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SENATE LABOR AND HUMAN RESOURCES COMMITTEE
SEPTEMBER 25, 1997

QUESTIONS AND ANSWERS

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DOES THE ADMINISTRATION ENDORSE THE SETTLEMENT?

QUESTION:

Is the Administration endorsing the settlement?

ANSWER:

- The Administration called for a legislative solution to the public health issue of tobacco and children in August 1995. The President thought that national legislation would be the best way to protect our children, and that is still the Administration's position. The settlement announced last June creates an historic opportunity to enact this legislation. The President's plan builds on the settlement by demanding:

  - A comprehensive plan to reduce teen smoking, including tough penalties if targets are not met, a public education and counter advertising campaign, and expanded efforts to restrict the access of youth to tobacco products;

  - Full authority for the FDA to regulate tobacco products;
  - Changes in the way the tobacco industry does business
  - Progress toward other public health goals, including reduction of second-hand smoke, expansion of smoking cessation programs, strengthening of international efforts, and funding for health research and other health objectives; and

  - Protection for tobacco farmers and their communities.

WILL YOU DRIVE COMPANIES AWAY?

QUESTION:

Many believe that by not accepting the settlement, you will drive the tobacco companies away and kill any chances of legislation. Is this true?

ANSWER:

We want national legislation focused on curbing youth smoking – but we want it to be comprehensive and we want it to be right. We are proposing the principles that we believe are necessary for such legislation. What the tobacco industry thinks of those principles is not what should guide us.

WHAT TOOK SO LONG?

QUESTION:

Why did it take you so long to comment on the settlement – especially when you have provided so few specifics?

ANSWER:

This is an extremely important and complex subject, and we wanted to make sure we got everything right. We have never intended to write legislation or provide details of a legislative proposal. We will need to work closely with Congress on this issue and we think that providing principles is the best way to start what we hope will be a bipartisan process to enact legislation.

IS THE WHITE HOUSE TO BLAME FOR NO CONGRESSIONAL ACTION?

QUESTION:

Is the White House to blame that there's no chance of getting national legislation through Congress this year?

ANSWER:

- No. The Republican leadership has made clear for some time that it would not be ready to enact legislation this year. And we understand why not. This is a complicated issue. It needs to be done with great thought and care in order to get it right.

- But we have great hopes that the Administration and Congress can work together to enact bipartisan legislation in the next several months.

WHAT IS THE ADMINISTRATION DOING TO WORK WITH CONGRESS?

QUESTION:

What is the Administration doing to get Congress to pass national tobacco legislation?

ANSWER:

The President will invite congressional leaders and key members to the White House ~~in the coming weeks~~ next wk to launch a bipartisan effort to enact tobacco legislation. The President has also asked the Vice President to lead the effort to ~~mobilize support around the nation for tobacco legislation~~ build broad bipartisan support for our plan.

WHY ARE YOU PROPOSING AN INCREASE OF $1.50 PER PACK?

QUESTION:

Why is the Administration proposing price increases of up to $1.50 per pack?

ANSWER:

- We know that significant price increases will hep reduce underage smoking -- some experts estimate that for each 10 percent increase in price, there is a 7 percent drop in youth smoking.

- The President called for a combination of industry payments and penalties to increase the price of a pack of cigarettes by up to $1.50 in the next decade, as necessary to meet youth reduction targets. If companies meet the goals of reducing youth smoking, penalties will not be levied, and the price increases may be smaller. What is key is that the price go up as needed to meet the targets.

WHAT WILL COMPRISE THE $1.50?

QUESTION:

How much of the $1.50 will be collected in base payments and how much will be in the form of penalties for industry failure to meet youth smoking reduction targets?

ANSWER:

- We will work with Congress in addressing that issue. It may be that penalties will account for a much more significant portion of the total cost than in the initial settlement proposal.

- There is considerable debate about the best mixture. Relying more on penalties that are imposed when a specific company does not reduce the number of teens who are using that company's product would give the company greater incentive to work for the reduction target. That will help make the industry more responsible for reducing teen smoking.

- On the other hand, if the mixture includes more direct payments that are imposed for past malfeasance then the industry will receive the message that such practices are punishable. In addition, more money would be collected sooner for the purposes of funding the necessary additional activities that must accompany higher prices to make sure young people don't begin smoking.

NO

WHY NOT AN EXCISE TAX?

QUESTION:

Why doesn't the Administration just propose an increased excise tax?

ANSWER:

We are for increasing the tobacco excise tax. But we just fought a huge battle to increase the excise tax by a modest 15 cents – only to have the tobacco industry insert a provision in the Balanced Budget Act to recoup the money. We believe our proposal can more easily be achieved – and that it will be just as effective in accomplishing our of reducing youth smoking.

WHAT SHOULD FDA'S AUTHORITY BE?

QUESTION:

What should FDA's full authority consist of?

ANSWER:

Full authority for FDA means no special restrictions on the agency's ability to regulate tobacco products. This means doing away with procedural and substantive obstacles – such as having to make a contraband finding – that would have restricted the agency's ability to protect the public. And it means retaining the FDA's flexibility to adjust federal regulation in the future to respond to changes in the way the industry manufactures, markets, or advertises it products.

SHOULD THE FDA ELIMINATE NICOTINE FROM TOBACCO PRODUCTS?

QUESTION:

Do you want the FDA to start eliminating nicotine from tobacco products?

ANSWER:

- No. The experts say that much more needs to be known, including information from the documents the industry has kept secret, before the FDA can even consider regulating the nicotine content of tobacco products.

- Our point is simple -- we need a strong FDA, and we need to make sure the FDA has all the information it needs so that it can properly evaluate issues like nicotine content. Nothing should stand in the way of FDA's oversight of the development and introduction of reduced-risk, less addictive tobacco products.

WHAT ABOUT DISCLOSURE OF INDUSTRY DOCUMENTS?

QUESTION:

What is your position on the disclosure of tobacco industry documents?

ANSWER:

- This industry has hidden the truth from the American public for many decades. We must have broad disclosure of what the industry has known, but kept secret, about scientific and health issues, and about marketing to children.

- Legislation should respect essential principles of attorney-client privilege and trade secrets. But the legislation should establish effective mechanisms to turn over to the public all non-privileged documents (including ones the industry has falsely claimed to be privileged) and disclose scientific and health information in even privileged documents.

CIVIL LIABILITY

QUESTION:

What are your views on the industry's demand for civil liability protection as part of any legislation?

ANSWER:

- We must have legislation that protects our children from the hazards of tobacco. The Administration will not support any bill that fails to do that. Any limits on liability are conditional on the legislation meeting the Administration's full set of demands.

