HEALTH SCIENCE ANALYSIS PROJECT

Policy Analysis No. 5

ALLOCATION OF TOBACCO CONTROL FUNDS

A Consensus Paper

by the

HSAP Executive Committee

June 3, 1998

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HSAP Executive Committee
Consensus Paper

EXECUTIVE SUMMARY

As Congress considers proposals for comprehensive tobacco control legislation, past experience and scientific evidence strongly support significant new investment in tobacco control efforts to reduce the social and health costs of tobacco use. This paper describes the components of a comprehensive program, highlights key areas where increased funding is especially important, and evaluates the effectiveness of five current legislative proposals in providing the resources and structure to implement a strong national tobacco control program.

The History, and Current Status, of Tobacco Control

While the anti-tobacco movement in the United States dates back at least to the 1880's, modern tobacco control policies and programs followed the release of the first Surgeon General's Report on Smoking and Health in 1964. Today, public support for policies is strong, but resources to implement them have been relatively limited.

There are strong arguments in favor of increasing investment in tobacco control:

Tobacco-related disease is the nation's leading cause of death, accounting for approximately 20 percent of all deaths.[1] The very magnitude of this problem indicates that even modestly effective interventions could have a significant positive effect on the nation's health.

Tobacco control is cost-effective. While quantifying a specific "cost per life saved" is difficult, there is considerable evidence that tobacco prevention and treatment is a cost-effective way to save lives. Comparatively, anti-tobacco activities receive far less funding than other public health and safety problems, both in absolute terms and relative to their impact on public health.

Americans are not adequately informed about tobacco's hazards. Despite the oft-repeated claims by the tobacco industry and others that "everyone knows about the (alleged) risks of smoking," studies have established that people's understanding of those risks remains partial at best. Many beginning smokers are unaware of the addictiveness of tobacco, and most smoking and non-smoking Americans do not grasp the magnitude of tobacco's health impact.

The public supports tobacco control programs and policies. This support extends to smokers; one poll found that 88 percent of nonsmokers and *83 percent of smokers* believe that employees should be protected at work from secondhand tobacco smoke.[2] A 1996 poll done for the American Cancer Society found that adults feel the highest priority for funding from tobacco tax revenue should be for public education programs to prevent young people from starting to smoke.[3]

Necessary Components of a National Tobacco Control Policy

A truly comprehensive tobacco control policy would require a diverse array of research,

policy, and programmatic components, including:

1. **A process for allocating tobacco control funds and setting tobacco policy priorities**, reflecting the views of public health experts and free from industry and political influence;

2. **A broad, systematically-planned tobacco research agenda**, including research to develop new tobacco prevention interventions, evaluation of interventions, surveillance of disease & prevalence and basic biobehavioral & health effects research;

3. **A coordinated set of tobacco control programs and policies**, including:

   -- **programmatic interventions** (counter-advertising, educational programs, nicotine management/treatment programs, and other information efforts)

   -- **policy interventions** (price increases, clean indoor air policies, advertising and promotion restrictions, warnings on product labeling and advertising, youth access restrictions, and tobacco product regulation)

   -- **strategies that link and coordinate programs and policies** synergistically for maximum impact, and significant resources to effectively enforce policy compliance and regulatory efforts at the local, state, and national levels.

   -- **support for advocacy** as an integral part of making tobacco control programs and policies effective over the long term.

4. **A strategy to address tobacco's international dimension**, both because of our responsibilities as a world leader, and to address the domestic impact of worldwide tobacco marketing and use.

Within the above blueprint, investment is particularly critical to support:

-- a major national educational/mass media campaign to discourage tobacco use;

-- full implementation of FDA's authority to regulate tobacco, and for thorough and timely enforcement of its tobacco-related rules and regulations;

-- local, state, and Federal efforts to maintain active tobacco control prevention and treatment programs, and to enforce of tobacco control regulations aggressively;

-- diverse tobacco control coalitions and advocacy "watchdogs" to promote tobacco control, monitor policy implementation, and identify new industry efforts;

-- federal and state programs to build the capacity of both public and private non-profit tobacco control organizations;

-- leadership within the National Institutes of Health for a coordinated program of tobacco control research and development;

-- collection and analysis of comprehensive data on tobacco use, behavior, and attitudes, down to the local level;

-- comprehensive, policy-focused, state-wide innovative intervention research, development, and dissemination.

-- specific resources for research, demonstration, implementation and dissemination of targeted cessation and prevention programs to racial and ethnic minorities and other special populations. This should include support for effective coordination between Federal agencies and state minority health entities.

Avoiding Pitfalls

In crafting a comprehensive program, Congress must also take care to "do no harm" by avoiding the following:

Preemption of state and local tobacco control efforts. Federal tobacco control laws should not preempt stronger measures at the state and local level. Legislation should expressly disclaim any Congressional intent or authority to preempt the imposition of higher standards by states and local jurisdictions.

Restrictions on advocacy. Government-funded programs such as ASSIST have provided training and support for local and state tobacco control advocacy. Congress should avoid any restrictions on the use of tobacco control funds for policy advocacy.

Limiting the scope or intended audience of educational efforts. The effectiveness of tobacco control programs could be undermined if authorizing legislation limits the target audience of educational messages to children or prevents efforts that highlight the role of the tobacco industry in smoking initiation.

Diverting tobacco funding to non-tobacco programs. Tobacco control funding should be specifically designated for that purpose, without loopholes to permit spending on vaguely-defined "other activities" that could shift funds to non-tobacco priorities.

EVALUATION

While the paper describes and evaluates the tobacco control program funding proposed by each bill, a number of critical flaws recur in many of the bills:

- **Most bills offer no central coordinating mechanism for tobacco control policy.** A tobacco policy director or other coordinating body is necessary to ensure that programs work together to accomplish their goals, avoid redundancy, and are effectively coordinated government-wide.

- **No bill offers explicit protection for community-based policy advocacy.** Some bills ignore the important role of advocates and other independent groups. Those bills that fund such organizations lack explicit authorization for state and local policy advocacy as an effective strategy to improve tobacco control policies.

- **Many bills do not adequately address the needs of special populations.** The needs of minorities, low-income rural and urban populations, and women should be addressed throughout an overall national tobacco control strategy, including research, programs, and policies.

- **There are significant restrictions on the scope of many proposed tobacco control programs that could hamper their effectiveness.** For example, many require that programs focus only on tobacco use by minors. This focus on youth alone may not be the most effective way to discourage consumption by that sub-population, much less by others. The programs should be authorized to set their focus based on the most effective strategies to reduce and prevent tobacco use of all kinds.

- **Proposed sponsorship-replacement programs do not specifically provide that new sponsorship funds should advance tobacco control.** Sponsored groups should identify the support they receive as tobacco control funds, and should be required to integrate tobacco

prevention messages into their activities as appropriate.

- **Most bills offer no strategies or resources for international tobacco issues.** Addressing these issues is necessary both to deal with our domestic tobacco problems, and to meet our responsibilities as the "home nation" of the leading transnational tobacco companies.

NOTES

[1] McGinnis JM, Foege WH, "Actual Causes of Death in the United States," JAMA, vol. 270, no. 18 (11/10/93), pp. 2207-2208.
[2] Levin, Myron, "Even Smokers Found to Favor Workplace Ban," *Los Angeles Times*, June 22, 1996.
[3] American Cancer Society, "Tobacco Tax Survey," September, 1996, p. 13.

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INTRODUCTION

As Congress considers proposals for comprehensive tobacco control legislation, past experience and scientific evidence strongly support significant new investment in tobacco control efforts. The best current programs and policies, at the local, state, and national levels, have been shown to be effective and cost-effective in preventing and reducing the social and health costs of tobacco use. Given the burden of death, disease, and lost productivity that tobacco imposes, and the much higher levels of resources allocated to other social and health problems of comparable magnitude and importance, it is imperative that an effective nationwide program be developed and funded to control America's epidemic of tobacco-related disease.

This paper describes the components of such a comprehensive program, and highlights key areas where increased funding is especially important. It also evaluates the effectiveness of five current legislative proposals – S. 1414 (the "Universal Tobacco Settlement Act") sponsored by Senators McCain and Hollings, S. 1530 (the "Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act"), sponsored by Senator Hatch, S. 1492, (the "Healthy and Smokefree Children Act"), sponsored by Senator Kennedy, S. 1638 (the "Healthy Kids Act"), sponsored by Senator Conrad, and S. 1648 (the "Preventing Addiction to Smoking among Teens (PAST) Act"), sponsored by Senator Jeffords – in implementing and supporting a strong national tobacco control program.

DESCRIPTION

History and Current Status

While the anti-tobacco movement in the United States dates back at least to the 1880's, the release of the first Surgeon General's report on smoking and health in 1964 is generally viewed as a watershed event in modern tobacco control. Although the release of the report was dramatic in terms of its impact on the public's perception of the health effects of smoking, the only immediate response from government was the FTC's ruling that warning labels be required on cigarette packs and that tobacco advertising be strictly regulated. Before this ruling could be implemented, the Federal Cigarette Labeling and Advertising Act of 1965 weakened the warning that the FTC had proposed and prohibited the FTC or any other federal, state or city authority from restricting cigarette advertising.

Although Congress debated and even considered more extensive FTC regulations, as well as specific consideration of tobacco product regulation by the Food and Drug Administration, Congress chose not to act in this area. This was due, at least in part, to the industry's repeated assurances that they would implement strong and effective voluntary measures, coupled with extensive support for "independent" research in the "allegations" that smoking caused disease. Subsequent history has revealed these disingenuous claims as part of a long-term strategy to keep its products free from government regulation.

The decline in smoking rates following the release of the 1964 Surgeon General's report was a modest 0.5% per year. That rate did not increase until the late 1970's with the birth of the nonsmokers' rights movement and the beginning of a more active governmental response in implementing tobacco control policies. Throughout the 1980's and the early 1990's, the momentum to implement tobacco control policies increased.

Clean indoor air laws were passed, primarily at the local level, first restricting then prohibiting smoking in public areas. At the federal level, smoking was banned on airline flights of two hours or less, then on all domestic flights and eventually in federal buildings and on Amtrak. Tobacco warning labels were improved. Modest excise tax increases were passed at the federal level; higher taxes were passed at the state level. Television advertising for cigarettes was taken off the air in 1970; by the 1990's, some newspapers and magazines were voluntarily declining to run tobacco ads and some local governments had passed restrictions or bans on tobacco billboards.

The anti-tobacco movement has grown from an active, virtually unfunded loose network of advocates around the country, to a better-funded community of health professionals, government employees, academic researchers and a growing number of policy-oriented activists. Funding for anti-tobacco activities today comes from private sources, including individuals and foundations, and state and federal government agencies.

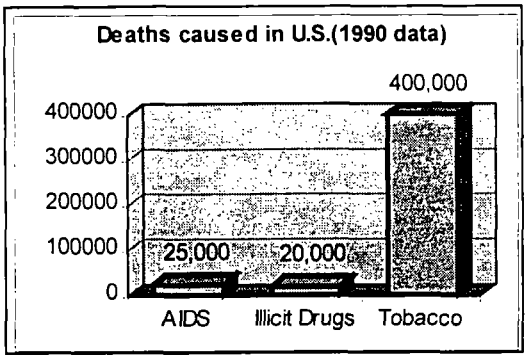
A highlight of federal action on tobacco in the recent past was the COMMIT (Community Intervention Trial for Smoking Cessation) trial, focusing efforts on promoting smoking cessation, especially among heavy smokers. Sponsored by the NCI, COMMIT was the largest smoking intervention trial in the world when it was launched in 1988. The ASSIST (American Stop Smoking Intervention Study for Cancer Prevention) project, a partnership of the NCI and the American Cancer Society, launched in 17 states in 1991, was designed to "increase the smoking control capacity for existing community groups and organizations" and "to sustain and enhance their role as smoking control agents."[1] The ASSIST project was mandated to go beyond smoking cessation efforts to work toward changing social norms regarding tobacco, including influencing policies that relate to tobacco.

In 1993 the Centers for Disease Control launched its Initiatives to Prevent and Control Tobacco Use (IMPACT) program. IMPACT provides cooperative agreements to the 33 states that do not receive ASSIST funding.

In fiscal year 1997, the federal government spent about $46 million for tobacco control efforts.[2]

At the state level, excise tax increases dedicated in part to tobacco control, have created large anti-tobacco efforts in a few states. In 1988, California voters approved of a 25-cent-per-pack increase in cigarette taxes with approximately 20% of the revenues generated earmarked for tobacco control efforts; in FY 1996, the state spent over $132.5 million on tobacco control programs, ranging from educational programs to cessation efforts to support for local community efforts to a statewide media campaign. In 1992, Massachusetts voters passed a similar increase and by 1996 the state was spending about $65 million on its anti-tobacco programs. Voters in Arizona and Oregon have also passed excise tax increases partially earmarked for tobacco control purposes; Oregon's FY 1997 tobacco control spending was proposed at $8.5 million.[3]

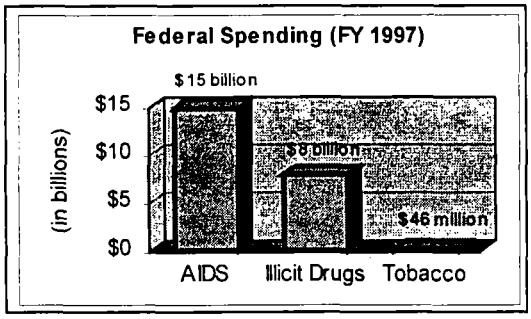
Government spending on tobacco control has been supplemented by private efforts, led by the Robert Wood Johnson Foundation, which spent about $30.5 million for tobacco control purposes in 1997, and almost $110 million over its history. A variety of smaller efforts from other foundations and some private and business donors have also contributed significantly.



The Need for New Resources in Tobacco Control

While significant new resources have been committed in recent years to tobacco prevention and treatment activities, it is clear for a variety of compelling reasons that these activities remain significantly underfunded relative to their importance and socio-economic value:

-- ***Tobacco-related disease is the nation's leading cause of death***, accounting for approximately 20 percent of all deaths.[4] Eliminating the harm caused by tobacco products would result in a net gain in the average American life expectancy of about 2 years – a similar gain to that which would result from the elimination of *all* cancers not caused by tobacco. For those who would otherwise have died early from tobacco-related disease, the actual gain in life expectancy would be an average of fifteen years.[5] While the actual reductions in tobacco-related health impacts resulting from specific tobacco control interventions are difficult to quantify, the very magnitude of the problem indicates that even modestly effective interventions could have a significant positive effect on the nation's health.



-- ***Tobacco control is cost-effective.*** While quantifying a specific "cost per life saved" is difficult, there is considerable evidence that tobacco prevention and treatment is a cost-effective way to save lives. Many policy interventions, such as tobacco tax increases and clean indoor air policies, can be carried out at low cost relative to other public health measures. Even those interventions that require significant investment, however, have been shown to be cost-effective. Physician counseling and treatment of nicotine addiction have been shown to be at least as cost-effective as other preventive medical practices.[6] Similarly, the impact of mass media campaigns, such as those being conducted in California and Massachusetts, appear to have a significant impact on tobacco use, for relatively low costs. One researcher concluded that, "[i]n general, anti-smoking campaigns are among the most cost-effective measures to improve health and are surpassed only by childhood immunizations. By spending less on treatment and more on anti-smoking efforts, many more years of life can be saved with the available resources." [7]

From a comparative perspective, anti-tobacco activities receive far less funding than other public health and safety problems, in absolute terms and relative to their impact on public health. The total amount of money supporting tobacco control efforts -- $46 million-- is dwarfed by the amount the United States spends to address other issues, such as illicit drugs and AIDS.

The disparity is especially significant considering the total number of deaths caused by each of these problems. (See the charts on page 3 for comparison.[8])

The evidence to date indicates that the most successful government funded anti-tobacco programs are the ASSIST project and the state campaigns in California and Massachusetts. Cigarette consumption in California and Massachusetts has fallen dramatically since their anti-tobacco campaigns were launched. Smoking rates in California fell by 28% between 1988 and 1993, twice the rate of decline prior before 1988. A comparable decrease in consumption has been observed in Massachusetts.[9] Three years after the seventeen ASSIST states were fully funded under that project, smokers in those states were consuming 7% less cigarettes per capita than smokers in non-ASSIST states.[10] Expanding the ASSIST program nationally would cost about $70 million. Creating a comprehensive national campaign on the scale of what has been done in California and Massachusetts would cost about $2.5 billion annually.

It should be kept in mind that while these programs are the most effective efforts yet, they have not solved the problem. Although they have created a bigger decline in smoking rates than have other efforts, they have only succeeded in making relatively modest dents in these rates. A comprehensive public health effort should aim to accomplish much more dramatic gains in what remains the number one public health problem in the country.

So, although a national level of public health spending at two or even three billion dollars per year would undoubtedly have a positive impact on reducing rates of tobacco use, given the extraordinary amount of death and disease caused by tobacco, spending ten billion dollars a year, or more, could still represent a well-justified and effective health investment. We do not argue that programs to address other health problems should be shifted to tobacco; rather, tobacco control funding should be increased to match its disproportionate negative impact on public health.

-- *Americans are not adequately informed about tobacco's hazards.* Another clear indication of the need to increase investment in tobacco control is the continued lack of understanding among current and prospective tobacco users about the hazards of the product. Despite the oft-repeated claims by the tobacco industry and others that "everyone knows about the (alleged) risks of smoking," studies have established that people's understanding of those risks remains partial at best. For example, the 1989 Surgeon General's report found that "[d]espite the growing level of public knowledge...a substantial number of Americans are still uninformed or do not believe the health risks of smoking."[11] It noted particularly that teenagers—an age group that comprises a large proportion of new smokers—often do not appreciate their own potential for tobacco addiction.[12]

More recently, an American Cancer Society study found that only one in five Americans could correctly identify cigarette smoking as the leading cause of death from a list of causes of death.[13] This clear lack of knowledge, exacerbated by the massive disinformation campaign conducted by the tobacco industry over the past decades, underscores the importance of additional tobacco control efforts to provide citizens the knowledge they need to make informed choices about tobacco use.

-- *The public supports tobacco control programs and policies.* Even beyond the massive health impact of tobacco use, thousands of Americans are effected negatively by tobacco. Two-thirds of adults who smoke

say they wish they could quit;[14] they need access to effective information and treatment. Non-smokers do not want to be harmed by secondhand smoke; they deserve policies that protect them. Parents work to discourage their children from smoking; there should be educational and counter-advertising programs that support their efforts.[15]

Significantly, public support is strong for measures to address these needs through well-financed tobacco control interventions. For example, a 1996 Gallup poll found that 88 percent of nonsmokers and *83 percent of smokers* believe that employees should be protected at work from secondhand tobacco smoke.[16] A 1996 poll done for the American Cancer Society found that adults feel the highest priority for funding from tobacco tax revenue should be for public education programs to prevent young people from starting to smoke.[17]

Necessary Components of a National Tobacco Control Policy

A truly comprehensive tobacco control policy would require a diverse array of research, policy, and programmatic components, each working toward a common goal. A blueprint of the necessary components for a successful, overall campaign would include:

1. A process for allocating tobacco control funds and setting tobacco policy priorities, reflecting the views of public health experts and free from industry influence. Two new organizational entities are critical to develop and implement a coherent domestic tobacco control strategy:

-- *Tobacco Control Task Force*, reporting to the Assistant Secretary for Health, that would set funding levels and strategic priorities for tobacco control programs government-wide; and

-- *Tobacco Policy Coordinating Committee*, including representatives of the Departments of Health and Human Services, Treasury, Agriculture, Defense, Labor, and Justice, and the Federal Trade Commission, that would coordinate federal policies related to tobacco. The Committee could be administered as part of the Office of Management and Budget.

2. A broad, systematically-planned tobacco research agenda, including:

- *Intervention development research* (clinical trials, economic analyses, demonstrations, advocacy research, etc.)
- *Evaluation* (program evaluation, treatment/therapy evaluation, diffusion research, etc.)
- *Surveillance* (epidemiology of disease & prevalence)
- *Basic health research* (biobehavioral research, health effects research, etc.)[18]

3. A coordinated set of tobacco control programs and policies that build on experience and scientific evidence to realize major reductions in tobacco prevalence and related disease. Components include:

– *Programmatic interventions* to prevent tobacco use, and offer treatment and addiction management therapies to current users. These include:

-- *Counter-advertising:* Mass media is an important strategic channel to encourage smokers to quit and others not to start. Television, radio and print advertisements reach a large number of people and convey messages persuasively. Some of the most persuasive counter-advertising strategies directly address the efforts of the tobacco

industry to market their hazardous products.[19]

-- *Educational programs:* An effective anti-tobacco agenda must include programs that inform current and prospective users about the health problems that result from tobacco use, and the options available to help them reduce their consumption or quit. These programs should be offered through a variety of channels, including schools, health care providers, worksites, and community institutions, among others. Since most tobacco users begin as children and teenagers, mandatory school-based programs that educate both teachers and students are particularly important to prevent tobacco use.

-- *Nicotine management/treatment programs:* Treatment programs are critical to aid tobacco users in quitting, and in managing nicotine addiction. Treatments targeting the needs of tobacco users should be universally available to all populations of tobacco users in the United States.[20]

-- *Other Information Efforts:* Reports and policy recommendations issued by the Department of Health and Human Services, the Federal Trade Commission, and other government agencies synthesize and disseminate important scientific, economic, and other information about tobacco and health to policymakers, journalists, researchers, health professionals and advocates. This in turn helps to educate the public, and informs further tobacco control efforts.

-- *Policy interventions* that can reduce and prevent tobacco use, and otherwise reduce the health damage caused by tobacco. Key policies include:

- price increases
- clean indoor air policies
- restrictions on advertising and promotion
- warnings on product labeling and advertising
- restrictions on youth access
- tobacco product regulation, including disclosure of the constituents of tobacco products and tobacco smoke.[21]

While programs and policies can be understood as separate categories of tobacco control activity, they are most effective when implemented as part of a unified, coordinated strategy. In particular, specific policies should be fully integrated with complementary educational efforts and other programmatic interventions (described above) that work synergistically for maximum impact.

In addition, policy interventions themselves require significant commitments of resources to succeed. Policy implementation must include an effective enforcement program, funded with significant long-term resources, that supports compliance and regulatory efforts at the local, state, and national levels.

-- *The structural role of advocacy:* These programs and policies must be advanced and supported by a vigorous tobacco control movement, including policy advocacy, in States and localities nationwide. Tobacco control activists play a critical role in empowering communities to work for tobacco prevention policies, monitoring tobacco industry actions, and fighting to keep tobacco control programs and policies up-to-date in the face of new industry challenges.

Policy advocates, especially those engaged in change at the community level, have been prime movers in the effort to secure a pro-health tobacco policy. But their work is far from over. Advocates must perform a variety of ongoing functions to keep these policies

rigorous and effective into the future -- monitoring industry behavior, ensuring strong enforcement of existing policies, using research and other data to identify and build support for promising new initiatives, and making sure that new approaches embodied in legislation are well-implemented and effective. By staying focused on new opportunities and threats and keeping connected with local communities, advocates are integral to the structure of an effective tobacco control strategy. A comprehensive federal tobacco policy law should recognize and support policy advocacy with resources and with safeguards from intimidation by the tobacco industry and its surrogates.

4. A strategy to address the international dimension of the tobacco pandemic not only represents an important humanitarian priority, and part of our national responsibility as the home of the world's largest international tobacco firms, it also serves critical domestic needs. Because our nation is comprised largely of immigrants from other lands, global tobacco use has and will have a significant cross-cultural impact. Assistance to other countries, and the sharing of lessons on effective anti-tobacco strategies, will bolster our ability to reduce the toll of death and disease caused by tobacco.[22]

While these four categories represent an overall blueprint for tobacco control, there are certain areas where increased investment is especially critical:

- Support for a major national educational/ mass media campaign to discourage tobacco use.

- Support for full implementation of FDA's authority to regulate tobacco, and for thorough and timely enforcement of its tobacco-related rules and regulations.

- Support for local and state health departments and other agencies, as well as Federal agencies, to maintain active tobacco control prevention, treatment, and addiction management programs, and to pursue the aggressive enforcement of tobacco control regulations.

- Support of diverse tobacco control coalitions and watchdog advocacy organizations in all states to promote tobacco control broadly, including the freedom and resources to monitor legislative implementation and regulatory enforcement, and to monitor and expose potential industry efforts to undermine reforms and regulation. It is particularly important that funds be used to strengthen those culturally diverse, community-based organizations working in and for those populations at greatest risk.

- Support for Federal and State programs to provide communications infrastructure, technical assistance, training, and other resources to build the capacity of both public and private non-profit tobacco control organizations.

- Leadership within the National Institutes of Health to establish a coordinated program of tobacco control research and development. Funding should be earmarked for specific research categories (intervention development, evaluation, surveillance and basic health research).

