NLWJC - Kagan

DPC - Box 042 - Folder 015

Tobacco-Settlement – Access

Tob-sct - access

Cynthia A. Rice 07/22/98 05:27:57 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Laura Emmett/WHO/EOP, Cynthia Dailard/OPD/EOP

cc:

Subject: Thursday Roll Call Story on Tobacco

I hear from Waxman's folks that Roll Call will run a story tomorrow with the results of a Lung Assoc. sting operation of 15 year olds who tried to purchase cigarettes at stores located in the House, Senate, and the Capitol. The tries were 100% successful in the House, 50% in the Capitol, and 25% in the Senate.

FYI -- I checked and the snack shop in the OEOB does sell cigarettes ($3.00 a pack).

Tob-ref-advertising and Tob-ref-access

FDA Rule

Youth Access Restrictions

- Sets minimum age of purchase at 18 years
- Requires age verification by photo ID for anyone 26 or younger
- Requires face-to-face sales (except for mail order sales)
- Bans vending machines and self-service displays except in facilities where only adults are permitted

Advertising Restrictions

- Bans outdoor advertising within 1000 feet of schools and public playgrounds
- Restricts advertising to black-and-white text only (publications, outdoor, point of purchase, direct mail, etc.), except in publications with a predominant adult readership or at adult only facilities
- Prohibits sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos
- Prohibits brand-name sponsorship of sporting or entertainment events, but permits it in the corporate name
- Constitutionally valid advertising restrictions are based on a strong factual record and are narrowly tailored to restrict advertising that contributes to young people's use of tobacco.

Point of Purchase Restrictions

- Prohibits sales of single cigarettes or "loosies"
- Bans free samples
- Sets minimum package size at 20 cigarettes
- Restricts all point of purchase advertising and labeling to black-and-white text only, except in adult only facilities

Tob - str - access

AN ANALYSIS OF H.R. 2519 WHICH WOULD REQUIRE ALL STATES TO INCREASE THE MINIMUM LEGAL AGE FOR THE SALE OF TOBACCO PRODUCTS FROM 18 TO 21

Working Paper #9 in a Series on Legal Issues in the Proposed Tobacco Settlement

May 19, 1998

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An Analysis of H.R. 2519 Which Would Require All States to Increase the Minimum Legal Age for the Sale of Tobacco Products from 18 to 21[1]

by
Raymond C. Porfiri and Richard A. Daynard

1. Introduction

Congress will soon debate and then likely decide this country's national tobacco policy for the next generation. In this complex debate, one simple proposal embodied in H.R. 2519[2] has received insufficient discussion. That idea is to increase the minimum legal sale age of tobacco products (MLSA) from 18 to 21.[3] In this working paper, we examine data concerning the onset of nicotine addiction, the enforcement of current tobacco age and identification laws and the national experience with an increase in the minimum legal drinking age (MLDA) from 18 to 21. Based on this information, we anticipate a significant decline in the regular use of tobacco products by young people if the MLSA is increased from 18 to 21, especially if the new law is vigorously enforced. Finally, we briefly discuss the reasons why congressional action, as opposed to piecemeal state action, is preferable on this specific issue.

2. The problem

Tobacco use is the single leading preventable cause of death in the United States.[4] Approximately 3000 young children and adolescents become regular smokers every day.[5] An estimated 1000 of these new smokers will ultimately die from their habit.[6] Youth

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[1] This analysis is largely confined to the probable public health impact of H.R. 2519 in the form it was originally filed. See appendix 1 of this working paper for a copy of H.R. 2519, 105th Congr., 1st Sess. (1997) as filed. We do suggest one amendment to the current language of the bill. *See* note 24, *infra.*

[2] The official short title of H.R. 2519 is the "Tobacco-Free Youth Act." H.R. 2519, 105th Congr., 1st Sess. § 1 (1997).