- The tobacco industry is looking for significant limits on their civil liability for past and future-related suits. The proposed settlement would not only settle the state law suits, but also would protect the tobacco industry from all class action suits, would prohibit all claims based on addiction or dependence, and would deny plaintiffs the right to recover punitive damages for claims based on past misconduct. In addition, all future judgments would be subject to an annual cap, limiting the amount of damages that the industry would have to pay out in any single year.

- These are significant concessions that we must not take lightly. Our civil judicial system protects the public not only by providing a mechanism through which injured parties are compensated, but also for deterring harmful behavior and exposing misconduct.

NO

RESTRICTIONS ON SMOKING PUBLIC PLACES

QUESTION:

Aren't there sufficient restrictions on smoking in public places?

ANSWER:

Increasing the protections for the nation's nonsmokers is a very high priority. Every day we learn more about the adverse effects of "environmental tobacco smoke," or ETS, particularly among youth. ETS causes about 3,000 lung cancer deaths each year in nonsmoking adults, has been linked to other health problems such as heart disease and SIDS, and causes numerous respiratory illnesses. Reducing smoking in workplaces and other public places is one of the most important objectives of comprehensive tobacco legislation.

TOBACCO FARMERS

QUESTION:

What about farmers? What will you do to protect them?

ANSWER:

- The President made it clear that any tobacco legislation must protect tobacco farmers and their communities. Most tobacco farmers live and work on small family farms; in many cases, their families have been growing tobacco for generations. In some states, entire communities rely on income from the tobacco crop. The Administration is committed to working with members of Congress in both parties to ensure that we protect the financial well-being of tobacco farmers, their families, and their communities.

- Many of the rural towns and communities that serve the families of these tobacco farmers including input suppliers, warehouse operators and local retailers are completely dependent of the tobacco crop, and their futures must be taken into account, as well.

- The representatives of the farming communities and the Senators and Representatives from tobacco-growing regions have told us that market stabilization and consistent price supports are essential.

- Some of the ways to help these farmers and their communities range from direct buy-outs of tobacco quotas and financial support for effective local economic development activities to requiring quota protection through long-term purchase commitments from the tobacco companies and industry-subsidized crop insurance.

- The best solution will probably be some mixture of federal and industry actions, but the fundamental point is that the farmers and their communities must not be penalized for the actions of the industry.

about farmers

As the President said last week: "~~They're good, hard working, tax-paying citizens, and~~ they have not caused this problem." We are trying to change America and make everybody whole. Farmers and their communities deserve a chance to have ASL/14 their lives and be made whole. I can say I speak for the President and his entire Administration when I say we are determined to see that they're a part of this.

PAYMENT OF LEGAL FEES TO ATTORNEYS

QUESTION:

What provisions will you make for the payment of legal fees to attorneys for the settling parties?

ANSWER:

The settlement did not address this issue, and our proposal certainly will not. Our proposal is focused on reducing youth smoking. The resources we are asking for are the resources that will allow us to meet this objective and to meet other critical public health needs. What lawyers for any of the parties get is not our concern, nor will it ever be.

FAILURE TO SEIZE OPPORTUNITY

QUESTION:

What will happen if we fail to seize this opportunity?

ANSWER:

If current trends continue and nothing is done to curtail tobacco use in America, we can expect an additional 25 million painful and premature deaths among currently living Americans, including five million or our children. On average, smokers who die from smoking-related disease lose an average 12 years of life, and result in medical expenditures of $50 billion per year.

TOBACCO IS IMPORTANT TO THIS ADMINISTRATION

QUESTION:

Why has regulation of tobacco become such an important issue to this Administration?

ANSWER:

We have been working on this for two years now. Each day 3000 young people become regular smokers, replacing many of the adult smokers who have quit or died. As the 20th century come to a close, we need to "right our past wrongs" and bring to a close a century of neglect in dealing with the greatest preventable cause of death in our society. We need to protect our children from being seduced, and then addicted, and finally afflicted. We need to center the 21st century with policies and programs in place which treat tobacco commensurate with the harm that it causes.

TOBACCO-RELATED RESEARCH

QUESTION:

The Settlement would allocate significant amounts of money for tobacco-related research. How does the Administration feel this should be managed?

ANSWER:

These funds should (1) be distributed on a scientifically objective basis; (2) be used for tobacco-related research, defined as research related to reducing tobacco use and the burden of disease on society caused by tobacco; and (3) add to but not replace existing research funding.

EXTENT OF FOCUS ON KIDS

QUESTION:

The Administration's' response to the Settlement brings a new interest in the health of adult users despite repeated assurances that the administration was interested only in preventing under-age use of tobacco. Why is the Administration involved now in restricting legal adult choices?

ANSWER:

~~Everyone agrees that the ultimate solution to tobacco use and its related health problems will come from preventing this Nation's youth from becoming addicted to tobacco. Nevertheless,~~ since the 1964 Surgeon General's Report, ~~this~~ every Administration ~~government~~ has been involved in the public health mission to provide accurate information on the dangers of tobacco use that may help ~~all current smokers~~ American's to decide ~~whether~~ not to smoke ~~or not~~. ~~Over~~ Today, 70% of ~~current~~ smokers want to quit yet only 2.5% are able to quit each year. Experts agree that the best way for us adult currently have to solve nicotine addiction is to prevent this nation's youth from becoming addicted in the first place.

We are not shifting our focus, and we will not be involved in restricting adults' legal choice to smoke. Instead, we will be able to provide an opportunity to smokers who want to quit to potentially have better access to the best methods available. In addition, it provides an opportunity to further reduce the health hazards resulting from exposure to second-hand smoke [or Environmental Tobacco Smoke (ETS)].

SUFFICIENCY OF FUNDING

QUESTION:

Is the Settlement adequate to address the health and social costs of tobacco and to finance the costs of cessation activities?

ANSWER:

No, the Settlement does not adequately address the health and social costs of tobacco, but it does provide significant resources –that are not available outside of the Settlement –to fund and expand public health activities across the country.

If the Settlement is intended to compensate the Nation for the health care costs of tobacco, it falls woefully short of what is needed. Likewise, the $368.5 billion payment would be unable to reimburse adequately health insurers and individual consumers for the costs of nicotine cessation therapy, and to redress decades of corporate wrongdoing and the conscious addiction of millions of American teenagers to nicotine.

But we are not rejecting the Settlement, instead we are building on it. ~~The~~ Tobacco ~~Settlement~~ must meet the goals the President has laid out including strengthened provisions for payments and penalties. At the end, this would result in an unprecedented increase in funding for tobacco control activities –funding at levels that have never been contemplated by any nation or by any previous Administration or Congress. It represents the largest settlement of its kind and would contribute to reducing premature deaths and preventable disease attributed to tobacco use over the next several decades.

legislation

HEALTH INVESTMENTS AND TOBACCO USE CESSATION

QUESTION:

Should legislation provide cessation services, either by directly paying for these services, or by stimulating the provision of these cessation services through the public and private sectors?

