibits the sale of less than a full pack of cigarettes.

- 1. Does the Administration support this prohibition? If so, why? If not, why not?**

The Administration supports this prohibition based upon FDA's findings regarding the ability of persons under 18 to obtain cigarettes when they are sold in units of less than a full pack. See, e.g., 61 Fed. Reg. 44443, 44445-48.

- 2. What change in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.**

The Administration does not recommend any changes in the legislative language.

XVIII. STATE LICENSURE TO SELL TOBACCO

The agreement (bill page 44) requires states to license sellers of tobacco products.

- 1. What data, if any, does the Administration have to indicate that licensure will effectively reduce access to tobacco by minors?**

Licensure of retailers will give authorities the means to identify those retailers who sell tobacco. States that do not require licensure are having difficulties complying with the Synar amendment, because they have problems identifying outlets that sell tobacco products. In addition to providing a list of retailers, the threat of license revocation for noncompliance is extremely motivating to retailers. Furthermore, license fees can be used to cover the cost of enforcement, which is an important determinant of compliance.

- 2. What entity does the Administration envision would enforce the licensure requirement if a state should be unable or unwilling to implement the licensure program?**

The Administration supports a licensing program that primarily operates at the state or local levels. The Administration is available to work with the Committee on issues concerning the relationship of such programs to federal standards or registration activities.

3. **Has the Administration developed or formulated the cost of the licensure program? If so, why? If not, why not?**

The Administration has not completed work regarding the cost of a licensure program.

4. **Does the Administration support the licensure program? If so, why? If not, why not?**

The Administration supports an effective licensing program. Federal legislation that calls upon states to establish regulatory programs must be sensitive to federalism concerns. The Administration would be happy to work with the Committee to ensure that the licensing provisions achieve federal objectives while according due respect to state sovereignty.

5. **What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.**

The resources of the Administration are available to work with the Committee in evaluating provisions for a licensing program.

XIX. ANTI-TRUST EXEMPTION

The agreement (bill page 94) provides anti-trust exemption for the tobacco industry.

1. **Does the Administration support such an exemption? If so, why? If not, why not?**

The antitrust laws are the most important protector of the free-market economy against anticompetitive actions that would undermine its integrity to the detriment of consumers. Accordingly, exceptions to the antitrust laws should be made only in rare instances, when the fundamental free market values underlying the antitrust laws are overwhelmed by a paramount policy objective; and a proposed exemption must be necessary to permit the paramount policy objective to be pursued. The proponents of broad antitrust exemptions -- for example, an exemption that allowed companies to set prices jointly -- have not yet met this heavy burden.

2. **Could such an exemption be used to set prices beyond those necessary to deter youth smoking, but to increase profits for the industry?**

An antitrust exemption that allowed tobacco firms to set prices jointly could be used by firms to increase prices beyond what is necessary to deter youth smoking and thereby to increase profits at the expense of consumers. It would be very difficult to restrict use of the exemption to its intended purpose, because the tobacco companies would have both the opportunity and the incentive to effect unnecessary price increases and to conceal them under the guise of restrictions

on youth smoking. While the resulting collusive price increase would be likely to reduce demand for tobacco products, it would also increase profits for the tobacco companies, at least to the point at which they are collectively charging the "monopoly price." The tobacco companies would thereby be able to use an antitrust exemption to enrich themselves at the expense of those confirmed with smoking habits.

3. What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.

Before any exemption is considered for enactment, the proponents of the exemption need to meet the burden of demonstrating that this is one of the rare instances in which the antitrust laws are incompatible with a clearly paramount policy objective. The Administration is extremely skeptical that the proponents of this case will be able to meet the burden, except possibly in certain limited circumstances to restrict advertising to children.

Even in those rare instances in which that burden is met, any antitrust exemption should be carefully and narrowly crafted to address that objective in the least anticompetitive manner available. If Congress should decide to move forward with consideration of antitrust exemptions for the tobacco industry, the Administration would assist in crafting them as narrowly and precisely as possible to achieve their purpose without creating unnecessary anticompetitive effects.

XX. APPLICABILITY TO NEW ENTRANTS IN TOBACCO INDUSTRY

1. Under the agreement, and the implementing legislation, what is the assurance that new entrants into the tobacco industry will comply with the statute and any related consent agreements not to challenge the legality of the agreement implementation legislation?

The proposed settlement and legislation do not deal expressly with new entrants into the tobacco industry. However, it appears that under S.1415 a new entrant would be treated like any other manufacturer. Under Title VI, any non-participating manufacturer would be subject to the advertising and access restrictions that are contained in the Act and to regulatory oversight but would not receive the limitations on liability that are contained in Title VII. Non-participating manufacturers also would be required to pay an annual fee to be determined by the Secretary and to make annual deposits to an escrowed reserve fund to be used solely to make tobacco-related liability payments.

ADDITIONAL REFERENCES

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Tobacco deal legislation gaining momentum

Senators say they'll draft new proposal

02/25/98

By [Mark Curriden](#) / The Dallas Morning News

WASHINGTON - Comprehensive legislation affirming the proposed national settlement with the tobacco industry gained more momentum Tuesday when leaders of the Senate Commerce Committee said they hope to draft a new proposal with bipartisan support within a month.

With the chief executive officers of the major cigarette makers looking on, committee chairman Sen. John McCain, R-Ariz., said that he and Sen. Orin Hatch, R-Utah, who is chairman of the Judiciary Committee, plan to work together to have a revised bill ready for a vote by summer.

Both senators, who Congressional insiders say have seized the leadership roles in the tobacco debate, say they are committed to passing a comprehensive anti-tobacco plan this year that "tweaks" the \$368.5 billion national settlement agreement reached last year by the cigarette makers and 40 state attorneys general.

That deal would require the industry to pay \$15 billion a year for an indefinite period in Medicaid reimbursements, restrict tobacco advertising, give the FDA regulatory control over nicotine and provide liability protections from lawsuits for the cigarette makers.

Both men say they are opposed to various watered-down versions of the tobacco deal circulating around Capitol Hill.

Not everyone on Capitol Hill is as optimistic that a tobacco agreement will become law this year. Sen. Don Nickles, R-Okla., told the nation's governors Monday not to expect any money from a congressionally approved



tobacco bill in 1998.

Other members of the House and Senate say they prefer a stripped-down version of the settlement agreement that simply raises cigarette prices but doesn't include any of the other elements of the proposed settlement.

However, White House officials made it clear Tuesday they want any legislation to be comprehensive and to address the issue of teenage smoking. President Clinton is so confident that the settlement will pass this year that he has included \$65 billion from the deal in his upcoming budget to pay for new programs.

"We plan to mark up a bill starting March 12," said Mr. McCain, who estimated that it would take a week or so to draft the legislation.

"The president has been provided 80 specific questions regarding what he would like to see in this legislation, and his people have told us they will have those answers back to us by the end of this week," he added.

Mr. McCain said he and Mr. Hatch plan to hold a series of hearings over the next few weeks to address every significant issue involved in the settlement agreement.

One specific element of last year's settlement that most senators agree will change is the price tag. Mr. Hatch's bill increases the amount to \$398 billion over 25 years. Another proposal hikes the penalty to \$500 billion.

The problem, according to Sen. Wendell Ford, D-Ky., is that Mr. Clinton and many senators are already spending the money before they have it.

"You're down and everybody wants to kick the hell out of you," Mr. Ford told tobacco executives at Tuesday's hearing. "And every time they kick, the price tag goes up. Well, it's funny money and it's just not right."

