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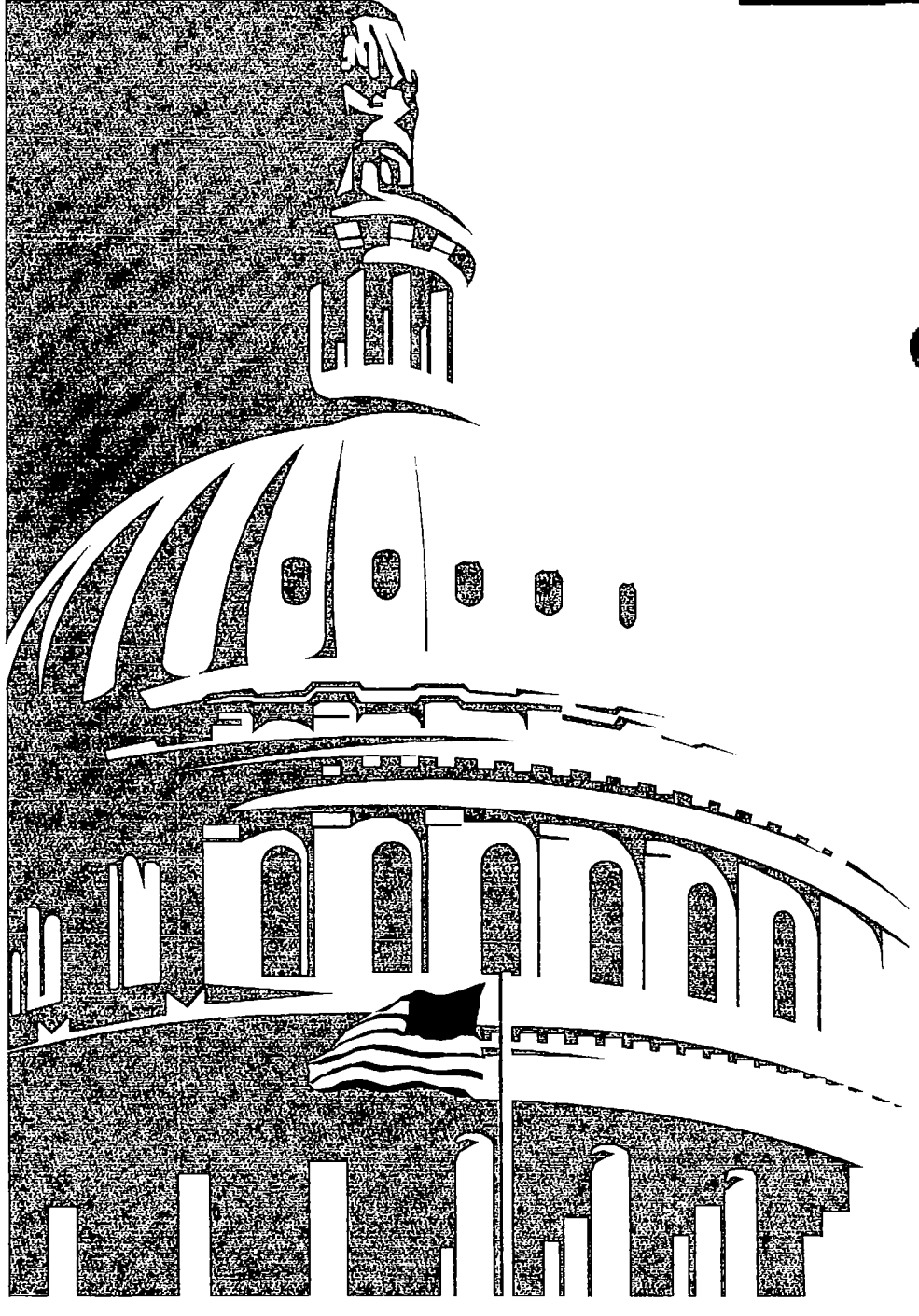

AMERICAN CANCER SOCIETY®

An Analysis and Review of the Proposed Tobacco Settlement

AMERICAN CANCER SOCIETY®

Memorandum

To: *Ms. Elizabeth Drye*
Associate Director
Domestic Policy
From: *Linda Hay Crawford*
National Vice President
Federal and State Government Relations
cc: *John Seffrin, Ph.D.*
CEO
Date: *Wednesday, July 16, 1997*
Subject: *ACS Primer*