ANSWER:

We believe the tobacco industry should be responsible for providing cessation services to all smokers who want to quit. ~~Therefore, we are pleased that for~~ Legislation should provide smokers who are interested in quitting an opportunity ~~will be provided~~ to gain access to the help they need to quit.

Proven cessation interventions do exist, including medical advice to quit, individual or group counseling, telephone hotlines, and nicotine replacement therapy. Access to these services is the problem. The issue is how the Settlement money should be used to provide cessation services. There are two options: (1) directly pay for cessation interventions for all smokers or (2) only pay for these services for under served populations and use the rest of the money to give incentives for the provision of services through the private sector.

COUNTER-ADVERTISING

QUESTION:

With respect to counter-advertising, some have suggested that HHS should manage the program. What would be HHS' role in such a program?

ANSWER:

One HHS role would be to manage and administer the overall counter-advertising effort. Services for media planning, production, and buying could be procured through contracts with a number of general and specialized advertising agencies. HHS has longstanding experience in developing media campaigns in support of long-term program outcomes. In addition, HHS' leadership would help ensure coordination of the three core components of the public health program: media, cessation, and public education, as well as integration of these components at the state and local levels. Oversight of the media campaign by a private entity, with no experience managing grassroots public health programs, might hamper this national-state-local program coordination.

HHS also could ensure that the campaign maximizes use of existing high-quality media materials produced by the government, voluntary agencies, and a number of individual states. A large collection is currently available through HHS' Media Campaign Resource Center for Tobacco Control.

NATIONALLY COORDINATED STATE/LOCAL COUNTER-ADVERTISING

QUESTION:

Others have suggested that the counter-advertising program be a coordinated national-state-local effort. Why are efforts needed at all levels?

ANSWER:

A national media campaign can expand and deliver message reach and frequency with the greatest cost efficiencies. It can have a powerful influence on the public's perceived tobacco control "agenda" and set an overall supportive climate for state and local tobacco control efforts.

At the same time, tobacco marketing increasingly has been moving away from traditional mass media advertising toward targeted promotional activities at the local level. In the same way, our counter-marketing campaigns need to include a strong grassroots component.

State and local campaigns are necessary for stimulating and maintaining actual behavior change. Local media such as radio stations and ethnic newspapers are critical for reaching at-risk populations and for promoting community education tie-ins to the national campaign such as talk shows, special events, and sports contests. A coordinated approach is critical to ensure that the national and local campaigns complement and reinforce each other.

NECESSITY OF COUNTER-ADVERTISING

QUESTION:

If legislation modeled on the President's proposal and on the settlement virtually eliminates young people's exposure to tobacco advertising, why is there still a need for a counter-advertising campaign?

ANSWER:

We estimate that today's teens already have been exposed to nearly $20 billion worth of image advertising. This exposure has created a "friendly familiarity" for tobacco products – an environment in which smoking is seen as glamorous, social, and normal. It will take an intensive, sustained campaign to counteract this positive association.

In addition, there are many non-advertising influences that provide young people powerful cues to use tobacco, such as parent and peer modeling and glamorization in the entertainment media. Counter-advertising, and other education efforts, are needed to negate these influences and make tobacco use seem less normal and less glamorous.

Finally, ~~our greatest~~ another concern is that the tobacco industry will direct its advertising to attract young adult smokers (18 to 24 year olds). Our concern is that such advertising is likely to be seen and perceived as alluring by our teenagers who increasingly look at young adults as their role models and exemplars.

EFFECT OF STATE SETTLEMENTS

QUESTION:

How do the recent Mississippi and Florida settlements affect the President's call ~~proposed national settlement?~~ for legislation?

ANSWER: need answer

Any national settlement would supersede the provisions of the state settlements. The tobacco industry's monetary payments to Mississippi and Florida are the industry's good-faith estimates of the amounts those states would receive through a national settlement. Any money paid to individual states would be credited toward the total amount of the national settlement. Both state settlements make direct reference to the terms of a national settlement.

BACKGROUND:

Both state settlements stipulate that the terms of their agreements will be revised if future state settlements contain terms that are more favorable. The Florida settlement agreement further stipulates that if no national settlement is reached, the Florida courts will retain authority for the non-economic terms of the state settlement (such as billboard restrictions and a statewide media campaign) and that the state's lawsuit against the tobacco industry will proceed to trial in August 1998.

HHS EFFORTS TO REDUCE TOBACCO USE

QUESTION:

What is HHS currently doing to reduce tobacco use?

ANSWER:

HHS is working on two complementary fronts: reducing the supply of tobacco and reducing the demand for tobacco. Supply reduction activities focus on restricting youth access to tobacco through implementation and enforcement of the Synar and FDA regulations.

Demand reduction is the focus of a new HHS-wide Initiative on youth tobacco use. It is built around five major strategies: offering positive alternatives to tobacco use through sports and other youth-centered activities; empowering young people; deglamorizing tobacco use through a coordinated entertainment industry approach; implementing a national paid advertising campaign; and involving parents and families.

The primary delivery channels for these activities are states and communities. With HHS support, all states now have dedicated funding for tobacco control for all populations. We need to maintain and expand that support. Our goal is funding states at levels comparable to California and Massachusetts which have earmarked excise taxes to support comprehensive tobacco control programs. These states have the most success in the Nation in combating tobacco use by youth and adults.

STATE AND LOCAL EFFORTS

QUESTION:

What are states and local communities doing to reduce tobacco use?

ANSWER:

All states are actively involved in efforts to reduce both teen and adult tobacco use. These programs are being implemented with broad based community support and citizen participation.

Forty-nine states and the District of Columbia carry out tobacco control activities with support from either NCI or CDC. In addition, the Robert Wood Johnson Foundation also provides funding to states for such activities. Further, five states have dedicated a percentage of their tobacco excise tax funds to support comprehensive tobacco control programs.

The funding for many of these programs, however, is far below what is necessary to sustain comprehensive state programs. Such comprehensive programs would include major media campaigns, school and local community programs, cessation programs, and state and local level surveillance and evaluation. The focus of these programs would be threefold: preventing initiation of tobacco use, reducing exposure to environmental tobacco smoke, and encouraging tobacco use cessation.

Finally, State activities are critical to the successful implementation of Federal policy initiatives; State programs are our primary partners in implementing the FDA and Synar regulations to reduce tobacco access and appeal among youth.

EFFECT ON MINORITY AND LOW-INCOME COMMUNITIES

QUESTION:

What is the effect of legislation drafted according to the proposed legislative principles on ethnic minority and low-income communities?

ANSWER:

Minorities and other special populations, because they suffer a disproportionate burden of tobacco-related disease and are among the greatest users of tobacco products, are the groups most likely to be affected by changes in tobacco control policies.