- Support for the collection and analysis of comprehensive data on tobacco use, behavior, and attitudes, down to the local level.

- Support through appropriate Federal agencies and their partners in chronic disease prevention for comprehensive, policy-focused, state-wide innovative

intervention research, development, and dissemination, including demonstration programs for implementing effective interventions.

- Specific resources for research, demonstration, implementation and dissemination of targeted cessation and prevention programs to racial and ethnic minorities and other special populations. These efforts should include:

  Research to support ongoing development of cessation and prevention protocols, including the development and production of related materials, for communities of color. Such research and program development should be conceived and implemented by those who are sensitive to values of diversity and the cultural, historical, and other needs of communities across all demographic segments. Efforts should be made to promote the participation of researchers from communities of color. The Pathways to Freedom program, supported by the Centers for Disease Control and Prevention, offers a good model (i.e., protocols tailored to multiple channels reaching African Americans) for efforts that could be similarly tailored to address the complexity inherent in the full spectrum of racial and ethnic communities.

  Prevention and cessation/treatment programs that are responsive to the specific ways in which communities of color are organized (i.e., community-based organizations, churches, etc.). Such programs should provide both services and the mechanisms to build tobacco prevention and control infrastructure and help close the critical gap in infrastructure that exists relative to the mainstream community.

  Effective federal/state coordination. OSH, CDC's Office of Minority Health, and other Federal agencies should work closely with their partners in state health departments, especially state-level minority health entities, to plan and implement programs that focus on the specific needs of groups within the states. Resources should be earmarked to support these efforts.

Avoiding Pitfalls

In addition to supporting and enforcing a full range of tobacco control programs and policies, a comprehensive tobacco control agenda must take care to "do no harm" by avoiding the following restrictions or limitations, which could be advanced by opponents of an effective tobacco policy:

Preemption of state and local tobacco control efforts. Beginning with the Federal Cigarette Labeling and Advertising Act of 1965, the tobacco industry has successfully lobbied for broad laws at the federal and state level that preempt stronger laws at, respectively, the state or local level. Legislation should include unambiguous non-preemption provisions, expressly disclaiming any intent of, or authority from, Congress to preempt the imposition of higher standards by states and local jurisdictions, except to the extent that such standards violate constitutional constraints.[23]

Restrictions on advocacy. Government-funded programs such as ASSIST have provided training and support for local and state tobacco control advocacy efforts. Congress should avoid restricting in any way the use of tobacco control funds for policy advocacy.

Limiting the scope or intended audience of educational efforts. The effectiveness of tobacco control programs could be blunted or jeopardized if authorizing legislation limit the target audience of educational messages to children or that prevent efforts that highlight the role of the tobacco industry in smoking initiation. The parameters of tobacco education efforts should be simply "what works."

Diverting tobacco funding to non-tobacco programs. At the state level, funds secured through excise tax increases and earmarked for tobacco prevention have frequently been impounded and used for other needs. However the valuable other worthy causes may be (health care, illicit drugs, biomedical research), they should not be used as a means of diverting resources away from tobacco. Funds should be specifically designated for tobacco control, and should not include a loophole to permit spending on vaguely-defined "other activities" that could result in a shift of funds to non-tobacco priorities.

EVALUATION

The following section describes the tobacco control programs proposed by each bill, and evaluates their strengths and weaknesses.[1] One general characteristic common to all of the bills is that most programs are proposed using broad, general language. Implementation under any of the bills would require a great deal of planning, with significant discretion left to the implementing agencies. For that reason, the comparisons between the bills necessarily involves some interpretation and conjecture.

[1]It is important to note that the paper does not evaluate the size or mechanism of Medicaid reimbursement offered in each bill, nor does it examine funding for a variety of non-tobacco-related programs that are also proposed in many of the bills.

While each proposal is different, a number of critical flaws recur in many of the bills:

- **Most bills offer no central coordinating mechanism for tobacco control policy.** While most tobacco control programs would be administered under the authority of the Secretary of Health and Human Services, few of the bills provide for a tobacco policy director or other coordinating body within the department, or elsewhere in the government. This role is necessary to ensure that the programs proposed work together to accomplish their goals, avoid overlap and redundancy, and are effectively coordinated with other aspects of tobacco policy in other agencies. Without such strategic oversight, tobacco control policy could become fragmented and ineffective.

- **No bill offers explicit protection or authorization of community-based policy advocacy.** Some bills provide funding only to state and local governments, ignoring the important role of advocates and other independent groups. Even those bills that provide funds to non-governmental organizations at the community level lack explicit authorization for state and local policy advocacy as an effective strategy to improve tobacco control policies.

- **Many bills do not adequately address the needs of special populations.** The needs of minorities, low-income rural and urban populations, and women should be addressed as a fundamentally important part of an overall tobacco control strategy, including research, programs, and policies, that is coordinated at the Federal level.

- **There are significant restrictions on the scope of many proposed tobacco control programs that could hamper their**

effectiveness. For example, many require that programs focus only on prevention and reduction of tobacco use by minors. While all acknowledge this as a worthy goal, this focus on youth alone may not be the most effective way to discourage consumption by that sub-population, much less by those of other ages whose health is jeopardized by tobacco use. The programs should be authorized to set their focus based on the most effective strategies to reduce and prevent tobacco use of all kinds.

- **Proposed sponsorship-replacement programs do not specifically provide that new sponsorship funds should advance tobacco control.** Sponsored groups should identify the support they receive as tobacco control funds, and should be encouraged to integrate tobacco prevention messages into their activities as appropriate.

The detailed descriptions below provide specific critiques of each bill regarding these and other aspects of tobacco control.

S. 1414 - The Universal Tobacco Settlement Act

This bill was presented by its sponsors as an effort to draft the June 20, 1997 "Proposed Resolution" developed by the tobacco industry and state attorneys general into legislative language. Like the "Resolution," the bill would authorize the Secretary of Health and Human Services to develop a number of tobacco control and prevention programs. Unlike the June 20 document, however, the bill as introduced does not include specific funding levels for anti-tobacco programs. The tobacco control programs created by the legislation include:

- **National Smoking Cessation Program.** Provides authority to award grants "to eligible public and nonprofit entities and individuals for smoking cessation purposes."

- **National Reduction in Tobacco Usage Program.** Authorizes grants to:

(1) carry out education, prevention, and cessation campaigns "to discourage the use of tobacco products by individuals who are under 18 years of age and to encourage those who use such products to quit;"
(2) research, develop, and disseminate technologies and methods to reduce the risks of tobacco products;
(3) identify, test, and evaluate the health effects of tobacco product constituents, and
(4) "carry out any other activities determined by the Secretary to be consistent with the purposes of this Act."

- **National Tobacco-Free Public Education Program.** Directs the HHS Secretary to appoint an independent nine-member "Tobacco-Free Public Education Board," including three members who are "widely recognized by the general public" in their field, and three "who are heads of...major public health organizations".

  The board shall award grants and contracts "to conduct multi-media public educational or informational campaigns that are designed to discourage and de-glamorize the use of tobacco products, which "shall be designed to discourage the initiation of tobacco use by minors and encourage those using such products to quit." In awarding the grants and contracts, the Board shall "take into consideration the needs of particular populations."

- **National Event Sponsorship Program.** Provides funding for athletic, artistic,

social, and cultural entities that previously received tobacco industry sponsorship. After ten years, the program is ended, and any remaining funding is divided between multi-media campaigns, enforcement of tobacco laws, and community action programs (see below.)

- **National Community Action Program.** Authorizes grants to "eligible State and local governmental entities to carry out community-based tobacco control efforts that are designed to encourage community involvement in reducing tobacco product use."

- **National Cessation Research Program.** Authorizes grants for research and development of "methods, drugs, and devices to discourage individuals from using tobacco products and to assist individuals who use such products in quitting such use."

As noted above, S. 1414 as introduced did not include funding levels for these programs. If the settlement agreement proposed last June serves as a guide, this bill could allocate significant new resources to tobacco control. Yet it is also clear that the bill includes significant barriers to a fully effective tobacco control program:

- The bill does not propose a central strategic planning mechanism for tobacco control policy to ensure that the programs it proposes are effectively coordinated with each other and with other aspects of Federal tobacco policy .

- Both the National Reduction in Tobacco Usage Program and the National Tobacco-Free Public Education Program are explicitly required to focus on prevention and reduction of tobacco use by minors. The programs should be permitted to use whatever strategies are most effective in reducing and preventing tobacco use of all kinds.

- The National Community Action Program provides funding only to state and local governments. Funding should also be provided to non-governmental organizations at the community level, and should explicitly authorize state and local policy advocacy as an effective strategy to improve tobacco control policies.

- The sponsorship-replacement program does not specifically provide that new sponsorship funds should advance tobacco control.

- The bill does not adequately address the needs of special populations. While the National Tobacco-Free Public Education Board is directed to "take into consideration the needs of particular populations" in administering its program, other programs in S. 1414 are not so designed.

S. 1530 - Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act

S. 1530 supports tobacco control programs through two mechanisms: by directly authorizing a number of new programs at the Federal level, and by making certain payments to states contingent upon their use for "anti-smoking or tobacco-related purposes."

The latter mechanism will require states to develop a plan, approved by the Attorney General, Secretary of the Treasury, and Secretary of Health and Human Services, to provide tobacco control services in coordination with existing state-level programs, as well as with a variety of federal

children's health and education programs. The funds available for tobacco control under this option begin at $1.6 billion in the first year, reach $4 billion in the sixth year, and continue at $4 billion in perpetuity.

S. 1530 also authorizes a number of federal programs. It creates the **"National Institutes of Health Trust Fund for Health Research."** This trust fund, which receives $2.15 billion in the first year after enactment, reaches $4 billion in the fifth year, and continues in perpetuity, funds a variety of basic biomedical and behavioral research activities, including some National Institutes of Health administrative costs.

As part of the Trust Fund section, the bill requires the NIH Director to collaborate with a number of other key federal health officials to develop a **National Tobacco Research Agenda**, for submission to the HHS Secretary and Congress. While the Agenda would include tobacco control research, it would also encompass a wide range of other topics, including the health effects of "illicit narcotics" and genetic bases for tobacco-related disease.[24]

The bill would establish **a "national anti-tobacco product consumption and tobacco product cessation public health program."** Funding under this section starts at $1.1 billion in first year, reaches $4 billion in sixth year, and continues into perpetuity. The general mandate of the program would be

> to discourage individuals from beginning to use tobacco products and other substances of abuse and to assist individuals who consume such products to discontinue such use, with special emphasis placed on health promotion and disease prevention activities that discourage children under the age of 18 from initiating or continuing use of such products;[25]

This mandate, with its focus on children and its inclusion of "other substances of abuse," could easily be used to proscribe or discourage certain activities, or to divert attention and resources away from tobacco. The funding for FDA regulations concerning tobacco would derive from the funding for this section, guaranteeing that agency a source of funding, but further diluting the potential impact of the tobacco control activities competing for those same resources.

The program would include the following activities:

-- **Public Education:** Includes --
- development of model curricula "to influence the knowledge, attitudes, and behavior of young Americans" with regard to the health risks of tobacco use
- technical assistance by CDC to state and local authorities and parents in developing effective anti-tobacco educational materials
- development of materials to inform chronic tobacco users of health risks and the benefits of quitting, and
- "appropriate action" by CDC to inform consumers of effective therapies to cease tobacco use.

-- **Counter-Advertising:** Authorizes a "mass media public education campaign designed to counter the effects of marketing practices of tobacco product manufacturers and distributors."

-- **Model Smoking Cessation Program:** Establishes a model program that States can use in developing state-based cessation programs. The program will fund grants by States to entities within the state to run tobacco prevention and cessation programs

-- **Other Activities:** As the HHS Secretary deems appropriate, including programs to

reduce the use of "other abused substances such as illicit drugs."

At least half of the funds earmarked for this program must be distributed to states in the form of block grants.

While S. 1530 would create a single, integrated program, it is not a central authority that can coordinate these programs with other tobacco control policies, undermining the potential for a unified federal tobacco control policy. While enlisting and paying the States to carry out these programs could help to direct attention to the needs of specific regions and populations, the requirement that block grants receive half of the funding could hamper the effectiveness of the federal portions of the program.

The provision permitting the HHS Secretary to use funds for "other activities," including programs dealing with illicit drugs, is likely to divert significant resources away from tobacco control.

A variety of important tobacco control activities would be carried out under the program. In particular, the language on the counter-advertising campaigns is strong and clear, and lacks the conditions on content or scope that could reduce its effectiveness. However, the funding for the program in general is not adequate to carry out its responsibilities, and the lack of specific authorized amounts for different activities could result in neglect of some actions, especially controversial ones, in favor of others.

As with other bills, S. 1530 makes no provisions for the needs of special populations, and offers no explicit protection for policy advocacy.

S. 1492 - The Healthy and Smokefree Children Act

This bill earmarks a significant portion of a tobacco tax increase to a number of non-tobacco children's health and biomedical research initiatives. Its tobacco control program is substantial, totaling $2.1 billion in the first year and earmarking specific funding for each activity. All funding levels are adjusted over time for population and inflation. Specific program areas include:

- **Use Reduction and Addiction Prevention Research:** Provides $100 million per year to research "methods, drugs, and devices to discourage individuals from using tobacco products and to assist individuals who use such products in quitting such use."

- **Counter-Advertising:** Provides $500 million per year for programs "to reduce tobacco usage through media-based (such as counter-advertising campaigns) and nonmedia-based education, prevention and cessation campaigns designed to discourage the use of tobacco products by individuals and to encourage those who use such products to quit."

- **Centers For Disease Control And Prevention Programs:** Provides $60 million in the first year, gradually increasing up to $100 million starting in 2001, for the Centers for Disease Control and Prevention to deliver "programs to discourage the initiation of tobacco use, reduce the incidence of tobacco use among current users, and for other activities designed to reduce the risk of dependence and injury from tobacco products."

- **FDA Enforcement:** Provides $300 million for "the activities of the Food and Drug Administration relating to tobacco."

-- **National Tobacco Usage Reduction And Education Block Grant Program:** Provides $1.144 billion in the first year, increasing up to $1.750 billion in 2009, for block grants for states to carry out a variety of tobacco control activities, such as --

- Tobacco cessation, including a model program and delivery of cessation assistance programs and devices approved by HHS
- Activities to reduce tobacco usage, including campaigns to reduce underage tobacco use, "informational campaigns that are designed to discourage and de-glamorize the use of tobacco products", and school- and community-based programs
- Replacement of tobacco sponsorship for athletic, musical, artistic, and other social or cultural activities

By earmarking specific amounts for particular activities, S. 1492 ensures a broad range of tobacco control activities. This also, however, reduces administrative discretion to allocate resources to particular activities.

S. 1492 provides significant flexibility in its educational and media-based programs. Most do not require a focus on youth.

The bill makes no provisions for the needs of special populations, other than a general policy to tailor cessation activities to the needs of "individuals." It offers no explicit protection for policy advocacy.

S. 1638 - The Healthy Kids Act

Tobacco control efforts in S. 1638 are funded through earmarking specific percentages of a "Health Enhancement and Lowered Tobacco Hazards for Young (HEALTHY) Kids Trust Fund," which is funded through a phased-in $1.50 per pack tax increase. As a result, firm funding levels under the legislation are not available; proponents of the bill have estimated that it would provide $13 billion for tobacco control over the first five years after enactment[26]. Specific programs include:

-- **School- and community-based "tobacco danger education":** Authorizes grants to states to conduct school-based programs on the dangers of tobacco, and community-based prevention programs, "using methods that are proven and effective."

-- **Counter-advertising programs:** Mandates "education, prevention and cessation campaigns designed to discourage the use of tobacco products by individuals and to encourage those who use such products to quit." The programs shall "target [those] who have been targeted by tobacco industry advertising."

-- **National Tobacco Cessation Program:** Establishes a national program to support cessation services consistent with Agency for Health Care Policy and Research guidelines and "such additional guidelines as are necessary to assure the quality, accessibility and cost effectiveness of services receiving funds."

-- **Assistance for those suffering from tobacco-related illnesses:** Provides need-based "assistance and compensation" to those suffering from tobacco-related illnesses and conditions.

-- **International tobacco control:** Authorizes the HHS Secretary, in consultation with the Secretary of State, to assist foreign countries and international organizations in reducing youth tobacco use. Also sets up the American Center on Global Health and Tobacco (ACT), a non-

governmental organization to help other countries reduce tobacco use.

- **National Event Sponsorship Program:** Authorizes grants to replace tobacco sponsorship for athletic, musical, artistic, and other social or cultural activities

- **Programs to reduce alcohol and illicit drug use by minors:** Authorizes grants to States to support existing programs to reduce alcohol and illicit drug use by minors.

While specific dollar amounts have not been set, this bill proposes to allocate significant new resources to tobacco control, and earmarking them to a broad range of activities. (Projected funding levels still fall short of those that past experience suggests would be optimally effective in reducing tobacco use.) Some specific programs are carried out through state grants, but S. 1638 is not designed to distribute funds to states through block grants, as other legislation proposes.

Like other bills, S. 1638 does not create a central coordinating authority for federal tobacco control policy and programs.

S. 1638 offers some small but significant improvements over other proposals with regard to tobacco control. It is drafted to be particularly sensitive to the needs of special populations, requiring that programs be "culturally and linguistically appropriate," and directing special attention to at-risk populations and groups that have been targeted by tobacco industry marketing, including women and minorities.

The bill is also unique in its attention to international tobacco control, authorizing the government, and providing funds for a private entity, to assist other nations in reducing tobacco use.[27]

S. 1638 offers no explicit protection for policy advocacy.

S. 1648 - The Preventing Addiction to Smoking among Teens (PAST) Act

This bill would create four major tobacco control programs - a "State and Community Action Program" for tobacco control, a tobacco cessation program, a tobacco research program, and a public health education and promotion program. The tobacco control and cessation programs would be administered through state grants, while the research and education programs would be controlled primarily at the federal level:

- **State and Community Action Program:** Funding totaling $145 million in the first two years, and increasing gradually to $440 million in the tenth year, would be provided to states through the Office on Smoking and Health (OSH) to conduct a variety of tobacco control activities, including:

  - "evidence-based state & community initiatives for tobacco prevention and control;
  - "infrastructure development" modeled after ASSIST;
  - counter-advertising;
  - anti-tobacco education and "public policy initiatives";
  - school-based prevention.

  States will submit plans, developed through a public process, to HHS for approval to receive funding. They will also be required to appoint an advisory committee, including representation of the general public and state and local health departments to oversee implementation of the state plan. (Groups that receive funding from the state program may be

represented on the advisory committee.) The program will be terminated after ten years.

- **Smoking Cessation Programs:** A state-based cessation program, modeled on the same structure as the "State and Community Action Program," would be developed to provide cessation services to individuals, training for health-care providers and health plans, and "to encourage insurers and health plans to provide coverage" for cessation services. Funding for the program would total $1 billion in each of the first three years, and $1.5 billion in each of the subsequent six; the program would terminate after ten years. [28]

- **Reducing Youth Smoking and Tobacco-Related Diseases Through Research:** Mandates the preparation of a tobacco research agenda report by the Institute of Medicine; creates a National Tobacco Task Force, including top federal officials, representatives from state and local government and non-governmental "public health or tobacco control organizations," to carry out a tobacco research agenda.[29]

- **Public Health Education and Promotion:** Directs the HHS Secretary to appoint an independent nine-member "Tobacco Use Prevention and Cessation Board," which shall develop multi-media, youth-oriented anti-tobacco campaigns. The legislative language creating the board and defining its duties is almost identical to that defining the "Tobacco-Free Public Education Board" in S. 1414, except that the Board in S. 1648 must also include two members who are "recognized as experts in the field of advertising and marketing." The bill provides $500 million per year for the program for ten years.

Unlike most programs in other proposals, S. 1648 only projects funding levels out for the first ten years after enactment, and explicitly "sunsets" the tobacco control and cessation programs. Funding during the period falls short of levels that could further promote tobacco use reduction.

The focus on state level activity in the bill provides important opportunities to tailor the programs to local and regional needs, and the open planning process provides opportunities for community advocates to participate. However, the structure of the program does not provide for overall central coordination of federal tobacco-related policies.

The anti-tobacco media/education campaign authorized in S. 1648 includes at least a partial focus on youth, which could hamper its effectiveness somewhat. It also provides only cursory attention to the needs of special populations.

Although the State and Community Action Program alludes to support for "public policy initiatives," there is no explicit protection for policy advocacy in the legislation.

CONCLUSION

The current momentum towards comprehensive tobacco control legislation reflects a change from the incremental efforts of the past. But it also represents the cumulative impact of years of efforts to call attention to the huge social and health costs of tobacco use, and to secure programs and policies that effectively reduce these costs. It represents a unique opportunity that must be used wisely.

Any plan to comprehensively address tobacco should build on the solid experience of the past, and devote significant resources – on the

order of tens of billions of dollars – to properly confront the devastating tobacco epidemic. It should also look forward, by permitting all those involved in tobacco control to contribute to creative, innovative solutions to the problems caused by tobacco, both now and into the future.

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Policy Analysis No. 6

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EXECUTIVE SUMMARY

Legislative preemption is accomplished whenever a legislative body, such as the United States Congress, enacts into law a measure that restricts or prohibits the enactment or enforcement by lower jurisdictions of their own legislation in a given topic area.[1] For more than three decades, the tobacco industry lobby has pursued passage of federal and state legislation that either expressly or impliedly preempts the implementation of more stringent measures by lower government jurisdictions. The industry's success in doing so has hampered efforts to more effectively combat the epidemic of tobacco-caused illness and premature death at the state and local levels. For this reason, leading public health organizations in the United States have adopted formal positions opposing federal preemption of state and local regulation relating to the use and marketing of tobacco products. An analysis of the tobacco control legislation now before Congress must include a careful review of the potential preemptive effects of such legislation on state and local authority, as well as on the authority of federal regulatory agencies.

This analysis of five major bills currently pending in the United States Senate makes the following findings:

- The pending bills -- S. 1414,[2] S. 1492, S. 1530, S. 1638 and S. 1648 -- differ markedly in their preemptive effects involving regulation of the following key areas: 1) youth access; 2) advertising, promotion and health warning labels; 3) environmental tobacco smoke; and 4) manufacturing practices and product ingredients.

- S. 1638 most consistently safeguards state and local regulatory authority, followed by S. 1492.

- S. 1414, S. 1530 and S. 1648 are consistently more apt to restrict or prohibit state and local regulatory authority.

- Some bills, in particular S. 1648, partially preempt the regulatory authority of the Food and Drug Administration (FDA) and assign Congress the role of micro-managing such areas as product regulation and labeling best left to the scientific and medical expertise of the agency.[3]

- An anti-preemption section found in a bill often cannot be taken at face value, because it has been qualified or even negated in another section of the same bill.

- While the language relating to preemption sometimes seems quite similar from one bill to the next, the actual effects of such language sometimes differ due to the placement of the language in the legislation or because of slight differences in wording, such as in the case of regulation of environmental tobacco smoke. Moreover, in some cases redundant or inconsistent

language is found within the same bill, creating confusion over the bill's preemptive or anti-preemptive effects.

The public health interests of the American people will be better served if political leaders firmly reject federal legislative measures that either expressly or impliedly preempt the authority of states, localities, or federal health agencies to regulate tobacco products in the most effective manner.

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INTRODUCTION

> "Historically, state and local laws have been as effective as, if not more so than, federal statutes. Thus, legislation should include specific statements that ensure that state and local laws that strengthen public health are not vaguely supported in large print and specifically destroyed in small print. Federal public health legislation must be expressed in terms that establish a minimum level of protection above which states and communities are able and encouraged to do much more and to innovate where federal laws are silent."[4]

This cautionary note, which was sounded recently in an editorial in the *Journal of the American Medical Association* by former Surgeon General C. Everett Koop, former Commissioner of Food and Drugs David Kessler, and *JAMA* editor George Lundberg, recognizes that, for more than three decades, the tobacco industry lobby has pursued passage of preemptive legislation as one of its primary legislative goals.

"Preemption" is a straightforward concept. Simply put, preemption is the restriction or prohibition by state or federal law of the enactment or enforcement by lower jurisdictions of their own law in a given topic area. While easily defined, in practice the issue of preemption is enormously complex. While preemptive language occasionally is clear and aboveboard, it often is ambiguous, convoluted, indirect, or merely implied - emanating as it almost always does from political negotiation and the serpentine legislative drafting process. Sometimes the ambiguity and complexity are inadvertent; at other times, they are deliberately contrived to benefit tobacco and affiliated business interests. Even where there is no express preemption, it is possible that a court will conclude that a state's law is impliedly preempted, particularly where Congress has adopted a "comprehensive" regulatory scheme.