For their part, the tobacco company CEOs made few friends in the Senate on Tuesday. Each refused to flatly state that nicotine is addictive, and they all denied that they manipulate the level of nicotine in cigarettes to increase the kick.

The executives were criticized by several senators as being less than forthright in their testimony. Mr. McCain described their refusal

to admit that nicotine is addictive as "very disappointing."

The CEOs also refused to swear under oath that they would cease all advertising that might attract minors to cigarettes if the national settlement agreement is not approved. Under the settlement agreement, the industry agrees to voluntarily end all current and future advertising efforts.

Philip Morris chairman Geoffrey Bible angered senators when he described his company as a "good and responsible corporate citizen."

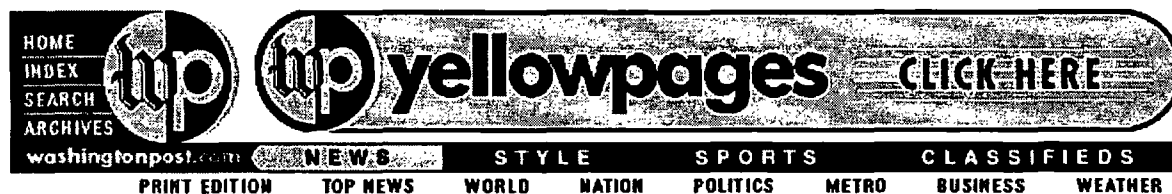
"I don't think the executives helped themselves here today," said Martin Feldman, a tobacco industry analyst with Salomon Smith Barney. "There was only one answer they should have given when asked if nicotine is addictive and the answer was 'yes.' Instead, they came across as if they are still dancing around trying to hide the truth."

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Tobacco Execs Change Attitude

By Laurie Kellman

Associated Press Writer

Wednesday, February 25, 1998; 1:11 a.m. EST

WASHINGTON (AP) -- Unless Congress grants them the lawsuit protection they seek, tobacco companies will not curb their advertising as their \$368 billion agreement with the states would require, executives say.

"I think we would have a very difficult time not asking for our First Amendment rights and maintaining them in light of that situation," Laurence Tisch, co-chairman Lorillard Tobacco Co.'s parent firm, told the Senate Commerce Committee on Tuesday.

Steven Goldstone, chairman and chief executive officer of RJR Nabisco, agreed that the industry would challenge legislation curbing advertising.

"Our company wouldn't survive, so I'd have to assert my constitutional rights," Goldstone said.

The industry's confrontational approach departed from the contrite tone taken by the executives during a hearing before the House Commerce Committee on Jan. 29.

Sen. John Kerry, D-Mass., asked the executives if they would voluntarily steer their advertising away from children regardless of whether Congress grants the industry immunity. Saying the vast majority of smokers are adults, the executives wouldn't commit to that pledge. But they said their company policies preclude them from targeting children.

"There is not a voluntary willingness or acknowledgment of the need to change the way you're advertising, whether or not there is an agreement," Kerry scolded. "If you're not willing to say that under any circumstances you're not going to advertise in any way that targets those kids, or that could target them, then there's something lacking in the good faith of the dialogue."

Convincing Congress of its good faith remains the tobacco industry's highest hope of attaining the lawsuit protections they demand, lawmakers say. But last June's settlement that includes those

protections has received a frosty welcome on Capitol Hill from legislators up for election this year.

Republican leaders have indicated little willingness to do favors for an industry that, recently released documents show, tried to hook kids on tobacco in past decades.

Another exchange before the panel on Tuesday further damaged the industry's credibility with Congress, several lawmakers said. The tobacco company executives wavered anew on whether tobacco is addictive, departing from their briefer remarks last month before a House panel.

"I wouldn't personally, in a serious debate about smoking, label tobacco as addictive," said Nick Brookes, chairman and CEO of Brown and Williamson Tobacco Corp. "What addiction, in my use of that word, means, is that people can't quit."

"I would consider it more of a habit, than I would an addiction," said Vincent A. Gierer Jr. of U.S. Tobacco.

"I've always thought, and I was a smoker, that cigarette smoking is habit-forming, and I think that most Americans believe that kind of activity is addictive," said Steven Goldstone, chairman and CEO of RJR Nabisco.

Their testimony before the Senate Commerce Committee "disappointed" Chairman John McCain, R-Ariz., the author of a bill that would make law much of the June settlement the tobacco industry wants passed by Congress.

"There's a lot of symbolism in that question" about whether nicotine is addictive, McCain told reporters later. "It's symbolic of the skepticism that exists about their sincerity."

Mississippi Attorney General Michael Moore, who headed the states' negotiations with the industry, said the executives "dancing around" the question "wasn't very smart."

"There's a simple answer: Yes," nicotine is addictive, Moore told reporters after the hearing.

Democrats on the panel challenged the industry's veracity on other issues, such as why a catalog from Goldstone's company continued to sell products with the Joe Camel likeness after the firm pledged to halt that advertising campaign. Critics say it appeals to children.

Goldstone said that catalog will be out of date this summer and that Joe Camel will not appear on company products thereafter.



U.S. SENATE COMMITTEE ON

Commerce, Science, and Transportation

JOHN McCain, Chairman

www.senate.gov/~commerce

*Tobacco -
McLain Questions - fw*

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WASHINGTON, DC 20510-6125

JOHN RADT, STAFF DIRECTOR
MAN A. SCHLAGER, DEMOCRATIC CHIEF COUNSEL AND STAFF DIRECTOR

February 2, 1998

The Honorable William Clinton
The White House
Washington, DC 20500

Dear Mr. President:

As you know, Congress intends to consider comprehensive tobacco legislation during the upcoming legislative session.

The issues raised by the global tobacco settlement and involved in the crafting of legislation to implement responsible national tobacco policy, are extremely diverse and intensely complex.

As I stated in my letter to you of six weeks ago, it's imperative that Congress and the administration work together in a cooperative and bi-partisan fashion if we are to craft a bill that will gain public support, Congressional approval and your signature.

In that regard, it will be particularly important for the Administration to exercise its executive responsibilities by providing Congress with detailed assessment of the provisions of pending tobacco legislation, and your specific policy and legislative recommendations.

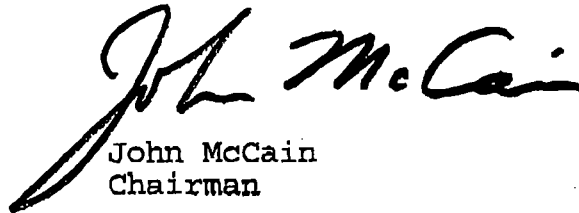
The Senate Commerce Committee which I chair, and which has jurisdiction over key components of tobacco legislation, will hold hearings on the issue early this year. To assist with these deliberations I would like to request the administration's answers to the attached tobacco related questions.

These are the first in a series of questions to which we must have answers if we are to properly assess global tobacco settlement legislation, and move forward with the most effective and appropriate bill.

With the advice and expertise of the executive branch, we can ensure that federal tobacco legislation is based on a firm understanding of the facts, grounded in a solid understanding of the true consequences of our actions, and formulated by consensus. Most importantly, these disciplines will enhance our ability to achieve our most important goal of dramatically reducing youth smoking.

Thank you for your assistance in providing the Committee and Congress with the information requested. With regards,

Sincerely,

A handwritten signature in black ink, reading "John McCain". The signature is fluid and cursive, with the first name "John" written in a larger, more prominent script than the last name "McCain".