These changes can have a positive effect provided that programs and other benefits reach the communities most at risk. On the other hand, minority communities are more likely than other communities to be dependent on the tobacco industry for philanthropic support of civic, cultural, and community activities. Because of this greater dependence on tobacco industry largesse, minority communities may experience a disproportionate adverse economic effect from efforts to restrict industry contributions.

BACKGROUND:

Smoking rates are highest among American Indian/Alaskan Natives (42%) and blacks (27%), as well as among people who, regardless of race, are living below the poverty level (35%).

Black men are approximately 50% more likely to die of lung cancer than are white men.

YOUTH SMOKING RATES IN CALIFORNIA AND MASSACHUSETTS

QUESTION:

Youth smoking rates have not gone down in California or Massachusetts, despite the many millions of dollars poured into media and community programs in those states. Why do you think it will be different with a national campaign?

ANSWER:

Dramatic progress against teen smoking in California and Massachusetts has been hampered by the tremendous levels of tobacco marketing in those states, as in every state.

However, the news from California and Massachusetts is actually quite positive. In recent years teen smoking in those states has ***increased at a significantly slower rate than in the rest of the country***. A program evaluation of the California media campaign concluded that it was successful in stopping the rise in teen smoking that had been occurring in California prior to the campaign launch. Surveys show that young people in Massachusetts are significantly more likely to have negative attitudes about smoking than their counterparts nationally; we expect this attitude change will lead to actual behavior change over the next 1-2 years. In fact, tobacco use among 7th and 8th grade Massachusetts boys is now going down.

A comprehensive national tobacco control program would work to curb or eliminate young people's exposure to tobacco advertising and promotion, thereby increasing the effectiveness of education programs in the schools, communities, and media.

EFFECTIVENESS OF ANTI-TOBACCO CAMPAIGNS

QUESTION:

Do we have any evidence that community programs and media campaigns can actually prevent young people from using tobacco products?

ANSWER:

Yes. Analysis of multi-faceted youth tobacco use prevention programs shows that comprehensive education efforts can postpone or prevent smoking onset in adolescents by 20 to 40 percent when compared to those communities without such comprehensive programs. (Comprehensive programs are those that combine school efforts, community approaches, and media campaigns.)

For example, the University of Vermont School and Mass Media Project, which featured an intensive paid counter-advertising campaign combined with a school-based program, reduced smoking onset among high-risk youth by 30 percent, with the effects persisting 2 years after the campaign ended.

PRIVATE-SECTOR CESSATION TREATMENT

QUESTION:

Why should we pay for cessation treatment when the private sector is already doing this?

ANSWER:

Unfortunately, access to cessation services is currently restricted by the lack of, or restricted, insurance coverage for proven cessation interventions.

o Only 28% of the largest managed care plans covere nicotine replacement therapy as a standard drug benefit; in addition, while most plans do refer members to outside-of-plan cessation programs, only 32% cover any portion of the cost of those programs.

o Indemnity plans are even less likely than managed care plans to cover preventive services such as smoking cessation treatment.

o Further, over half of corporations self-insure for their employees' health insurance benefits; few of these corporations include coverage for smoking cessation services in their health insurance benefit designs.

Finally, we believe the tobacco industry should be liable for funding cessation services for all those who need and want such services.

OVERLOADING FDA

QUESTION:

Some have questioned FDA's ability to carry out its existing duties. How could it possibly manage all of the additional responsibilities that would be delegated to it under the settlement?

ANSWER:

President's plan Tobacco legislation

The ~~settlement~~ does give FDA numerous responsibilities. ~~But if it is enacted into law as drafted, it would also give FDA $300 million each year to carry out those responsibilities~~. It is critically important that this is new or "additive" money. As long as that is the case, the additional duties under the settlement can be performed adequately.

would need to add to the $34M

Of course, FDA cannot possibly inspect each of the 500,000 retailers who sell tobacco products. Traditionally, we work in partnership with state and local officials who help enforce FDA regulations for dairy farm inspections, retail food sanitation inspections, and mammography facility inspections in communities across the country.

During the current fiscal year FDA will sign contracts with 10 states for compliance checks during which adolescents, accompanied by a state or local official trained and commissioned by FDA, will enter a retail establishment and attempt to purchase cigarettes or spit tobacco. This program will have a minimal impact on FDA's overall resources. For the new fiscal year we asked Congress for just $34 million for FDA's tobacco efforts out of an overall agency budget of about $1 billion.

The President's plan does give FDA numerous responsibilities. Tobacco legislation would need to add to the $34M the Administration received for FDA's tobacco-related work in FY98.

FEDERAL LICENSING OF RETAILERS

QUESTION:

The licensing program appears to be a huge undertaking for the federal government. What are the benefits that justify the costs?

ANSWER:

One goal of FDA's rule is limiting the access that young people have to tobacco products. This goal will be accomplished by restricting sales to those under 18 and requiring ID's for anyone under 27. FDA will be enforcing its access provisions by inspecting retail stores and issuing warning letters and seeking civil money penalties. This should prove to be effective.

But FDA's enforcement would be strengthened if a mechanism existed to also suspend or revoke a license to sell tobacco products of retailers who routinely violate the law. ~~The settlement~~ provides an opportunity for the FDA to add this weapon to its enforcement arsenal. It will greatly enhance FDA's presence and therefore is worth some extra cost.

However, the program, if it is to exist, must be operated at the State or local levels. FDA would not and should not seek to create and administer a national licensing program- it would be too costly in time and money. If FDA has the leeway, under the settlement, to devise a program and set national standards which states must follow, then the benefits would far exceed the costs of the program.

Tobacco Legislation

EFFECTIVENESS OF FDA RULE

QUESTION:

Will the restrictions imposed by FDA in its 1996 rule (~~and strengthened by the settlement~~) actually reduce youth smoking?

ANSWER:

Yes. The FDA rule – working in concert with the Synar Amendment, CDC prevention efforts as well as State and local initiatives – will succeed in reducing teen smoking because it provides a comprehensive approach to this difficult public health problem based on the best available scientific evidence. In designing its regulatory program, FDA was guided by the recommendations of many public health experts, including the National Academy of Science's prestigious Institute of Medicine, the American Medical Association, and the World Health Organization. The Agency was especially mindful of the experts' admonition that, in order to be successful in reducing teen smoking, it is necessary to attack it in a meaningful way from a number of different perspectives.

Therefore, FDA included in its rule strong restrictions on the easy avenues of access that young people have traditionally had to tobacco products, on the devastatingly effective advertising and promotion of tobacco, and an educational component. Many of these restrictions, such as requiring photographic identification to ensure a purchaser is of legal age, have already been demonstrated to be effective in the jurisdictions that have adopted and enforced them. Thus, the Administration is confident that the full implementation of FDA's rule will help reduce the death and disease that are caused by tobacco use by significantly reducing the number of young people who smoke.