[3] We note that we are *not* suggesting that the *purchase* or *possession* of tobacco products be criminalized for 18-20 year olds. We are suggesting that Congress require the states to raise the legal age for merchants to sell tobacco from 18 to 21. For a detailed treatment of the criminalization issue, see Graham Kelder, *The Perils, Promises and Pitfalls of Criminalization of Youth Possession of Tobacco*, TOBACCO CONTROL UPDATE, Vol.1, Issues 1 & 2 (Winter 1997). This article can be found on the Internet at http://tobacco.neu.edu/tcu/3-97/YPFINAL.HTM.

[4] J. Michael McGinnis & William H. Foege, *Actual Causes of Death in the United States*, 270 JAMA 2207 (1993).

[5] John P. Pierce et al., *Trends in Cigarette Smoking in the United States: Projections to the Year 2000*, 261 JAMA 61 (1989).

[6] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44396, 44399 (1996) [Hereinafter FDA Final Rule].

smoking rates are soaring. On April 27, 1998, U.S. Surgeon General David Satcher issued the 24th Surgeon General's report since 1964 on the perils of tobacco use. The report documents that smoking among U.S. high school students has increased 33 percent over the past six years.[7] Kids are smoking more than ever and the trend seems difficult to reverse. The problem is that nicotine use begins at a very early age in the United States, and once a kid is hooked, it is exceptionally difficult for that child to stop.[8]

Data from the 1991 National Household Survey on Drug Abuse[9] indicates that among individuals who had ever tried a cigarette, the average age of first trying a cigarette was 14.5 years.[10] Eighty two percent (82%) had tried a cigarette before age 18, 89 % before age 19, 91% before 20, and 98% before age 25.[11] The time interval from the initial experimentation with smoking to the stage of regular use of cigarettes averages 2 to 3 years.[12] Of surveyed individuals who had ever smoked daily, 53% begin smoking daily before age 18, 71% before age 19, 77 % before 20, and 95% before age 25.[13] The earlier a young person's smoking habit begins, the more likely he or she will suffer a greater risk of diseases caused by smoking.[14]

In sum, most kids who become regular smokers have tried cigarettes and become daily users of them by age 21. To break or change this pattern, Congress must make it

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[7] Bob Hohler, *Teenage Smoking Up Sharply*, THE BOSTON GLOBE, April 28, 1998, at A1, A12. The prevalence of current cigarette smoking among U.S. high school students increased from 27.5% in 1991 to 36.4 % in 1997. *See* Centers for Disease Control and Prevention, *Tobacco Use Among High School Students-United States, 1997*, 47 MORBIDITY & MORTALITY WKLY. REP. 229 (1998).

[8] In 1988, the U.S. Surgeon General's Report officially designated nicotine as an addictive drug in the same class as alcohol, marijuana, cocaine and heroin. *See* U.S Dep't of Health and Human Servs., THE HEALTH CONSEQUENCES OF SMOKING-NICOTINE ADDICTION: A REPORT OF THE SURGEON GENERAL iii-v (1988). According to the 1994 National Household Survey on Drug Abuse, the following symptoms were reported by 12 to 17 year olds who had smoked cigarettes in the past year: 57.5% wanted to cut down; 28.2% had used more than intended; 30.5% reported that tolerance had developed; and 12.8% reported that cigarettes had caused problems at home or at work. *See* U.S Dep't of Health and Human Servs., REDUCING TOBACCO USE AMONG YOUTH: COMMUNITY BASED APPROACHES 12 (1998).

[9] A survey of 30-39 year olds who had ever smoked daily. *See* FDA Final Rule, *supra*, note 6,at 44440.

[10] *Id.*

[11] *Id.*

[12] H. Leventhal et al., *A Cognitive-Developmental Approach to Smoking Intervention, in* TOPICS IN HEALTH PSYCHOLOGY: PROCEEDINGS OF THE FIRST ANNUAL EXPERT CONFERENCE IN HEALTH PSYCHOLOGY 79-105 (S. Maes et al. eds.).