John McCain
Chairman

JM/jr

QUESTIONS REGARDING GLOBAL TOBACCO SETTLEMENT LEGISLATION

THE FOLLOWING IS THE FIRST SET IN A SERIES OF QUESTIONS PERTAINING TO S. 1415, LEGISLATION IMPLEMENTING THE GLOBAL TOBACCO SETTLEMENT PROPOSAL AGREED TO BY THE ATTORNEYS GENERAL OF THE VARIOUS STATES AND THE TOBACCO INDUSTRY.

QUESTIONS RELATED TO SPECIFIC LEGISLATIVE LANGUAGE SHOULD USE S. 1415 AS THE REFERENCE. ADDITIONAL QUESTIONS WILL FOLLOW.

I. BAN ON OUTDOOR ADVERTISING, INCLUDING IN STADIA AND ARENAS

The agreement (bill page 15) bans outdoor tobacco product advertising, and tobacco advertising in stadia and arena.

1. What data does the administration have to substantiate that a ban on outdoor advertising, including stadia and arenas will reduce smoking and, in particular, youth smoking?

2. To what extent do you believe such restrictions be expected to reduce smoking?

3. Does the administration support such a ban. If so, why? If not, why not?

4. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.

II. BAN ON HUMAN FIGURES AND CARTOON FIGURES IN ADVERTISING

The agreement (bill page 15) bans the use of human figures and cartoons in tobacco advertising.

1. What data does the administration have to substantiate that barring the use of human figures and cartoon advertising will reduce smoking, in particular, youth smoking?

2. To what extent do you believe such restrictions can be counted on to reduce smoking?

3. What entity would you propose to determine what constitutes a human image or cartoon character?

4. What penalty do you believe is appropriate and should accrue for a violation of the prohibition on material containing figures deemed to be human or cartoon?

5. Does the administration support this ban. If so, why? If not why not?

6. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.

III. BAN ON INTERNET ADVERTISING

The agreement (bill page 16) bans tobacco advertising on the internet.

1. Does the administration support such a ban? If so, why? If not, why not?

2. How can and should a ban on internet advertising of cigarettes be enforced?

3. What, if any, concerns does the administration have regarding Constitutional free speech issues raised by any such ban?

4. What specific changes, if any, in the legislative language implementing the ban would the administration propose?

IV. BAN ON POINT-OF-SALE ADVERTISING

The agreement (bill page 16) bans point-of-sale tobacco except for advertisements which comply with that certain restrictions.

1. What data does the administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?

2. Does the administration support such a ban? If so, why? If not, why not?

3. Is the exemption of point-of-sale advertisement for adult stores and tobacco outlets appropriate?

4. Is it appropriate to grant companies with greater cigarette market share additional point-of-sale advertising rights? If so, why? If not, why not?

5. Does such a privilege constitute a statutorily granted competitive advantage? Please discuss.

6. Does the administration support this grant? If so, why? If not, why not?

7. What specific changes, if any, in the legislative language implement the ban would the administration propose? Please provide specifics.

FEB. 2, 1958

V. LIMITATIONS ON POINT-OF-SALE ADVERTISING

The agreement (bill page 17) specifies the size and design of permissible point-of-sale advertising.

1. What data does the administration possess to suggest that such limitations will reduce smoking, particularly among youth?

2. Does the administration support this provision? If so, why? If not, why not?

3. If so, what is the justification for statutorily determining a particular size limitation and for the particular size and restrictions proposed?

4. What specific changes in legislative language, if any, does the administration propose? Please provide specifics.

VI. BAN ON ADVERTISING RESTRICTION AGREEMENTS

The agreement (bill page 17) includes a prohibition on arrangements to limit the ability of a retailer to display permissible point-of-sale advertisement or promotional material originating with another manufacturer or distributor.

1. Are such agreements currently against federal or state law? If so, is such a provision necessary?

2. Does the administration support such a provision? If so, why? If not, why not?

3. Does the administration support the limitation. If so, why? If not, why not?

4. What specific changes, if any, in the legislative language implement the ban would the administration propose? Please provide specifics.

VII. GLAMORIZATION OF TOBACCO

The agreement, (bill page 20) prohibits payments to glamorize or promote the image or use of tobacco through pint, films or live performance that appeals to individuals under 18 years of age.

1. What data does the administration possess to indicate whether and to what extent this provision will reduce smoking, particularly among youth?

2. What entity does the administration propose will determine what activity constitutes promoting the image or use of a tobacco produce?

3. How does the administration envision such a ban will be enforced?

4. Does the administration support such limitations?

5. What specific changes, if any, in the legislative language would the administration propose? Please provide specifics.

VIII. RESTRICTION ON COLOR ADVERTISEMENTS

The agreement (bill page 21) prohibits the use of color advertising except in adult publications.

1. What data does the administration have to substantiate that a ban on color ads, except in publications with limited youth readership, will reduce smoking, particularly youth smoking?

2. Does the administration believe that the threshold for the restriction of two million readers is the appropriate threshold?

3. How does the administration envision readership demographics being determined?

4. How would this restriction be enforced?

5. Does the administration support this restriction? If so, why? If not, why not?

6. What specific changes, if any, in the legislative language implementing the restriction does the administration propose? Please provide specifics.

IX. GENERAL QUESTION REGARDING MARKETING/ADVERTISING BAN

1. Can the marketing and advertising restrictions envisioned in the settlement be constitutionally imposed, with or without the industry's consent? Please discuss.

X. WARNING LABELS

The agreement, (bill page 26- 28), authorizes a variety of new warning labels for tobacco products.

1. Does the administration believe that these are appropriate warning labels?

2. Does the administration possess data suggesting that these warning will effectively reduce smoking, particularly youth smoking?

3. What data suggests that the various new warnings will

be as or more effective than the current warning requirements?

4. Does the administration support the provisions authorizing specific new labels? If so, why? If not, why not?

5. What specific changes, if any, in the legislative language implementing this provision would the administration propose? Please provide specifics.

IX. WARNING LABEL SIZE AND LOCATION REQUIREMENTS

The agreement (bill page 28-29) specifies, the size, placement and print type of the various tobacco warning labels.

1. What data does the administration have to suggest that these specifications will reduce smoking, particularly youth smoking?

2. Does the administration support these particular specifications? If so, why? If not why not?

3. Does the administration support the exception (page 29) provided for flip-top cigarette packages? If so, why? If not, why not?

4. What specific changes, if any, in the legislative language to implement these restrictions would the administration propose? Please provide specifics.

X. SMOKELESS TOBACCO ALTERNATIVE LABELS

The agreement (bill page 34) provides for various new warning label options for smokeless tobacco

1. What data does the administration have to suggest that the various new warning labels will effectively reduce the use of smokeless tobacco, particularly among youth?

2. Does the administration support the use of these alternative labels?

3. What changes, if any, to the legislative language implementing this provision would the administration propose? Please provide specifics.

XI. ENFORCEMENT OF ADVERTISING, MARKETING AND LABELING RESTRICTIONS

The agreement (bill page 36-37) provides for the enforcement of advertising, marketing and labeling restrictions.

1. Does the administration support the enforcement provisions regarding advertising, marketing and labeling? If so why? If not, why not?

2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specific language.

XII. PREEMPTION OF STATE AND LOCAL ACTION

The agreement (bill page 38) prohibits state and local requirements related to the packaging or advertising of cigarettes or smokeless tobacco.

1. Does the administration support such preemption? If so, why? If not, why not?

2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specific language.

XIII. EXEMPTION OF EXPORTS

The agreement (bill page 40) exempts exports from the packaging, labeling and advertising requirements.