FDA'S AUTHORITY OVER NICOTINE

QUESTION:

FDA's 1996 tobacco regulations contain no provisions whatsoever for nicotine regulation, and the agency has repeatedly stated that it has no intention to ban tobacco products. Given this, why is the Administration making FDA's authority over nicotine a critical issue?

ANSWER:

Nicotine regulation has been raised as a concern because of the restrictions the settlement imposes on FDA's authority. While FDA today is in no position to begin lowering nicotine levels, and has no intention to take such action based on current knowledge, there may come a day where some future FDA will be able to address this issue. That will only happen if critically important information comes into being that simply does not exist today, such as an explanation of what the threshold level of addiction actually is.

If and when FDA is ready to act, it must be free to do so without one hand tied behind its back. ~~Unfortunately, that is exactly the position the Settlement places FDA in.~~

NICOTINE AND YOUTH SMOKING

QUESTION:

If FDA has the authority to regulate nicotine, how would this authority contribute to the reduction of youth smoking?

ANSWER:

Imagine a world, perhaps many years from now, where the only tobacco products on the market were not capable of either creating or sustaining addiction to nicotine. In such a world, where kids will undoubtedly still experiment with tobacco, few – if any – kids would ever become addicted if the only products they experimented with were not addictive.

CREATING A BLACK MARKET

QUESTION:

Why shouldn't FDA be concerned that its regulation might create or strengthen a black market in cigarettes?

ANSWER:

It should and is. FDA carefully considered this issue during the rule making that resulted in the August 1996 Tobacco Rule. The rule was narrowly drafted to limit the access that children and adolescents have to tobacco products, as well as those aspects of tobacco product advertising that are most appealing to children and adolescents, while ensuring that the products continue to be legally available for adult users. As a result, the FDA regulation should not influence the creation of a black market in tobacco products.

With respect to the proposed Settlement's provisions involving the regulation of nicotine, the Administration has indicated that these provisions unacceptably alter FDA's authority over nicotine by imposing numerous new substantive and procedural obstacles before the Agency could reduce or eliminate nicotine levels. These provisions must be modified to allow FDA greater flexibility and discretion in this area.

ENCOURAGING REDUCED-RISK PRODUCTS

QUESTION:

Some proposed modifications to the reduced-risk provisions appear likely to significantly lessen the incentives to the development of such products. Shouldn't we be encouraging ~~such~~ reduced-risk products?

ANSWER:

The reduced risk provisions of the settlement raise a serious public policy question. The Settlement appears to assume that reduced risk products can actually be developed and that these products should be marketed in the U.S. The public health community is split on this issue, and there are very strong opinions on both sides of the argument. This is a very complex question that should be the subject of vigorous national debate before being decided. That debate has not as yet taken place, and it would be unwise and premature to settle such a momentous question at this time. It would be far more appropriate for the Department/ or Administration to decide the answer to this question in the future, after the necessary debate has occurred.

~~For decades the~~

We should encourage the development of reduced-risk, less addictive tobacco products, but we need to be very careful to make certain that they truly are reduced risk. For decades, the tobacco industry has conducted extensive research on reduced-risk products, but has hidden the results from the American people. We should insist upon seeing the results of their work, and we should insist upon an unfettered FDA hard at work on seeing reduced-risk, less addictive products become a reality in the marketplace.

INGREDIENT DISCLOSURE

QUESTION:

~~Why is it necessary to strengthen the ingredient disclosure provisions?~~ have

Is there something wrong with the ingredient disclosure provisions contained in the AGs settlement?

ANSWER:

Tobacco products, as drug delivery devices, would be subject to ingredient disclosure requirements under the device provisions of the FDCA. In the proposed Settlement, the ingredient disclosure provisions are based on the FDA requirements applicable to foods, which are less stringent than those for devices. Under the food labeling rules, for example, many harmful ingredients could be hidden by using general terms such as "flavoring." The public health would be best served if the ingredients in tobacco products are fully disclosed so that consumers may make informed decisions regarding tobacco products.

The proposed Settlement also provides inadequate mechanisms for FDA's evaluation of tobacco product ingredients. Under the Settlement, the industry is given five years to provide available safety data regarding each ingredient. (It is unclear whether FDA would have the authority to require a manufacturer to develop such data if none currently exists.) Once FDA finally has this information, the agency has only 90 days to review this safety data, and the ingredient would be deemed approved if the Agency fails to act within the specified time. It is not realistic to expect that the Agency could adequately review the data within that time period.

EXPANDING FDA REGULATION

QUESTION:

The Administration's statements have emphasized the need, for FDA especially, to retain flexibility to respond to changing circumstances. Does this mean that, in the absence of legislation, FDA intends to expand its regulation of tobacco in the near future?

ANSWER:

No, FDA believes that it has designed a comprehensive set of access and advertising restrictions that, if observed by manufacturers, retailers, and others, will significantly reduce the number of young people who smoke or use cigarettes or smokeless tobacco. However, we must not give the tobacco industry a green light to develop new tactics to reach children and adolescents by freezing FDA's ability to issue new regulations if needed.

For example, there are reports today that one of the largest tobacco manufacturers in the world is considering buying a Formula One motor racing team to get around the U.K.'s proposed ban on tobacco sponsorship of sports by becoming the owner rather than the sponsor. We must not let that happen here.

In addition, we must be able to respond to new evidence. That is why at the time of the final rule FDA specifically stated that it would closely monitor the sale of cigarettes through vending machines in adult-only locations and through the mail and that if the Agency found evidence that children were getting tobacco through these venues, it would take additional action. Preserving the FDA's flexibility to undertake additional rule making if necessary is the only way to protect our children now and in the future.

CONTENTS OF UNDISCLOSED DOCUMENTS

QUESTION:

Several of the state Attorneys General have stated that additional industry documents are not going to reveal anything that is not already known. What is the basis for the Administration's concern in this area?

ANSWER:

The only people who know what are in the undisclosed documents are not allowed to discuss their contents. But we have been advised, by many members of the public health community as well as others, that the Administration needs to know what the industry knows in order for us to make an informed evaluation of the settlement.

FDA'S PREFERRED ACCESS TO DOCUMENTS

QUESTION:

Why should FDA have greater access to documents than others?

ANSWER:

While there are others who are seeking tobacco industry documents for legitimate purposes, FDA is the only entity that would seek them to accomplish its statutory mission of regulating products to determine their safety and effectiveness in order to protect the health of the American public. For the Agency to carry out its regulatory responsibilities under the Food, Drug, and Cosmetic Act, FDA requires certain information from the manufacturers of regulated products. Under the Act, the Agency has the authority to inspect and copy relevant documents and information.

The Agency's authority to obtain documents from tobacco manufacturers should be at least as great as its current authority over the documents of drug and device manufacturers. In fact, because of the highly secretive practices of the tobacco industry, a compelling argument can be made that the Agency's authority to obtain documents should be expanded to include subpoena authority against the tobacco industry.