John Seffrin has asked me to forward the attached document as an advance on what will be delivered to every member of Congress this afternoon as part of a three stage process by ACS to provide background and analysis to Congress and the public on tobacco control issues within the proposed tobacco settlement. Today's information contains a review of the proposed settlement, the FDA rule, an analysis on regulating nicotine as a drug and background on health and smoking. Next week we will release the ACS comments on the settlement in detail, including our priority issues and a full legal and constitutional analysis of the proposed settlement. ACS is prepared to then provide expertise or review of any congressional request on tobaaco control policy as discussions with the public and Congress continue and specific issues are identified.

Please call me if you have any questions. Please know that our experts are available to you as you deem appropriate. The ACS National Government Relations Office, in Washington DC, has the lead for all issues related to the settlement and is available to share information. My direct dial number is (202) 546-4011 ext. 147. Thank you.

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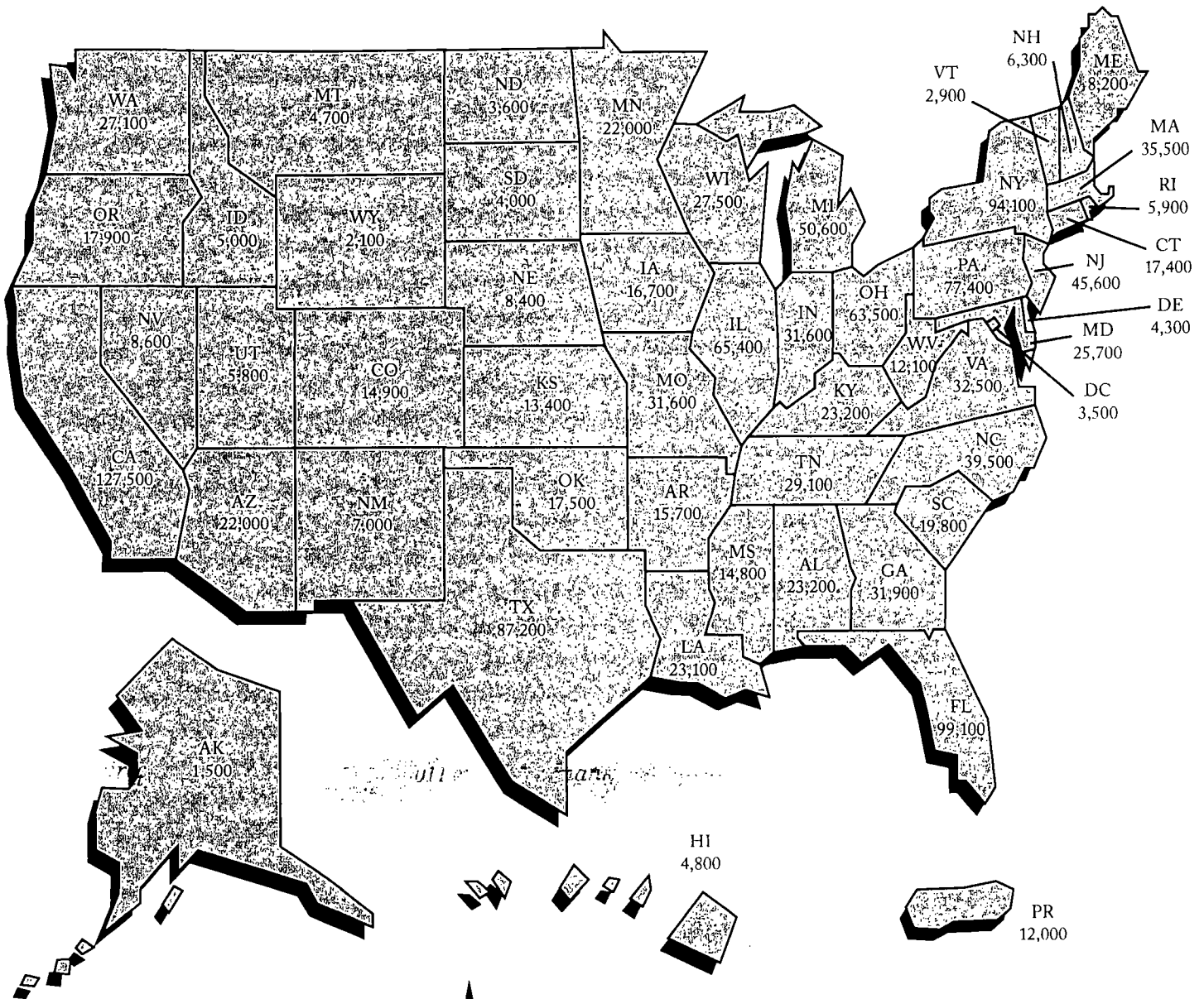


