THE WHITE HOUSE

WASHINGTON

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

VII. GLAMORIZATION

Basil MD. The danger of cigarette "special placements" in film and television. Health Communication 1997:9(2):191-198.

Davies J. The impact of the mass media upon the health of early adolescents. Journal of Health Education 1993 Supplement:S28-S35.

Mermelstein R. The CDC Tobacco Control Network: understanding factors that influence youth tobacco use. Progress Report October 1995 - September 1997. Chicago, IL: Prevention Research Center, University of Illinois at Chicago.

Pechmann C. Inoculation effect of tobacco counter-advertising. University of California-Irvine, 1997.

Signorielli N. Mass media images and impact on health: a sourcebook. Westport, CT: Greenwood Press, 1993.

Terre L, Drabman R, Speer P. Health-relevant behaviors in media. Journal of Applied Social Psychology 1991:21:1303-1319.

Thumbs Up! Thumbs Down! Teens take a look at tobacco use in the movies. American Lung Association of Sacramento-Emigrant Trails, 1997.

Tye JB. Tobacco and youth reporter. Longmeadow, MA: Stop Teenage Addiction to Tobacco, 1990.

X. WARNING LABELS

Borland R, Cappiello M, Hill D. Impact of the new Australian health warnings on tobacco products. Carlton South, Victoria: Anti-Cancer Council of Victoria, 1996.

Health Canada. Effectiveness of health warning messages. Toronto, Ontario: Tandemar Research Inc., 1996.

Institute of Medicine. Warnings and packaging. Growing up tobacco free: preventing nicotine addiction in children and youths. Washington, DC: National Academy Press, 1994:236-246.

Robinson TN, Killen JD. Do cigarette warning labels reduce smoking? Paradoxical effects among adolescents. Archives of Pediatric and Adolescent Medicine 1997;151:267-272.

U.S. Department of Health and Human Services. Warning labels on tobacco products. In Preventing tobacco use among young people: a report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention, 1994:257-264.