[13] FDA Final Rule, *supra* note 6, at 44440.

[14] Emanuela Taioli & Ernst L. Wynder, *Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood*, 325 NEW ENG. J. MED. 968-969 (1991).

more difficult for merchants to sell to minors.[15] If children have difficulty buying tobacco, the initiation of tobacco use can be delayed or prevented.[16]

3.Current tobacco age and identification laws reduce access to and consumption of tobacco products when properly enforced

The experience with the enforcement of current tobacco control laws suggests that an increase in the MLSA from 18 to 21 will make purchases of tobacco products more difficult for individuals under 21 *and much more difficult for individuals under 18.* Ultimately, this change will delay "first use" and reduce "daily use" of tobacco products.

Studies demonstrate that the requirement for proof of age in order to make a purchase of tobacco products can significantly reduce the rate of successful purchases by minors.[17] Research evidence also indicates that vigorous enforcement efforts undertaken by communities to reduce sales to minors can lead to significant decreases in smoking by young people.[18] One study revealed a 69% decline in smoking among adolescents in Woodridge, Illinois, after active law enforcement using underage buyers and hefty fines decreased illegal sales rates from 70% to 3% of attempted purchases.[19] According to one recent national study, "[l]aws and ordinances that restrict purchase of cigarettes to those 18 years of age or older, do appear to have a negative effect on smoking participation by both boys and girls." [20]

It is clear that serious enforcement of *current* age and identification requirements can reduce access to and consumption of tobacco products by individuals under 18. If that is so, why increase the MLSA to 21? As minors grow increasingly closer to the

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[15] Cigarettes remain readily available to most American teenagers. According to the most recent results of the Monitoring the Future Study (MFS), 90% of 10th graders (who are 15 or 16 years old) said they could get cigarettes "fairly" or "very easily." The results of the 1997 MFS have been summarized and may be found on the Internet at http://www.health.org/mtf/tables/cgrttes/mtfcig97.htm.

[16] *See* U. S. Dep't of Health & Human Servs, PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: SURGEON GENERAL'S REPORT (1994).

[17] For example, in one Massachusetts study, a sale to a minor was made in only 1.5% of instances in which proof of age was requested, in comparison with 45% of instances in which no request was made. *See* Joseph R. DiFranza et al., *Youth Access to Tobacco: The Effects of Age, Gender, Vending Machine Locks, and "It's the Law" Programs*, 86 AM. J. PUBLIC HEALTH 221, 223 (1996).

[18] *See, e.g.*, Leonard A. Jason et al., *Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors*, 266 JAMA 3159-3161 (1991).

[19] *Id.*

[20] Eugene M. Lewit et al, *Price, Public Policy, and Smoking in Young People*, 6 TOBACCO CONTROL (suppl 2) s17, s22 (1997).

current MSLA of 18, it becomes progressively easier for them to buy tobacco.[21] Thus, even with enforcement of the current age requirement, a certain percentage of 12-17 year old individuals will still have access to and will begin to use tobacco products.[22]

4. An increase in the MLSA from 18 to 21 will significantly reduce sales of tobacco products to kids under 18

An increase in the MLSA from 18 to 21 can be expected to reduce the sales to teenagers under age 18 by about 50% if the new restriction is seriously enforced. In the leading study on the effect of age on access to tobacco products, researchers tested the effects of having young people aged 12, 13, 14, 15, 16, and 17 each attempt to purchase cigarettes at the same retailers.[23] The researchers found that the teenagers who were under 16 (more than two years below the minimum age) completed purchases 25% of the time, while those 16 and over (less than two years below the minimum age) completed purchases 48% of the time.[24] Obviously, retail clerks were much more willing to sell to young people who were close to the legal age than to those who were obviously below it. Applying this finding to the proposed increase in the MLSA to 21, we would expect that there would be a sharp drop in sales to teenagers under 18, who would now be more than three years younger than the new minimum age of 21.