AMERICAN CANCER SOCIETY®

Estimated number of new cancer cases in 1997 by state, total: 1,382,400 (excluding Puerto Rico).*
Estimates for Puerto Rico are based on 1990–1991 data from the Central Cancer Registry of Puerto Rico.
*Excluding basal and squamous cell skin cancer and carcinoma in situ except bladder.

AMERICAN CANCER SOCIETY®

Dear Member of Congress:

The recent settlement between the tobacco industry and state attorneys general has prompted renewed public attention to issues of tobacco control. In order to promote public awareness and understanding of these critical public health issues, the American Cancer Society, on behalf of its more than 2 million volunteers, has prepared briefing materials regarding major policy issues on tobacco control. This analysis includes a thorough evaluation of the original FDA rule, information on the regulation of nicotine as a drug, facts on the health aspects of smoking, and other issues. We understand you will be acting on this issue in the next several months and offer to you our expertise during the process.

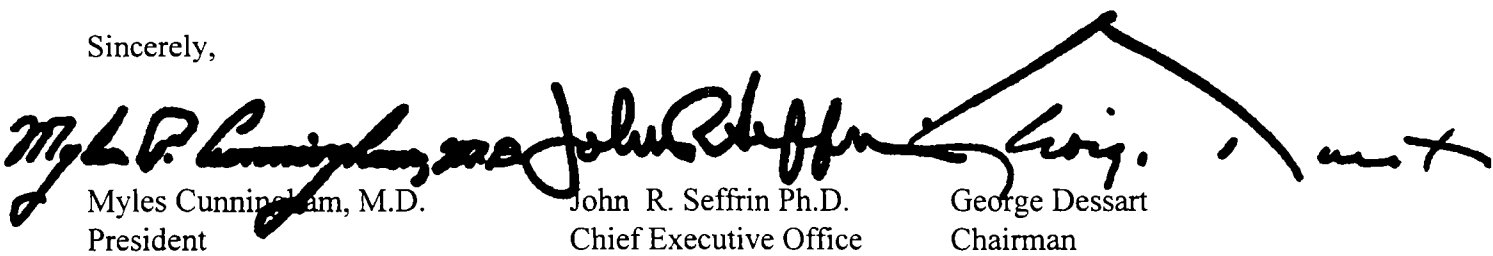
We present this document as part of a three stage process. Within the next week, we will also be forwarding to you a complete analysis of the legal and constitutional ramifications of the settlement and the American Cancer Society's review of the proposed settlement with recommendations. Thereafter, throughout the next several months we will be forwarding to you background information as it is developed specific to questions or issues Congress and the public might have on tobacco control and policy implications.

While the American Cancer Society believes the comprehensive legislation which will result from the settlement discussions has more potential for advancing public health than the uncertain outcome of lengthy continued litigation or piecemeal legislation, we do have serious concerns. There are major elements of the current settlement proposal that will require substantial revision for the agreement to succeed in its most important potential benefit to public health -- reducing tobacco use and therefore tobacco-caused disease and death.

If you have any questions, or would like additional information specific to your state and district, please do not hesitate to call Linda Hay Crawford, National Vice-President of Federal and State Government Relations (x147) or Susan Polan, Director of Federal Government Relations (x124) at (202) 546-4011.

Thank you for your time and attention to this critical public health matter.