JUDICIAL DETERMINATION OF DOCUMENT DISCLOSURE

QUESTION:

The Administration has indicated that it does not favor the proposed system for centralized determinations of privilege. Please explain why.

ANSWER:

This position is based on Constitutional and legal problems, as well as policy concerns. The proposed use of a panel of three Federal appellate court judges and the responsibilities of this panel do not appear to be an appropriate use of Federal appellate resources. The Administration also is concerned about the fairness and appropriateness of a one-time, nationally-binding determination on the public disclosibility of these important documents. The Administration is concerned about the binding all future litigants, including those who are not parties to this settlement and who may not be parties to any specific dispute resolved by the panel. This is particularly true in the context of those privilege determinations that would require the panel to balance the need of a particular litigant for the document against the purpose served by the privilege to determine whether the document should be disclosed.

Further, the proposed system does not appear to provide a particularly effective mechanism for evaluating claims of privilege. It is likely that the panel would be asked to review enormous numbers of documents (in the ongoing Minnesota action, for example, a special master is reviewing privilege claims involving more than a million documents). A centralized process would likely significantly delay proceedings in numerous trial courts as parties wait for their document disputes to be heard and decided upon by a single panel that is reviewing an enormous number of documents.

Finally, other than making it more accessible to a wider range of people to obtain court review of a document that is claimed to be privileged, the proposal does not alter substantively the requirements tobacco manufacturers must meet to sustain a claim of privilege. Tobacco manufacturers will continue to be able to claim privilege over, and withhold from review, the same documents that they have withheld as privileged in existing litigation as easily as they currently do. Notably, the proposal's requirement that the manufacturers prepare a privilege log of these documents with all of the descriptive detail required by the Minnesota court is a requirement currently imposed by them under the Federal Rules of Civil Procedure. Because of the industry's history of improperly invoking privilege, this standard is inadequate here.

FDA'S DOCUMENT DISCLOSURE AUTHORITY

QUESTION:

Since FDA does not have much authority to require disclosure of documents, aren't the provisions in the Settlement a reasonable concession by the industry?

ANSWER:

No, the Settlement's provisions regarding the release of documents are not reasonable as they apply to FDA. The Settlement provides a procedure under which a three-judge panel would be created having sole authority to resolve all disputes concerning the public availability of tobacco industry documents being sought by all parties. This procedure would therefore relegate FDA to taking its place in a very long line of litigants, public health officials, academics, and others seeking access to industry documents. The procedure would of necessity be cumbersome and extremely slow. This could seriously hamper the Agency in its ability to carry out its statutory responsibilities and thus its ability to protect consumers. The inevitable delay resulting from this process benefits no one but the tobacco industry. It does not serve the public health.

EFFECT OF BRADY BILL DECISION

QUESTION:

Several of the provisions of the Settlement appear inconsistent with the Supreme Court's recent decisions regarding the Brady Bill. Does the Administration agree? If so, can these provisions be salvaged?

ANSWER:

In the Supreme Court's recent *Printz* decision on the Brady bill, the Court held that the Federal government may not "command" State governments or State officials to adopt or administer a Federal program. However, the decision leaves open the prospect that the Federal government may offer strong incentives for States to choose to adopt Federal programs. For example, the Federal government may grant funding conditioned upon specified State government action, such as highway funding conditioned on the adoption of a specified minimum drinking age. Likewise, the Federal government might offer to States the option of either adopting Federal standards or having State law preempted by Federal regulation, such as occurs under the Clean Water Act. The key is that the States are offered the choice not to adopt the Federal program.

The Supreme Court had earlier found that Federal programs that allow for State choice are constitutional, and the *Printz* ruling did not overturn those findings. Thus, any provision in the proposed Settlement that provides for Federal legislation that would "command" State governments to adopt certain provisions should be modified to provide incentives but ultimately allow States to decline to adopt them.

FDA EXEMPTION AUTHORITY

QUESTION:

Why should FDA, ~~rather than Congress,~~ be the one to grant exemptions for preemption?

ANSWER:

The preemption of State and local laws under the proposed settlement, particularly in areas involving FDA regulation, goes further than the Federal Food, Drug, and Cosmetic Act (FDCA), as implemented by FDA. The FDCA contains a provision that preempts certain State or local requirements involving devices. FDA, however, has authority to grant an exemption from preemption for a State or local requirement if the requirement is more stringent than the applicable FDA requirement or is required by compelling local conditions and would not cause the device to be in violation of the FDCA. A similar waiver procedure exists in the Nutrition Labeling and Education Act, and in the FDA reform bill currently being considered in the Senate.

The Settlement would modify this authority in a number of ways. Most significantly: (1) it appears to heighten the standard FDA must apply in determining whether to grant an exemption from preemption with respect to certain provisions; and (2) it appears to preempt, absolutely, State requirements and enforcement penalties that are more stringent than Federal standards. The Administration believes that consistent with the FDCA, FDA should retain the ability to grant exemptions from preemption with respect to provisions it will be responsible for.

From a public health perspective, Federal regulations (except in the area of labeling and warnings, which should have uniform national standards) should set the floor, with FDA having the discretion to permit State or local requirements that are more restrictive. FDA is uniquely qualified to determine whether a particular provision of State law is an obstacle to the accomplishment and execution of the full purposes and objectives of FDA requirements because of its understanding of the likely impact of both State and Federal requirements, as well as an understanding of the extent to which particular State requirements may interfere with Federal objectives involving FDA.

ADMINISTRATION POLICY REGARDING LIMITS ON LITIGATION

QUESTION:

The limits on litigation in the settlement seem inconsistent with the Administration's position regarding limits on litigation generally. Please explain.

ANSWER:

Liability litigation acts as a deterrent on behavior that is detrimental to the public health and welfare. Previous proposals to limit tort litigation *generally* were not acceptable because, among other things, they contained little to make up for this loss of deterrence and to ensure adequate compensation. The Administration does not accept the tobacco proposal's limits on litigation, but might consider accepting some limits on tobacco liability litigation if the comprehensive public health proposals of the Administration are enacted.

NO

UNDISCLOSED DOCUMENTS AND FUTURE LAWSUITS

QUESTION:

Does it make sense to accept many of these limitations on lawsuits despite the fact that as yet undisclosed documents could reveal information that would justify permitting certain lawsuits?

ANSWER:

We ~~must very carefully consider granting the kinds of immunity~~ with conditions limits on liability for the tobacco industry ~~and limitations on citizens' legal rights to sue this industry that are contained in the Settlement~~. There may be much to be learned from the undisclosed documents, and from the ongoing criminal investigations at the Department of Justice, that are not yet public and that could bear on the tobacco industry's culpability.

on whether we can achieve a comprehensive plan to reduce youth smoking.

To: Pellicci
FM: MANDE
RE: DPC comments.