5. An increase in the MLSA from 18 to 21 will also reduce access to and consumption of tobacco products by individuals 18 to 20 years of age

The national experience with the increase in the minimum legal drinking age (MLDA) from 18 to 21 suggests that an increase in the MLSA from 18 to 21 will save several thousand additional lives each year by deterring 18 to 20 year olds from smoking.[25] In 1984, Congress passed the "Uniform Drinking Age Act"[26] which provided

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[21] *See* Difranza et al., *supra* note 17, at 221 and studies cited therein.

[22] *See* Nancy A. Rigotti et al., *The Effect of Enforcing Tobacco-Sales Laws on Adolescents' Access to Tobacco and Smoking Behavior*, 337 NEW ENG. J. MED. 1044 (1997).

[23] *See Difranza* et al., *supra* note 17.

[24] *Id.* at 223.

[25] A transitional problem is presented by individuals who are between 18 and 21 years of age at the time the Act takes effect. It might be considered both unfair and impractical to bar sales to individuals to whom tobacco products had previously legally been sold. H.R. 2519 should therefore be amended so as to guarantee that no individual who can be sold tobacco products prior to the effective date of the Act is thereafter barred. This can be done very simply. Assume that the Act takes effect January 1, 1999. The transition provision could then read: "Between January 1, 1999 and December 31, 2001, no tobacco product may be sold to any individual born after December 31, 1980. Beginning January 1, 2002, no tobacco product may be sold to any individual under the age of 21."

[26] 23 U.S.C. § 158 (1998).

for a decrease in federal highway funding to states that did not establish an MLDA of 21 by 1987. All states had an MLDA of 21 by 1988. The increase in the MLDA has been a notable public health success because it has reduced the consumption of alcohol by young people. An increase in the minimum legal smoking age from 18 to 21 should have a similar impact on the consumption of tobacco products.

A major study of high school seniors revealed a 28.2% decrease in drinking (over the past 30 days) following an increase in the MLDA from 18-21.[27] Just as significantly, national data show that this decrease in consumption lingers *after* young people turn 21. Opponents of an increase in the minimum legal drinking age had suggested that a "rubber band" effect might occur. The hypothesis was that as youth turned 21, they would drink to "make up for lost time" and thus drink at higher rates than they would had they been allowed to drink alcohol at an earlier age.[28] However, researchers have determined that lower rates of alcohol use due to the increase in the MDLA continue even after young people turn 21.[29] Finally, the decrease in consumption of alcohol due to the increase in the MLDA has also significantly reduced alcohol-related traffic fatalities in the 18-20 age group.[30]

The clear public health gains from the increase in the minimum legal drinking age have occurred despite limited enforcement of the laws[31] and while minors still enjoy access to alcohol.[32] Ideally, there will be adequate money and political will to enforce the proposed increase in the minimum legal sale age of tobacco products to 21. If there is not strong enforcement of the law and 18-20 year old individuals retain reasonably good access to tobacco products, the experience with the increase in the MLDA at least

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[27] Patrick M. O'Malley & Alexander C. Wagenaar, *Effects of Minimum Drinking Age Laws on Alcohol Use, Related Behaviors and Traffic Crash Involvement among American Youth: 1976-1987*, 52 JOURNAL OF STUDIES ON ALCOHOL 478, 485 (1991).

[28] *See* Traci L. Toomey et al., *The Minimum Legal Drinking Age: History, Effectiveness and Ongoing Debate*, 20 ALCOHOL HEALTH AND RESEARCH WORLD 213 (1996).

[29] *See* O'Malley and Wagenaar, *supra* note 27, at 484.