The industry began employing preemptive strategies at the federal level soon after Surgeon General Luther Terry issued the first report on smoking and health in 1964, which indicted cigarette use as a direct cause of lung cancer.[5] In response to the Surgeon General's findings, the Federal Trade Commission (FTC) issued regulations in July 1964 requiring tobacco manufacturers to post detailed health warning prominently on cigarette packages. Cigarette makers quickly prevailed upon Congress to pass a weaker warning label measure in the form of the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965,[6] which at the same time preempted the FTC as well as state and local

health authorities from imposing their own, stronger health warnings. The FCLAA of 1965 also required the FTC to transmit to Congress annual reports on the effectiveness of cigarette labeling, current cigarette marketing practices, and recommendations for legislation.

The FTC complied with Congress' new mandate by submitting its first report in June 1967, in which it recommended strengthening the warning label from the weak, preemptive one legislated by Congress in 1965 ("Caution: Cigarette Smoking May Be Hazardous to Your Health") to one that was both stronger and disease-specific ("Warning: Cigarette Smoking is Dangerous to Health and May Cause Death from Cancer and Other Diseases"). In 1969, Congress amended the FCLAA, preempted the authority of the FTC and state and local governments to prescribe different cigarette warning labels, and at the behest of the tobacco industry adopted a new warning label that, once again, was weaker than the one proposed by the FTC: "Warning: The Surgeon General Has Determined That Cigarette Smoking is Dangerous to Your Health." Further, the industry enlisted its congressional supporters to include a second preemptive section in the amended FCLAA that has since been interpreted by the courts as barring many lawsuits brought by individual smokers for harm suffered from smoking done since 1970, the year the new preemption was adopted.

While preemption of stronger state and local tobacco-control laws by federal statute has been pursued by tobacco interests and their supporters since the 1960s, most of the industry's focus in this area since the late-1980s has been in support of weak state tobacco-control laws that preempt stronger local regulation. The tobacco industry lobby has supported bills across the country to preempt local action against tobacco, and, as of August 1997, had succeeded in having such measures enacted in 29 states. Of these, 18 preempt stronger clean indoor air laws, 21 preempt stronger youth access measures, and 11 preempt stronger advertising and promotion restrictions. In a few states, such as Mississippi and South Carolina, the tobacco industry has succeeded in preempting local laws in all three categories.[7]

Evidence demonstrates that such preemption of local tobacco regulation impairs efforts to protect the public health by:

- Eliminating local control of public health policy;
- Establishing weak public health standards that will be enormously difficult to strengthen in the future;
- Eliminating strong, community-based tobacco-control interventions; and
- Dividing tobacco-control coalitions when differences arise over the competing need for enactment of state tobacco-control interventions and the consequences of doing so in a manner that simultaneously preempts stronger local initiatives.[8]

The concern over the effects of preemptive legislation is further heightened by the knowledge that once installed, preemptive measures are almost impossible to repeal. Of the six state legislatures which have considered proposals to repeal preemption, only one has repealed a tobacco preemption law.[9]

Given the industry's recurrent pursuit of legislative preemption to block effective tobacco control efforts in lower government jurisdictions, the industry may be expected to lobby its supporters in Congress to weave preemptive language into, or to establish implied preemptive effects in, pending proposals for comprehensive tobacco control

legislation. An analysis of the proposals being considered in the Second Session of the 105th Congress must, therefore, include a careful review of the potential preemptive effects of such legislation on state and local authority, as well as on the authority of agencies of the executive branch.

DESCRIPTION

Until revelations of tobacco companies' manipulation of nicotine to addict smokers and various other forms of industry malfeasance made media headlines starting in 1994, followed soon thereafter by a spate of major lawsuits seeking billions of dollars in compensation for state governments and millions of addicted and injured individuals, the tobacco industry had been on the defensive almost solely because of legislative action taken by local government entities. Indeed, by mid-1997, more than 1,150 counties, cities and towns had implemented or strengthened laws restricting youth access to tobacco products, limiting or banning cigarette vending machines, or restricting smoking in restaurants and the work place. By contrast, fewer than 400 such laws had existed only one decade earlier.[10]

In response to the burgeoning threat posed by local government action, during the last ten years the tobacco industry lobby has expended considerable resources in a coordinated national effort to block local ordinances through enactment of preemptive state legislation. This industry strategy was recounted by Victor Crawford, a now deceased Maryland state senator, heavy smoker, and lobbyist for the Tobacco Institute. Explaining the perspective of his former client, he said:

> "We could never win at the local level. The reason is, all the health advocates, the ones unfortunately I used to call 'health Nazis,' they're all local activists who run the little political organizations. They may live next door to the mayor, or the city councilman, and they say 'Who's this big-time lobbyist coming here to tell us what to do?' When they've got their friends and neighbors out there in the audience who want this bill, we get killed. So the Tobacco Institute and tobacco companies' first priority has always been to preempt the field, preferably to put it all on the federal level, but if they can't do that, at least then on the state level, because the health advocates can't compete with me on a state level."[11]

Legislation containing language preempting the authority of lower jurisdictions to regulate the sale, distribution, advertising, promotion or use of tobacco frequently is touted by its backers as constituting a comprehensive and uniform approach to tobacco control that will benefit the public health. Internal tobacco industry strategy memos disclose that the industry has sought enactment of substantively weak bills that appear superficially to crack down on tobacco at the same time they prohibit more stringent local regulation. A 1991 memo circulated by the Smokeless Tobacco Council, summarizing a meeting held by Philip Morris officials with sympathetic California state legislators, including the speaker of the state assembly, illustrates what some have dubbed the industry's "Trojan horse" strategy:

> "At that time the Speaker made clear a significantly more proactive tobacco control effort would be needed to secure preemption. Out of these discussions the notion of a Comprehensive Tobacco Control Act

> (that would provide preemption) evolved. In order to gain preemption, the Speaker wanted a 'Comprehensive Tobacco Control Act' along the lines of the alcohol model. The Speaker believes the trick to doing this would be that such an act would have to have the 'appearance' of a comprehensive scheme."[12]

This strategy culminated in the industry-backed introduction of Proposition 188 in California in 1994, which attempted to overturn strong local clean-indoor-air ordinances and substitute them with weak, preemptive provisions.

In recognition of the unique political challenges the industry faces at the local level, many community leaders, local government officials, health advocates and other concerned citizens assert that any legislation enacted by Congress, no matter how strong it may appear to be, must not preempt the authority of state and local governments to control tobacco more stringently, and perhaps more effectively, than prescribed by federal statute. If such care is not taken, they believe, comprehensive federal tobacco-control legislation could become "the mother of all preemption,"[13] as one advocate put it, threatening to impede state and local tobacco-control efforts far into the future.

Opposition to preemption is embraced by all of the nation's leading health organizations with expertise in tobacco control, including the American Cancer Society, the American Heart Association, the American Lung Association, the American Medical Association, the American Public Health Association, Americans for Nonsmokers' Rights, the Association of State and Territorial Health Officials, the Campaign for Tobacco-Free Kids, and the Institute of Medicine of the National Academy of Sciences, among many others. The State Attorneys General Working Group on Tobacco likewise has adopted a position opposing preemption.

A review of the policy positions adopted by the two leading tobacco-control coalitions in the United States, whose views on national legislation vary in certain other respects, reveals steadfast opposition to federal preemption of stronger state and local regulation of tobacco. The ENACT coalition (Effective National Action to Control Tobacco) has adopted principles that include two specific references to the preemption issue, as follows:

> "NO PREEMPTION: Any federal legislation should explicitly provide that state and local governments are not preempted from establishing or retaining requirements equal to or more stringent than any federal requirement (including taxation) relating to tobacco control, other than requirements regulating the content of tobacco products. ...
>
> "SECONDHAND SMOKE: The public's protection from secondhand smoke hazards should be included as an integral part in any national tobacco policy. This should include federal environmental tobacco smoke restrictions for restaurants without preempting tougher local and state laws."

Save Lives, Not Tobacco, a coalition of public health, consumer, medical, civic, labor and business organizations that advocates "fair and effective tobacco control policies at local, state and national levels," has adopted the following position on preemption:

> "Existing law and proposed legislation regulating tobacco products should

> contain unambiguous anti-preemption provisions, expressly clarifying that higher standards of public health protection may be imposed by state and local governments."

The coalitions' policy stances are further echoed by the recommendations of the Advisory Committee on Tobacco Policy and Public Health, co-chaired by Drs. Koop and Kessler. The advisory committee proposed that any federal tobacco-control legislation be required to include the following:

> "Unambiguous non-preemption provisions in any Federal regulation of tobacco, expressly disclaiming any intent of, or authority from, Congress to preempt the imposition of higher standards by states and local jurisdictions, except to the extent that such standards violate constitutional constraints."[14]

The Koop-Kessler committee also recommended that Congress repeal the portion of the Federal Cigarette Labeling and Advertising Act that preempts state and local governments from regulating tobacco promotion and advertising occurring entirely within a state's borders.[15]

The deleterious effects of preemption on local efforts to reduce children's access to tobacco products and to protect non-smokers against involuntary exposure to environmental tobacco smoke in public places are well-documented.[16] State-level preemption of health-related tobacco legislation was first employed by tobacco industry supporters in Florida in 1985. In that case, the state legislature enacted a statewide clean indoor air law that eliminated nearly a dozen stronger ordinances passed by local communities in the state.[17] Since the Florida action, the tobacco industry lobby has persuaded legislatures to enact preemptive legislation in 29 states. Twenty-one states have preempted stronger local youth access-reduction laws restricting vending machines and self-service displays and licensing tobacco retailers, while 18 states have preempted stronger local restrictions on smoking in work places, restaurants and other public places. Moreover, 11 states have preempted local ordinances affecting tobacco advertising and promotion, including restrictions on product sampling, billboards and other advertising.[18] Local authority to increase excise taxes on tobacco products also has been preempted, as it was done in Illinois in recent years.

There also is a complex new issue that emerges in the context of consideration of comprehensive federal legislation - one that has not been a focus of the traditional debate over state preemption of local authority. As described earlier, the principles and recommendations of the national tobacco control coalitions and the Koop-Kessler committee focus on opposing federal preemption in such areas as youth access, advertising and promotion, environmental tobacco smoke and taxation. The new area of concern involves regulation of tobacco product manufacturing practices and product ingredients. Only the principles set forth by the ENACT coalition address the question of preemption in this area. As noted, ENACT has recommended that, with respect to regulation of tobacco product manufacturing practices, an exception be made to the standard no-preemption stance; thus, the federal government would retain exclusive authority to regulate the contents of tobacco products.[19]

EVALUATION

This section describes the preemption-related merits and limitations of five major pieces of legislation currently pending in the United States Senate. (Certain companion measures also have been introduced in the U.S. House of Representatives.) In reviewing the specific provisions of these bills, it is important to remember that none is etched in stone. Where no preemptive effect is now evident, eleventh-hour modifications could result in the insertion of language having preemptive effect or, conversely, the removal of language that now explicitly prohibits preemption. Such are the risks inherent in the negotiation and drafting of any complex legislation, as was clearly demonstrated last year when the tobacco industry lobby persuaded congressional leaders to slip a $50 billion tax break into major budget legislation, an action which became public only after the bill had passed Congress.

This analysis examines the treatment of preemption in the five following bills: S. 1414, S. 1492, S. 1530, S. 1638 and S. 1648, whose lead sponsors are, respectively, Senators John McCain (R-AZ), Edward Kennedy (D-MA), Orrin Hatch (R-UT), Kent Conrad (D-ND) and James Jeffords (R-VT). It reviews the question of preemption chiefly with respect to four areas of tobacco regulation:[20]

- Youth access
- Advertising, promotion and health warning labels
- Environmental tobacco smoke
- Manufacturing practices and product ingredients

The analysis is, thus, organized around these four major areas, which are addressed separately in the following sections. The reader is alerted to the fact that, in some instances, the analysis addresses multiple issues under a single topic heading. Wherever this is done, the objective is to help clarify the substance and preemptive effects of the legislation being examined.

Regulation of Youth Access

S. 1414, the "Universal Tobacco Settlement Act"

S. 1414 would essentially codify into federal law the agreement reached by state attorneys general, the tobacco industry and other parties on June 20, 1997. Senator McCain, in announcing the introduction of S. 1414, characterized it as a starting point for consideration by Congress of a comprehensive approach to addressing the tobacco epidemic.

Section 1003 is the primary provision addressing the preemptive effects of this legislation, and it applies to the entire Act. It begins with the following general statement:

> "(a) General Preemption.--Except as otherwise provided for in this section, nothing in this Act shall be construed as prohibiting a State from imposing requirements, prohibitions, penalties or other measures to further the purposes of this Act that are in addition to the requirements, prohibitions, or penalties required under this Act. To the extent not inconsistent with the purposes of this Act, State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products by minors."

As a general matter, therefore, S. 1414 provides that lower jurisdictions are not preempted from implementing their own additional measures to reduce youth access to, and use of,

tobacco products. However, the preemption section then sets forth several exceptions to the overall anti-preemption standard, including the following one:

> "(b) Enforcement.–A State may not impose obligations or requirements relating to the enforcement of this Act in a manner that conflicts with the provisions of Title VI."

Title VI, which governs "Consent Decrees, Non-Participating Manufacturers, and State Enforcement," requires tobacco manufacturers and distributors to enter into a consent decree with each state that, under Section 611, "shall contain provisions to clarify the application and requirements of this Act" as they apply to, among others things, "restrictions on tobacco product advertising and marketing *and youth access to such products*" (emphasis added). While there are no substantive preemptions covering consent decrees, Section 611 contains certain restrictions on state authority, including, among others, the two following examples: First, under subsection (c), the consent decree must be approved by the Secretary of Health. Second, under subsection (d)(2), while a state can take action to enforce the consent decree, it "may seek injunctive relief only and may not seek criminal or monetary sanctions" against the tobacco industry.

Title VI's Section 621(b)(3), governing enforcement, mandates that each state adopt a law placing enforcement authority solely in the hands of the state police or of local law enforcement authorities designated by the state police, and that such police authorities conduct random, unannounced inspections in accordance with regulations promulgated by the Secretary of Health and Human Services. This federal enforcement scheme appears to preempt state and local governments from placing the enforcement of the youth access restrictions in the hands of non-police agencies that in some jurisdictions might be better suited to the enforcement responsibility.

S. 1414 further limits state authority by providing for penalties against states that fail to demonstrate compliance with youth-access requirements. It requires that a state forfeit money received under the legislation if it fails to meet compliance rates on retailer sales. The bill is inflexible in this area. For example, states and localities are afforded no opportunity to apply for a waiver. This is unfortunate, given the evidence that such compliance rates do not necessarily correlate closely to actual youth consumption.[21] Therefore, the effect of this provision is that a state could be penalized for weak enforcement of youth-access laws, even if the weak enforcement resulted from a decision by the state to use its resources to implement other, potentially more effective programs. S. 1414 would thus preempt states from flexibly tailoring their tobacco-use reduction strategies in ways that might work best within their borders.

S. 1492, the "Healthy and Smoke Free Children Act"

S. 1492 attempts to avoid inadvertently preempting the authority of state and local governments to control tobacco within their jurisdictions. The bill contains a number of sections setting forth an explicit anti-preemption standard. Some of these sections make clear, however, that with respect to certain areas – such as the proposed new health warning label scheme – lower jurisdictions are explicitly precluded from taking action.

Title I of S. 1492 amends the Public Health Service Act (PHSA) as it relates to tobacco. Section 101 of Title I, concerning "Public health and education programs," adds a new Title XXVIII to the end of the PHSA,

governing "Public Health and Education Programs and Tobacco Control." The proposed new title addresses a variety of matters, including public health and education programs, national health initiatives, reduction in underage tobacco use, and miscellaneous topics such as whistleblower protections, a national tobacco document depository, and a new tobacco oversight and compliance board. Title XXVIII includes the following section on preemption:

> "SEC. 2844. PRESERVATION OF STATE AND LOCAL AUTHORITY.
>
> "Except as otherwise provided for in this title or the Healthy and Smoke Free Children Act (or an amendment made by such Act), nothing in this title or such Act shall be construed as prohibiting a State from imposing requirements, prohibitions, penalties or other measures to further the purposes of this title or Act that are in addition to the requirements, prohibitions or penalties required under this title or Act. To the extent not inconsistent with the purposes of this title or Act, State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products by minors."

The express purpose of Subtitle C, which covers "Reduction in Underage Tobacco Use," is as follows:

> "SEC. 2831. PURPOSE.
>
> It is the purpose of this subtitle to encourage the achievement of reductions in the number of underage consumers of tobacco products through the imposition of additional financial deterrents relating to tobacco products if certain underage tobacco-use reduction targets are not met."

Subtitle C provides for no exception to the explicit presumption against preemption set forth in Section 2844. Therefore, it appears that the bill leaves in place the authority of state and local jurisdictions to "impose additional tobacco product control measures to further restrict or limit the use of such products by minors," as long as such measures do not conflict with the purposes of Title XXVIII. The measure is potentially confusing, however, in that it includes what might be considered the "extra" anti-preemption language pertaining to restrictions on the use of tobacco products by minors. If the anti-preemption nature of the section is as absolute as it purports to be, it is unclear why this additional language is needed; this may raise the risk of exposing the anti-preemption measure to otherwise avoidable judicial interpretation.

Clear preemptive effect may be found in Section 2826, governing a new "National Tobacco Usage Reduction and Education Block Grant Program." This section mandates state compliance with a series of specific requirements involving, among other things, tobacco-use cessation projects and media-based, informational and school-centered educational campaigns. Section 2826 (a) provides that states "shall" use the block grant funds received under this section to carry out such activities.

Title II of S. 1492 amends the Food, Drug and Cosmetic Act (FDCA). Section 204 of Title II, governing "General Health and Safety Regulation of Tobacco Products," inserts a new Chapter IX in the FDCA, labeled "Tobacco Products." The new Chapter IX includes the following general section on

preemption:

> "SEC. 912. MISCELLANEOUS PROVISIONS.
>
> (a) Preservation of State and Local Authority.–Except as otherwise provided for in this chapter, nothing in this chapter shall be construed as prohibiting a State from imposing requirements, prohibitions, penalties or other measures to further the purposes of this chapter that are in addition to the requirements, prohibitions, or penalties required under this chapter. To the extent not inconsistent with the purposes of this chapter, State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products by minors."

The express purpose of Chapter IX is as follows:

> "SEC. 902. PURPOSE.
>
> It is the purpose of this chapter to impose a regulatory scheme applicable to the development and manufacturing of tobacco products..."

Section 902 goes on to focus on mandated ingredient disclosure, reduction of harmful ingredients, and manufacturing performance standards. No reference is made to youth access measures. Therefore, it appears that the authority of state and local governments to further restrict or limit the use of tobacco products by minors is not preempted by S. 1492's amendments to the FDCA.

S. 1530, the "Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act"

Of the five bills analyzed, S. 1530 is the most preemptive of state and local authority to control youth access to tobacco, an area which, as a matter of policy, should not be subject to federal government impediments. Mirroring the preferences of the convenience store industry, S. 1530 prohibits, in ways both express and implied, stronger, and potentially more effective, action by lower government jurisdictions.

For example, the bill provides retailers with significant protection against liability for illegal sales made by their employees, while taking the controversial step of holding children legally responsible for purchasing tobacco products.[22] Indeed, the language used in S. 1530, described below, resembles language that has been promoted by the tobacco industry and retailers at the state level in recent years.

Title III of the bill is subtitled the "Tobacco Use by Minors Prevention Act." Section 302 of Title III sets forth a "Model State Law," whose provisions must be contained in a state's statute and in effect by a date certain, or that state will not be eligible for funding under the act. The so-called model law contains various controversial provisions, such as the following example in Section 1:

> (d) Enforcement.–A person who violates subsection (a) [prohibiting the selling of tobacco products to persons younger than 18] shall not be liable for a civil money penalty unless the individual who received the tobacco product is proceeded against under section 2(a) [making those under age 18 liable for purchasing tobacco products] ..."

While mandates such as this are believed by

some experts to be counter-productive to the goal of reducing tobacco use by children, though they may be favored by the tobacco industry and some members of the retail community, the mandatory language of S. 1530 effectively preempts a state from implementing alternative, more effective strategies to reduce youth access. A state that failed to implement the measure just quoted would stand to lose substantial funding.

This adverse outcome is not cured under the general preemption provision included in the model state law section, which states:

> "SEC. 11. PREEMPTION.
>
> (a) In General.--The provisions of this Act shall not preempt any provisions of State or local law that provide greater restrictions than those required in this Act so long as such State or local laws do not conflict with regulations issued under section 910 of the Federal Food, Drug and Cosmetic Act."

In addition, the placement of this anti-preemption section within the model law itself is illogical. Since the model law is intended to be adopted by the states, this federal anti-preemption measure should be found, if anywhere, in the proposed federal statute, not in state law. Assuming that this provision actually belongs in Section 301 ("State Laws Regarding Sale of Tobacco Products to Individuals under the Age of 18"), which governs the adoption of the model law, it would allow state and local laws that provide greater restrictions than those required by this Act "so long as such State or local laws do not conflict with regulations issued under section 910 of the Federal Food, Drug and Cosmetic Act."

The proposed new Section 910 of the FDCA, which is set forth under Title IV, Section 401, is yet another section on preemption. Section 910(a) prohibits states from enacting or enforcing laws that conflict with several new sections (902, 903, 904, 905) of the FDCA that deal with issues *unrelated to* youth access. Section 910(b), which sets forth a "Rule of Construction," covers similar ground but in anti-preemption terms, prescribing that states and their political subdivisions may enact laws "so long as [they] do not conflict with the requirements of Sections 902 through 905." The new section 906 of the FDCA, concerning "Tobacco Product Marketing Restrictions," is not covered by this anti-preemption clause. Therefore, states and localities could not issue more stringent requirements, such as raising the age of sale from 18 to 21, raising the verification age from 27 to an older age, or strengthening the requirements on vending machines and displays. There is no apparent justification for exempting these provisions while allowing stronger state and local action on others, but S. 1530 does so.

In addition, assuming that Section 910 is construed as applying to the model state law provisions, a state probably would be effectively preempted from choosing *not* to apply the enforcement mandate quoted above because to do so would not be considered as "providing greater restrictions" - even where a state had evidence that its enforcement efforts would in fact be more effective if it did not implement the model law enforcement provision.

The model state law section also has preemptive effect in that it prohibits individuals from bringing a private action for any violation of the act (Section 13).

S. 1530's requirement that each state adopt the provisions of the model state law also includes numerous other, detailed mandates involving such regulatory areas as licensure, distribution and enforcement. In

each of these areas, the legislation has preemptive effect over state and local government authority.

It also is notable that some of the forms of preemption prescribed in S. 1530 differ from the traditional types of preemption commonly seen at the state level. This underscores the need for members of Congress to carefully analyze this and all other proposals before marking up and voting on the measures pending before them.

S. 1638,the "Healthy Kids Act"

S. 1638 is a bill intended, in the words of its preface, "[t]o help parents keep their children from starting to use tobacco products [and] eliminate or greatly reduce the illegal use of tobacco products by children." The bill's youth access provisions are set forth in amendments to the Food, Drug and Cosmetic Act, which make explicit the Food and Drug Administration's regulatory authority over the sale, distribution, manufacture and marketing of tobacco products. S. 1638 gives significant attention to the issue of preemption, generally endeavoring to avoid preemptive effect except where explicitly identified, and includes the following general anti-preemption provision:

> "Sec. 804. PRESERVATION OF STATE AND LOCAL AUTHORITY.
>
> Except as otherwise provided for in this Act (or an amendment made by this Act), nothing in this Act shall be construed as prohibiting a State or political subdivision of a State from imposing requirements, prohibitions, penalties or other measures, whether by statute, rule, regulation, ordinance, judicial decree, consent decree, or settlement agreement, to further the purposes of this Act that are in addition to the requirements, prohibitions, or penalties required under this Act. Nothing in this Act (or an amendment made by this Act) shall preclude or deny the right of any State or political subdivision of a State to adopt or enforce any requirements, prohibitions, or penalties relating to tobacco products to the extent that such requirements, prohibitions, or penalties are not less stringent than those required under this Act (or amendments)."

S. 1638's primary coverage of youth access is found at a new Section 577 of the Food, Drug and Cosmetic Act, governing "Restrictions on Youth Access to Tobacco Products." Subsection (b)(1), which requires each state to adopt a program providing for licensure of tobacco retailers, explicitly provides that a state's program can exceed the requirements of the model state program set forth in subsection (b)(3). Perhaps to avoid any ambiguity, subsection (f) further specifies, concerning the entire youth-access regulatory scheme set forth in Section 577, that "[t]he provisions of this section shall not preempt any provision of State or local law that provides greater restrictions than those required in this section."