ANTI-TRUST CONCERNS

QUESTION:

Many provisions of the proposed settlement appear to promote collusion among the tobacco companies. Won't this unduly benefit the companies and be generally detrimental to the public?

ANSWER:
(This answer should be checked with either the Department of Justice's Antitrust Division or the Domestic Policy Council or both)

The anti-trust issues raised by the proposed settlement and by any tobacco legislation are complex, and will require much discussion in the coming months.

The tobacco industry has always been a highly concentrated industry, with 3 companies having 90% of the market. A number of the provisions in the proposed settlement could have the effect of reducing competition. ~~For example, it would require that all payments required of the industry be passed through to consumers in the form of higher prices – a requirement that will ensure higher, but collusively set, prices. In addition,~~ Because the proposed settlement contains an exemption from antitrust laws for the firms with regard to actions taken in accord with it there will be no brake on anti-competitive and collusive behavior. Some fear that the collusion encouraged by this state of affairs could result in the industry seeking prices higher than assessed costs, thus ensuring, in addition to greater collusion, greater profitability.

The Administration needs to assess the effect that the higher prices will have on both the major public health goal of the proposed settlement, which is reduced smoking, but also on Federal revenues and company profitability. In addition, we must determine if the balance struck between these goals is appropriate.

One last word on the exemption from antitrust laws. The provisions of the proposed settlement appears to grant a blanket immunity without limitation. This provision must be carefully written to spell out exactly what type of immunity is granted and what continuing authority DOJ has over companies' conduct.

Any anti-trust exemption should be narrowly written to prevent price-gouging.

ANTI-TRUST CONCERNS

QUESTION:

Many provisions of the agreement appear to promote collusion among the tobacco companies. Won't this unduly benefit the companies and be generally detrimental to the public?

ANSWER:
(This answer should be checked with either the Department of Justice's Antitrust Division or the Domestic Policy Council or both)

The tobacco industry has always been a highly concentrated industry, with 3 companies having 90% of the market. A number of the provisions in the Settlement will have the effect of reducing competition further and are of great concern to the Administration. For example, the Settlement requires that all payments required of the industry be passed through to consumers in the form of higher prices- a requirement that will ensure higher, but collusively set, prices. In addition, because the Settlement contains an exemption from antitrust laws for the firms with regard to actions taken in accord with the Settlement, there will be no brake on anti-competitive and collusive behavior. Some fear that the collusion encouraged by this state of affairs will result in the industry seeking prices higher than assessed costs, thus ensuring, in addition to greater collusion, greater profitability.

The Administration needs to assess the effect that the higher prices will have on both the major public health goal of the settlement, which is reduced smoking, but also on Federal revenues and company profitability. In addition, we must determine if the balance struck between these goals is appropriate.

One last word on the exemption from antitrust laws. The provisions appears to grant a blanket immunity without limitation. This provision must be carefully written to spell out exactly what type of immunity is granted and what continuing authority DOJ has over companies' conduct.

NOTE : There are additional anti-competitive features of the Settlement. For example, the advertising restrictions will prevent competition between existing firms and make it difficult if not impossible for new firms to gain entry.

FDA/18

Any antitrust exemption should be narrowly written to prevent collusion.

CONSTITUTIONALITY OF ADVERTISING RESTRICTIONS

QUESTION:

Some experts have raised constitutional concerns regarding the advertising restrictions in the settlement. Does the Administration believe that the FDA regulations are constitutional?

ANSWER:

The short answer is yes, of course. The Administration would never propose something that it believed was unconstitutional.

These provisions were reviewed by FDA's legal counsel and by the Department of Justice. The restrictions comport with applicable legal standards set down by the Supreme Court in *Central Hudson* and its progeny, in that:

(1) there is a substantial Government interest in support of these regulations- i.e., reducing tobacco use by young people;

(2) FDA has demonstrated with substantial evidence that the various restrictions will advance that public interest in a direct and material manner; and

(3) the restrictions are crafted as narrowly as possible.

I would suggest that those who have questioned FDA's restrictions on Constitutional grounds should read FDA's lengthy factual and legal discussion in the preamble to the final rule. The analyses are exhaustive and compelling and provide adequate justification for each and every restriction.

BANKRUPTCY OF THE TOBACCO COMPANIES

QUESTION:

Does the Nation's public health require the bankruptcy of the tobacco industry?

ANSWER:

This isn't about bankrupting the tobacco industry. This is an opportunity to do what is best for this Nation's children and the public health, generally.

SYNAR REGULATION AND SETTLEMENT

QUESTION:

What is the relationship between the Synar Amendment and the ~~proposed settlement?~~ President's call for comprehensive tobacco legislation.

ANSWER:

- The Synar Amendment and ~~the proposed settlement~~ tobacco legislation are both efforts to reduce youth use of tobacco. The Synar Amendment does this by making the sale of tobacco to minors illegal at the State level and by requiring States to enforce that law in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under age 18.

- Portions of the proposed settlement supplement and support the Synar Amendment by codifying all of the access measures contained in the FDA final rule, including 18 as the Federal minimum age of sale, requiring photo ID, eliminating free samples in person and through the mail, eliminating the sale of single cigarettes or "kiddie packs" (packs of less than 20 cigarettes), and restricting vending machines and self-service displays only to those areas where no one under 18 would have access. The proposed settlement further works toward reducing youth access to tobacco products by eliminating all vending machines and prohibiting mail order sales.

SYNAR AND FDA REGULATIONS AND THE SETTLEMENT

QUESTION:

The FDA regulation and parts of the proposed settlement seem duplicative of the Synar law and regulation. How do they relate? Why do we need any of this other if we already have the Synar law/reg?

ANSWER:

- The Synar law and regulation is one piece of a comprehensive effort to reduce use of tobacco by youth. For such an effort to truly be successful, issues of access, availability, and appeal must all be addressed.

- The Synar regulation addresses access and availability by making the sale of tobacco to minors illegal at the State level. Both the FDA regulation and provisions of the proposed settlement supplement and support the Synar regulation also by making the sale of tobacco to minors illegal. In addition, the FDA regulation and the settlement would restrict advertising and other promotional activites that enhance the appeal of tobacco.

- We know that in order to be truly successful, a comprehensive approach is necessary, with Federal, State, and local efforts working together to reduce and eliminate youth access to tobacco products. A comprehensive tobacco use prevention strategy which protects our youth must address both State and Federal enforcement of laws on the sale of tobacco products to minors and the advertising, promotion, and sales practices of the tobacco industry.

- We welcome any effort to reduce children's use of tobacco products that achieves the results in protecting children from tobacco use in the same way as the FDA final rule and the Synar regulation.

SYNAR AND YOUTH SMOKING

QUESTION:

What has been your experience in the reduction of youth use under Synar?

ANSWER:

- While we are in the early stages of implementation of the Synar law and regulation, we do anticipate a positive impact on reducing youth access and youth use.