[30] The National Highway Traffic Safety Administration estimated that in 1987 alone, 1,071 traffic crash fatalities were prevented because of the MLDA of 21. NHTSA, THE IMPACT OF MINIMUM DRINKING AGE LAWS ON FATAL CRASH INVOLVEMENT: AN UPDATE OF THE NHTSA ANALYSES, NHTSA Technical Report No. DOT HS 807 349, Washington, DC (1989).

[31] One leading study found that only 38 percent of the alcohol merchants surveyed thought it was likely that they would be punished for selling to a minor. Mark Wolfson et al., *Alcohol Outlet Policies and Practices Concerning Sales to Underage People*, 91 ADDICTION 589 (1996).

suggests that consumption of tobacco products may *still decline by some amount* for that age group. A small decrease in "regular use" attributable to the increased MLSA and related access measures like identification requirements could have a big impact. Using the data discussed above, a 5% decline in new daily users could ultimately prevent 18,250 tobacco-related deaths per year. By comparison, the increase in the minimum legal drinking age from 18 to 21 has resulted in preventing approximately 1000 alcohol related traffic deaths per year in the 18–20 year age group.[33] If there is vigorous enforcement of the new MLSA, it is not unreasonable to anticipate even greater public health gains.

6. Congress should increase the MLSA from 18 to 21

Three states already have a MLSA of 19 and several others have proposed raising the MLSA to 21.[34] Why not let each state decide this question for itself? Each state can of course chart its own path. We believe, however, that Congress will likely *require* every state to pass additional laws regulating the sale and use of tobacco products in the immediate future. Should this occur, we suggest that Congress also *require* each state to raise its MLSA to 21. In the absence of a federal mandate, individual states will likely face significant enforcement and legal hurdles if they attempt to increase the MLSA to 21 on their own.[35]

The enforcement hurdle is a geographic one--the cross-border problem. Again, the experience with alcohol is instructive. Prior to the enactment of the "Uniform Drinking Age Act," the fifty states had enacted a variety of laws that set the MLDA at anywhere between 18 and 21.[36] This created a number of cross-border problems where 18-20 year olds could drive a short distance to obtain alcohol. Individual states that take the step of increasing the MLSA to 21 will likely confront similar cross-border problems.

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[32] Youth under 21 can successfully purchase alcohol without showing identification in 50 percent or more of their attempts. Jean L. Forster et al., *Commercial Availability of Alcohol to Young People: Results of Alcohol Purchase Attempts,* 24 PREVENTIVE MEDICINE 342 (1995).

[33] *See* NHTSA, *supra,* note 30.

[34] Alabama, Alaska and Utah currently restrict the sale of tobacco products to individuals who are at least 19 years old. At last count, legislators in Minnesota, New York and Ohio have proposed an increase in the MLSA to 21.

[35] Despite these problems, individual states can and should act on their own if the federal government fails to do so. To minimize the cross-border problem, states should act on a regional basis if possible.

[36] *See generally,* Toomey et al., *supra* note 28.

The legal hurdle is preemption. Any state that enacts an MLSA of 21 must obtain an exemption from FDA preemption prior to enforcing its own law because the FDA age limit is 18[37] and higher age limits are preempted by the lower FDA limit.[38] Obtaining an exemption from FDA preemption is a time consuming process that would seriously delay enforcement of any new state law that mandated an increase in the MLSA to 21.[39] A second potential preemption issue is the impact of a state MLSA of 21 on local laws with a MLSA of 18. Individual communities could probably amend their laws to bring them up to a new state standard if necessary. However, these communities would then need to also apply to the FDA for an exemption from preemption. Again, the preemption exemption process is a time consuming one that would seriously delay enforcement of new local laws. These preemption hurdles can be surmounted by the individual states and by cities and towns. However, it would be far simpler and quicker to establish a national MLSA of 21.