1. Does the administration support this exemption? If so, why? If not, why not?

2. What ramifications does this provision have in the area of foreign relations?

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XIV. RESTRICTION ON ACCESS TO TOBACCO PRODUCTS

The agreement (bill page 40-41), prohibits the sale of tobacco products to individuals under 18 years of age; requires that retailers verify the age of individuals purchasing tobacco; and exempts individuals 27 years of age or older from the photo identification requirement.

1. Does the administration support these provisions? If so, why? If not, why not?

2. How does the administration envision that this provision will be enforced and can it be enforced effectively?

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XV. PROHIBITION ON SALE OF LESS THAN A FULL PACK OF CIGARETTES

The agreement (bill page 41) prohibits the sale of less than a full pack of cigarettes.

1. Does the administration support this prohibition? If so, why? If not, why not?

2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XVI. STATE LICENSURE TO SELL TOBACCO

The agreement, (bill page 44) requires states to license sellers of tobacco products.

1. What data, if any, does the administration have to indicate that licensure will effectively reduce access to tobacco by minors?

2. What entity does the administration envision would enforce the licensure requirement if a state should be unable or unwilling to implement the licensure program?

3. Has the administration developed or formulated the cost of a licensure program?

4. Does the administration support the licensure program? If so, why? If not, why not?

5. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XVII. ANTI-TRUST EXEMPTION

The agreement, (bill page 94), provides anti-trust exemption for the tobacco industry.

1. Does the administration support such an exemption? If so, why? If not, why not?

2. Could such an exemption be used to set prices beyond those necessary to deter youth smoking, but to increase profits for the industry?

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XVIII. APPLICABILITY TO NEW ENTRANTS IN TOBACCO INDUSTRY

1. Under the agreement, and the implementing legislation, what is the assurance that new entrants into the tobacco industry will comply with the statute and any related consent agreements not to challenge the legality of the agreement implementation legislation.

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especially if combined with even
further voluntary agreements to
restrict advertising,

[Note: For the underlined section, preferred by HHS, the Department of Justice would prefer the paragraphs that are in boldface and in italic.]

Dear Mr. Chairman:

comprehensive, bipartisan

The Clinton Administration looks forward to working with you and others in Congress to develop legislation that will reduce teen tobacco use. In addition to the enclosed responses to your questions, we are prepared to provide the appropriate staff to give the Committee the technical assistance you request. We also are providing you with a number of resource documents cited below that we hope will be of assistance as you work to develop comprehensive legislation to protect our nation's children from tobacco-related disease and death.

To protect children and adolescents, FDA adopted comprehensive regulations restricting the sale and distribution of nicotine-containing tobacco products in its final tobacco rule issued August 28, 1996. The rule's advertising and access restrictions were based upon a multi-year investigation, and resulted from the analysis of myriad studies and research on issues related to reducing youth tobacco use and the consideration and analysis of more than 700,000 comments submitted in response to its proposed rule. FDA detailed its analysis and findings in two documents: a proposed rule and preamble published in 60 Fed. Reg. 41314 (August 11, 1994); and a final rule and preamble published in 61 Fed. Reg. 44396 (August 28, 1996). Copies of those documents are provided with this response and citations to pages in those documents are provided. In addition, FDA's administrative record contains the studies described in those documents as well as public comments received by the agency. That record is contained on 5 CDs, which are provided. Two new studies on the effect of advertising on young people, and a collection of studies and reviews on the effectiveness of warning labels also are provided. Finally, two other documents are provided: The Institute of Medicine's Report, *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youth* (1994) (IOM); and the Department of Health and Human Services' Centers for Disease Control and Prevention's Report, *Preventing Tobacco Use Among Young People, A Report of the Surgeon General* (1994) (1994 SGR). These two reports contain summary discussions about tobacco advertising and its effect on young people. See especially 1994 SGR Chapter 5 and IOM Chapter 4.

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of this
power.

DOT
is much
better

Many of the provisions included in S.1414 would codify the comprehensive regulations on nicotine-containing tobacco products that the FDA adopted in its final Tobacco Rule issued August 28, 1996. The FDA restrictions were carefully crafted on the basis of a multi-year investigation, and resulted from the analysis of myriad studies and research on the effects of advertising, specifically tobacco advertising, on young people and the consideration and analysis of more than 700,000 comments submitted in response to the proposed FDA rule.

providing
authority

As you know, the Admin believes strongly that the FDA has jurisdiction over tobacco advertising restrictions and that comprehensive tobacco law should be enacted. The Administration believes, as the Department of Justice has explained at length in the FDA litigation, that the FDA's regulations that restrict the advertising of tobacco products are consistent with the First Amendment, under the currently controlling framework for First Amendment review of restrictions on advertising, set out by the Supreme Court in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980), and subsequent cases. The FDA restrictions would, if implemented, substantially advance the Government's

As part of such a
comprehensive
effort,

has long recognized the importance of the Admin. is deeply committed to ~~the importance of~~

~~the~~ ~~restricting~~ the advertising of tobacco products to young people. ~~For the long the~~ ~~marketing~~ ~~paid for by~~ ~~that tobacco advertising aimed at~~ ~~young people~~ is a significant factor in ~~the~~ ~~their~~ decision to ~~start~~ ~~smoking~~. Comprehensive tobacco legislation ~~is an opportunity for Congress to~~ ~~reinforce the FDA's efforts in this area.~~

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Do we also
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ad restrictions
that go beyond
FDA are not
difficult to enact
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significant v.
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wholly legitimate and compelling interest in curtailing minors' demand for and use of tobacco products by reducing minors' exposure to tobacco product advertising. Moreover, the FDA's regulations are tailored to serve this objective. For these reasons,

We believe the advertising restrictions in S.1414 that track the FDA regulations are constitutional. Other restrictions contained in S.1414 give rise to constitutional concerns that are not presented by the FDA regulations, such as whether such restrictions would be sufficiently tailored to serve the governmental interest in reducing teenage smoking. In any event, it is important to emphasize that any comprehensive tobacco legislation should provide express statutory reaffirmation of the FDA's jurisdiction and authority to impose additional advertising restrictions based on substantial evidence when the agency determines that such additional restrictions are necessary, efficacious, and constitutionally tailored. The enclosed response detail these concerns. Such ~~restrictions~~ ^{limits on advertising} nonetheless may be extremely valuable in reducing youth smoking and protecting the public health, and the Administration strongly encourages the tobacco industry to address them voluntarily.

To assist the committee in developing legislation regulating tobacco products, including legislation restricting the advertising of tobacco products, we have provided with this response copies of the two documents which detail the analysis and findings on which the FDA regulations are based: the FDA's proposed rule and preamble published in 60 Fed. Reg. 41314 (August 11, 1994); and the FDA's final rule and preamble published in 61 Fed. Reg. 44396 (August 28, 1996). Our answers to your questions include citations to these documents where appropriate. In addition, the FDA's administrative record contains the studies described in those documents as well as public comments received by the agency. That record is contained on 5 CD's, which are also provided with this response. Two...

We hope this material is helpful and we look forward to providing you and the members of the Committee with any additional assistance that may be needed.

Sincerely,

Enclosure

PUT
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SOMEWHERE

As you know, the President has called on Congress to enact comprehensive legislation that raises the price of cigarettes by up to \$1.50 a pack over the next ten years, gives the FDA full authority to regulate tobacco products, ~~changes~~ gets tobacco companies out of the business of marketing to children, furthers public health research and goals, and protects tobacco farmers and their communities. ~~Any piecemeal approach will not meet our overriding goal must be to reduce teen smoking.~~ Any piecemeal approach will not meet our overriding goal, which ~~is~~ ^{is} to cut teen smoking.