- The Synar Amendment and its regulations focus on reducing the sale of tobacco products to minors through the enforcement of State laws. Reductions in youth use of tobacco are expected to follow as minors' access to tobacco products diminishes.

- All States now have laws making it illegal to sell tobacco to minors. They have all developed methods for measuring state-wide tobacco compliance and have all conducted inspections of outlets. Examples of States that have made significant progress in reducing sales include:

STATE	REDUCING SALES FROM:
- California	**52% to 29% in two years**
- South Dakota	**84% to 31% in two years**
- Minnesota	**67% to 30% in two years**

- By 2002, we expect to reach the Synar regulation goal of a rate of less than 20 percent of outlets inspected allowing under-age customers to purchase tobacco products and that this will facilitate the reduction in the number of youth who use tobacco.

STATE COMPLIANCE WITH SYNAR REGULATION

QUESTION:

What has State compliance been with regard to Synar?

ANSWER:

- We are pleased with the progress the States have made in implementing Synar, including identifying outlets and establishing sound sampling plans. We have observed tremendous collaboration within individual States to modify agency and State policy and to identify resources to support the compliance requirements.
- All States and jurisdictions currently have tobacco laws prohibiting tobacco sales to minors (completed FY95);
- All States have submitted their inspection methodologies and sampling designs and have conducted random, unannounced inspections;
- All States have been and continue to work with SAMHSA to negotiate baseline and target rates.

YOUTH ACCESS AND USAGE

QUESTION:

Does reducing youth access really reduce youth use? If so, why do we need to do anything else other than focus on reducing youth access?

ANSWER:

- Reducing youth access is an important component of reducing youth use of tobacco productsby young people. However, we are not likely to truly reduce the harmful effects of the use of tobacco without addressing all aspects of tobacco use.

- Reductions in use of tobacco by youth are likely to reflect the effects of the many tobacco control efforts currently underway at the Federal, State, and community levels. Truly reducing such use requires a comprehensive approach addressing access, availability, and appeal at all levels of government and all sectors of society.

- Without this, community leaders have no hope of getting through to young people about the dangers of tobacco use. With over 3000 young people becoming regular smokers each day in the United States, a comprehensive approach becomes all the more important.

SYNAR IMPLEMENTATION

QUESTION:

If more money were provided for SAMHSA to implement and strengthen the Synar regulation and off-set the costs to States, would these other provisions be necessary?

ANSWER:

- While the Synar law and regulation is an important component in efforts to reduce tobacco use among children, it does not provide a fully comprehensive approach.

- The Synar law and regulation is directed at some, but not all of the important access issues that affect the use of tobacco among youth. It does not provide for minimum package size (e.g. kiddie packs), free samples, self-service displays, or the appeal of tobacco through advertising, promotion, and sponsorship.

- To defray the costs associated with the sample survey design and for conducting inspections, States may use the primary prevention set-aside funds from the Substance Abuse Prevention and Treatment Block Grant (SAPT). In addition, funds from the Centers for Disease Control and Prevention's Preventive Health and Health Services Block Grant may be used. The total cost per State for sample frame and inspections is approximately $290,000. Other costs related to enforcement need not be substantial.

SUMMARY OF REQUIREMENTS OF SYNAR

- The Synar Amendment (Section 1926 of the Public Health Service Act) requires each State to have in place and to enforce State laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18. The objective of the amendment is to reduce the sale of tobacco products to minors.

- The Synar Amendment is a critical component of the block grant program. States are required to conduct inspections of retail and vending outlets to prohibit the sale of tobacco to youth. The Secretary is required by statute to withhold all funds from States that have not enacted the required prohibitions and to decrease the annual Substance Abuse Prevention and Treatment (SAPT) Block Grant award for States that do not comply with the enforcement and reporting requirements.

- The SAMHSA regulation implementing the Synar Amendment requires the State to:

    - Have in effect a law prohibiting any manufacturer, retailer or distributer of tobacco products from selling or distributing such products to any individual under the age of 18.

    - Enforce such laws in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.

    - Conduct annual random, unannounced inspections to ensure compliance with the law. These inspections are to be conducted in such a way as to provide a valid sample of outlets accessible to youth.

    - Develop a strategy and time frame for achieving an inspection failure rate of less than 20% of outlets accessible to youth.

    - Submit an annual report detailing the State's activities to enforce their law, the overall success the State has achieved during the previous fiscal year (FY) in reducing tobacco availability to youth, describing how inspections were conducted and the methods to identify outlets, and plans for enforcing the law in the coming fiscal year.

COMPARISON OF THE SAMHSA TOBACCO REGULATION AND FDA'S FINAL RULE

ISSUES	SAMHSA REGULATION	FDA'S FINAL RULE
Status	All states and jurisdictions have tobacco laws prohibiting sales to minors (Completed FY95) All states have submitted their inspection methodologies and sampling designs and have conducted random, unannounced inspections 25 states have negotiated their baseline and target rates 23 states have received grant awards	Final rule was released in August 1996 First wave of rule implemented on February 28, 1997: - Federal minimum age of 18 to buy tobacco products - Require age verification and face-to-face sales - Ban vending machines and self-service displays Second wave of rule (advertising restrictions) will be implemented in August 1997
Who is Affected?	States	Manufacturers and Retailers

ISSUES	SAMHSA REGULATION	FDA'S FINAL RULE
Penalties	For NOT having a law: The penalty for the states for not having a law prohibiting the sale and distribution of tobacco products to minors is that they do not receive any Substance Abuse Block Grant funds. For failing to comply with the enforcement requirements: A state will be penalized 10% of their grant in the first applicable year, 20% in the second, 30% in the third, and 40% in the fourth and thereafter. For most states, FY96 is the third applicable year, with 30% penalty. 7 states (AR, KY, MT, ND, NV, OR, TX) have delayed applicability of one year because their state legislatures did not meet in FY93 or FY94	Manufacturers, retailers, and the industry is accountable to the FDA and would face the possibility of civil monetary penalties under the Food, Drug, and Cosmetic Act.

ISSUES	SAMHSA REGULATION	FDA'S FINAL RULE
Actual Requirements	States must: - Have a law in effect - Conduct random, unannounced inspections - Enforce the law - Achieve a percentage rate of violations of no more than 20% in a negotiated timeframe with the Secretary	Rule requires: - minimum age of 18 to buy tobacco products - ban vending machines and self-service displays except in "adult only" facilities - ban kiddie packs, loosies, or free samples - ban billboards w/in 1,000ft of schools and playgrounds - other billboards and outdoor advertising restricted to black/white, text only except "adult only" facilities - advertising in publications with more than 15% youth readership limited to black/white, text only - ban brand name sponsorship of sporting or other events, only corporate name permitted - ban brand names on hats, t-shirts, gym bags, etc.