7. Conclusion- the public health burden of proof is on the opposition

We are unaware of any public health argument that an increase in the MLSA from 18 to 21 will result in *increased* consumption of tobacco products and increased tobacco-related disease and death. The experience with raising the MLDA and the enforcement of current age restrictions on tobacco suggest the opposite result. The burden of proof is on opponents of this proposal to demonstrate how an increase in the MLSA to 21 could worsen the problem of teenage addiction to nicotine or how an increase in the MLSA to 21 will not reduce consumption and deaths.

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[37] The new FDA tobacco control regulations prohibit the sale of cigarettes and smokeless tobacco to individuals under 18 and provide for stringent identification of the age of prospective purchasers of such products. 29 C.F.R. §§ 14 (a) & (b) (1998).

[38] *See* 21 U.S.C. § 360k(a) (1998). For an extended discussion of FDA preemption of state and local tobacco control laws, see Raymond C. Porfiri, *FDA Regulations Alter Tobacco Control World but Local Efforts Remain Critical*, TOBACCO CONTROL UPDATE, Vol. 1, Issues 1 & 2 (Winter 1997). This article can be found on the Internet at http://tobacco.neu.edu/tcu/3-97/FDAREGSUM.html.

[39] For example, the state of Alabama applied for an exemption from FDA preemption for its MLSA of 19 on October 28, 1996. Exemption From Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Applications for Exemption Submitted by Various State Governments (Proposed Rule), 62 Fed. Reg. 7390, 7391 (February 19, 1997). Alabama did not receive approval from the FDA to enforce its stricter law until November 28, 1997, over one year later. Exemption From Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Applications for Exemption Submitted by Various State Governments (Final Rule), 62 Fed. Reg. 63271 (November 28, 1997) (to be codified at 21 C.F.R. 808). That exemption did not go into effect until December 29, 1997. *Id.*

Three states with a MLSA of 19-- Alaska, Utah and Alabama-- applied to the FDA for exemption from preemption. In response to these requests, the FDA stated that the age 19 restrictions in these states should be exempt from FDA preemption because the higher minimum age restrictions in these states would "provide increased public health benefits and [would] not impose a significant burden on retailers."[40] The FDA is correct.[41] A higher legal age *will* increase public health benefits by saving thousands of lives. Congress should follow this lead and hike the MLSA to 21 if it hopes to achieve its goal of reducing teen smoking in the near future.

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[40] Exemption From Preemption of State and Local Cigarette and Smokeless Tobacco Requirements; Applications for Exemption Submitted by Various State Governments (Proposed Rule), 62 Fed. Reg. 7390, 7392 (February 19, 1997).

[41] The FDA itself considered raising the MLSA to 21 but declined to do so. FDA Final Rule, 61 Fed. Reg. 44440-44441 (August 28, 1996). The FDA noted that it would revisit the issue if "the evidence indicates that the number of new cases of nicotine addiction does not significantly decline, consistent with the agency's stated goal of a 50 percent reduction." *Id.* at 44441. Based on the logic of its own exemption analysis, the FDA should increase the MLSA in its regulations from 18 to 21 if Congress fails to do so.

Appendix One

105TH CONGRESS
1ST SESSION

H. R. 2519

To increase the legal age of smoking from 18 to 21.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 23, 1997

Ms. DEGETTE introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To increase the legal age of smoking from 18 to 21.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Tobacco-Free Youth Act".

SEC. 2. INCREASE IN LEGAL AGE OF SMOKING.

Section 1926 of the Public Health Service Act (42 U.S.C. 300x–26) is amended by striking "under the age of 18" each place it occurs and inserting "under the age of 21".

SEC. 3. EFFECTIVE DATE.

The amendments made by section 2 shall take effect with respect to the first fiscal year beginning after the date of the enactment of this Act, except that in the case of a State the legislature of which does not convene a regular session in such fiscal year or the next fiscal year, such amendments shall take effect with respect to the third fiscal year beginning after such date.

O

Tob - set - access

? But want wording to delete Synar in new legislation?