Sincerely,



Myles Cunningham, M.D.	John R. Seffrin Ph.D.	George Dessart
President	Chief Executive Office	Chairman

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American Cancer Society Leadership

- **Myles P. Cunningham, MD**
  President
- **George Dessart**
  Chairman of the Board
- **John R. Seffrin, PhD**
  Chief Executive Officer

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AMERICAN CANCER SOCIETY

AN ANALYSIS AND REVIEW OF THE PROPOSED TOBACCO SETTLEMENT

TAB

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THE PROPOSED TOBACCO SETTLEMENT: BACKGROUND

I. INTRODUCTION

The proposed settlement is the result of months of negotiations involving the State Attorneys General, private plaintiffs and the tobacco industry. Although most public commentary refers to the agreement as a "settlement," the proposal does not simply resolve pending litigation between the parties. It also calls for complex and far-reaching federal legislation addressing public health and tobacco control policies.

The existence of a settlement requiring Congressional action and public scrutiny presents a potentially historic opportunity to make progress in reducing the massive death and disease resulting from tobacco use. Indeed, many of the legislative proposals in the settlement, if properly drafted, represent a clear gain for public health. On the other hand, the settlement as proposed is not perfect; there are a number of obvious omissions and weaknesses. As the public begins to evaluate and debate the proposal, we urge that the Administration and Congress to build on its strengths and work to correct its weaknesses.

The American Cancer Society believes that a settlement package can be crafted by Congress in a way that provides significant public benefit in the fight

against tobacco. However, no single piece of Federal legislation can represent a permanent, long-term approach to the problem of smoking. The American Cancer Society will continue to work for adoption of even stronger tobacco control policies by Congress, state legislatures, local governments, and public health officials.

II. THE TOBACCO LITIGATION

The settlement is the result of negotiations that included major tobacco companies operating in the United States, the State Attorneys General (AG), and attorneys representing plaintiffs in private class actions. In addition, two representatives from the public health community were present at the table during the talks. The Food and Drug Administration was not a party to the negotiations.

The negotiations were triggered by a number of lawsuits brought against the tobacco industry by state AGs and private plaintiffs. The first case was filed May 23, 1994, by the State of Mississippi. By September of 1996, fourteen other states had filed similar claims, including Minnesota, West Virginia, Florida, Massachusetts, Louisiana, Texas, Maryland, Washington, Connecticut, Kansas, Arizona, Michigan, Oklahoma and New Jersey. As of today, 40 states have sued the industry. Additionally, a large number of local governments have brought similar suits, including New York City, San Francisco, Los Angeles and several counties. In the Minnesota case, Blue Cross-Blue Shield of Minnesota joined with the state as a co-plaintiff.

While the claims in the suits vary somewhat, the basic allegation by the states and local governments is that the industry engaged in decades of fraud and deception. In particular, these suits allege that the tobacco industry was aware that cigarettes are unsafe and addictive. Nevertheless, the industry's own internal documents demonstrated that tobacco companies had withheld research findings from the public and from government agencies that revealed the dangerous and addictive properties of tobacco products. At the same time that the industry withheld these documents from the public, industry representatives at various times stated that cigarettes are safe, that the link between smoking and disease is unproved, and that cigarettes are not addictive.

In addition to the basic allegation of fraud, many suits allege other types of wrongful conduct, including marketing cigarettes to minors, manipulating nicotine content levels and conspiring to suppress development of a safer cigarette. Because there has not been a trial involving these claims, the allegations have yet to be established in a court of law. Based on publicly available information, it is clear that overwhelming evidence is available to support many, if not all, of these allegations.

In addition to the government lawsuits, a number of private lawsuits have been brought against the industry. Private plaintiffs have been largely unable to recover against the tobacco industry in personal injury actions. 1/ The success of

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1/ See, e.g., Kelder and Daynard, The Role of Litigation in the Effective Control of the Sale and Use of Tobacco, 8 Stanford Law & Policy Rev. 71-72 (1997).

the industry in these suits is partly explained by the reluctance of courts to apply conventional product liability theories to tobacco and, to some extent, by the tendency of juries to blame the smoker for injuries incurred as a result of smoking. Private plaintiffs also have been hampered by federal preemption of certain tort claims. 2/