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DRAFT 2-23-98 6P.M.

I. BAN ON OUTDOOR ADVERTISING, INCLUDING IN STADIA AND ARENAS

- 1. What data does the administration have to substantiate that a ban on outdoor advertising, including stadia and arenas, will reduce smoking and, in particular, youth smoking?**

The FDA tobacco rule prohibits outdoor advertising within 1,000 feet of public playgrounds and elementary and secondary schools. All other outdoor advertising is restricted to black text on a white background, devoid of color and imagery. FDA's regulations are based on the agency's finding that children and adolescents spend a great deal of time in areas around schools and playgrounds and these areas, therefore, should be free of tobacco product advertising. All other outdoor advertising should be restricted to text information only, which generally is not appealing to young people. (See response to II below.) Data supporting this conclusion are detailed at 61 Fed. Reg. 44501-08.

- 2. To what extent do you believe such restrictions can be expected to reduce smoking?**

FDA's advertising restrictions are based on quantitative and qualitative studies of cigarette advertising that show that a causal relationship exists between tobacco advertising and tobacco use by young people and that stringent advertising restrictions, when combined with a comprehensive program designed to reduce initiation and use among young people, will have a positive effect on reducing smoking rates and youth tobacco use.

FDA's findings regarding the ability of advertising restrictions to reduce youth tobacco use are summarized at 60 Fed. Reg. 41330-34 and 61 Fed. Reg. 44466-500.

- 3. Does the administration support such a ban. If so, why? If not, why not?**

The administration supports appropriate restrictions on outdoor advertising, as evidenced by the FDA tobacco rule (21 C.F.R. 897.30(b)) which prohibits outdoor advertising for cigarettes and smokeless tobacco, including billboards, posters, or placards, from being placed within 1,000 feet of the perimeter of any public playground or playground area in a public park, elementary or secondary school. All other outdoor advertising is limited to black text on a white background (21 C.F.R. 897.32(a)).

The prohibition set forth in Section 101(a)(1), however, would prohibit "any form of outdoor tobacco product advertising, including bill boards, posters, or placards." It does not contain the exception for tombstone advertising in certain locations that is included in the FDA regulation. Because that exception ensures that the FDA regulations are appropriately tailored to

serve the government's substantial interest in reducing teenage smoking, Section 101(a)(1)'s broader restriction on all outdoor tobacco advertising raises significant constitutional concerns that are not presented by the FDA regulations. *We believe, however, that voluntary limits of this kind would be of significant value to the public health.*

4. **What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.**

As discussed above, the administration's efforts have been focused on supporting the restrictions now codified in FDA regulations. The administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the outdoor advertising of tobacco products. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

II. BAN ON HUMAN FIGURES AND CARTOON FIGURES IN ADVERTISING

1. **What data does the administration have to substantiate that barring the use of human figures and cartoon advertising will reduce smoking, in particular youth smoking?**

FDA's regulations restrict advertising, with certain exceptions, to black text on a white background. No color or imagery is permitted. These restrictions encompass a prohibition of human figures and cartoon characters. The restrictions apply to billboards, publications, in-store advertising, and direct mail advertisements. FDA's findings in this area are summarized at 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44466-68, 44508-13. FDA's *Federal Register* documents contain specific evidence and summaries of studies. See 60 Fed. Reg. 41333-34 and 61 Fed. Reg. 44475-82.

2. **To what extent do you believe such restrictions can be counted on to reduce youth smoking?**

See response to I.2. *Y* above.

3. **What entity would you propose to determine what constitutes a human image or cartoon character?**

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Food, Drug, Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

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4. **What penalty do you believe is appropriate and should accrue for a violation of the prohibition on material containing figures determined to be human or cartoon?**

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Food, Drug, Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

5. **Does the administration support this ban? If so, why? If not, why not?**

The administration supports appropriate advertising restrictions, as evidenced by the FDA tobacco rule. Section 101(b) of S. 1414 provides that "[n]o manufacturer, distributor, or retailer may use a human image or a cartoon character or cartoon-type character in its advertising, labeling, or promotional material with respect to a tobacco product." This restriction would go beyond the FDA regulation restricting the use of images in the advertising of tobacco products, which provides that, in general, tobacco advertising must take the form of tombstone advertising but permits images to be used without restriction in an "adult publication," one whose readership is at least 85 percent adult and includes less than two million children. 21 C.F.R. § 897.32(a)(2)(i)-(ii). The provision's broader restriction on the use of images in the advertising of tobacco products would raise significant constitutional concerns that the FDA regulation does not present.

addition,
In any event, *also supports enactment of legislation*
the administration *insists* urges the Congress to provide statutory confirmation of the existing authority of the FDA to regulate the use of images in the advertising of tobacco products. This regulatory approach would ensure that the FDA would be authorized, based on existing and future research, to develop necessary and appropriately tailored supplements to its current restrictions, if and when such supplements are needed.

however, that

We believe a voluntary industrywide ban would be of significant value to the public health

6. **What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.**

ask BN what this means. Never mind
→ *Constitutional concerns*
As discussed above, the administration's efforts have been focused on the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in discussing how these restrictions will be implemented and the associated penalties, and whether further restrictions are constitutional and otherwise appropriate.

III. BAN ON INTERNET ADVERTISING

1. **Does the administration support such a ban? If so, why? If not, why not?**

While we would applaud a
voluntary limit of this kind, we

2. **How can and should a ban on Internet advertising of cigarettes be enforced?**
3. **What, if any, concerns does the administration have regarding the constitutional free speech issues raised by any such ban?**
4. **What specific changes, if any, in the legislative language implementing the ban would the administration propose?**

In response to III.1 - III.4, the administration believes that, because there may be more narrowly tailored means of achieving the government's underlying interest in restricting the advertising of tobacco products on the Internet, the categorical prohibition that Section 101(c) of S.1414 would impose ~~would~~ raises significant constitutional concerns. See Reno v. ACLU, 117 S.Ct. 2329,2348 (1997) (explaining that compelled tagging schemes are obvious less restrictive alternative to banning Internet transmission of content harmful to minors). ~~We would~~ therefore caution the Congress about adopting such a broad measure at this time.

In order to ensure that the government retains necessary flexibility to regulate the advertising of tobacco products on the Internet, we recommend that the Congress provide express statutory confirmation of the FDA's existing authority to regulate such advertising. This regulatory approach will ensure that any future restrictions are targeted at the right forms of Internet advertising and are fashioned in a manner that is appropriately sensitive to First Amendment concerns. Alternatively, we are prepared to work with Congress to fashion a more narrowly focussed Internet restriction.

IV. BAN ON POINT-OF-SALE ADVERTISING

1. **What data does the administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?**

See responses to I.2. and II.1., above, regarding FDA's proposal restricting point-of-sale advertising. In its tobacco rulemaking, FDA found that young people get their information and product imagery from all types of advertising, including at the point of sale. See 61 Fed. Reg. 44509 - 44510. Point-of-sale advertising presents the child with an enticement at the time when purchase is immediately available.

Manufacturers and retailers limited to text-only advertising at point of sale will not be prohibited from promoting products at retail. Adult consumers looking for price and product information will be able to find that information even without imagery and colors, which are particularly attractive to children. While text-only advertising can still be effective with adults, it will have less allure and be less appealing to young people. Children and adolescents, who are less willing than adults to process print information in a leisurely setting (such as reading a

magazine), will find textual material even less appealing in the few moments spent at the retail counter.