S. 1648, the "Preventing Addiction to Smoking Among Teens (PAST) Act"

The stated overall purpose of S. 1648 is, among other things, "to provide for reductions in youth smoking." Title II (Section 201 et seq.) of the bill proposes amending the Public Health Service Act (PHS Act) by adding a new

Title XXVIII, which would enact the new "Tobacco Use by Minors Prevention Act." Under the new Act, the Office of Smoking and Health of the Centers for Disease Control and Prevention (CDCP), rather than the Food and Drug Administration, would have regulatory and enforcement authority in the area of preventing youth access to tobacco products - a controversial approach.

Subtitle B, Section 2821 of the "Tobacco Use by Minors Prevention Act" requires that each state, to avoid losing substantial federal funding, enact laws that include the provisions of a model state law, which includes a host specific mandates at Section 2823. The model law prescribes a minimum-age standard, as well as rules governing licensure, sale and distribution, signage at retail, enforcement and a potentially controversial provision holding minors legally responsible for purchasing tobacco products. It also provides that in the event of an illegal sale, an employer may raise as a defense the fact that it made its employees aware of the minimum-age law, an approach advocated by the tobacco and convenience store industries. Nowhere is the issue of preemption specifically addressed in connection with the proposed amendments to the PHS Act.

In contrast, Title I of S. 1648 specifically provides for substantial preemptive effect with regard to a number of the bill's proposed amendments to the Food, Drug and Cosmetic Act, most of which involve non-youth access prevention measures (discussed later in this paper). One curious exception to this is found in a proposed new Section 908 of the FDCA, which prescribes enforcement authority of the Centers for Disease Control and Prevention (again, rather than the FDA) over certain marketing prohibitions involving sales to minors. It is not readily apparent why the provisions of Section 908 are found within the proposed amendments to the FDCA, rather than as part of the proposed amendments to the Public Health Service Act located under Title II. At any rate, Section 908 is not listed among the FDCA sections deemed explicitly as having preemptive effect over state and local government authority.

In the absence of any anti-preemption language to the contrary, it appears that the proposed "Tobacco Use by Minors Prevention Act" would have preemptive effect over states and localities by requiring those lower jurisdictions to carry out certain strategies that in some cases might be found to be detrimental to the state's youth access-prevention efforts. Thus, the state would risk losing substantial funds if it chose not to carry out certain of the model-law mandates, even if it determined that complying with them could actually serve to hamper the state's efforts to reduce tobacco use by minors.

Regulation of Advertising, Promotion and Health Warning Labels

S. 1414, the "Universal Tobacco Settlement Act"

The bill's restrictions on advertising and promotion of tobacco products are found at Sections 101 through 106. New warning label schemes for cigarettes and smokeless tobacco products are set forth at Sections 111 and 112. Preemption is addressed specifically at Section 115, in part, as follows:

> "(a) Federal Action.–No statement relating to the use of cigarettes or smokeless tobacco products and health, other than the statements required by sections 111 or 112, shall be required by any Federal agency to appear on any package or in any advertisement of cigarettes or a smokeless tobacco product.

> (b) State and Local Action.--No statement relating to the use of cigarettes or smokeless tobacco products and health, other than the statements required by sections 111 and 112, shall be required by any State or local statute or regulation to be included on any package or in any advertisement of cigarettes or a smokeless tobacco product."

Thus, S. 1414 preempts federal agencies, such as the FDA, and all state and local government bodies from changing the health warning labels slated to appear on tobacco product packages and advertisements.

While the bill preempts further action to regulate health warnings, the general anti-preemption provision, Section 1003 (quoted earlier), may protect the authority of lower jurisdictions to take regulatory action against tobacco advertising and promotion. This possibility is supported by S. 1414's repeal of the Federal Cigarette and Labeling Act and the Comprehensive Smokeless Tobacco Health Education Act, including their preemption provisions, at Section 118. Nonetheless, the recurrent concern arises that while there is no express preemption, courts might interpret the comprehensive regulatory scheme set forth in the legislation as implicitly preempting stronger state or local action.

S. 1492, the "Healthy and Smoke Free Children Act"

A new health warning label scheme is set forth under Title II, which proposes granting the FDA broad "authority to regulate the manufacture, sale, distribution, advertising and marketing of tobacco products" (Section 203(g)) by adding a new Chapter IX to the FDCA (Section 204). Proposed Section 910 of the FDCA prescribes warning labels on packages and advertisements for cigarettes (subsection (a)) and smokeless tobacco products (subsection (b)). The following subsection applies to the warning label provisions:

> "(f) Limited Preemption.--
>
> (1) State and local action.--
>
> (A) Limitation.--No warning label with respect to cigarettes or smokeless tobacco products, other than the warning labels required by subsections (a) and (b), shall be required by any State or local statute or regulation to be included on any package or in any advertisement of cigarettes or a smokeless tobacco product.
>
> (B) Rule of construction.--Nothing in this section shall be construed as prohibiting a State or political subdivision of a State from enacting statutes or regulation concerning cigarettes or smokeless tobacco products so long as such statutes or regulations do not conflict with the labeling and advertising requirements of this section or require additional statements on cigarette or smokeless tobacco packages."

Subsection (f)(1)(A) thus forbids states and localities from imposing requirements for warning labels or advertisements. While subsection (f)(1)(B) appears to reinforce the preceding subsection, it also calls into question, in a non-specific way, the breadth of the limitation on preemption.

Subsection (e) makes clear that the Secretary of Health, presumably through the FDA regulatory process, would retain the authority to "change the text or layout of any

of the warning statements, or any of the warning provisions, under subsections (a) and (b), if determined necessary by the Secretary."

S. 1492 does not itself amend federal law pertaining to tobacco product advertising and promotion, except perhaps indirectly, and it explicitly does not repeal the Federal Cigarette Labeling and Advertising Act (FCLAA) or the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), which contain their own preemptive language. However, Section 202, which sets forth the FDA's "general authority" in the area, specifies that the Secretary, "acting through the [FDA], shall have the authority under the [FDCA] (above and beyond the existing authority of the Secretary to regulate tobacco products as of the date of enactment of this Act) to regulate the manufacture, labeling, sale, distribution, *and advertising* of tobacco products" (emphasis added). In addition, Section 910(i) states that "[t]he Secretary shall exercise the authority provided for in this section notwithstanding the provisions of the [FCLAA] and the [CSTHEA]." Therefore, it seems reasonably clear that S. 1492 provides for: 1) FDA jurisdiction over tobacco product advertising; and 2) concurrent authority to the states to further restrict tobacco product advertising within their own jurisdictions, providing they do not impede interstate commerce.

S. 1530, the "Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act"

The provisions governing tobacco product advertising and promotion restrictions and those governing health warning labels are set forth in separate sections of S. 1530.

Restrictions on advertising and promotion are covered by Title II, Subchapter A, which provides for a "National Tobacco Control Protocol." The protocol sets forth rules for the use of consent decrees by the states under which the tobacco industry would agree to limit its advertising and promotional activities in exchange for civil liability protections (Subtitle A, Chapter 2, Subchapter A).

While there are no expressly stated preemptions involving consent decrees, S. 1530 explicitly restricts the ability of the states to enforce the consent decrees. For example, Subtitle B, Section 242 provides that a state may obtain "injunctive relief only and may not seek or impose criminal or monetary relief" in certain circumstances. Moreover, enforcement of the consent decree is to be carried out with deference given to the actions of the U.S. Attorney General. Under Subtitle A, Section 232, a state must let the U.S. Attorney General's office proceed if it is diligently prosecuting a case. The state must also give notice of at least 30 days to the Attorney General before taking any action to enforce a consent decree. Finally, the remedies are restricted to those provided under this Act, which, under Sections 232(c) and 231(b), limits civil penalties against a manufacturer to "an amount not to exceed $10,000,000 for all such violations adjudicated in a single proceeding."

A new health warning label scheme is set forth under the amendments to the FDCA, at Section 904. Several significant preemptions are applied to the labeling scheme. Subsection (e) states:

> "Preemption.--No statement relating to the use of cigarettes or smokeless tobacco products and health, other than the statements required by subsections (a), (b), or (c), shall be required on any package or in any advertisement of cigarettes or a smokeless tobacco product."

Subsection (e) thus precludes the states from altering in any way the rotating health warning labels as set forth at subsections (a) and (b), or the statement of intended use set forth at subsection (c). The language of subsection (e) is not limited to the states, and presumably also applies to federal agencies.

Subsection (d) expressly limits the power of the FDA to improve upon the tobacco product labeling statements. First, while subsection (d)(2)(A) authorizes the FDA to issue rules that change the text of the rotating health warning labels, it prohibits requiring such changes until a full year has passed from the time the final rule is published in the *Federal Register*. It also explicitly withholds authority from the FDA to modify the statement of intended use that would appear on product packages and advertisements. Subsection (d)(2)(B) goes even further, stating that "[t]he Secretary may not promulgate any rule under subparagraph (A) during the 5-year period beginning on the effective date of the PROTECT Act unless the Secretary can demonstrate extraordinary circumstances." The justifications for restricting FDA authority over health warning labels and statements of intended use, as well as the five-year moratorium on any efforts by the FDA to improve federal labeling law, are not readily apparent.

S. 1638,the "Healthy Kids Act"

The provisions governing tobacco product advertising and promotion restrictions and those governing health warning labels are set forth in separate sections of S. 1638.

Advertising and promotion is addressed as part of a proposed "National Tobacco Control Protocol," set forth at Title VII, Subtitle C, Section 725 et seq. In addition, the bill repeals the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act of 1986, including their preemption sections. The protocol provisions do not themselves address preemption. Rather, it appears that the general anti-preemption language set forth at Section 804 applies. That section, quoted earlier, strongly preserves state and local authority to impose and enforce "requirements, prohibitions, penalties or other measures" that further the purposes of the Act and are "not less stringent than" those required under the Act or amendments.

Unlike the preemptive provisions found in S. 1530, enforcement actions concerning the federal advertising and promotion provisions may be pursued by state attorneys general if the alleged violation occurred within their state, under Section 732. While the U.S. Attorney General also may bring an enforcement action under Section 731, nothing in the bill suggests that this would preclude the chief law enforcement officer of a state from bringing an action. In addition, Section 733 provides, among other things, that "any person may bring a civil [enforcement] action against a manufacturer," an option not offered by S. 1530.

A new warning label scheme for cigarette and other tobacco product packages and advertisements is set forth at Title II, governing "FDA Jurisdiction Over Tobacco Products," which adds a new Subchapter F to the FDCA. Included among the proposed amendments to the FDCA is a new Section 575, which prescribes the new health warning label scheme. Section 575(e) sets forth the general rule prohibiting states and localities from requiring the placement of any additional or different warning labels on cigarette or other tobacco product packaging:

"(e) LIMITED PREEMPTION.--

(1) STATE AND LOCAL

> ACTION.--No warning label with respect to cigarette or smokeless tobacco products, or any other tobacco product for which warning labels have been required under this section, other than the warning labels required under this Act, shall be required by any State or local statute or regulation to be included on any package of cigarettes or a smokeless tobacco product."

Section 576, which appears to apply to the entire set of amendments to the FDCA, adds the following:

> SEC. 576. PRESERVATION OF STATE AND LOCAL AUTHORITY.
>
> "Except as otherwise provided for in section 575(e), nothing in this subchapter shall be construed as prohibiting a State or locality from imposing requirements, prohibitions, penalties or other measures to further the purposes of this subchapter that are in addition to the requirements, prohibitions, or penalties required under this subchapter. State and local government may impose additional tobacco product control measures to further restrict or limit the use of such products."

Read together, and coupled with the repeal of the FCLAA, these sections on preemption appear to protect the authority of states and localities to further restrict tobacco advertisements within their own jurisdictions. However, two observations are in order:

- First, Section 576 would avoid ambiguity and be strengthened by the insertion of the word "expressly" immediately before "provided for" in line one, and the phrase "or different from" immediately before "the requirements" in line four.

- Second, regardless of the strength of the anti-preemption intent displayed in this (or in any other legislation), courts are likely to adjudicate challenges to state or local attempts to restrict localized tobacco advertising (billboards) differently from state or local attempts to restrict interstate tobacco advertising (national magazines). In short, "advertising" is not a unified concept, and efforts to regulate it may receive contrary treatment depending on whether the advertising is purely local or disseminated through a national publication.

In addition, Sections 575(a)(1)(C), 575(b)(1)(C), 575(c) and 575(d)(1) make clear that the Secretary of Health, presumably through the FDA, would be empowered to review and revise health warning label language, text and layout on cigarette and other tobacco product packages and advertisements.

Finally, S. 1638 makes explicit, at Section 207, that "[n]othing in [Title II], or an amendment made by [Title II], shall be construed to in any way reduce the jurisdiction of the Federal Trade Commission over the advertising of tobacco products."

S. 1648, the "Preventing Addiction to Smoking Among Teens (PAST) Act"

Title I, entitled "Regulation of Tobacco Products and Tobacco Product Development," amends the FDCA and adds a new Chapter IX to that statute. Chapter IX covers tobacco product advertising and promotion, as well as labeling.

Proposed FDCA Section 906 sets forth restrictions on a variety of tobacco product marketing and advertising activities. Section 913, which governs "Preservation of State and Local Authority," identifies the specific preemptive effects of the new Chapter IX, stating in part:

> "(a) ADDITIONAL REQUIREMENTS. --
>
> (1) IN GENERAL.--Except as provided in paragraph (3), nothing in this Act [i.e., the FDCA] shall be construed as prohibiting a State or political subdivision thereof from adopting or enforcing a requirement applicable to a tobacco product that is in addition to, or more stringent than, requirements established under this Act.
>
> (2) APPLICATION OF STATE LAW.--In the case of a requirement of a State or political subdivision thereof that is more stringent than a requirement established under this Act, the requirement of the State or political subdivision shall apply.
>
> (3) EXCEPTION.--This subsection shall not apply to requirements under sections 902, 903, 904, 905, 906(a)(1)-(3), 906(b)-(d), and 907."

Thus, while subparagraphs (1) and (2) contain strong anti-preemptive language, the exceptions set forth in subparagraph (3) render Section 913 highly preemptive of state and local authority. State and local government authority is explicitly preempted by subparagraph (3) in all of the following areas (note: while only some of these preemptions deal with advertising and labeling, all are identified together here for purposes of clarity):

- Section 902 ("Submission of Health Information to the Secretary"), governing ingredient disclosure
- Section 903 ("Tobacco Product Health Risk Reduction Standards"), providing for establishment of standards for reduced-risk tobacco products
- Section 904 ("Good Manufacturing Practice Standards"), instructing the Secretary to issue regulations "appropriate for the manufacture of a product derived from a raw agricultural commodity for which no therapeutic claim is made" (see subsection (a)(4)
- Section 905 ("Tobacco Product Labeling, Warning, and Packaging Standards")
- Section 906 ("Restriction on Marketing and Advertising"): Preemption applies to subsections (a)(1)-(3) and (b)-(d), which govern prohibitions on outdoor advertising, the use of human images and cartoons in advertisements and advertising on the Internet; restrictions on the use of product names, product placement in entertainment media, and sponsorship; and certain format and content requirements.
- Section 907 ("Reduced Risk Tobacco Products"), providing for the development and designation of tobacco products deemed to be less hazardous

Measures that are *not* designated by Section 913(a)(3) as having preemptive effect include Sections 906(a)(4), which covers point-of-sale advertising, and Section 908, setting forth marketing prohibitions involving sales to minors. (It is not readily apparent why the

provisions of Section 908 are found within the proposed amendments to the FDCA, rather than as part of the proposed amendments to the Public Health Service Act located under Title II of S. 1648.) Furthermore, Section 913(b), which prescribes a "Rule of Construction Regarding Product Liability," states:

> "No provision of this Act relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."

This section appears to overturn the Supreme Court's ruling in the *Cipollone* case, thus opening the door to individual products liability lawsuits which, until now, have been preempted to the extent they allege injuries suffered from smoking done after the federal preemption went into effect in 1970.

Proposed FDCA Section 905 prescribes a new scheme for health warning labels and statements of intended use on cigarette and smokeless tobacco product packages and advertisements. As noted above, Section 913(3) preempts state and local governments from regulating in this area.

Subsection (d) of Section 905 mirrors a similar provision in S. 1530, discussed above, expressly limiting the power of the FDA to improve upon the tobacco product labeling statements. First, while subsection (d)(2)(A) authorizes the FDA to issue rules that change the text of the rotating health warning labels, it prohibits requiring such changes until a full year has passed from the time the final rule is published in the *Federal Register*. It also explicitly withholds authority from the FDA to modify the statement of intended use that would appear on product packages and advertisements. Subsection (d)(2)(B) goes further, stating that "[t]he Secretary may not promulgate any rule under subparagraph (A) during the 5-year period beginning on the effective date of the PAST Act unless the Secretary can demonstrate extraordinary circumstances." The justifications for preempting FDA authority over health warning labels and statements of intended use in this fashion are not readily apparent.

Section 102 of Title I repeals the Comprehensive Smokeless Tobacco Health Education Act of 1986, while it provides that the provisions of the Federal Cigarette Labeling and Advertising Act "that apply to cigarettes shall be superseded by the provisions of this title (and the amendments made by this title)."

Regulation of Environmental Tobacco Smoke

S. 1414, the "Universal Tobacco Settlement Act"

Title III of S. 1414 sets forth "Standards to Reduce Involuntary Exposure to Tobacco Smoke," and gives regulatory jurisdiction over environmental tobacco smoke (ETS) to the Occupational Safety and Health Administration (OSHA), at Section 305. A threshold concern is the potential preemptive effect of OSHA regulation over smoking in the work place under the Occupational Safety and Health Act of 1970 (the OSHA Act). Some experts have argued that the adoption of regulations by OSHA, which would be required by every one of the five bills analyzed in this paper, preempts states and local governments from adopting stronger measures within their own jurisdictions. This is of particular concern where, as is the case with S. 1414, the secondhand smoke provisions represent a rollback of the current authority of OSHA to regulate broadly.

S. 1414 includes two anti-preemption sections – which are partly redundant, but also

somewhat inconsistent -- that govern control of ETS under Title III. They state:

> "Sec. 304. PREEMPTION.
>
> Nothing in this title shall preempt or otherwise affect any other Federal, State or local law which provides protection from health hazards from environmental tobacco smoke."
>
> "Sec. 1003. PREEMPTION.
> . . .
> (c) Public Exposure to Smoke.--Nothing in title III shall be construed to preempt or otherwise affect any other Federal, State or local law which provides greater protection from the health hazards of environmental tobacco smoke."

The language of Sections 304 and 1003(c) raises perplexing questions. The former purports to allow other government jurisdictions to provide "protection" against exposure to ETS, while the latter purports to allow other government jurisdictions to provide "*greater* protection" (emphasis added). In the area of preemption, such inconsistencies are a recipe for legal challenges and confusion.

As serious, if not more so, by purporting to protect the effect of *other* federal law, both provisions confirm the possibility that the enactment of S. 1414 would not negate the likely preemptive effects of the OSHA Act, and could thereby result in de facto preemption of stronger state and local measures to control involuntary ETS exposure, notwithstanding the reference to "greater protection" contained in Section 1003(c). While it may seem a bit arcane, it is important to note that both preemption sections are presented as part of the proposed Universal Tobacco Settlement Act, not as amendments to the OSHA Act. Indeed, S. 1414, in contrast to S. 1492, would not amend the OSHA Act. Therefore, any reference to "other" federal law presumptively *includes* the OSHA Act. While the language of these preemption provisions closely resemble a similar provision in S. 1492, for the reasons just noted their actual effects may differ dramatically. In the absence of a clarifying amendment to the OSHA Act itself, the preemptive effects of OSHA regulation may remain intact.

Finally, the inclusion of Section 1003(c) in S. 1414 is further confusing in that it appears to be wholly unnecessary if the general preemption provision found at Section 1003(a) is to be taken at face value.

S. 1492, the "Healthy and Smoke Free Children Act"

Title III of S. 1492 sets forth "Standards to Reduce Involuntary Exposure to Tobacco Smoke." Like the other bills analyzed here, S. 1492, at Section 301, directs OSHA to regulate the use of tobacco in a variety of public places. As noted, S. 1492, unlike S. 1414, would amend the OSHA Act by adding a new Section 35, which contains the following subsection:

> "(d) Preemption.--Nothing in this section shall preempt or otherwise affect any other Federal, State or local law which provides protection from health hazards from environmental tobacco smoke that are at least as stringent as those provided for in this section."

While the anti-preemption language contained in Section 35(d) generally tracks that of S. 1414, it is materially different in two respects: First, it is contained in amendments

to the OSHA Act, so that its reference to "other" federal law logically would not include the OSHA Act itself. Thus, the possible preemptive effect of the OSHA Act probably is negated. Second, it appends a clause emphasizing that stronger regulations may be implemented by other government entities; this differs from S. 1414's Section 304, although it resembles S. 1414's Section 1003(c).

S. 1530, the "Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act"

Title VI sets forth "Standards to Reduce Involuntary Exposure to Tobacco Smoke." Like S. 1414, but unlike S. 1492, the bill directs OSHA to regulate the use of tobacco in a variety of public places without amending the OSHA Act. The relevant preemption section states as follows:

> "SEC. 603. PREEMPTION.
>
> Nothing in this title shall preempt or otherwise affect any other Federal, State or local law which provides protections from health hazards from environmental tobacco smoke that are equal to or greater than the protections provided for under this title."

As reflected in the analysis of similar preemption language in S. 1414, by purporting to protect the effect of *other* federal law, Section 603 affirms the possibility that the enactment of S. 1530 would not negate the likely preemptive effects of the OSHA Act, and could thereby result in de facto preemption of stronger state and local measures to control involuntary ETS exposure, notwithstanding the potentially inconsistent language ("equal or greater to") contained in Section 603.

S. 1638,the "Healthy Kids Act"

S. 1638 covers ETS restrictions at Title V, "Standards to Reduce Involuntary Exposure to Tobacco Smoke." Under Section 501 et seq., the bill amends the OSHA Act by adding a new Section 35, much as S. 1492 does. Section 35 provides strong anti-preemption language, as follows:

> "(d) PREEMPTION. -- Notwithstanding section 18, nothing in this section shall preempt or otherwise affect any other existing or future Federal, State or local law which provides protection from health hazards from environmental tobacco smoke that are at least as stringent as those provided for in this section."

"Section 18," referred to in subsection (d), is the preemption section in the OSHA Act. It states, in part:

> "(a) Assertion of State standards in absence of applicable Federal standards Nothing in this chapter shall prevent any State agency or court from asserting jurisdiction under State law over any occupational safety or health issue with respect to which no standard is in effect under section 655 of this title."[23]

If the effect of the proposed amendments to the OSHA Act is interpreted as creating a new "standard" whereby OSHA regulates indoor smoking nationally, preemption of stronger state or local action is likely in the absence of explicit language to the contrary. Therefore, it is noteworthy that S. 1638 is the only bill of the five analyzed here which explicitly negates the preemptive effects of Section 18 with

regard to the regulation of environmental tobacco smoke.

S. 1648, the "Preventing Addiction to Smoking Among Teens (PAST) Act"

The bill contains a very brief Title III, entitled "Standards to Reduce Involuntary Exposure to Tobacco Smoke." Section 301 (the title's only section) amends Section 6 of the OSHA Act by adding the following paragraph:

> "(h) Not later than 12 months after the date of enactment of this subsection, the Secretary [of Labor] shall promulgate a final standard on indoor air quality in indoor work environments in accordance with subsection (b). Such standard shall include provisions addressing control of environmental tobacco smoke in both industrial and nonindustrial indoor and enclosed worksites."

Since nothing is said regarding preemption, this measure likely would result in de facto preemption of stronger state and local measures to control involuntary ETS exposure. While the "Goals and Purposes" section of S. 1648 provides that "It is the purpose of this Act to . . . establish a minimum Federal standard to limit smoking in public places, including the halls of Congress" (Section 3(b)(8)), it is unlikely that this provision would negate any preemptive effect found in the OSHA Act.

Regulation of Manufacturing Practices and Product Ingredients

This is a complex new issue, one that has not been a focus of the traditional debate over preemption. Some hold the view that, with respect to regulation of tobacco product manufacturing practices, an exception be made to the standard anti-preemption stance, thus allowing the federal government to retain exclusive authority to regulate the contents of tobacco products. The rationale for this position may be that only the FDA will have the expertise and resources to effectively regulate in this area. A contrary argument may be found in the interest of states to implement the most effective protections for their citizens in cases where the federal government is perceived to be moving too slowly or unproductively.[24]

A different issue concerns the power of state and, perhaps, local governments to regulate the disclosure of tobacco product ingredients to regulatory agencies and consumers. There is no apparent justification for federal preemption in this area, which involves the very basic right of consumers to be fully informed before purchasing and using a dangerous product.

S. 1414, the "Universal Tobacco Settlement Act"

Under S. 1414, the regulation of manufacturing practices and product ingredients is placed in the hands of the FDA under Title I, Subtitle E, which amends the FDCA by adding a new Chapter IX. Preemption is not addressed under Title I. Thus, the general anti-preemption provision found at Section 1003(a) might be assumed to apply, which would leave states free to further regulate tobacco manufacturing practices and product ingredients. However, the "purpose" language contained in the proposed amendments to the FDCA makes clear that the FDA's regulatory authority is intended to be comprehensive, and it is therefore likely that the law would be interpreted as implicitly preempting state action in this area. The precise language is as follows:

"SEC. 902. PURPOSE.