Recent litigation has emphasized the addictive properties of nicotine. In addition, these recent cases have had the benefit of the disclosure of substantial number of internal industry documents. As a result of these developments, a large number of class actions suits that are currently pending allege that the industry knew about the addictive properties of nicotine but hid this and other crucial information from the public. 3/

These lawsuits all seek monetary damages from the industry. For example, states are seeking compensation for smoking-related medical expenses paid through the Medicaid program. Many of the government cases seek additional remedies, including controls on advertising, corrective advertising, and industry-

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2/ The Public Health Cigarette Smoking Act of 1969 had the effect of preempting certain kinds of tort claims against the industry. See Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

3/ The basic allegations in these class actions are set out in Castano v. American Tobacco Company, 84 F.3d 734 (5th Cir. 1996). In that case, the court found that there are not sufficient common issues for the cases to proceed as a class action. Part of the concern was variations in state law. Id. at 751. Consequently, this original action has been divided into a series of actions brought in several state courts.

funding for smoking cessation programs. The private cases also seek damages for personal injury, medical expenses, smoking cessation programs, and other expenses. Overall, the aggregate liability claims against the industry amount to hundreds of billions of dollars.

As the time approached for the first state cases to go to trial, settlement discussions began between the industry and some of the state AGs. Attorney General Mike Moore of Mississippi, who brought the original case, was instrumental in initiating these early discussions. These early talks focused on only a few cases and a narrow range of issues. Ultimately, however, the talks expanded to include an extremely broad range of policy issues. The participants in the talks also expanded from a few State AGs to a committee representing all the AGs, as well as some members of the public health community.

During the course of these negotiations it became clear, that the policy issues raised by the litigation went beyond the scope of the cases themselves. Thus, the parties concluded that an overall resolution would require federal legislation in addition to the conventional procedure of court-approved settlements between the litigating parties. Thus, the "settlement" consists not only of proposed consent agreements but also comprehensive federal legislation. Federal legislation is required because many key aspects of the settlement proposal, such as modifications in FDA authority and limitations on private tort claims, can only be implemented by Congress. The parties, including the states, the private plaintiffs

and the industry have stated that, in the event that the legislation they have recommended is adopted, they will terminate their litigation. The task for the Congress and the public is to determine whether such legislation, in the recommended form or in some other version, is in the public interest.

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FDA REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS

With the publication of its 1996 final rule concerning the sale, distribution, and promotion of cigarettes and smokeless tobacco to children and adolescents, the Food and Drug Administration (FDA) for the first time asserted regulatory jurisdiction over tobacco products. The Federal Register notice of the Final Rule 1/ contains a lengthy preamble detailing the agency's regulatory rationale, its jurisdictional analysis, and its response to the voluminous commentary generated by the 1995 proposed rule.

This memorandum summarizes the proposed rule and FDA's supplementary information as follows: Part I describes the rationale under which FDA decided to restrict tobacco sales and advertising to minors while allowing tobacco products to remain on the market; Part II summarizes the provisions of the final rule; Part III summarizes FDA's jurisdictional analysis; and Part IV summarizes the procedural and constitutional objections to the final rule raised by the tobacco industry and other interested parties.

I. FDA's Regulatory Rationale

A. Smoking is a Pediatric Disease

Rather than subjecting nicotine-containing products to all potential regulatory controls, the 1996 final rule FDA imposed limited regulations on the sale and marketing of cigarettes and smokeless tobacco to children and adolescents under the age of 18. The FDA has concluded, based upon a review of the scientific and medical literature, that nicotine addiction is a pediatric disease. To support this conclusion the agency cites evidence that nicotine addiction most often begins in childhood, and, conversely, that unless a person begins smoking as a child he or she is unlikely to smoke as an adult. Preventing the pediatric use of tobacco products is, in FDA's estimation, the most effective means of decreasing future numbers of addicted adults, and of lessening the financial and public health burden of tobacco-related illness and death.