2. Does the administration support such a ban? If so, why? If not, why not?

The administration supports appropriate restrictions on point of sale advertising, as evidenced by the FDA tobacco rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

3. Is the exemption of point-of-sale advertisement for adult stores and tobacco outlets appropriate?

The administration's focus has been on preventing children and adolescents from using tobacco products. Restrictions on the advertising that makes these products appealing to young people is a vital component of these efforts. FDA's regulations exempt adult-only locations and publications read primarily by adults because the evidence then available showed that advertising in locations where children are never present, such as adult-only locations, or are rarely exposed, as is the case with publications with an insignificant youth readership, would not have a significant adverse effect on efforts to reduce youth tobacco use.

4. Is it appropriate to grant companies with greater cigarette market share additional point-of-sale advertising rights? If so, why? If not, why not?

5. Does such a privilege constitute a statutorily granted competitive advantage? If so, why? If not, why not?

6. Does the administration support this grant? If so, why? If not, why not?

7. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.

Section 101(d) would impose a general prohibition on the use of what is termed "point-of-sale advertising" of tobacco products but would include a significant exception for "adult-only stores and tobacco outlets." Sec. 101(d)(2). The FDA regulations contain restrictions that are targeted at point-of-sale advertising, however, they are not as broad as those set forth in S.1414 primarily because they do not prohibit tombstone advertising. See 21 C.F.R. §§ 897.32, 897.16. The resources of the administration are available to assist the Committee in crafting restrictions on point-of-sale advertising that avoid any significant constitutional concerns that the restrictions on point-of-sale advertising in S.1414 would raise.

Section 101(d)'s exception permitting manufacturers with a greater market share to engage in more point of sale advertising than their competitors appears inconsistent with the government's asserted interest in restricting such advertising. Granting manufacturers point-of-sale advertising opportunities consonant with market share is unrelated to the objective of reducing youth tobacco use; indeed, it may run counter to that goal. Moreover, the proposal presents constitutional and anti-competitive concerns that should be addressed. The resources of the administration are available to assist the Committee in exploring those concerns.

V. LIMITATIONS ON POINT-OF-SALE ADVERTISING

- 1. What data does the administration possess to suggest that such limitations will reduce smoking, particularly among youth?**

See response to IV.1., above.

- 2. Does the administration support this provision? If so, why? If not, why not?**

The administration supports appropriate restrictions on point of sale advertising, as evidenced by the FDA Tobacco Rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

VI. BAN ON ADVERTISING RESTRICTION AGREEMENTS

- 1. Are such agreements currently against federal or state law? If so, is such a provision necessary?**

Ordinarily, under the free market system, retailers are permitted to decide from whom and to whom they will buy and sell, and on what terms. While an agreement of the sort described -- between a manufacturer and a retailer to limit the ability of a competing manufacturer to display advertising on the retailer's premises -- might be anticompetitive under certain circumstances, such agreements are usually not condemned under the federal antitrust laws. The administration has not undertaken a review of state laws to determine whether such an arrangement would violate the law of any state.

- 2. Does the administration support such a provision? If so, why? If not, why not?**

The administration's primary concern is not the relationship of retailers, manufacturers, and distributors between or among one another with respect to advertising. Rather, the

administration wants to ensure that point-of-sale advertising and promotional material, whatever their source, consist only of black text on a white background.

3. **Does the administration support the limitation. If so, why? If not, why not?**

See answer to question 2 above.

4. **What specific changes, if any, in the legislative language implement the ban would the administration propose? Please provide specifics.**

See answer to question 2 above.

VII. GLAMORIZATION OF TOBACCO

1. **What data does the administration possess to indicate whether and to what extent this provision will reduce smoking, particularly among youth?**

A number of studies (Tye 1990; Terre, Drabman, and Speer 1991; Hazan, Lipton, and Glantz 1994; Thumbs Up! Thumbs Down! 1997) show that depictions of tobacco use in the entertainment media, particularly feature films, are on the increase and exaggerate greatly the actual prevalence of tobacco use in the U.S. population. Research also suggests that adolescents are highly susceptible to pro-smoking messages and images conveyed in entertainment media (Signorielli 1993; Davies 1993; Basil 1997). Focus group research found that young people are able to recall virtually no anti-smoking messages on TV or in the movies, yet they are able quite readily to recall specific movies that portray smoking and to identify actors and actresses who smoke in their entertainment roles (Mermelstein 1997). Deglamorizing tobacco use in the entertainment media can be achieved both by decreasing pro-smoking cues and by increasing anti-smoking cues. A study by researchers at the University of California at Irvine suggests that anti-smoking ads before movies can help inoculate young people against the positive images of smoking that appear in movies. Ninth graders who watched the movie "Reality Bites" (in which the cast smokes in about one-third of the scenes) preceded by a California Department of Health Services anti-smoking ad were much less likely to find smoking exciting compared with teens who watched the movie without the counter-advertisement (Pechmann, 1996).

2. **What entity does the administration propose will determine what activity constitutes promoting the image or use of a tobacco product?**
3. **How does the administration envision such a ban will be enforced?**

- 4. Does the administration support such limitations?**
- 5. What specific changes, if any, in the legislative language would the administration propose? Please provide specifics.**

In response to Questions VII.2 - VII.5, the administration believes that the scope of the restriction on glamorization in S. 1414 is unclear. For example, is the provision intended only to restrict attempts to promote certain brand names of tobacco products or is it intended to restrict the promotion of smoking generally? If the latter were the case, then the provision would appear to reach some noncommercial speech, raising significant constitutional concerns. It is also not clear what is meant by the use of the word "promoting." Finally, the phrase "appeals to individuals under 18 years of age" could be subject to challenge on vagueness grounds.

Alternatively, no such constitutional concerns would be raised if Congress enacted legislation that would confirm the authority of the FDA to regulate the advertising of tobacco products through such indirect means as the use of product placement agreements.

VIII. RESTRICTIONS ON COLOR ADVERTISEMENTS

- 1. What data does the administration have to substantiate that a ban on color ads, except in publications with limited youth readership, will reduce smoking particularly youth smoking?**

See response to II.1., above.

- 2. Does the administration believe that the threshold for the restriction of two million readers is the appropriate threshold?**

FDA's tobacco rule requires that advertising be restricted to black and white text, except in publications that are read primarily by adults or in adult-only facilities. The text-only requirement is intended to reduce the appeal of cigarettes and smokeless tobacco advertising on young people without unduly affecting the informational messages conveyed to adults. Therefore, FDA proposed in its rulemaking that advertising in publications that are read primarily by adults should be allowed to use imagery and color because the effect of such advertising on young people should be nominal. The agency set the definition of adult publication as those whose readers age 18 or older constitute 85 percent or more of the publication's total readership, or those which are read by two million or fewer people under age 18, whichever method results in the lower number of young people. (Magazines with small readership numbers but which appeal to young people may not attract two million young readers but may still be primarily youth oriented; that is, 15 percent or more of their readers are under 18.) In addition, the agency noted that at some point, the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless

of the percentage of the readership. For example, a magazine with a large total readership base may attract as many as 5 million young people, or more, but those numbers would still not be 15 percent of the magazine's readership. See 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44513-19.

3. How does the administration envision readership demographics being determined?

In its tobacco rulemaking, FDA explained that readership demographics would be determined by measuring the total number of people that read any given copy of a publication. Readership demographics would be measured according to industry standards and, at a minimum, would be based on a nationally projectable survey of people. Two examples of currently available surveys are Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK. FDA also indicated that it would be willing to work with industry on this issue. See 61 Fed. Reg. 44516-19.