It is the purpose of this chapter to impose a regulatory scheme applicable to the development and manufacturing of cigarettes and smokeless tobacco products/tobacco products. Such scheme shall include the approval of the ingredients used in such products and the imposition of standards to reduce the level of certain constituents contained in such products, including nicotine."

Such preemption would, for example, block the ability of states to require that tobacco manufacturers gradually reduce nicotine to non-addictive levels in the event the FDA failed to do so. Proposed Sections 905 and 907, governing performance standards for tobacco products and requirements relating to nicotine and other constituents, explicitly prohibit the FDA from ordering the elimination of nicotine without first overcoming substantial, possibly insurmountable obstacles. Similarly, states would be preempted from enacting and enforcing their own laws requiring ingredient disclosure and the production of less hazardous products, subjects which are covered by proposed Sections 908 through 910.

S. 1492, the "Healthy and Smoke Free Children Act"

Regulation in this area is governed by S. 1492's proposed amendments to the FDCA, which begin at Title II, Section 201. Section 912 of the proposed new Chapter IX of the FDCA includes the following general section on preemption:

(a) Preservation of State and Local Authority.--Except as otherwise provided for in this chapter, nothing in this chapter shall be construed as prohibiting a State from imposing requirements, prohibitions, penalties or other measures to further the purposes of this chapter that are in addition to the requirements, prohibitions, or penalties required under this chapter. To the extent not inconsistent with the purposes of this chapter, State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products by minors."

The express purpose of Chapter IX is as follows:

"SEC. 902. PURPOSE.

It is the purpose of this chapter to impose a regulatory scheme applicable to the development and manufacturing of tobacco products..."

Section 902 goes on to state that the scheme shall include regulatory action concerning ingredient disclosure, reduction of harmful ingredients, and manufacturing performance standards.

The authority of states to regulate in this area is, at best, open to interpretation. The bill sets forth a comprehensive scheme that might be found implicitly to preempt state authority in such areas as performance standards (see Section 203(e), amending FDCA Section 514(a); and new FDCA Section 906), reduced risk products (new FDCA Section 907), good manufacturing practice standards (new FDCA Section 908), and ingredient disclosure (new FDCA Section 909). The inclusion of specific language clarifying that states retain authority to restrict tobacco use by minors calls into further question the level of authority remaining to the states to regulate

in the other areas within the FDA's jurisdiction.

S. 1530, the "Placing Restraints on Tobacco's Endangerment of Children and Teens (PROTECT) Act"

The relevant sections are found in proposed amendments to the FDCA, set forth in the form of a comprehensive scheme contained in a new Title IX. FDA jurisdiction under the new title governs, among other matters, tobacco product health risk management standards (new FDCA Section 902), good manufacturing practice standards (new FDCA Section 903), and reduced risk tobacco products (new FDCA Section 905). (The new FDCA Section 904 deals with labels on packaging and advertisements, as discussed above.) The pertinent preemption section states, in part, as follows:

> "SEC. 910. PREEMPTION.
>
> (a) Limitation.–No requirement with respect to a tobacco product shall be applied by any State or local statute or regulation if such requirement conflicts with the requirements of section 902, 903, 904, or 905.
>
> (b) Rule of construction.–Nothing in this section shall be construed as prohibiting a State or political subdivision of a State from enacting statutes or regulations concerning tobacco products so long as such statutes or regulations do not conflict with the requirements of section 902, 903, 904, or 905."

Thus, in the enumerated areas of tobacco product control, states would effectively be precluded from conducting their own regulatory activities.

Such preemption would, for example, block the ability of states to require that tobacco manufacturers gradually reduce nicotine to non-addictive levels, a matter that is covered under Section 902(f). Section 902(f) also explicitly prohibits, as does a similar provision in S. 1414, the FDA from ordering the elimination of nicotine without first overcoming substantial, possibly insurmountable obstacles. Similarly, it appears that states implicitly would be preempted from enacting and enforcing their own laws requiring *both* ingredient disclosure *and* the production of less hazardous products, which are covered by Sections 902 and 905.

S. 1638,the "Healthy Kids Act"

The bill grants regulatory authority in this area to the FDA through amendments prescribed under Title II, which governs "FDA Jurisdiction Over Tobacco Products" and adopts the regulations promulgated by the agency on August 28, 1996. Title II also adds a new Subchapter F to the FDCA, which sets forth regulations covering, among other things, performance standards (new FDCA Section 573) and disclosure and reporting of tobacco and nontobacco ingredients (new FDCA Section 574).

Subchapter F contains the following language pertaining to the effects of FDA regulation on the regulatory authority of lower jurisdictions; its anti-preemptive thrust is the strongest of the bills analyzed here:

> "SEC. 576. PRESERVATION OF STATE AND LOCAL AUTHORITY.
>
> Except as otherwise provided for in section 575(e) [pertaining to labeling, advertising and liability law], nothing in this subchapter shall be

> construed as prohibiting a State or locality from imposing requirements, prohibitions, penalties or other measures to further the purposes of this subchapter that are in addition to the requirements, prohibitions, or penalties required under this subchapter. State and local governments may impose additional tobacco product control measures to further restrict or limit the use of such products."

It is notable that Subchapter F, unlike its proposed counterpart in S. 1492, contains no "purpose" section. As discussed above, the purpose section in S. 1492 states explicitly that the new FDA subchapter is intended to serve as a regulatory scheme, increasing the likelihood that it would later be interpreted as implicitly preempting some areas of state or local government regulation. In the absence of such explicit language of purpose within Subchapter F, with its potentially limiting effects, S. 1638 appears to safeguard the authority of lower jurisdictions to further regulate tobacco products in the areas of performance standards and disclosure and reporting of tobacco and nontobacco ingredients.

S. 1638's general "purposes" measure, Section 3, "affirm[s] the authority of the [FDA] to regulate the manufacture, labeling, sale, distribution, and advertising of tobacco products to the fullest extent authorized by the commerce clause of the United States Constitution" (see subsection 5). Nothing in this language appears to suggest the placement of implicit limitations on state or local government authority.

S. 1648, the "Preventing Addiction to Smoking Among Teens (PAST) Act"

As discussed above, Title I adds a new Title IX to the FDCA that places regulatory authority over tobacco products in the hands of the FDA. New FDCA Section 902 governs ingredient disclosure. Sections 903 and 907 provide, respectively, for the establishment of standards for reduced-risk products and for the development and designation of such products. Section 904 provides for the adoption of regulations governing good manufacturing practice standards. All are given explicit preemptive effect by Section 913(a)(3), which is quoted in full, above. This is consistent with the express purposes of S. 1648, which states the following at Section 3:

> "(b) PURPOSES.–It is the purpose of this Act to–
>
> . . .
>
> (5) provide for the establishment of national standards to control the manufacturing of tobacco products and the ingredients used in such products;
>
> (6) provide certain regulatory powers to the Secretary of Health and Human Services to encourage the development and marketing by the tobacco industry of 'less hazardous tobacco products', including the power to regulate the level of nicotine in such products . . ."

The sweeping preemption of state regulatory provided under the amendments to the FDCA could have significant consequences. For example, Section 903 provides, in part:

> "(c)REGULATION OF THE COMPOSITION OF TOBACCO PRODUCTS.–
>
> (1) IN GENERAL.–The

> Secretary *may* adopt a health risk reduction standard under this section that requires--
>
> > (A) the modification of a tobacco product in a manner that involves--
> >
> > > (I) the gradual reduction of nicotine yields of the product."

(Emphasis added.) Thus, in the event the Secretary, presumably through the FDA, chose not to order the gradual reduction of the nicotine yields of tobacco products, the states would be precluded from taking such action within their own borders, even if they determined that it would more effectively serve to protect the health of their own citizens.

Even more onerous is the fact that the FDA itself would be explicitly preempted under Section 903(c)(3)(B) from ordering the elimination of nicotine in cigarettes or smokeless tobacco products unless it first received approval in the form of a joint resolution passed by Congress. The same section also provides that Congress may review and disapprove any rule adopted by the Secretary that establishes, amends or revokes a tobacco product health risk reduction standard. This proposes an extraordinary level of micro-management by Congress of the regulatory affairs of a health agency which one assumes possesses greater expertise in the subject matter area than the United States Congress. Indeed, these provisions may go further to impede FDA authority than do those of any of the other bills analyzed here.

By including such provisions in federal law, rather than allowing the FDA to regulate based on scientific and medical considerations, the FDA would be limited in its authority to make future adjustments in regulating tobacco products or to respond to new scientific or medical developments.

CONCLUSION

Close analysis of the five bills considered here yields the following major conclusions.

- Preemption should be avoided except in very rare instances where it is abundantly clear and uncontroverted that federal law must "occupy the field" or the policy initiative will fail. It is arguable which subjects might qualify for this category. Some believe, for example, that health warning labels and at least some advertising belong in this category, but there is significant disagreement in this regard. Fear of inconsistent package warnings from state to state and burdens on interstate commerce may not provide a sufficient basis for preempting state authority to require additional information in the interest of most effectively disclosing hazards to citizens in their jurisdictions.[25]

- Where an overriding need for preemption cannot be demonstrated, legislation should explicitly disavow any preemptive effect in a simple, unambiguous manner. This should apply in such areas as (for example) state and local regulation of smoking in public places and enforcement of youth access restrictions, and the authority of the Food and Drug Administration (FDA) to regulate tobacco products without micromanagement by Congress. In the case of FDA authority, if it is clear that the FDA is granted authority that is broad and full, it may be appropriate to preempt the field, although this is debatable.

- Some of the principal problems with the preemption provisions contained in several

of the bills analyzed here is that they are not carefully drafted, they are located in hard-to-find places, their coverage is uncertain, and the negative inferences that might be drawn from some of their exclusions render them inconsistent with broader anti-preemption provisions found within the same bill.

- As observed recently by former Federal Trade Commission chairman Michael Pertschuk and writer David Corn, if federal "settlement" legislation includes preemptive "limits on the ability of state and local governments to go further than Congress in protecting citizens from tobacco marketing abuses," then "a bad deal is under way."[26] The public health interests of the American people will be better served if legislative proposals that either explicitly or implicitly preempt the authority of states, localities or federal health agencies to regulate tobacco products in the most effective manner are rejected.

NOTES

[1]. Reference to a "legislative body" is used as a catch-all, since the preemption examined in this paper deals principally with that which might be imposed by the United States Congress. It should be understood, however, that preemption also can be imposed by other government entities, such as administrative agencies, through the implementation of rules or orders, thus precluding conflicting or, in some cases, more stringent action by other government bodies.

[2]. A similar bill, S. 1415, also was introduced. It differs from S. 1414 in that it lacks certain provisions relating to taxation and revenue.

[3]. The imposition by Congress of limitations on the power of a federal regulatory agency is somewhat different from what is considered classic "preemption." Nonetheless, this analysis discusses the potential effects of pending legislation on the authority of the FDA in order to provide a fuller understanding of the limitations that such legislation would place on the power of any government entity -- be it local, state or federal -- to regulate tobacco products.

[4]. C.E. Koop, D.C. Kessler, G.D. Lundberg, "Reinventing American Tobacco Policy: Sounding the Medical Community's Voice" (editorial), *JAMA*, Vol. 279, No. 7 (February 18, 1998).

[5]. U.S. Public Health Service, *Smoking and Health: Report of the Advisory Committee ot the Surgeon General of the Public Health Service*, 1964.

[6]. P.L. 89-92.

[7]. M. Siegel, J. Carol, J. Jordan, R. Hobart, S. Schoenmarklin, F. DuMelle, P. Fisher, "Preemption in Tobacco Control: Review of an Emerging Public Health Problem," *JAMA*, Vol. 278, No. 10, pp. 858-863.

[8]. Id.

[9]. Id.

[10]. M. Pertschuk and D. Shopland, *Major Local Smoking Ordinances in the United States*, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, NIH Publication No. 90-479, September 1989; unpublished data compiled by the Americans for Nonsmokers Rights Foundation; *see also* "Big Tobacco's Hidden War: Hardball Politics at the Local Level as It Pursues a National Deal," *Business Week*, October 30, 1997.

[11]. Victor Crawford, *JAMA*, July 19, 1995 (cite)

[12]. M.J. Kerrigan, "A Proposed Comprehensive Tobacco Control Act in California" (Washington, DC: Smokeless Tobacco Council, Inc.), June 28, 1991. (Also quoted in American Cancer Society et al., *Report: Actions Speak Louder than Words: The Tobacco Industry's Stealth Strategy in State Legislatures*, May 28, 1996, p. 6.)

[13]. "Big Tobacco's Hidden War: Hardball Politics at the Local Level as It Pursues a National Deal," *Business Week*, October 30, 1997.

[14]. *Final Report of the Advisory Committee on Tobacco*

Policy and Public Health (C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.D., Co-chairs) (July 1997), Appendix 3, p. E1.

[15]. *Id.*, Appendix 3, p. B8.

[16]. M. Siegel, J. Carol, J. Jordan, R. Hobart, S. Schoenmarklin, F. DuMelle, P. Fisher, "Preemption in Tobacco Control: Review of an Emerging Public Health Problem," *JAMA*, Vol. 278, No. 10, pp. 858-863.

[17]. American Cancer Society et al., *Report: Actions Speak Louder than Words: The Tobacco Industry's Stealth Strategy in State Legislatures* (report), May 28, 1996, p. 5.

[18]. M. Siegel, J. Carol, J. Jordan, R. Hobart, S. Schoenmarklin, F. DuMelle, P. Fisher, "Preemption in Tobacco Control: Review of an Emerging Public Health Problem," *JAMA*, Vol. 278, No. 10, pp. 858-863.

[19]. Some argue that a similar approach should be taken with respect to interstate tobacco advertising. This approach would permit federal preemption of state or local regulation of, for example, tobacco advertising that appears in national magazines. It would retain state and local authority to restrict tobacco advertisements, such as billboards, that appear solely within their jurisdiction.

[20]. The analysis does not discuss tobacco taxation, since none of the bills proposes changes to the existing authority of states to impose excise taxes on tobacco products. In addition, the analysis does not address the distinct issues that involve the interaction of the federal government with Indian tribes and tribal organizations, although some of the pending bills contain provisions addressing this area. *See, e.g.*, Section 1003(e) of S. 1414, which, with certain exceptions, preempts states from "impos[ing] obligations or requirements relating to the application of th[e] Act to Indian tribes and tribal organizations."

[21]. N.A. Rigotti, J.R. DiFranza, et al., "The Effect of Enforcing Tobacco-Sales Laws on Adolescent Access to Tobacco and Smoking Behavior," *NEJM*, Vol. 337, pp. 1044-1051 (1997).

[22]. Advocacy Institute, Smoking Control Advocacy Resource Center, "Information Alert - Issue: Penalizing Youth for Possession of Tobacco Products: Two Views," March 27, 1998. Tobacco prevention and policy consultant Rick Kropp writes, for example: "Widespread cigarette sales to minors and blatant cigarette advertising targeting kids are major reasons why kids smoke. Easy access and targeted marketing encourage kids to smoke. To penalize young people for behaving in this way is a form of entrapment."

[23]. Title 29 U.S.C. Section 667.

[24]. An example of this is the stronger auto emission standards enacted in California, which mandated product changes for automobiles.

[25]. A substantive question involves whether an increasingly cluttered package face or advertisement might be more or less effective than having a simpler, federally-mandated label, but the fact that this question exists does not appear to justify preempting state or local authority in the area.

[26]. M. Pertschuk and D. Corn, "Tobacco Scorecard," *The Nation*, February 23, 1998, p. 15.

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By

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April 14, 1998

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MANAGING AND TREATING TOBACCO DEPENDENCE

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EXECUTIVE SUMMARY

This paper describes the necessary components of an effective national policy to manage and treat tobacco dependence, and examines the provisions for treatment of tobacco/nicotine dependence in five tobacco bills currently in the Senate: S. 1414 (the "Universal Tobacco Settlement Act") sponsored by Senators McCain and Hollings; S. 1530 (the "Placing Restraints on Tobacco's Endangerment of Children and Teens [PROTECT] Act"), sponsored by Senator Hatch; S. 1492, (the "Healthy and Smokefree Children Act"), sponsored by Senator Kennedy; S. 1638 (the "Healthy Kids Act"), sponsored by Senator Conrad; and S. 1648 (the "Preventing Addiction to Smoking among Teens [PAST] Act"), sponsored by Senator Jeffords.

Reducing the use of tobacco among those who already smoke, dip and chew is an essential part of any national tobacco control program. While preventing future illness is critical, the only way to reduce illness and death caused by tobacco in the next several decades is to lower tobacco use among those who already use these products.

Lower rates of tobacco use among adults may, in turn, contribute to reducing the rates of uptake among youth because tobacco use is, in part, spread from person to person. To some extent, reducing the rate of tobacco use overall should contribute to preventing tobacco use by new generations.

Though most tobacco product users (2/3 to 3/4) report that they would like to quit, a large proportion find quitting extremely difficult. With the support of effective nicotine dependence treatment programs, many find they can succeed, greatly reducing their risk of tobacco-related illness or death.

A national policy for funding treatment for tobacco users should include the following elements:

- All treatments should be scientifically based with proven efficacy. These treatments should be consistent with evidence based guidelines such as those developed by the Agency for Health Care Policy and Research or scientific literature showing demonstrated efficacy of a treatment approach.

- A mechanism should be established that will continue to update the guidelines for the treatment of tobacco dependence.

- Treatments of varying intensities that target the needs of tobacco users should be available to all tobacco users in the United States.

- Specialized providers of tobacco treatment should be certified through a nationally-based examination and must demonstrate continued competency through mechanisms that might include obtaining continuing education credits. This certification will ensure that those providers of tobacco cessation treatment are qualified and are aware of up-to-date effective treatment techniques.

- Training should be provided to health care providers, allied health professionals and health plans that include at minimum basic factual information and instruction on various intensities of treatment methods.

- A national resource center should be established that provides information on treatment certification, resources and materials and updated information on effective treatments and guidelines. The Centers for Disease Control and Prevention currently maintain a tobacco website.

- Outreach efforts are needed in order to inform the public of the availability of treatment. These efforts must be particularly targeted toward children and other underserved populations including ethnic minorities, the uninsured and others who are economically disadvantaged.

- Treatment policies must be coordinated with other Federal and State initiatives.

- It is critical to address barriers and provide incentives for tobacco cessation treatment in health care delivery and other settings.

- Research must be supported to develop new technologies and methods for treatment of tobacco users, to improve access to treatment, and to evaluate treatment programs. Included should be a consideration of harm reduction strategies and the costs/benefits of those strategies for those who are unwilling or unable to maintain total abstinence. Currently little is known about the effectiveness of harm reduction strategies or whether such strategies may detract from abstinence oriented approaches.

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INTRODUCTION

Reducing the use of tobacco among those who already smoke, dip and chew is an essential part of any national tobacco control program because:

- It will take decades before preventing the new use of tobacco products has any impact on the occurrence of illness and death from tobacco. The only way to reduce illness and death caused by tobacco in the next several decades is to lower tobacco consumption among those who already use these products.

- Most (2/3 to 3/4) of those who use tobacco products would like to quit but often find this extremely difficult. With assistance and support, many find that they can succeed.

- Reducing smoking helps control the problems caused for nonsmokers by exposure to environmental tobacco smoke.

- Lower rates of tobacco use among adults may contribute to reducing the rates of uptake among youth because tobacco use is spread, in part, through "person to person" interaction. To some extent, reducing the rate of tobacco use overall should contribute to preventing tobacco use among children.

This paper is about the treatment of nicotine dependence. While often thought of as "smoking cessation" or "tobacco use cessation," these terms have become outdated. The act of cessation is something that the user accomplishes as he or she becomes abstinent from using tobacco products. It does not describe what a clinician does in treating that person's tobacco problem or the processes which a person undergoes to achieve abstinence.

The work of the clinician and the steps taken by individuals in quitting are more accurately thought of as "treatment" or "management" of nicotine dependence. Furthermore, a number of experts in the field are actively debating whether abstinence from nicotine is the only successful endpoint for those who are addicted to tobacco products. Nicotine maintenance, the ongoing use of nicotine in a form far less poisonous than a cigarette, may be an appropriate temporary or permanent solution for many tobacco users. Thus, the term "cessation" appears overly limited in considering possible future clinical approaches to the problem of tobacco dependence.

Needed is an infrastructure to ensure availability and dissemination of effective treatment techniques on a cost-effective basis. Close monitoring, evaluation, and quality control of programs are essential. Tobacco cessation and reduction programs should meet national standards for accreditation; providers of treatment should be certified as having mastered relevant treatment content. Barriers to widespread availability of treatment should be identified and addressed. These barriers certainly include cost and failure to reimburse tobacco intervention services. The program should be closely informed by current research and should be responsive to new research findings. The program may help to identify additional questions and priorities for

further research which in turn will improve the quality of treatment options available. Other facets of a model tobacco control program (e.g., media campaigns, increased prices) should increase interest in treatment options. The resources must be available to meet increased demand for treatment.

It should be noted that the Federal government is one of the largest providers and payers in the health care system through the military and the Veterans Administration, on the one hand, and through Medicare on the other. This provides an opportunity --indeed, a necessity--for the Federal government to directly implement the types of policies and programs described in this document, and not simply to recommend and fund what is prescribed for others. Model policies implemented by the federal government through its agencies and programs also can serve as exemplars to the states.

Elements of a model nicotine dependence program include both basic (minimal) and specialized treatment programs. Low-cost, low-intensity programs have been found to be effective and should routinely be integrated into health care. Several pharmacological agents have been demonstrated to improve quit rates and should be widely available to interested tobacco users. More specialized and intensive tobacco treatments should be available to more dependent smokers who may need more assistance in quitting or in managing their nicotine dependence. Tobacco use should be viewed as a chronic long-term relapsing and remitting condition which may require repeated treatment. Barriers to treatment access including most notably limited availability (e.g., programs must be available when the tobacco user is ready to change his/her behavior and must be offered at convenient times and locations) and lack of reimbursement for services must be reduced or eliminated insofar as possible.

In order to increase the availability of treatment services and resources, training programs and workshops on nicotine dependence and treatment should be provided to health care providers, allied professionals and health care delivery plans. Additionally, tobacco content and tobacco treatment issues should be incorporated into the curricula for professional training programs including medicine, dentistry, nursing, and other allied health professions.

THE COMPONENTS OF AN EFFECTIVE TREATMENT POLICY

The following policy recommendations were guided by the recommendations made by the Ad Hoc Working Group on Treatment of Tobacco Use, which was convened by the Center for the Advancement of Health.[1] Key topics include: infrastructure to support basic level of intervention, specialized treatments, certification of specialized treatment providers, accreditation of treatment programs, centralized resource/guidelines update, outreach for treatment, coordination of other state and federal initiatives, and research. We also consider the impact of the proposed national policy on women and socioeconomically disadvantaged populations, impact on youth, history of federal legislation/regulation, and synergistic effects with other tobacco control policies. Finally, we critique provisions for treatment of nicotine dependence in five tobacco bills currently in the Senate.

Infrastructure to Provide Basic Level of Intervention

Goal: **Effective nicotine cessation and management programs will be available to all who are interested.** Much can be accomplished by delivering low-cost, low-

intensity interventions to large populations of tobacco users, primarily using existing health-care delivery channels which may also include schools and worksites. More intensive and more costly (yet perhaps more cost effective) intervention programs also should be available to more dependent smokers or those with life or limb threatening medical conditions. Although abstinence will be the primary objective, there are many tobacco users who are unable or unwilling to quit altogether. It will be important to consider "harm reduction" approaches including alternative nicotine delivery systems for these tobacco users while maintaining complete abstinence as a preferred alternative. It should be recognized, however, that little is known about the effectiveness of harm reduction strategies or whether such strategies may detract from abstinence oriented approaches.

Training programs should be offered to health care providers, allied health professionals and health plans that include at a minimum basic factual information and instruction on minimal treatment methods. More intensive training should be available to interested health professionals who prefer a more thorough grounding in tobacco knowledge and intervention techniques. Completion of such training programs should not, however, be a requirement or a barrier for health care providers who wish to provide minimal interventions, but rather should be required for those who wish to provide more intensive treatment.

Method: In order to target a large number of tobacco users, funding is essential to develop health care delivery infrastructures that enable the assessment, assistance and follow-up of tobacco users, based on established scientifically recognized guidelines. The guidelines established by the Agency for Health Care Policy and Research (AHCPR) represent the best current practice. These guidelines must be updated regularly and must be based on a rigorous assessment of the scientific literature. The AHCPR guidelines provide recommendations for minimum intervention by health care providers. A key component of the current guidelines is the need to systematically identify all tobacco users.