Questions from Senator Faircloth

F1
Question:

Both the FDA tobacco regulation and the Synar Amendment are directed at reducing minors' ability to purchase tobacco products. The Administration repeatedly refers to these efforts as "complementary." Will you explain to the Committee why two federal agencies are needed to enforce the prohibition against state sales to minors?

Answer:

It has been the intent of the Department for the SAMHSA and FDA efforts to provide a multi-level approach to addressing youth access to and availability of tobacco products. The SAMHSA Synar regulation is one piece in a comprehensive effort to reduce youth tobacco use. For such an effort to be successful, the Department must address issues of tobacco access, availability and appeal. While the FDA and SAMHSA regulations both address access and availability, Synar is not an enforcement program and Synar monitoring is not substitute for active enforcement of the FDA rule. The HHS response to youth tobacco use provides resources for enforcement activities, as well as a method of monitoring the success of State and Federal efforts. FDA rule enforcement is required to achieve the Administration's goal of reducing, by 50% over the next seven years, the young people who use cigarettes and smokeless tobacco.

Under the Synar amendment States are required to conduct random, unannounced inspections of a representative sample of the State's tobacco vendors to assess their compliance with State access laws. States that fail to meet the goal of reducing violation rates to no more than 20 percent can lose a percentage of their federal Substance Abuse Prevention and Treatment Block Grant funds. The Synar activities are specifically designed to measure if stores are selling to minors, and this measurement provides SAMHSA with concrete evidence of the success of State enforcement efforts of their own State laws. ~~The Synar provisions, although requiring the States to enforce their youth tobacco access laws, offer no specific financial support to States for such efforts.~~ Accurate measurement can only be made if visits are random and unannounced, which are difficult to achieve if visits are accompanied by enforcement action.

The FDA rule makes it a federal violation to sell cigarettes or spit tobacco to anyone younger than age 18 and requires retailers to ask for photo identification from anyone younger than 27. FDA activities are designed to actually enforce, not measure. The FDA regulations complement on-going State and local activities and establish mandatory conditions on the sale and distribution of tobacco products. The State agency administering the FDA rule must be an agent of FDA and funds are needed to pay State agencies. FDA needs flexibility to select non-Synar agencies to act as FDA agents, especially in poorly performing States. Enforcement of the FDA rule can only be done through compliance checks separate from SAMHSA, backed by fines, administered through FDA.

F2
Question:

The Administration's budget calls for a $100 million increase in FDA funding for tobacco enforcement -- and a $46 million increase for CDC's existing state tobacco-prevention activities. Please detail for the Committee the differences in these two programs, and what procedures HHS has in place to ensure that these programs are not duplicative?

Answer:

FDA's tobacco programs seek to restrict access to tobacco products, while CDC programs are targeted to reduce the demand for cigarettes. As FDA fully implements the tobacco rule and expands their activities to the full extent of the law, there will be increased workload and a need for increasing appropriations, $100 million in FY 1999. The FY 1999 goals for the FDA tobacco program include a significant expansion of the outreach and enforcement activities initiated in FY 1998. With this increased funding, FDA can ensure fundamental progress in all States, through partnerships with States and local authorities, to reduce use of tobacco products among our nation's youth. FDA will primarily engage in enforcement, outreach, and product regulation.

FDA has developed a general enforcement strategy aimed at conducting compliance checks in a significant percentage of the roughly 400,000 retail outlets that sell tobacco products. FDA will commission State and local officials to conduct unannounced purchase attempts using young people under the age of 18. FDA follow-up enforcement includes special monitoring projects, demonstration projects, and an enforcement strategy for national chains. Evaluation activities include an inquiries and reporting system and other legal requirements. The outreach activities include compliance outreach, trade advertising and direct mail targeted to retailers and clerks, advertising, and media and public education. A strong outreach program is one of the most effective ways of increasing compliance with this rule. In FY 1999 FDA plans to intensify its advertising campaign and use community organizations, parent groups, voluntary health groups, and the media to raise awareness of the tobacco rule and encourage compliance. FDA will design and, to the fullest extent permitted under law, begin to implement a regulatory program for cigarettes and smokeless tobacco products under the Food, Drug, Cosmetic Act. This includes a procedure for the classification of devices to determine the level of controls required by the products' characteristics to provide a reasonable level of safety, a process of reviewing and analyzing ingredients used in cigarettes and smokeless tobacco, establishing a framework for the evaluation and review of new and existing cigarette and smokeless tobacco products, and beginning the inspection process by reviewing the practices of tobacco companies.