4. How would this restriction be enforced?

The restriction would be enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Federal Food, Drug and Cosmetic Act which provides for the imposition of civil money penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

5. Does the administration support this restriction? If so, why? If not, why not?

The administration supports the regulation in the FDA rule based upon the findings of the Food and Drug Administration regarding the role and attractiveness of images and color in advertising to young people. See, e.g., 61 Fed. Reg. 44467-68, 44509 (1996).

6. What specific changes, if any, in the legislative language implementing the restriction does the administration propose? Please provide specifics.

As discussed above, the administration supports effective restrictions on the use of color and imagery in tobacco advertising. The administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the advertising of tobacco products.

IX. GENERAL QUESTION REGARDING MARKETING/ADVERTISING BAN

1. Can the marketing and advertising restrictions envisioned in the settlement be constitutionally imposed, with or without the industry's consent? Please discuss.

DRAFT 2-23-98 6P.M.

The answers to Parts I-VIII above address the government's authority to impose restrictions on advertising and marketing without the industry's consent. We address here the degree to which "the industry's consent" may affect the constitutional analysis of the advertising restrictions.

~~Basically Voluntary~~ ^{commitments} ~~agreements~~ to restrict advertising are of course constitutional. We believe that the constitutional analysis of such restrictions might be affected if the industry's adoption of these advertising restrictions that either could not be constitutionally imposed upon the industry, or that exceed the restrictions that are imposed by the FDA-regulations, were in some way made contingent upon the industry's willingness to adopt them. For example, we believe that the inclusion of such restrictions in state court consent decrees between states and tobacco manufacturers -- rather than in federal legislation -- would significantly increase the likelihood that the restrictions would be upheld if challenged in the future. However, the inclusion of such restrictions in a federal statute that made adherence to such restrictions a condition of the receipt of certain federal benefits would continue to raise substantial constitutional questions. Such a statute, depending on how it were framed, ~~would be~~ ^{could} subject to substantial challenge under the unconstitutional conditions doctrine.

X WARNING LABELS

1. Does the administration believe that these are appropriate warning labels? This potential problem.

The administration supports the concept of strengthening warning label statement requirements. Several recent studies (Health Canada 1996; Borland, Cappiello, and Hill 1996; Robinson and Killen 1997) and literature reviews (USDHHS 1994; IOM 1994) are available concerning the effectiveness of warning labels in conveying information to consumers. The administration's resources are available to help the Committee evaluate possible improvements to warning label requirements.

2. Does the administration possess data suggesting that these warnings will effectively reduce smoking, particularly youth smoking?

See response to X.1., above.

3. What data suggests that the various new warnings will be as or more effective than the current warning requirements?

See response to X.1., above.

4. Does the administration support the provisions authorizing specific new labels? If so, why? If not, why not?

As noted, we believe that certain of those restrictions raise significant constitutional concerns.

Should it be
reg?
const.
concerns
about
restriction
beyond
FDA reg?

this reason,

consequence

The resources of the Administration are available to assist the Committee in evaluating legislative designed to minimize problem.

- 5. What specific changes, if any, in the legislative language implementing this provision would the administration propose? Please provide specifics?**

As stated above, the administration is available to work with the Committee in determining whether changes to the warning statement requirements are appropriate.

IX. WARNING LABEL SIZE AND LOCATION REQUIREMENTS

- 1. What data does the administration have to suggest that these specifications will reduce smoking, particularly youth smoking?**

See response to X.1., above.

- 2. Does the administration support these particular specification? If so, why? If not, why not?**
- 3. Does the administration support the exception provided for flip-top cigarette packages? If so, why? If not, why not?**
- 4. What specific changes, if any, in the legislative language to implement these restrictions would the administration propose? Please provide specifics.**

The administration, as discussed above, has focused its efforts on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are appropriate.

X. SMOKELESS TOBACCO ALTERNATIVE LABELS

- 1. What data does the administration have to suggest that the various new warning labels will effectively reduce the use of smokeless tobacco, particularly among youth?**

See response to X.1., above.

- 2. Does the administration support the use of these alternative labels?**
- 3. What changes, if any, to the legislative language implementing this provision would the administration propose? Please provide specifics.**

The administration, as discussed above, has focused its efforts on supporting the

restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are appropriate.

XI. ENFORCEMENT OF ADVERTISING, MARKETING AND LABELING RESTRICTIONS

- 1. Does the administration support the enforcement provisions regarding advertising, marketing and labeling? If so why? If not, why not?**

Section 114 of the bill provides FTC with the authority to enforce sections 111 and 112, the provisions relating to warning statement requirements. Section 114 also contains a penalty provision for violations of section 113, the requirement that companies provide ingredient information to the Secretary of HHS pursuant to a new provision of the Federal Food, Drug, and Cosmetic Act, and authorizes the FTC to bring actions to enforce that provision. With respect to sections 111 and 112, section 114 appears to maintain the status quo with respect to warning label enforcement issues. Some other proposed bills would shift that authority to FDA. The administration is available to assist in the Committee in considering these differing approaches. With regard to section 113, which relates to a provision of FDA law, the administration would be pleased to assist the Committee in evaluating whether enforcement authority for the ingredient disclosure requirements may be more appropriately vested entirely in FDA.

- 2. What changes in legislative language, if any, does the administration recommend regarding these provisions? Please provide specific language.**

As discussed above, the administration would be pleased to assist the Committee in evaluating issues related to the enforcement of advertising, marketing, and labeling restrictions, and in developing modifications, if appropriate, to legislative language.

XII. PREEMPTION OF STATE AND LOCAL ACTION

- 1. Does the administration support such preemption? If so, why? If not, why not?**
- 2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specific language?**

The administration generally supports the limited preemption of state and local requirements related to the packaging of cigarettes or smokeless tobacco, but does not support the preemption of state and local restrictions on advertising. FDA's current regulations address advertising. Although the regulations are preemptive, the Federal Food, Drug and Cosmetic Act

allows states and localities to apply for waivers to be exempted from federal thresholds. This would allow states and localities to enact or retain existing advertising restrictions that would be more stringent.

The administration is available to work with the Committee with respect to the broader issues of preemption raised by other provisions of the bill. The administration is committed to allowing states and localities the maximum flexibility practicable to develop strong public health policies to prevent and reduce youth tobacco use.

XIII. EXEMPTION OF EXPORTS

1. Does the administration support this exemption? If so, why? If not, why not?

No. As the world's leading exporter of tobacco products, the United States has the obligation to guarantee that its companies will behave responsibly no matter where they do business. There should be no exemptions for policies that would safeguard the health and well being of people anywhere in the world.

2. What ramifications does this provision have in the area of foreign relations?

Adopting a less stringent policy towards exported tobacco products would send a negative message to the countries where these products are sold -- that the health and well being of their citizens, particularly their children, are less important than the health and well being of Americans.

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

Proposed response: The provision should be revised as follows:

- "It shall be unlawful for any domestic concern or any officer, director, employee, or agent of such concern to make use of the mails or any means or instrumentality of interstate commerce to contribute, either directly or through a foreign subsidiary, joint venture, affiliate, or licensee to--

 "(1) the sale or distribution of tobacco products in a foreign country to children; or
 "(2) the advertising or promotion of tobacco products in a foreign country in a manner that appeals to children.
- "It shall be unlawful for any domestic concern or any officer, director, employee, or agent

*BR: Have we discussed/
agreed to this??*

*I have
no idea
what
this is
about*

of such concern either directly or through a foreign subsidiary, joint venture, affiliate, or licensee, to make use of the mails or any means or instrumentality of interstate commerce to cause or contribute to the export from the United States any tobacco product the package of which does not contain a warning label that--

“(1) is in the primary language of the country in which the tobacco product is sold or distributed to consumers; and

“(2) except for the requirement of paragraph (1)--

“(A) complies with Federal requirements for labeling of similar tobacco products manufactured, imported, or packaged for sale or distribution in the United States; or

“(B) complies with the labeling requirements of the foreign country in which the product is sold or distributed to consumers and which the labeling requirements the Secretary of Health and Human Services determines are substantially similar to Federal requirements and are adequately enforced by such country.”