Funding these infrastructures should not only support resources such as treatment materials and dedicated staff, training, and systems for evaluation of programs, but also incentives to make prescription and over-the-counter pharmacological interventions, with demonstrated proven effectiveness and FDA-approved, available to smokers. The AHCPR guidelines concluded that most smokers can benefit from such pharmacological treatment. The evidence for the effectiveness of brief advice is provided by the AHCPR meta-analyses which demonstrated that brief intervention (3 minutes or less) could improve success by approximately 20% relative to no intervention. The proposed infrastructure is intended to provide basic level of intervention consistent with the AHCPR recommendations for brief advice and pharmacologic treatment.

We also recommend availability of already existing effective treatments that can be accessed for those who choose not to have contact with a primary health delivery agency. These treatments may involve the use of FDA-approved over-the-counter pharmacological agents or future devices that also provide ancillary self-help behavioral treatments. These treatments may also include telephone support. For example, California has instituted an effective telephone helpline counseling service for adult and minor cigarette smokers. A mechanism should be established to make these programs readily available to tobacco users.

Furthermore, funding should be provided for innovative treatments. Possibilities include individually tailored computer messages, which have shown

promise to enhance treatment success and tobacco cessation contests which can be offered in worksites or communities and possibly to larger populations. Contests can increase awareness of and interest in quitting and also can facilitate enrollment in effective tobacco cessation programs.

For those who are unable to obtain tobacco cessation treatment through contact with the health delivery channel because they are uninsured, low cost or free treatment and pharmacological products can be made available to individuals by having them complete a treatment request at a state health agency, one of the health care delivery channels, worksites, Women Infants and Children clinics or schools and being provided vouchers for the purchase of pharmacological products or other scientifically recognized aids to cessation. Treatment and vouchers should be readily available and accessible in locations serving low income individuals.

Funding mechanisms: The infrastructure would be funded through block grants made available to the states. The states will accept grant applications from entities including nonprofit and for profit organizations and individuals and will determine funding based upon whether the proposed treatment is evidence-based and follows nationally based criteria for accreditation (developed by the DHHS), has broad outreach and, where appropriate, involves trained and certified staff.

The quality of the services supported through the state grants can be monitored by report to the DHHS. States shall prepare and submit to the Secretary of DHHS a State plan that describes:

- the manner in which the State intends to ensure that funded programs are consistent with Agency for Health Care Policy and Research or other evidence-based guidelines;
- the specific programs that will be funded and the amount of funds that will be used for each;
- the activities to be conducted under such programs, including the populations to be served, the eligibility standards for such populations, if any, and the goals and purposes of such programs;
- the measurable objectives that will be used to evaluate program outcomes;
- the procedures to be used by the state to conduct outreach to potential program participants; and
- the manner in which such programs will be coordinated with other Federal and State tobacco control initiatives.

Specialized Treatments

Goal: **Make more intensive, specialized treatments available to those who need them.** Not all tobacco users will benefit from the brief interventions delivered by the basic level of intervention established by the infrastructure or from self-help methods. Research literature has shown that some individuals require a more intensive treatment that may involve a greater number of follow-up sessions and/or pharmacological treatment. Heavily dependent individuals may benefit the most with this treatment approach. Other tobacco users who experience a comorbid disorder, who are pregnant and who do not quit tobacco use in spite of physician advice, or who do not have resources either psychologically or socially available to them may require more intensive treatment. Intensive treatments (as well as more minimal interventions) should be offered to hospitalized patients, especially to those patients with conditions related to tobacco use. Currently, far more work has been done in outpatient than in inpatient settings.

An apparent conundrum is posed by the fact that the AHCPR guidelines found that generally the more intense the intervention,

the better the abstinence outcomes, yet most tobacco users appear to prefer minimal intervention approaches. This may be due in part to the relative lack of availability of more intensive intervention methods and the very limited efforts to develop and promote specialized interventions that are more attractive to tobacco users. A challenge will be to offer effective specialized treatments that will reach a substantial proportion of tobacco users who may be in need of such treatments.

Method: Specialized tobacco treatment delivery services can either be a stand alone treatment facility or be incorporated in the infrastructure that provides basic level of intervention. These treatment services may include not only the basic level of care, but also more intensive sessions involving a longer duration of sessions, more frequent sessions and content of treatment that addresses issues more specific to the needs of the tobacco user. Specialized, as well as more basic, tobacco treatments should be better integrated with existing community-based treatment programs (e.g., substance abuse, mental health, public health, etc.). Proven behavioral and pharmacologic treatments can be delivered directly to individuals through multiple channels (e.g., general community, worksite, schools, health care organizations, churches), in varying levels of intensity (e.g., individual counseling; group programs; outreach telephone counseling; varying doses, lengths and combinations of pharmacotherapies).

Funding mechanism: Funding for these services will come from the funds to develop and maintain an infrastructure or grants to a stand alone treatment entity, and also from providing reimbursement for those who are uninsured or part of the Medicare and medical assistance programs. In addition, specialized treatment delivery services can obtain state funding to provide services to indigent populations. Reimbursement should also come from such currently existing sources as third party payment for fee for service and coverage by managed care organizations.

Certification of Specialized Treatment Providers

Goal: **Specialized treatment providers must demonstrate competency to provide tobacco cessation treatment.** This demonstration of competency will help to assure good quality of care.

Method: Specialists for tobacco cessation treatment could have a background in various disciplines, e.g., medicine, psychology, counseling, nursing, addictive disorders, health education, respiratory therapy, etc., and should not be restricted to one particular discipline. In order to ensure that treatment is provided by qualified individuals, a national certification process needs to be instituted. This certification process could involve a national examination that tests the knowledge of the treatment specialist in the area of nicotine addiction and the most effective currently available scientifically-based treatments. In addition, a specified number of supervised hours of training in tobacco cessation techniques is also recommended. In order to ensure the continuing competency of these specialists in the treatment of tobacco use disorders, a mechanism needs to be established in which the treatment specialist demonstrates awareness of updated information in this area. This mechanism could be completion of continuing education credits in areas of nicotine treatment and addiction from accredited programs.

The type of certification procedure can be similar to the "competency based model" instituted for providers of substance abuse treatment. This model entails a national written examination, experience that demonstrates training in substance abuse treatment, and a written case report and oral

examination. Administering of oral examinations involves difficult and complex logistics, and case based written examination questions plus factual questions may be sufficient. Although the exact details of the certification process remain to be specified, a central point is that certification will be based upon demonstrated competence and not upon professional affiliation or specific academic degrees. National certification standards and guidelines for certification should be formulated by the Secretary of DHHS with expert input.

Funding mechanism: Funds for administering certification requirements including the written examination should be made available as part of the block grants to the states.

Accreditation of Treatment Programs

Goal: **Guidelines for the approval or accreditation of treatment programs should be developed by the DHHS and made available to states that are funding treatment programs to ensure the best quality of care for tobacco users.** Accreditation standards are not intended to discourage new or innovative programs, but to subject all programs to careful monitoring and evaluation. A federally constituted advisory board which reports to the Secretary of DHHS should promulgate appropriate monitoring and evaluation standards and these standards should be updated regularly. States will be responsible for monitoring programs and for ensuring adherence to federal evaluation standards.

Method: Programs must engage in systematic evaluation and results of evaluation must be reported regularly to state funding agencies and to the Secretary of DHHS. State funding agencies will adhere to federally recognized standards for evaluation. Common evaluation standards are essential. It is recognized that programs may attract very different participants and that comparisons of absolute abstinence outcomes may be misleading (although there are methods of adjusting for participant characteristics). The intent of this section is not to require all treatment providers to engage in stringent systematic outcome research, rather any advertised abstinence claims must be supported by data and must not be inaccurate or misleading. False and/or misleading claims of effectiveness may be grounds for removal of accreditation and eligibility for state funding or reimbursement.

Funding mechanism: Funding should be made available to the Secretary of DHHS to implement these services.

Centralized Resource/Guidelines Update

Goal: **A centralized and national resource should be made available to entities that are interested in providing treatment as well as to individuals who want to access the variety of treatments that can be made available to them.** In addition, there should be regular updates of the AHCPR smoking cessation guidelines (e.g., every two years). Whether the agency responsible for the update in guidelines will be the same as the agency responsible for the centralized resource is left up the discretion of the Secretary of DHHS.

Method: The Secretary of DHHS will determine the location of this centralized and national resource. This national resource would include up-to-date information on effective, scientifically proven treatments for tobacco cessation, model treatment programs, guidelines for criteria to use in the accreditation of treatment programs, information on how to evaluate and obtain access to tobacco cessation products, pharmacological treatments and self-help or programmed computerized behavioral

programs as well as other programs or products found to be effective in the treatment of tobacco use. Currently the Office of Smoking and Health of the Centers for Disease Control and Prevention maintains a tobacco data base.

Funding mechanism: Funding should be made available to the Secretary of DHHS to implement these services.

Outreach for Treatment

Goal: **Outreach to the public either by media or nonmedia avenues to educate them about the benefits of quitting and to make them aware of available treatment programs is necessary to increase the utilization of services and produce a subsequent decrease in the number of people using tobacco.** In addition, marketing research is needed to determine the most attractive cessation modalities to tobacco users and methods of recruiting them to treatments which are known to be effective. Based on the experience in California, outreach to create a demand for tobacco cessation efforts by stimulating the motivation to quit is crucial in order to increase utilization of tobacco treatment programs. Enhancement of motivation can result from other federal and state initiatives to reduce the consumption of tobacco (e.g., increased taxes, bans on tobacco use in public areas, anti-tobacco use campaigns). A goal of previous community interventions was to create persistent and inescapable messages that would create a social environment conducive to tobacco cessation.

Method: Public awareness campaigns, such as through television and radio media, billboards, brochures provided at worksites, health care delivery services, WIC clinics, unemployment centers, should include educational information on the negative consequences of tobacco use, the benefits of cessation, and the resources that are available to quit tobacco use. Active outreach to underserved low SES and ethnic minority populations is necessary including promoting programs in WIC clinics and unemployment centers. Cessation and harm reduction programs must be able to meet increased demands for services that might result from public awareness campaigns including those undertaken as part of other tobacco control initiatives. Temporary and seasonal fluctuations in demand for services are likely, although these fluctuations will be influenced by specific promotions and more general public awareness campaigns.

Funding mechanism: Public awareness campaigns should be part of the funding for the infrastructure or funding made available to the states and a part of other tobacco initiatives or policies that may be implemented. Public awareness campaigns focused on cessation must be coordinated with and complement public awareness campaigns on other tobacco control issues.

Coordination of other State and Federal Initiatives

Goal: **Tobacco cessation efforts should be part of other initiatives aimed at the prevention and reduction of tobacco use.** This coordination will potentially provide an additive and synergistic effect. Coordination is important both between diverse tobacco related initiatives and between relevant state and federal entities.

Method: An administrative structure and scientific and public policy advisory board should be established by the state to oversee all tobacco control efforts and to coordinate efforts made in prevention, including counter-advertising and media campaigns, and other tobacco reduction efforts with tobacco cessation. The scientific and public advisory board should convene on a quarterly basis

either in person or by conference call with at least one annual meeting. In addition, there should be a federally constituted advisory board which meets regularly and which reports to the Secretary of DHHS. This advisory board should include experts in diverse areas of tobacco control and treatment.

Funding mechanism: The federal government should make funds available to the states and to the Secretary of DHHS to develop this infrastructure.

Research

Any effective tobacco reduction program must be supported by ongoing research. Research already has led to major advances in the treatment of tobacco dependence, including the development of effective behavioral treatments as well as pharmacotherapies. Further research needs to be conducted to more thoroughly understand the basis and components of nicotine/tobacco addiction and to adequately serve the needs of tobacco product users who want to quit using these products, including smokeless tobacco, cigars and pipes.

More study is needed, for example in the following areas:

- Development of tobacco treatment programs targeted to special populations such as adolescents, pregnant women, recovering substance abusers, smokers with comorbid disorders, ethnic/racial groups and low income tobacco users.

- Development of tobacco cessation programs targeted to high risk populations, most notably those who suffer from medical conditions worsened by tobacco such as peripheral artery disease, diabetes, coronary heart disease, chronic obstructive lung disease, cancer, etc.

- Development of new treatments including pharmacotherapies, tobacco cessation devices, methods for harm reduction (recognizing that little is known at present about the effectiveness of harm reduction strategies) and complementary and stand alone behavioral programs or other innovative interventions as well as treatments that effectively combine behavioral and pharmacologic approaches.

- Determination of cost effective methods of tobacco treatment.

- Determination of ways to increase delivery including health services delivery, acceptability, accessibility and utilization of treatment services.

Impact of the Policy on Women and Socioeconomically Disadvantaged Populations

Socioeconomically disadvantaged populations traditionally have not been well served by nicotine dependence programs (although this statement also is true for the vast majority of tobacco users). These populations now tend to have the highest prevalence of nicotine use. Primary medical contacts may be through emergency room visits in which brief tobacco cessation counseling is unlikely. Socioeconomically disadvantaged tobacco users tend to have less access to managed care in which AHCPR type guidelines are more likely to be implemented. There are significant barriers of both access and cost to specialized treatment programs including individual and group behavioral programs; these barriers have been particularly acute for low income tobacco users. Transportation to programs is likely to be a significant barrier for many of these tobacco users. Accessibility of pharmacologic treatment also is an issue. Typically, patients are required to make a rather substantial

upfront payment to procure a prescription or over-the-counter drug.

Policy changes can help to reduce barriers of cost and access by covering treatment costs, especially for low income tobacco users, including costs of pharmacologic adjuncts with proven efficacy. Intervention including pharmacologic adjuncts should be available either free of charge or at minimal cost. The requirement for sizable initial payments to procure pharmacologic treatment should be eliminated especially for low income tobacco users. In addition, barriers of location and access need to be addressed. Thus support programs should be available in locations that serve low income patients. Treatment should be sensitive to issues of low SES and ethnic diversity. Content should be accessible to individuals with low literacy skills and programs/materials should be available in languages other than English.

Women tend to be users of smoking cessation programs more than are men. Increasing the accessibility and attractiveness of both basic and specialized treatments should be beneficial for both genders but perhaps especially for men. Women tend to use the medical care system more than do men and therefore are more likely to be reached with basic level of care. The AHCPR guidelines did not recommend differential treatment for tobacco users by gender. Treatment programs should be sensitive to special issues pertaining to women including tobacco use during pregnancy and implications for osteoporosis. Child care issues may be important barriers to treatment for many women especially those who are low SES. Programs that specifically address weight and stress related issues may be especially attractive to and effective in recruiting female participants. These programs may represent one facet of marketing or offering treatments that are potentially attractive to the target audience.

Impact of the Policy on Youth

At this point far less is known about effective strategies for treating nicotine dependence in youth than in other populations. Research is clearly needed. Both basic and specialized nicotine dependence programs must be available for adolescents.

One issue will pertain to guidelines for pharmacologic treatment in underage tobacco users. Adolescents often meet criteria for nicotine dependence and older adolescents may have a history of multiple unsuccessful quit attempts. Basic care must be responsive to the needs of youth as well as adults. Thus routine identification of tobacco users is critical in youth and adolescents. Those who are current tobacco users should receive firm unequivocal advice to quit and should have access to additional treatment including recognized pharmacologic adjuncts and effective behavioral interventions. Programs might be offered in additional places frequented by adolescents including schools, worksites, and teen programs. Treatment may be more effective in the context of a comprehensive national tobacco control strategy in which minors do not have ready access to tobacco products, in which tobacco products are expensive, and in which there are relatively few opportunities for public tobacco consumption.

Issues of comorbidity may be important in adolescent smokers as well as in adults. Nicotine dependence treatment should be offered to those who evidence other forms of chemical dependency and chemical dependency programs should be tobacco free for both adolescents and adults. Nicotine dependence treatment should be available to those with psychiatric comorbidity. It also should be noted that adult tobacco users are a "vector" for tobacco use among adolescents, including serving as a major source of tobacco products. Emphasis on adult cessation should have indirect impact on adolescents and will

lead to reduced modeling of tobacco consumption.

History of Federal Legislation/Regulation

There has been relatively minimal federal legislation/regulation in the area of managing and treating nicotine dependence. The AHCPR has issued smoking cessation guidelines which may serve as an initial basis for accrediting tobacco intervention programs, including reimbursement for services. However, this is not currently at the level of legislation or regulation. Of particular concern is the fact that the AHCPR has no plans at present to issue further smoking cessation guidelines or to update the current guidelines. Several bills now pending in Congress do require accountability of tobacco dependence programs as a condition for reimbursement.

The primary Federal legislation/ regulation in the cessation area pertains to: 1. pharmacologic adjuncts and devices and 2. claims of treatment effectiveness. The Food and Drug Administration has required evidence of safety and effectiveness for drugs marketed as aids to tobacco use cessation. The FDA also has purview over tobacco cessation devices. To date, several pharmacologic adjuncts have been recognized as safe and effective aids to tobacco cessation and others are in process.

There has been very poor enforcement of regulations pertaining to tobacco cessation aids. This has had the unfortunate effect of allowing untested and ineffective products to crowd the marketplace. Also, legislation carves out broad exceptions to the FDA's "safe and effective" criterion for marketing products. Products marketed as homeopathic remedies and as dietary supplements are not required to meet such standards, thereby resulting in the marketing of untested and ineffective products. This contributes to consumer confusion and disaffection with tobacco cessation aids. Just as uniform, science-based standards are proposed for treatments and treatment providers, a clear standard for products and devices also needs to be applied and enforced.

The Federal Trade Commission is responsible for regulating claims of effectiveness for tobacco cessation products and programs in advertising and elsewhere and has investigated claims of treatment effectiveness for several types of tobacco cessation programs including hypnosis. FTC oversight may be especially important as greatly increased funds are available for tobacco cessation products and services.

There are, however, some serious concerns with respect to FTC regulation of tobacco products and aids to tobacco cessation. The FTC has not been aggressive in regulating advertising claims for tobacco products. Implied claims that low tar/nicotine cigarettes are "safer" alternatives to high tar brands have gone largely unchallenged by the FTC.

It is critically important that providers of cessation products document advertised success rates. In addition to the AHCPR guidelines, meaningful standards for evaluating advertised claims of effectiveness should be promulgated and published. These standards should be clear both to providers and to the general public. Included in standards for advertised claims might be a report of treatment outcomes at a defined outcome period (e.g., 6 months) including dropouts and nonrespondents to follow-up. Tobacco abstinence or reduction outcomes could be defined both in terms of continuous abstinence and point prevalence abstinence (e.g., no tobacco use in the previous 7 days).

Synergistic Effects With Other Policies

Managing and treating nicotine dependence must be integrated with other tobacco control policies. A comprehensive tobacco control program will increase

demands for tobacco cessation services and these services must accommodate these increased demands (e.g., a substantial increase in excise tax may create increased demands for assistance in quitting; a targeted media campaign may yield substantial but temporary increases in demands for services). Ideally, each of the policies will reinforce each other: restricted youth access, increased restrictions on involuntary smoke exposure, increased excise taxes, dramatic reduction in tobacco promotion along with counter advertising. Each of these policies should have natural impact in promoting cessation and harm reduction among continuing nicotine users, but cessation should be deliberately and systematically encouraged as well. A shortcoming of some previous community interventions is that they have promoted tobacco cessation (e.g., through media campaigns), but have provided little in the form of specialized cessation resources for dependent tobacco users.

EVALUATION OF LEGISLATION

The following section paraphrases the relevant parts of each of the bills, and evaluates their strengths and weaknesses.

S. 1492 - The Healthy and Smokefree Children Act

This bill includes a "National Tobacco Usage Reduction and Education Block Grant Program," which establishes a system of state block grants "
(for the purpose of planning, carrying out, and evaluating tobacco use reduction and education activities." Among other activities, states receiving grants should use them to offer "programs to assist individuals in quitting the use of cigarettes or other tobacco products";

In support of these state programs, HHS would establish a model smoking cessation program that may be used by the States in the design of State-based smoking cessation programs. Such a model program shall provide for the provision of grants and other assistance by such States to eligible entities and individuals in the State for the establishment or administration of tobacco product use cessation programs that are approved.

In addition, HHS, "using the best scientific information...shall promulgate regulations to provide for the approval of tobacco product use cessation programs and devices. Such regulations shall be designed to ensure that tobacco product users, if requested, are provided with reasonable access to safe and effective cessation programs and devices. Such regulations shall ensure that such individuals have access to a broad range of cessation options that are tailored to the needs of the individual tobacco user."

Block grant funds would also be used for a "tobacco usage reduction and education program," including "activities to reduce tobacco usage through media-based and nonmedical based education, prevention and education campaigns designed to discourage the use of tobacco products by individuals who are under 18 years of age and to encourage those who use such products to quit."

Strengths: The proposed bill has provisions for:

1. making smoking cessation available to all smokers;
2. a method to regulate and approve tobacco cessation programs and devices so that tobacco users will have access to safe and effective programs and devices;
3. a model tobacco cessation program;
4. coordination with other tobacco usage reduction and education activities. Funding for the tobacco cessation programs will be made available through block grants. This bill also states that

5. the Secretary should provide for the conduct of research concerning the development of methods, drugs and devices to discourage individuals from using tobacco products and assist individuals who use such products in quitting such use.

Weaknesses: This proposal lacks:
1. more defined and extensive emphasis on outreach efforts;
2. provisions to update guidelines;
3. specifications for the evaluation of tobacco product use cessation programs and devices;
4. specific funding for training of health professionals or health plans;
5. discussion of certification of smoking specialists (although #2-5 could be considered under establishing regulations to ensure safe and effective programs and devices to tobacco users);
6. establishment of a national resource center.

S. 1530 - The PROTECT Act

S. 1530 supports tobacco management and treatment through two mechanisms. It permits states to use the federal portion of Medicaid reimbursements (contingent upon approval of a state plan) to carry out a variety of tobacco control activities, including programs "consistent with the smoking cessation guidelines issued by the Agency for Health Care Policy and Research".

It also establishes a "National Anti-tobacco Product Consumption and Tobacco Product Cessation Public Health Program," that, among other purposes, would "assist individuals who consume [tobacco] products to discontinue use." Half of the program funding would be provided to the states through block grants. HHS, working with state and local public health officials, and private for-profit and non-profit entities, and coordinating the program through Centers for Disease Control, Office of Smoking and Health, would carry out a variety of direct federal activities, including:

- Educational efforts that "shall include the development of materials that advise members of the public who consume tobacco products of the risks of continuing to use such products and the benefits of discontinuing the use of these products;"

- a "cessation education" program, administered by the Center for Disease Control and Prevention in consultation with State and local public health officials, to "inform consumers of tobacco products about effective therapies for ceasing the consumption of tobacco products. Such actions shall be consistent with the tobacco use cessation guidelines issued by the AHCPR;"

- a "model smoking cessation program that may be used in the design of State-based tobacco cessation programs. Such model program shall provide for grants and other assistance by States to eligible entities and individuals in the State for the establishment or administration of tobacco product use prevention and cessation programs."

Strengths:.This bill provides for
1. a model treatment program that may be used by the State which is consistent with AHCPR guidelines;
2. educational and public awareness efforts for tobacco cessation products and programs;
3. a national resource center;
4. accountability and evaluation of funded treatment programs;
5. funding for outreach efforts;
6. coordination of Federal and State initiatives and

7. allocation of research money for the development of prevention and treatment modalities with respect to tobacco use and cessation.

Weaknesses: This proposal does not specify the methods to ensure the quality in care provided to tobacco users who want to be treated. These methods include :

1. the certification for the tobacco treatment specialist;
2. updating guidelines for treatment; and
3. training health care professionals.

S. 1414 – The Universal Tobacco Settlement Act

This bill establishes a "National Smoking Cessation Program" that provides for "grants to eligible public and nonprofit entities and individuals for smoking cessation purposes." Organizations can use grants to establish " tobacco use cessation programs;" individuals can use grants to enroll in such programs, or purchase treatment devices. Grants to individuals may be offered as vouchers for approved programs and devices.

DHHS shall establish, "[u]sing the best available scientific information," regulations to approve tobacco product use cessation programs and devices. The regulations shall "ensure that tobacco product users, if requested, are provided with reasonable access to safe and effective cessation programs and devices...[and]shall ensure that such individuals have access to a broad range of cessation programs that are tailored to the needs of the individual tobacco user."

S. 1414 also establishes a "National Reduction in Tobacco Usage Program," administered by DHHS, that would award grants to eligible public and nonprofit entities, including state health departments, "to carry out activities designed to reduce the use of tobacco products." These activities would include "media-based and nonmedia-based education, prevention and cessation campaigns designed to discourage the use of tobacco products by those who are under 18 years and to encourage those who use such products to quit."