The CDC increase of $46 million for tobacco prevention programs will fund a nationwide program that recognizes prevention and reduction of tobacco use is a core public health function. This will replace and expand CDC's Initiative to Mobilize for the Prevention and Control of Tobacco Use (IMPACT) program to include all 50 States and the District of Columbia. The IMPACT program funds a number of prevention and control activities which include training and

programmatic support for school-based smoking cessation programs, national surveillance activities, state prevention and control plans to protect nonsmokers from exposure to environmental tobacco smoke, and state programs to address oral cancer in high risk populations. This will also replace the NIH's American Stop Smoking Intervention Study (ASSIST). Of the CDC increase, $22 million of the $46 million funds NIH had been granting to States through the ASSIST program.

Tobacco – settlement – access

PRESIDENT CLINTON AND VICE PRESIDENT GORE: WORKING TO STOP TOBACCO SALES TO CHILDREN

February 26, 1998

"With this new campaign, and our call for bipartisan, comprehensive anti-tobacco legislation, we can give our young people a healthier, smoke-free tomorrow --and it can't come a day too soon."

Vice President Gore
February 27, 1998

Today, Vice President Gore announces a new national campaign to educate consumers and help retailers prevent illegal sales of tobacco products to children. In launching the new campaign, the Vice President also underscores the need for comprehensive national tobacco legislation to finish the job and dramatically reduce youth tobacco use.

The Vice President's announcement marks the first anniversary of the implementation of the landmark Food and Drug Administration (FDA) tobacco rule designed to reduce the incidence of youth smoking. The FDA rule made it a federal violation to sell cigarettes or spit tobacco to anyone younger than age 18, and required retailers to ask for photo identification from anyone younger than 27 who attempts to purchase these tobacco products.

A New Campaign To Prevent Youth Tobacco Use. The FDA's new national education campaign uses creative point-of-sale, radio, print, and billboard advertisements to make clear to consumers and retailers that tobacco sales to minors are against the law. The FDA plans to run its campaign in all 50 states by the end of 1998.

Building On State Efforts. The FDA's campaign will compliment the progress being made at the state level under the Synar Amendment -- a law requiring states to assess retailer compliance with state youth tobacco access laws. Already, four states -- Florida, Maine, New Hampshire and Washington -- have met the retailer compliance requirements set by the law. Three more states -- Delaware, Rhode Island and Vermont -- are scheduled to meet the goal in 1999. The remaining states are expected to achieve these results between 2000 and 2003.

An Historic Strategy For Reducing Youth Tobacco Use. Earlier this month the President announced a balanced budget plan that includes historic measures to reduce youth tobacco use and to prevent kids from starting use in the first place. This plan is expected to keep 2.8 million teens from smoking by the year 2003 and will save nearly one million lives. To ensure that these important efforts are successful, President Clinton is calling for tobacco legislation that includes:

- A comprehensive plan to reduce youth smoking by raising the price of packs of cigarettes by up to $1.50 over ten years through a combination of annual

payments and tough penalties on the tobacco industry;

- Full authority for the Food and Drug Administration to regulate tobacco products;

- Changes in the way the tobacco industry does business, including an end to marketing and promotion to children;

- Progress toward other public health goals, including biomedical and cancer research, a reduction of second hand smoke, promotion of smoking cessation programs, and other urgent priorities; and

- Protection for tobacco farmers and their communities.