XIV. RESTRICTIONS ON ACCESS TO TOBACCO PRODUCTS

1. Does the administration support these provisions? If so, why? If not, why not?

The administration supports access restrictions based upon FDA’s findings regarding the ability of persons under 18 to purchase tobacco products in the absence of a photo identification requirement. See, e.g., 61 Fed. Reg. 44437-39 (1996).

2. How does the administration envision that this provision will be enforced, and can it be enforced effectively?

FDA currently is enforcing aspects of its restrictions on youth access to tobacco products embodied in the FDA tobacco rule (21 C.F.R. §§ 897.14, 897.16). FDA is enforcing the age and photo ID provisions cooperatively with state and local officials. Because of the enormous number of retailers that sell tobacco, FDA has adopted a cooperative model. By way of comparison, this is how FDA regulations are enforced for dairy farm and retail food inspections in communities across the country—by commissioning the services of state and local officials.

In its initial enforcement efforts, FDA contracted with 10 states. Under these contracts, states are conducting between 200 and 330 unannounced retail compliance checks each month over a period of eight months. Information about the compliance checks is sent to FDA, which issues a warning for the first violation to retailers found selling to the adolescents. These retailers will be subject to repeat inspections. FDA will seek a fine of \$250 for the second violation and greater fines for subsequent violations. FDA is in the process of contracting with additional states.

FDA anticipates that state and local contracts will provide effective mechanisms to check compliance with other access restrictions, such as the requirement that all transactions be face-to-face, without the assistance of any electronic device. Commissioned state and local officials will be able to determine compliance with these and similar provisions by visiting facilities, and appropriately documenting observations.

XV. PROHIBITION ON SALE OF LESS THAN A FULL PACK OF CIGARETTES

1. Does the administration support this prohibition? If so, why? If not, why not?

The administration supports this prohibition based upon FDA's findings regarding the ability of persons under 18 to obtain cigarettes when they are sold in units of less than a full pack. See, e.g., 61 Fed. Reg. 44443, 44445-48.

2. What change in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

The administration does not recommend any changes in the legislative language.

XVI. STATE LICENSURE TO SELL TOBACCO

1. What data, if any, does the administration have to indicate that licensure will effectively reduce access to tobacco by minors?

Licensure of retailers will give authorities the means of identify those retailers who sell tobacco. States that do not require licensure are having difficulty complying with the Synar amendment, because they have difficulty identifying outlets that sell tobacco products. In addition to providing a list of retailers, the threat of license revocation for noncompliance is extremely motivating to retailers. Furthermore, license fees can be used to cover the cost of enforcement, which is an important determinant of compliance.

2. What entity does the administration envision would enforce the licensure requirement if a state should be unable or unwilling to implement the licensure program?

The administration supports a licensing program that ^{primarily operates} ~~is operated~~ at the state or local levels. ~~The responsible federal agency should have authority to devise a program and set national standards that the participating state and local programs implement.~~ ^{The Administrative} ~~is available to work with the committee~~ ^{is available to work with the committee} ~~on the details~~ ^{on the details} ~~issues concerning the relationship of~~ ^{issues concerning the relationship of} such programs to federal standards or regulation activities. ~~The Administrative will implement this program when it resolves these issues.~~

Edwards

3. **Has the administration developed or formulated the cost of the licensure program? If so, why? If not, why not?**

The administration has not completed work regarding the cost of a licensure program.

4. **Does the administration support the licensure program? If so, why? If not, why not? [Sentences that are bold and in italic still are proposed by DOJ without HHS concurrence.]**

The administration supports an effective licensing program. Federal legislation that calls upon states to establish regulatory programs must be sensitive to federalism concerns. *Section 131 would provide two incentives for states to establish licensing programs for retail distributors of tobacco products. States that establish satisfactory licensing programs (1) would avoid imposition of a federal ban on retail distribution of tobacco products within their borders; and (2) would qualify for block grants under section 502. Congress possesses authority, under principles discussed in New York v. United States, 505 U.S. 144, 173-74 (1992), to "offer States the choice of regulating that activity according to federal standards or having state law pre-empted by federal regulation." Congress also possesses authority, under Spending Clause principles discussed in South Dakota v. Dole, 483 U.S. 203 (1987), to condition the receipt of federal funds by states on their implementation of certain regulatory measures. Accordingly, although the section 131 incentives for state licensing may give rise to constitutional challenges, we believe that they are consistent with the Constitution.*

5. **What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.**

The resources of the administration are available to work with the Committee in evaluating provisions for a licensing program.

XVII. ANTI-TRUST EXEMPTION

1. **Does the administration support such an exemption? If so, why? If not, why not?**

The antitrust laws are the most important protector of the free-market economy against anticompetitive actions that would undermine its integrity to the detriment of consumers. Accordingly, exceptions to the antitrust laws should be made only in exceedingly rare instances, when the fundamental free market values underlying the antitrust laws are compellingly overwhelmed by a paramount policy objective; and a proposed exemption must be necessary to permit the paramount policy objective to be pursued. The proponents of an antitrust exemption

Edits
on antitrust for advertising

broad
an exemption
-- for example, that allowed
companies to contribute to
expenses jointly --

~~for the tobacco industry thus face a heavy burden, which they have not yet met~~ *this heavy burden.*

2. **Could such an exemption be used to set prices beyond those necessary to deter youth smoking, but to increase profits for the industry?**

An antitrust exemption that allowed tobacco firms to set prices jointly could be used by firms to increase prices beyond what is necessary to deter youth smoking and thereby to increase profits at the expense of consumers. It would be very difficult to restrict use of the exemption to its intended purpose, because the tobacco companies would have both the opportunity and the incentive to effect unnecessary price increases and to conceal them under the guise of restrictions on youth smoking. While the resulting collusive price increase would be likely to reduce demand for tobacco products, it would also increase profits for the tobacco companies, at least to the point at which they are collectively charging the "monopoly price." The tobacco companies would thereby be able to use an antitrust exemption to enrich themselves at the expense of those confirmed with smoking habits.

3. **What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.**

Before any exemption is considered for enactment, the proponents of the exemption need to meet the burden of demonstrating that this is one of the ~~exceedingly~~ rare instances in which the antitrust laws are incompatible with a clearly paramount policy objective. The administration is extremely skeptical that the proponents of this case will be able to meet that burden, *except perhaps to support agreements to restrict advertising to children.*

Even in those rare instances in which that burden is met, any antitrust exemption should be carefully and narrowly crafted to address that objective in the least anticompetitive manner available. If Congress should decide to move forward with consideration of antitrust exemptions for the tobacco industry, the administration would assist in crafting them as narrowly and precisely as possible to achieve their purpose without creating unnecessary anticompetitive effects.

XVIII. APPLICABILITY TO NEW ENTRANTS IN TOBACCO INDUSTRY

[Still have to work this one out.] Whatever the ultimate answer, it should make the following point -- The inclusion of provisions that would enable new entrants to "consent" to restrictions on their advertising would be subject to constitutional review in accord with the principles discussed in our answer to question 9.]

*2 I want to see this.
etc*

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