Strengths: This bill makes provisions for:

1. providing treatment accessible to all individuals;
2. promulgation of regulations by the DHHS secretary to provide approval of tobacco product use cessation and devices in order to provide reasonable access to safe and effective cessation programs and devices;
3. providing a broad range of treatment cessation programs tailored to the needs of the individual;
4. providing funding for campaigns to encourage those who use tobacco to quit; and
5. research funds allocated for the development of methods, drugs and devices to assist individuals who use tobacco products in quitting such use.

Weaknesses:

1. No discussion is given regarding the coordination of federal and state initiatives and rigorous outreach programs.
2. Furthermore, individuals can be given vouchers that are exchangeable for treatment. Not all individuals will require vouchers, particularly if they are affiliated with a health care delivery service or worksite. This may result in redundant payments for those who have services already available to them.
3. No specifications are given as to the regulations that will be promulgated by the Secretary to provide the approval of tobacco product use cessation programs. Presumably these regulations would include scientifically-based guidelines for effective treatments, accountability and evaluations of treatment programs, certification of tobacco treatment

specialists, and training programs for health care providers.

S.1638 - The Healthy Kids Act

The bill would establish a "National Tobacco Cessation Program," through which DHHS could "award grants to, and enter into contracts and cooperative agreements with, public and private entities for the purpose of expanding the availability and utilization of tobacco use cessation services[, including] planning, establishment or administration of tobacco use cessation programs."

The legislation stipulates that "[p]rograms receiving assistance...shall provide a range and quality of services consistent with the most recent cessation service guideline issued by the Agency for Health Care Policy and Research. Using the best available scientific information, the Secretary shall promulgate such additional guidelines as are necessary to assure the quality, accessibility and cost effectiveness of services receiving funds."

Strengths:

1. This bill discusses using funds not only to expand the availability of tobacco use cessation services, but also expanding the utilization of these services;
2. the funds will be used to plan, establish and administer tobacco cessation programs, thereby providing a wide range for the use of these funds to increase the availability and utilization of tobacco use cessation services;
3. programs receiving funds must provide services consistent with the guidelines issued by the Agency for Health Care Policy Research;
4. HHS shall promulgate additional similar types of guidelines to assure the quality of services; and
5. research is promoted on the effectiveness of drugs and devices in assisting individuals to stop using tobacco products.

Weaknesses:

1. This proposal does not specify the methods to ensure the quality in care provided to tobacco users who want to be treated. These methods include : (a) the certification for the tobacco treatment specialist, (b) training programs for health care professionals, (c) updated guidelines for treatment; and (d) evaluation of treatment programs;
2. no provisions are made to develop a national resource center that will provide information to providers of tobacco treatment services, including model tobacco treatment programs, and to tobacco users;
3. no methods to evaluate the programs or accountability are described;
4. no coordination with other state and federal initiatives for tobacco control; and
5. no research discussed for behavioral treatments or other innovative or broader approaches to treatment, developing and evaluating treatments for special populations, addressing barriers to treatment.

S.1648 - The PAST Act

The bill would allot specific percentages of a trust fund to states for use in providing "smoking cessation programs". States would prepare and submit to DHHS plans to use these funds for:

A. activities that include science-based programs designed to assist individuals who want to quit their use of tobacco products; training in cessation intervention methods for health plans and health professionals including physicians, nurses, dentists, and other health care providers;

and programs to encourage health insurers and health plans to provide coverage for science-based tobacco use cessation treatment;

B. planning, administration and educational activities related to the activities mentioned in A; and

C. monitoring and evaluation of activities carried out under A and B.

The tobacco use cessation activities may be conducted in coordination with a number of other federal programs and agencies. DHHS may provide technical assistance in planning and operating the activities that will be carried out. States will not be allowed to make cash payments to intended recipients of tobacco use cessation services. Financial assistance will not be made available to any other entity than public or nonprofit private entity.

More specifically, state plans must meet the following conditions:

- the plan is developed by the State agency with principal responsibility for public health programs in consultation with an advisory committee;
- the plan provides for tobacco use cessation treatment consistent with the smoking cessation guidelines issued by the AHCPR, or other evidence based guideline approved by the Secretary;
- the plan specifies the population in the State for which such activities are to be carried out, and specifies the populations in the state that have a desperate need for such activities;
- for each population specified in (3), the plan contains a strategy for expending such payments to carry out such activities
- a plan for training in tobacco use cessation methods for health plans and health professionals, including physicians, nurses, dentists and other health care providers;
- the plan ensures access to smoking cessation programs for rural and underserved populations;
- the plan describes measurable objectives, developed in consultation with the Secretary, that will be used to evaluate program outcomes. Uniform collecting and reporting of information on levels of youth and adult use of tobacco products will be developed by the Secretary and used by the States.

This bill is quite extensive in describing the allotments to states and payment of these allotments to states, application by states for payment, accountability (reports, data and audits), withholding of funds due to misuse, nondiscrimination and criminal penalty for false statements.

Strengths: The strengths of this bill include:

1. periodic analyses of the best available scientific information in the area of smoking and tobacco use product conducted by the Secretary, acting through the Administrator of the Agency of Health Care Policy and Research;
2. science-based treatment programs using AHCPR as well as other evidenced guidelines approved by the Secretary;
3. training in cessation intervention methods for health plans and health professionals;
4. programs to encourage health insurers and health plans to provide coverage for science-based tobacco use cessation treatment;
5. monitoring and evaluation of activities that are carried out using uniform criteria;
6. accessibility to smoking cessation programs for rural and underserved populations;
7. research targeted at an outline of cost-effective, accessible, and successful methods for tobacco use cessation among adults and youths who want to quit.

Weaknesses:

1. no certification for smoking cessation specialists;
2. no discussion of programs to increase outreach and activities to increase the desire for tobacco treatment services;
3. no discussion of the need to integrate with other state and federal tobacco control initiatives;
4. no provisions for a national resource center;
5. no guidelines for model tobacco treatment programs;
6. title should be tobacco treatment programs rather than smoking cessation programs.

CONCLUSION

Many of the elements of an effective national policy for managing and treating nicotine dependence are known and accessible. Critical components of such a policy include:

- Infrastructure to provide basic level of intervention and more intensive, specialized treatments
- Certification or evaluation of specialized treatment providers and accreditation of treatment programs
- A centralized and national resource that includes up-to-date information on effective scientifically proven treatments for tobacco cessation
- Regular updates of scientifically based tobacco cessation guidelines
- Active outreach to increase utilization of effective treatment services
- Coordination of tobacco cessation efforts with other state and federal initiatives focused on the prevention and reduction of tobacco use
- A strong program of ongoing research that will inform future treatment programs

An effective tobacco cessation policy must be coordinated with a broader and systematic tobacco control campaign at all levels. The tobacco cessation policy must be responsive to and facilitative of new research findings. Tobacco cessation guidelines must be regularly updated. Barriers to addressing tobacco treatment including most notably lack of reimbursement for recognized products and services must be reduced and incentives provided for tobacco treatment services both in primary care and elsewhere. Effective treatments must be available to all tobacco users. Close oversight will be needed at state and federal levels. An important concern will be the effective and cost-effective use of resources. Thus, a dramatic increase in tobacco cessation funding without clear guidelines and close monitoring may result in limited impact. Substantial funding should be available for tobacco cessation research and this research should inform treatment. A strong infrastructure at both state and federal levels including continued expert input will help to ensure continued effective implementation of the national tobacco cessation policy.

NOTE

[1] Center for the Advancement of Health, *Treating Tobacco Dependence in the U.S.: Ad Hoc Group Findings and Recommendations.* Washington, DC, February 11, 1998.

MANAGING AND TREATING TOBACCO DEPENDENCE
A COMMENT BY

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Managing and treating tobacco use, as Hatsukami and Lando point out, is an essential part of a national tobacco control policy. They set forth a rationale for the need to address the treatment of nicotine dependence and provide a comprehensive synthesis of the various components necessary for an effective national policy to manage and treat tobacco dependence. They also provide a rationale for the federal government to take responsibility for the implementation of policies and programs in the treatment of nicotine dependence.

The eight key components of an effective treatment policy recommended by Hatsukami and Lando are essential for ensuring access for all to high quality programs. The components recommended include: infrastructure to provide basic level of intervention; specialized treatments; certification of specialized treatment providers; accreditation of treatment programs; centralized resource/guidelines with regular updates; outreach for treatment; coordination with other state and federal initiatives; and research.

This comprehensive strategy for managing and treating tobacco could provide the needed persistent messages to stop tobacco use (or not to start), continuously available supports for cessation provided through multiple channels in the community, and environmental incentives that reinforce non-tobacco use behavior. Such a strategy also implies political involvement and the influencing of public policy on the part of health care providers directed towards action. It requires adequate funding directed at improving methods of dissemination of materials, and funds for training researchers and clinicians to carry out these efforts. An integrated, well-supported, high quality, evidence-based approach with access for all is the best public health approach.

As Hatsukami and Lando note, each of these components are important for an effective national policy to manage and treat tobacco dependence. There are several points which need emphasis and further exploration. For example, the authors state that training programs should be offered to health care providers regarding minimal treatment methods (more intensive training should be provided for those interested in providing intensive interventions), and that completion of training should not be a requirement for health care providers to provide minimal interventions. While we strongly agree with this, a question which needs to be addressed is who will be responsible for providing training in minimal treatment methods? Who will disseminate the Agency for Health Care Policy and Research (AHCPR) guideline in a way which will increase the likelihood of health care providers implementing the guideline? We know training increases

provider confidence, practice and patient outcome even with minimal interventions – how do we ensure quality training is made widely available to interested providers? We are concerned that no mention was made of the need for office systems to support routine provider intervention. We recommend this be addressed within the context of disseminating the intervention guidelines and that related training be offered.

Hatsukami and Lando lay out the need for more intensive, specialized treatments for smokers who are unable to quit with low-intensity interventions (e.g.. those who are heavily dependent, have comorbid diagnoses, are pregnant and unable to quit with physician advice alone) and would somehow be referred or have available to them a more intensive treatment. For such referrals to happen, a system needs to be developed to identify smokers who need further help and assure that they follow through and access the help. We agree with their concern that most tobacco users prefer minimal intervention approaches and "a challenge will be to offer effective specialized treatments that will reach substantial proportion of tobacco users who may be in (most) need of such treatment". But it is not necessarily true that "if we build it, they will come". The more such treatments are integrated into the lives and social context of special needs populations, the more acceptable specialized treatments will be. Tobacco dependence treatment experts have been reticent to use non-academic approaches in their work. However, we cannot simply build programs and services based on good science and expect health care providers and the public to access them. Good marketing will be needed to make the added expense of specialized programs pay off. This issue of outreach may be the key to the success or failure of tobacco dependence treatment policy.

One of the recommendations which the authors make for funding of specialized programs for indigent populations is state funds and existing third party/managed care for those covered. How would we pursue obtaining coverage from third party/managed care, since they are not under federal control? What incentives might there be for them to provide such services? This is a challenge, given the tendency toward needing more immediate paybacks from investments, which preventive services do not provide.

Certification of specialized treatment providers is important and, as Hatsukami and Lando state, specialized treatment providers can come from a variety of disciplines and must "demonstrate competency" to assure that good quality of care is offered. Relevant to this issue, we conducted a series of interviews with eighteen national tobacco cessation experts in conjunction with the Massachusetts Tobacco Control Program. Eight of the interviewees thought there should definitely be a certification program, six indicated support for one provided that certain issues be addressed to ensure its success. Two thought there was merit to certifying tobacco dependency treatment programs, but not individuals. One was adamantly opposed to certification and thought more research was needed to support the need for it. A main concern regarding certification was the potential exclusion of qualified individuals who might not meet certification requirements. Hatsukami and Lando address this concern by recommending that individuals who provide minimal intervention not be required to be certified or get specialized training, and only specialists delivering intensive interventions be required to be certified.

In terms of certification requirements, fourteen of sixteen respondents answering the question agreed certification should include a written examination with the additional requirement of professional preparation and experience, similar to that recommended by the authors. In addition, fourteen of these respondents believed that there should be a recertification process with CEU requirements. The majority of national tobacco treatment experts whom we

interviewed support pursuing some form of certification. The state of Massachusetts is currently in the process of developing a certification procedure, and is thus grappling with the issues stated by the authors. This state process can serve as a model for the issues which will arise if the development of a national certification program is pursued.

As Hatsukami and Lando note, treatment for youth will be more effective in the context of a comprehensive national tobacco control strategy which includes decreased access to tobacco, increased cost, and decreased public consumption. More research is needed on effective strategies to treat nicotine dependence in youth, including the earlier-stated issue of not just what to build in the way of programs and services, but how to get youth involved in treatment.

Hatsukami and Lando describe five national legislative bills which include provisions related to the management and treatment of tobacco dependence, and clearly delineate their strengths and weaknesses based on the parameters they set forth in the earlier portion of the paper. This approach allows for a more objective comparison of the bills and a review of the components set forth in the paper. It is of note that many of the bills addressed some of the key issues noted by Hatsukami and Lando such as making services available to all, regulating programs and devices, coordinating activities, and outreach. What was clearly missing from all five bills was provision for the certification of smoking specialists, and from four bills funding for training health care providers and plans. Why are these important elements missing from the consciousness of our lawmakers? Is it because, as one of our cessation experts stated, there is a lack of research into the benefits of certification? If certification of intensive treatment providers and the training of health care providers and plans are desired, how do we bring these issues to the forefront for those making the policies? It will be important that the components set forth by the authors make it to the hands of those developing policy – they did a superb job of laying out what is needed to move toward an effective policy on tobacco dependence management and treatment.

In summary, Hatsukami and Lando present a clear, comprehensive proposal for a national policy to manage and treat tobacco dependence. This proposal should serve as a framework for the development of legislative policy, incorporating the components presented by the authors as well as addressing the issues raised above. With science, professional experience and legislation working collaboratively, we can achieve an effective, intelligent national policy which will have the greatest impact on reducing the use of tobacco and tobacco-related illness and death in this country.

HEALTH SCIENCE ANALYSIS PROJECT

Policy Analysis No. 8

THE USE OF COUNTER-ADVERTISING AS A TOBACCO USE DETERRENT AND ANALYSIS OF PENDING FEDERAL TOBACCO LEGISLATION

By

K. Michael Cummings, Ph.D., M.P.H. and Hillary Clarke, J.D.
Department of Cancer Control & Epidemiology
Roswell Park Cancer Institute

April 14, 1998

With a comment by

John K. Worden, University of Vermont

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EXECUTIVE SUMMARY

1. Based on our review of the literature, we conclude that counter-advertising can be an effective deterrent to tobacco use and that a national public information campaign on tobacco is warranted.

2. Our review of the literature shows that the effectiveness of counter-advertising as a tobacco use deterrent depends on many factors. Among the factors that are judged to be critical are:

- adequate, long term funding;
- ability to administer the campaign free from political interference;
- a broad-based focus rather than one exclusively targeting children; and,
- ability of the campaign to be complementary of other tobacco control activities conducted at the federal, state, and local levels (e.g., support for indoor smoking regulations).

3. All five of the Congressional bills we examined provide substantial new resources for tobacco control. Each bill included a national counter-advertising campaign as part of their program of tobacco control. However, only two of the bills (S.1414 and S.1648) included minimum funding levels for a national counter-advertising campaign. We recommend that any federal tobacco control legislation that is enacted include a minimum funding level of $500 million per year to support a national counter-advertising campaign.

4. Experience with recent state level counter-advertising campaigns suggests that political interference with the program can be a serious problem. We favor the appointment of an independent board to administer funds associated with a national counter-advertising campaign. Only two of the Congressional bills examined (S.1414 and S.1648) provide for the creation of an independent board to oversee the administration of a counter-advertising campaign.

5. In no case should the tobacco industry be involved in the planning or administration of a national counter-advertising campaign on tobacco since their interests are directly at odds with the public health goal of reducing the use of tobacco products by consumers.

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INTRODUCTION

This paper reviews the scientific evidence on the use of counter-advertising as a tobaccocontrol strategy. In addition, this paper provides a comparative analysis of the provisions addressing counter-advertising in five pieces of pending federal legislation currently before Congress, and establishes principles by which future counter-advertising campaigns should be judged.

The five Congressional bills proposing to establish a national counter-advertising campaign against tobacco are:

- S. 1414, "Universal Tobacco Settlement Act", introduced by Senators John McCain (R-AZ), Ernest F. Hollings (D-SC), John B. Breaux (D-LA), and Slade Gorton (R-WA);

- S. 1530, "Placing Restraints on Tobacco's Endangerment of Children and Teens Act (PROTECT)", introduced by Senator Orrin Hatch (R-UT);

- S. 1492, "Healthy and Smoke Free Children Act", introduced by Senators Edward M. Kennedy (D-MA), Frank R. Lautenberg (D-NJ), Richard Durbin (D-IL), John F. Kerry (D-MA); and Jack Reed (D-RI);

- S. 1638, "Healthy Kids Act", introduced by Senators Kent Conrad (D-ND), Thomas A. Daschle (D-SD), Edward M. Kennedy (D-MA), Frank R. Lautenberg (D-NJ), Jack Reed (D-RI), Patrick J. Leahy (D-VT), Christopher J. Dodd (D-CT), Jeff Bingman (D-NM), Richard Durbin (D-IL), Max Baucus (D-MT), Byron L. Dorgan (D-ND), John D. Rockefeller IV (D-WV), John F. Kerry (D-MA), Ron Wyden (D-OR), Paul D. Wellstone (D-MN), Robert Torricelli (D-NJ), Barbara Boxer (D-CA), Robert J. Kerrey (D-NE), Dale Bumpers (D-AR), Daniel Patrick Moynihan (D-NY), Tim Johnson (D-SD), John B. Breaux (D-LA), Herb Kohl (D-WI), Mary Landrieu (D-LA), Carol Moseley-Braun (D-IL), Richard H. Bryan (D-NV), Daniel K. Alaka (D-HI), and Joseph I. Lieberman (D-CT); and

- S. 1648, "Preventing Addiction to Smoking Among Teens (PAST) Act", introduced by Senators James Jeffords (R-VT), Susan Collins (R-ME), and Mike Enzi (R-WY).

COUNTER-ADVERTISING AS A TOBACCO USE DETERRENT

Can the Mass Media be Used to Discourage Tobacco Use?

Few people would argue with the assertion that the mass media play a critical role in influencing what society knows and does with respect to tobacco. The tobacco industry spends billions of dollars in advertising each year to promote its

products (1). The reason for this spending is simple - it works. Cigarette advertising has shown a remarkable power to create a demand for cigarettes, greatly promoting their popularity, and inducing far more people to become smokers than would otherwise be the case (2). Tobacco advertising and promotional activities also serve to change the public's perceptions about tobacco, creating more positive attitudes toward tobacco, less consciousness and fear of unhealthy consequences, and a general perception that tobacco use is a socially approved and accepted, even desirable behavior. As marketing professor Richard Pollay points out,

> *to smokers advertising is a reminder and reinforcer, while to non-smokers it is a temptation and a teacher (3).*

While the mass media have been used to encourage tobacco consumption, it has also been used to discourage tobacco use. In his review of 56 evaluated mass media programs to influence tobacco use, Flay (4) identified three principal ways in which the mass media has been used to discourage the use of tobacco: 1) to inform the public of the health consequences of cigarette smoking; 2) to promote specific smoking cessation actions like calling a telephone helpline for assistance in stopping smoking; and 3) to provide smoking cessation clinics to those smokers who desire to stop smoking. Flay (4) concludes that while it is difficult to draw clear inferences about program effects from any single evaluation study, on the whole, the evidence strongly supports the view that mass media programming can produce meaningful, though small effects, in the smoking habits of the population.

Counter-Advertising Campaigns Against Tobacco

The first and to date the only large-scale national counter-advertising campaign to educate the American public about the health risks of tobacco use occurred between 1967 and 1970, when the Federal Communications Commission (FCC) required licensees who broadcast cigarette commercials to provide free media time for anti-smoking public service announcements (PSAs) under the Fairness Doctrine (5). The Fairness Doctrine, which was repealed by the FCC in 1988, obligated licensed broadcasters to:

> *...encourage and implement the broadcast of all sides of controversial public issues over their facilities, over and beyond their obligations to make available on demand opportunities for the expression of opposing views (6).*

In January 1967, John Banzhaf, an attorney, petitioned the FCC to apply the Fairness Doctrine to cigarette advertising (5). In June 1967, the FCC accepted Banzhaf's petition and ruled that licensed broadcasters were required to air anti-smoking messages to counter the impact of cigarette advertising. In July 1967, anti-smoking PSAs developed by the voluntary health agencies and the government began to air. Unlike most public service advertising campaigns, many of the anti-smoking ads aired during prime time. The time donated for the anti-smoking messages amounted to approximately $307 million per year (in 1997 dollars). The Fairness Doctrine campaign ended in January 1971, as a result of a federal law that banned cigarette advertising on television and radio. After 1970, the number of anti-smoking PSAs declined markedly as anti-smoking messages

were forced to compete for donated air time.

Between 1967 and 1970, cigarette consumption in the United States dropped at a much faster rate than during the period immediately before or after the time when the Fairness Doctrine anti-smoking campaign was operational (5). While it is impossible to rule out the effects of other influences that may have contributed to the decline in cigarette consumption between 1967 and 1970, several studies have concluded that the anti-smoking campaign messages mandated by the Fairness Doctrine were responsible for much of the reduction in smoking during that period (7-10). Support for this conclusion is found in the study published by O'Keefe (8) which found high levels of recall for the anti-smoking PSAs aired as part of the campaign among adults and youth. An analysis of trends in national survey data also supports the view that the Fairness Doctrine campaign contributed to increases in the public's knowledge of the health hazards of smoking (5).

Evaluations of anti-smoking campaigns conducted outside the United States also provide evidence that mass media programming can contribute to increases in the public's awareness of the hazards of tobacco use and influence smoking habits. A three month multi-media anti-smoking campaign conducted in Norway in 1977 is credited with reducing tobacco sales 4 per cent and encouraging an estimated 100,000 Norwegian smokers to attempt to stop smoking (4). A two-year anti-smoking television and radio campaign conducted in Greece between 1978 and 1980 is credited with reducing tobacco sales and increasing the number of smokers attempting to stop smoking (4,11). In the years prior to the campaign, annual tobacco sales had increased at approximately 6 per cent per year. During the campaign tobacco sales were flat, but started to rise again as in past years after the campaign ended. An evaluation of an Austrian anti-smoking campaign conducted between November 1980 and February 1981 credits the campaign with increasing public awareness of the hazards of smoking, promoting cessation, and reducing tobacco sales (4, 12). In the first quarter following the campaign, tobacco sales were reported to be down by 2.2 per cent. Pierce et al (13) reported positive findings for a four year mass media led anti-smoking campaign conducted in two Australian cities (Sydney and Melbourne). During the years before the campaign there was no observable trend in smoking prevalence in either city. At the beginning of the campaign, there was an immediate drop of more than 2 per cent in male and female smoking prevalence in both cities.

While evaluations of large scale mass media led anti-smoking campaigns support the view that such campaigns can significantly reduce smoking behavior, the major problem with implementing a counter-advertising strategy is how to fund it. In recent years, several states including Minnesota, California, Massachusetts, Arizona, Oregon, and Maine have implemented paid counter-advertising campaigns financed from cigarette excise tax collections. Two other states, Mississippi and Florida, have recently launched paid counter-advertising campaigns using funds obtained from tobacco litigation settlements. The impact of these counter-advertising campaigns on changing public knowledge, attitudes and behavior related to tobacco is still too early to judge since most of these campaigns have just recently begun. However, evaluations of two of the longer running anti-tobacco campaigns in California and Massachusetts suggest that the counter-advertising components of their programs have contributed to an overall

reduction in cigarette use and greater public awareness of the hazards of tobacco (14-16).

Is There Still a Need to Educate the Public About Tobacco?

Despite the past successes of public information campaigns against tobacco, critics of counter-advertising argue that in contrast to 30 years ago, the public today understands the basic facts about tobacco use. This argument suggests that there is not much to be gained by continuing to educate an already well-informed public about the hazards of tobacco use. However, as Warner (2) points out, despite the remarkable progress that has been made to inform the public about the health consequences of tobacco use, the public's understanding of tobacco's hazards is still remarkably superficial, particularly among segments of society at greatest risk of smoking - i.e., the poorly educated, minorities, and youth. Recent evidence indicates that many smokers are misinformed about features of cigarette design (i.e., meaning of FTC tar and nicotine yields, presence or absence of additives) and smoking behavior (i.e., compensation, blocking ventilation holes in filters) that influence their exposure to toxins in cigarette smoke (17,18). The recent popularity of so called "additive free" cigarette brands such as Winston and American Spirit are examples of how consumers may be confused about what the label of "additive free" implies. Studies conducted by R.J. Reynolds Tobacco Company suggest that the removal of certain tobacco additives such as glycerol and propylene glycol is likely to make the tar more toxic, not less so (19). Yet, it appears that many consumers attracted to cigarette brands marketed as "additive free" believe that these products are safer than conventional cigarettes (20).

Teenagers are another group that fail to appreciate the consequences of the decision to smoke. Evidence shows a tendency among adolescents who have begun to smoke to discount long-term health risks. Many youth fail to appreciate the nature of nicotine addiction, and as a result believe they will be able to avoid the harmful consequences of smoking by smoking for only a few years. This fact is well understood by the tobacco industry as evidenced by the following excerpt found in a 1971 marketing report for Imperial Tobacco, Ltd., a Canadian tobacco manufacturer:

> *Starters no longer disbelieve the dangers of smoking, but they almost universally assume these risks will not apply to themselves because they will not become addicted. Once addiction does take place, it becomes necessary for the smoker to make peace with the accepted hazards. This is done by a wide range of rationalizations .. The desire to quit seems to come earlier now than before, even prior to the end of high school. In fact, it often seems to take hold as soon as the recent starters admits to himself that he is hooked on smoking, However, the desire to quit, and actually carrying it out are two quit different things, as the would-be quitter soon learns (21).*

As Flay (4) suggests, so long as tobacco manufacturers continue to utilize the mass media to promote the use of tobacco, there will be a need to counter these messages. In addition, the mass media have other important roles to play in tobacco control. For example, the mass media can be used to educate the public about policies that discourage tobacco use

(i.e., higher tobacco taxes, ban on the sale of tobacco products to minors, restrictions on tobacco marketing, restrictions on smoking indoors). Also, as Flay (4) points out, the mass media can be used to assist tobacco users in breaking their dependence on tobacco products either by directing them to community resources and/or teaching behavioral skills for stopping smoking.

Should Counter-Advertising Campaigns Focus Exclusively on Youth?

In the federal legislation that is discussed in this paper, much of the justification for increasing funding for tobacco control, including paid counter-advertising, is based upon the concept that kids shouldn't use tobacco. While a focus on preventing kids from using tobacco can be justified on the basis that nearly all adult smokers begin smoking during adolescence, an exclusive focus on youth prevention is not likely to be effective and may actually be counterproductive (22, 23). For example, in Arizona where the voters enacted Proposition 200 which increased the tobacco tax and mandated an anti-tobacco education program, political pressure forced the program to focus exclusively on children. While a formal evaluation of the media campaign has not been completed, news reports suggest that the campaign may have backfired by making smoking more appealing to youth by promoting it as something that is not for kids. Ironically, even the tobacco industry recognized that promoting smoking as an adult behavior would serve to promote smoking by youth. In 1979, the Chairman of Philip Morris Tobacco Company, George Weissman, warned the Secretary of Health, Education and Welfare, Joe Califano Jr., that a special campaign emphasizing that smoking is not for children would likely backfire. In his letter to Califano, the Chairman of Philip Morris Tobacco Company warned that:,

> *It has been observed over many generations that attempts by authority figures to influence adolescents against adopting certain 'adult' customs are likely to have the reverse effects (23).*

While there is some evidence that the mass media when used in combination with school and other community-based prevention efforts can significantly reduce the uptake of smoking by children, an exclusive focus on youth prevention would appear to be unwise (22, 24). As Glantz suggests:

> *The public health community should realize that the best way to keep kids from smoking is to reduce tobacco consumption among everyone. The message should not be: 'we don't want kids to smoke'; it should be : 'we want a smoke-free society (22).*

Evidence in support of this view is found in a 1981 Philip Morris report analyzing trends in teenage smoking behavior (25). The report comments on the decline in teenage smoking that occurred between 1975 and 1980 and suggests that the decline is attributable in large part to the "anti-smoking propaganda". The author of the report points out that the percentage of high school seniors that rated smoking a "great risk" to health increased from 51% in 1975 to 65% in 1980.

Conclusions

In summary, the evidence reviewed finds support for the use of counter-advertising as a tobacco use deterrent. However, the main impact of counter-

advertising is likely to be seen in terms of shifting public knowledge and attitudes towards tobacco. Measured effects of counter-advertising on smoking behavior is likely to be modest given the addictive nature of smoking and complex process involved in producing lasting behavioral change. However, as shown in several evaluations of media-led anti-smoking campaigns, even a small percentage effect on smoking behavior translates into a large absolute impact when one considers the mass reach potential of the broadcast media (4). The lessons learned from previous public information campaigns against tobacco suggest that for counter-advertising to be an effective deterrent to tobacco use it must have high frequency, extended reach, and long duration. While there is an obvious need for better research to help guide the use of the mass media for tobacco control, it appears that an exclusive focus on youth smoking behavior would be a mistake and may actually be counterproductive (22). Also, common sense and the experience of some states that have implemented paid counter-advertising campaigns suggest that such campaigns should be free of political interference that can serve to undermine the goals of the program (26-28).

FEDERAL LEGISLATION CREATING COUNTER-ADVERTISING

Overview

The five Congressional bills proposing to establish a new national tobacco control policy are:

1. S. 1414, McCain/Hollings - Universal Tobacco Settlement Act
2. S. 1530, Hatch - PROTECT Act
3. S. 1492, Kennedy - Healthy and Smoke Free Children Act
4. S. 1638, Conrad - HEALTHY Kids Act
5. S. 1648, Jeffords - PAST Act

While all five pieces of proposed legislation do establish national anti-tobacco counter-advertising campaigns, only S. 1414, which is very similar to the proposed national settlement and S.1648, contain many details about how such a campaign would be implemented. This lack of detail makes it difficult to accurately assess which piece of legislation would best meet the needs of the health community in terms of counter-advertising. However, the bills do provide a framework for a discussion of the types of elements that should and should not be included in any national anti-tobacco counter-advertising campaign.

The three most important elements in a successful counter-advertising campaign are duration, frequency and oversight. While the first two of these are directly related to funding, the third is not. An outside, independent board must be established to oversee the development, implementation and evaluation of any anti-tobacco public information program. The tobacco industry should not be allowed a representative on this board, since its interests are directly at odds with the public health agenda of reducing the use of tobacco products. Finally, the content of the campaign should not have an exclusive focus on youth.

Description of Proposed Legislation

Table 1 provides a comparative look at the counter-advertising provisions found in the five pieces of pending legislation. The biggest difference between the five are the sources of funds and the funding levels for anti-tobacco activities. Three of the

proposed bills are funded through mandated industry payments (S.1414, S.1530, and S.1648), while the other two (S.1492 and S.1638) propose to raise revenue by increasing the federal tax on tobacco products. Only two of the bills, S.1414 and S.1648, sets specific minimum funding levels for counter-advertising activities. The specific counter-advertising provisions found in each of the bills are as follows:

S. 1414 - Universal Tobacco Settlement Act

S. 1414 requires the Secretary of Health and Human Services to establish an independent board known as the Tobacco-Free Education Board to enter into contracts with or award grants to eligible public and nonprofit private entities to carry out public informational and educational activities designed to reduce the use of tobacco products. All nine members of the Board are appointed by the Secretary. At least three must be heads of major public health organizations, and at least three must be individuals who are widely recognized by the general public for achievement in the athletic, cultural, entertainment, educational, business, or political fields. Members of the Board serve staggered terms as determined appropriate at the time of appointment by the Secretary. Members of the Board who are not officers or employees of the federal government are compensated for their services.

To be eligible for a grant from the Board, an entity must be a public entity or State health department, or a nonprofit private entity that is not affiliated with a tobacco product manufacturer or importer, has a demonstrated record of working effectively to reduce tobacco product use and has expertise in conducting a multi-media communications campaign. Funds allocated by the Board must be used to conduct multi-media public educational or informational campaigns designed to discourage and de-glamorize the use of tobacco products. Campaigns shall be designed to discourage the initiation of tobacco use by minors and encourage those using such products to quit. In awarding grants and contracts, the Board will take into consideration the needs of particular populations.

S. 1530 - PROTECT Act

S. 1530 requires the Secretary of Health and Human Services to carry out a mass media public education campaign to counter the effects of marketing practices of tobacco product manufacturers and distributors. To accomplish this, the Secretary may award grants and contracts to public and private entities, including for-profit entities if determined appropriate by the Secretary.

S. 1492 - Healthy and Smoke Free Children Act

S. 1492 requires the Secretary of Health and Human Services to carry out programs to reduce tobacco usage through media-based (such as counter-advertising campaigns) and nonmedia-based public education, prevention and cessation campaigns designed to discourage the use of tobacco products by individuals and to encourage those who use such product to quit.

S. 1638 - Healthy Kids Act

S. 1638 requires the Secretary of Health and Human Services to carry out programs to reduce tobacco usage through media-based (such as counter-advertising campaigns) and nonmedia-based public education, prevention and cessation

campaigns designed to discourage the use of tobacco products by individuals and to encourage those who use such products to quit. The programs shall include national and local campaigns, and shall target in a culturally and linguistically appropriate manner, adults, children, women and minorities who have been targeted by tobacco industry advertising.

S. 1648 - PAST Act

S. 1648 requires the Secretary of Health and Human Services to establish an independent board known as the Tobacco Use Prevention and Cessation Board to enter into contracts with or award grants to eligible public and nonprofit private entities to carry out public informational and educational activities designed to reduce the use of tobacco products. All nine members of the Board are appointed by the Secretary. At least three must be heads of major public health organizations, at least three must be individuals who are widely recognized by the general public for achievement in the athletic, cultural, entertainment, educational, business, or political fields, and at least two must be individuals who are recognized as experts in the field of advertising and marketing. Members of the Board serve staggered terms as determined appropriate at the time of appointment by the Secretary.

To be eligible for a grant from the Board, an entity must be a public entity or State health department, or a nonprofit private entity that is not affiliated with a tobacco product manufacturer or importer, has a demonstrated record of working effectively to reduce tobacco product use and has expertise in conducting a multi-media communications campaign. Funds allocated by the Board must be used to conduct multi-media public educational or informational campaigns designed to discourage and deglamorize the use of tobacco products. Campaigns shall be designed to discourage the initiation of tobacco use by minors and encourage those using such products to quit. In awarding grants and contracts, the Board will take into consideration the needs of particular populations.

Comparative Analysis

S.1414 and S.1648 are the only two of the five proposals to establish national anti-tobacco counter-advertising campaign as a separately funded programs. The other three bills lump counter-advertising in with other anti-tobacco activities, such as cessation, with which it must compete for funds. Only S.1414 and S.1648 set specific minimum funding levels for counter-advertising; S.1414 at $500 million per year for a period of 25 years, and S.1648 at $500 million per year for a period of 10 years.

Both S.1414 and S.1648 provide for the creation of an independent board to administer the counter-advertising program, with the term limits of board members determined at the time of their appointments. This is an advantage over the other three bills, all of which charge the Secretary of Health and Human Services with administering the program. Since the Secretary is appointed by the President and therefore subject to political influence, the appointment of an independent board as provided for in S.1414 and S.1648 is the preferred approach.

Legal Issues

A Constitutional issue has been raised as to whether a "compelled speech" concern might arise if money for counter-advertising comes directly from the industry and is placed in a dedicated fund. The industry might then be able to claim that it

is being taxed to pay for public statements with which it disagrees and which are designed to reduce the industry's profits. If this is a legitimate concern, it is only a concern with respect to S.1414, S.1530 and S.1648, which mandate annual industry payments into a National Tobacco Settlement Trust Fund. The other two bills propose to generate funds by increasing the federal cigarette excise tax. S.1492 would place the revenues raised by the tax into the general fund, while S.1638 would establish a HEALTHY Kids Trust Fund. This fund would be used to directly assist those that are paying into it, by providing monies for cancer research and other public health programs.

Conclusions

Counter-advertising is an essential element of any comprehensive tobacco control program. However, the effective use of counter-advertising campaign as a tobacco use deterrent depends on many factors. Adequate long-term funding is critical. The counter-advertising campaign waged under the Fairness Doctrine was funded at $307 million annually in 1997 dollars. Other than under the Fairness Doctrine, there has never been a sustained national counter-advertising campaign by which to compare levels of funding. However, it appears that the $500 million per year for 25 years provided for in S.1414 would be adequate to implement and evaluate an effective campaign.

As important as adequate funding are factors such as the ability of the campaign to operate free from political interference, a focus on a broad-based audience as opposed to just youth and the ability of the campaign to complement tobacco control efforts at the state and local levels. Campaigns should be designed based on sound market research and must be subject to sufficient oversight from a separate advisory board, such as the Tobacco-Free Education Board created under S.1414 or the Tobacco Use Prevention and Cessation Board created under S.1648.

Finally, an evaluation component must be included, consisting of data collection and analysis, ultimately leading to recommendations for future national counter-advertising campaigns.

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Table 1

Comparison of Counter-advertising Provisions in Pending Federal Tobacco Legislation

Bill	overall funding source	overall oversight	overall expenditures
S. 1414 – Universal Tobacco Settlement Act	establishes National Tobacco Settlement Trust Fund - mandates tax-deductible industry payments into Trust Fund for 25 years: an up-front sum of $10 billion, and annual payments beginning at $8.5 billion in the first year, increasing to $15 billion in the 5th through 25th years - total payments = $368.5 billion	trustees of the Fund are the Commissioner of the FDA and the Secretary of HHS	authorizes expenditures from Trust Fund to award block grants to states and support national tobacco control programs
S. 1530 – PROTECT Act	establishes National Tobacco Settlement Trust Fund - mandates industry payments into Trust Fund for 25 years: an up-front sum of $10 billion, and annual payments beginning at $9.8 billion in the first year, increasing to $16.5 billion in the 6th through 25th years - total payments = $398.3 billion	trustees of the Fund are the AG, the Secretary of the Treasury and the Secretary of HHS - advised by Advisory Board consisting of themselves plus 4 members appointed by the leaders of Congress	authorizes and allocates expenditures from Trust Fund: $8 billion a year to states and $8 billion a year for federal research and public health programs; $200 million a year for asbestos - related litigation; $200 million a year for Native Americans; and $16 billion over 25 years for the agriculture program
S. 1492 – Healthy and Smoke Free Children Act	increases tobacco tax by $1.50 per pack over 3 years - federal share of funds raised would be $20 billion per year, or $650 billion over 25 years	none specified in bill	allocates revenues from tax increase to biomedical research, child health and development research, national and state counter-advertising and smoking cessation programs, and existing children's health, nutrition and welfare programs
S. 1638 — HEALTHY Kids Act	establishes HEALTHY Kids Trust Fund - increases tobacco tax by $1.50 per pack in 50¢ increments over 3 years - expected to raise about $82 billion over 5 years, or $500 billion over 25 years	trustees of the Fund are the Secretary of the Treasury and the Secretary of HHS	authorizes and allocates expenditures from trust fund: 41.5% for payments to states (14.5% unrestricted, 27% for children's health care, child care and education); 15.5% for anti-tobacco programs; 21% for NIH research; 4% (increasing to 10%) for Medicare; 6% (increasing to 12%) for Social Security; and 12% for farmers (for 1st 10 years, then phased out)
S. 1648– PAST Act	establishes Tobacco Settlement Trust Fund - mandates industry payments into Trust Fund for 10 years	none specified in the bill	authorizes expenditures from Trust Fund to award block grants to states and support national tobacco control programs

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	funding for counter-advertising	administration/ oversight	implementation
S. 1414 – Universal Tobacco Settlement Act	$500 million per year from Trust Fund - roughly 3.4% of overall annual spending	creation of National Tobacco-Free Public Education Program administered by Tobacco-Free Education Board composed of members appointed by Secretary of HHS	Board charged with entering into contracts with and awarding grants to public and private entities to carry out counter-advertising campaigns
S. 1530 - PROTECT Act	$4 billion annually used to fund national anti-tobacco campaigns (including counter-advertising) and cessation programs - at least one half of funds must be made available to states as block grants	creation of National Anti-Tobacco Product Consumption and Tobacco Product Cessation Public Health Program administered by Secretary of HHS	Secretary charged with carrying out mass media public education campaign - could be done through grants or contracts to public or private entities
S. 1492 - Healthy and Smoke Free Children Act	counter-advertising is a part of public health activities funded at $500 million per year indexed to inflation	counter-advertising campaign carried out by Secretary of HHS	not specified in bill
S. 1638 - HEALTHY Kids Act	counter-advertising is a part of public health activities funded at $500 million per year from Trust Fund, or approximately 3% of overall annual spending	counter-advertising campaign carried out by Secretary of HHS	allows Secretary to transfer funds to individuals or entities to design and implement activities or to conduct research on the effectiveness of the program
S.1648 - PAST Act	$500 million per year from Trust Fund for a period of 10 years	public health education and promotion program administered by Tobacco Use Prevention and Cessation Board composed of members appointed by Secretary of HHS	Board charged with entering into contracts with and awarding grants to public and private entities to carry out counter-advertising campaigns

	content requirements	special populations	miscellaneous	strengths	weaknesses
McCain/Hollings - Universal Tobacco Settlement Act S. 1414	campaign to be designed to discourage the initiation of tobacco use by minors and encourage others to quit	in awarding grants and contracts, Board will take into consideration the needs of particular populations	very similar to proposed settlement - mandates annual industry payments for 25 years, whereas settlement requires payments indefinitely	sets specific minimum funding level for counter-advertising; creation of independent Board with terms determined at time of appointment will make it tougher for a hostile Administration to misuse the funds	campaign does not contain an evaluation component; guidelines for appointing members to Tobacco-Free Education Board are weak - could result in appointment of Board members with little expertise in counter-marketing or tobacco in general
S. 1530 - PROTECT Act	campaign to be designed to counter the effects of marketing practices of tobacco product manufacturers and distributors	none specified in bill	includes many of the provisions that appear in the settlement - mandates slightly higher industry payments over 25 years		campaign does not contain an evaluation component; there is no minimum funding level for counter-advertising; content requirements for campaign are vague
S. 1492 - Healthy and Smoke Free Children Act	campaign to be designed to discourage the use of tobacco by individuals and to encourage those who use such products to quit	none specified in bill	does not mandate annual industry payments		campaign does not contain an evaluation component; there is no minimum funding level for counter-advertising; bill lacks specifics - there are no provisions for oversight or implementation
S. 1638 - HEALTHY Kids Act	campaign to be designed to discourage the use of tobacco by individuals and to encourage those who use such products to quit	campaign shall target in a culturally and linguistically appropriate manner, adults, children, women and minorities who have been targeted by tobacco industry advertising	similar to the Kennedy bill in that it uses a tax increase, not industry payments, as its funding source - unlike the Kennedy bill, tax revenue does not just go into the general fund		campaign allows but does not require an evaluation component; no minimum funding level for counter-advertising
S.1648 - PAST Act	campaign to be designed to discourage the initiation of tobacco use by minors and encourage others to quit	in awarding grants and contracts, Board will take into consideration the needs of particular populations	mandates annual industry payments for 10 years, whereas McCain/Hollings and Hatch require payments for 25 years	sets specific minimum funding level for counter-advertising; creates independent Board with terms determined at time of appointment	campaign does not contain an evaluation component; guidelines for appointing members to Tobacco Use Prevention and Cessation Board are weak

A COMMENT ON COUNTER-ADVERTISING

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According to the summary prepared by Cummings and Clarke, most of the five Congressional bills proposing to establish a new national tobacco control policy have tobacco counter-advertising provisions that state: "campaigns shall be designed to discourage the initiation of tobacco use by minors and encourage those using such products to quit." This emphasis on implementing educational approaches to reduce youth tobacco use is strongly supported by the research literature: when school health education is supplemented by mass media or community programs, significantly lower smoking rates among adolescents have resulted (2-8).

With such a strong research base supporting the use of educational smoking prevention approaches directed toward youth, it is important to clarify one of the conclusions drawn in the paper prepared by Cummings and Clarke suggesting that an exclusive focus on youth prevention is not likely to be effective and may actually be counterproductive. This point was made chiefly on the basis of an editorial by Glantz in 1996 observing that campaigns saying "we don't want kids to smoke" may actually make smoking more appealing to youth by promoting it as something that is not for kids but is okay for adults (1). Glantz further observed that "the public health community should realize that the best way to keep kids from smoking is to reduce tobacco consumption among everyone." This point has its merits in promoting a non-smoking societal norm, but it also may be misinterpreted to extend to all forms of counter-advertising. To help explain what he meant, Glantz made an important distinction (not included in the Cummings and Clarke paper) that, while the government "should de-emphasize the law enforcement aspects of its proposal directed at keeping kids from buying tobacco," it also should "focus on keeping kids from wanting tobacco (1)."

Reduction of demand for cigarettes by young people through educational campaigns has been shown to be effective in several research studies (2-8). Keeping kids from wanting cigarettes (demand reduction) probably requires a combination of both direct and indirect messages. Educational campaigns focused directly on young people through schools and the mass media have been shown to reduce youth smoking substantially (2-6). Educational campaigns that combine school smoking prevention programs with media campaigns focused on adults and children also have been found to have substantial effects on youth smoking (7,8). In section 4 of the draft analysis, Cummings and Clarke seriously underestimate the potential effectiveness of media campaigns focused on youth; their analysis appears to be based more on tobacco industry perspectives and news accounts of a somewhat limited media campaign in Arizona than on the research literature which clearly indicates

that a combination of educational strategies is likely to be most effective.

How can a balance between promoting a smoke-free society for everyone (including adults) -- and keeping kids from wanting tobacco -- be achieved? It can be done through audience segmentation. It's simply a matter of creating separate media campaigns for youth and for adults that do not contradict each other. Segmentation for youth can be done through selecting specific programs on media used by youth -- as determined through audience research (e.g., cartoons, situation comedies) -- and then by designing messages that appeal to youth with the purpose of reducing their demand for tobacco. Segmentation to reach adults can be done through selecting specific programs on media used by adults, which are often quite different from those preferred by youth (e.g., news, sports), and by designing messages appealing to adults and addressing specific adult issues.

Reaching youth with tobacco prevention messages has been particularly successful because they are at a very impressionable age and spend a lot of time with the media. As main purveyors of youth culture, mass media have a unique capacity to restructure the attitudes, expectations and perceived social environments of young people. Media are particularly appropriate for reaching young people to prevent smoking, because children spend more time watching television than attending school, and those at increased risk of becoming cigarette smokers are often the heaviest media users (5). Smoking prevention messages that are skillfully made based on research about adolescent smoking behavior, lifestyles and interests, and are created and programmed in a well-conceived communications strategy, can be powerful influences in reducing youth demand for cigarettes. Such campaign messages can have a particularly strong impact if they are perceived by young people to fit into a media-generated "youth culture" that pervades our society and guides youth behavior throughout the United States. While adults perceive media messages differently, early tobacco campaign efforts in the 1960s reported by Cummings and Clarke indicate that campaigns may be effective with that audience segment, also.

While there is much to be achieved in tobacco use counter-advertising aimed at youth and adult audience segments, experience indicates that there also are several cautions to be considered. First, it is essential that messages aimed at one audience segment not interfere with those aimed at the other segment. This has been one of the problems experienced in previous tobacco control campaigns conducted by state governments. For example, one of the most powerful messages to be aimed at youth is the non-smoking norm message. It has been found that if young people ages 10-13 feel that they have to learn how to smoke to be like everyone else, they will be likely to start smoking. If they get the message that "most kids don't smoke," it may keep them in the non-smoking majority. However, if a message trying to shock adults into an awareness of a youth smoking issue says something like "more and more kids are smoking every day," it may inadvertently say to youth that smoking is the norm (when, in fact only about 20% of youth ages 12-13 smoke). Some of this interference can be reduced by

using media carefully targeted to youth and adult segments, but if the adult message were designed to say "even one child smoking is too many," it might be just as effective and less likely to contradict the youth campaign.

The second caution is closely related to the strong recommendation of Cummings and Clarke to avoid any tobacco industry participation or any form of political influence in the design or implementation of tobacco prevention campaigns. In an extension of the concept of appointing an independent board to administer funds for prevention campaigns, it is recommended that the campaign development and dissemination process be organized to take advantage of professionals with a range of backgrounds and skills. Obviously, messages should be written and produced with the highest creativity and quality and they should be placed as paid advertising in the most effective media reaching each audience segment; for these roles, production and media professionals should be involved. However, to ensure that messages are designed to meet the needs of, and appeal to the interests of each audience segment, the organization responsible for the campaign should engage a panel of professionals in health education, health behavior studies, human development and communication. This panel should be given the tasks of interpreting results of previous research, recommending guidelines for message development, reviewing message content as it is developed, overseeing audience research for message development and testing, and interpreting results of that testing to help determine the selection of messages to be disseminated. Message testing should be conducted at both preliminary production and final production stages with samples of individuals from each targeted audience segment to ensure that the messages have appeal, are communicating appropriate content, and are not inadvertently giving contradictory information that might undermine the purpose of the campaign.

With the high national priority to prevent future smoking in our society, we must use every influence available to diminish tobacco use. If used properly, mass media offer some of the most powerful of these influences, particularly for reaching young people.

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