In the preamble to the final rule, FDA justifies its advertising and access restrictions by pointing to evidence that tobacco companies deliberately

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1/ 61 Fed. Reg. 44396, August 28, 1996.

market their products to children. The agency also cites research indicating that advertising increases both smoking rates and brand identification among children and adolescents. 2/ To highlight the need for federal regulation, FDA cites recent evidence that state prohibitions on tobacco sales to minors are under-enforced and ineffective. Lastly, the FDA defends the most controversial of its regulatory provisions -- those restricting the advertisement of cigarettes -- as a necessary means of preventing the industry from undercutting Federal access restrictions with seductive promotions (e.g., Joe Camel ads) that are intended to create a demand for tobacco products among minors.

B. A Total Ban on Tobacco Sales Would not Serve the Best Interests of the Public Health

Although FDA has deemed tobacco products potentially dangerous to the public health (the preamble to the rule notes that tobacco use is the leading preventable cause of death in the US), the agency has declined -- at present-- to completely withdraw tobacco products from the market. 3/ The FDA's decision not to ban cigarettes and smokeless tobacco has engendered criticism from both proponents and opponents of tobacco regulation. These critics claimed during the public comment period that FDA is evading its full regulatory responsibility, or, alternatively, that FDA is selectively enforcing the FDCA in violation of the agency's statutory authority. In response, FDA cites its own discretion, upheld in

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2/ The record evidence cited by FDA to document a nexus between youth smoking and advertising includes an opinion by the American Psychological Association, a series of peer-reviewed scientific studies on the effects of advertising on cigarette consumption, internal documents from the tobacco industry concerning youth-oriented advertising campaigns, and reports by the Institute of Medicine and the Surgeon General.

3/ In the preamble to the final rule, FDA states its intention to eventually impose upon cigarettes and other tobacco products the full spectrum of regulatory controls applicable to medical devices (potentially including premarket approval requirements, which would effectively remove tobacco from the market). This process will require FDA to undertake a separate rulemaking to classify tobacco products according to degree of risk (i.e., as Class I, Class II, or Class III devices). In the interim, FDA intends to impose upon tobacco all of the general controls that apply prior to device classification (e.g., misbranding and adulteration provisions, registration, and manufacturing process controls). It is important to note, however, that the current rule does not regulate nicotine content or product development, and that imposition of the general controls on tobacco products will be phased in over a period of several years.

repeated court challenges, to narrow the scope of its regulatory actions in the interest of the public health. 4/

The FDA asserts that a sudden, complete withdrawal of tobacco from the U.S. market would create a new public health crisis in this country: the 77-92% of tobacco users who are nicotine-addicted would suffer immediate and adverse health consequences, straining a health care system that lacks adequate addiction treatment resources. The FDA further predicts that a sudden ban would spur the growth of a black market in cigarettes and smokeless tobacco, and would increase the availability of more dangerous tobacco products (e.g., cigarettes with higher tar and nicotine content or more toxic additives). Accordingly, the agency has adopted targeted regulations aimed at slowing the spread of tobacco use.

II. The Provisions of the 1996 Final Rule (21 C.F.R. Part 801 et al.)

- **Age limits:** The sale of cigarettes and smokeless tobacco to minors (children under the age of 18) becomes a violation of Federal law. Retailers must verify the age of all purchasers age 26 or younger by inspecting a photo ID.
- **Minimum package size:** Retailers are prohibited from opening packages to sell or distribute individual cigarettes or smaller amounts of tobacco. The minimum package size is defined as 20 cigarettes; the sale of small, inexpensive "kiddie packs" is prohibited.
- **Sales from vending machines:** Such sales are banned except in adult-only locations (locations where retailers or operators ensure that no person younger than 18 is present or permitted to enter at any time).
- **Self-service displays of cigarettes and smokeless tobacco:** These displays are banned except in adult-only locations.
- **Mail-order sales:** Mail order sales of cigarettes and smokeless tobacco are permitted, but mail-order redemption of coupons for free cigarettes or discounted cigarettes is prohibited.
- **The distribution of free samples:** The distribution of free samples of cigarettes and smokeless tobacco is prohibited.
- **Advertising format:** Advertisements may contain only black and white text, except for advertisements in primarily adult locations or in primarily adult publications (primarily adult publications are defined

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4/ An agency decision not to take enforcement action, or to take selective action, enjoys a presumption of non-reviewability. Heckler v. Chaney, 470 U.S. 821 (1985).

as those read by two million or fewer people under age 18, or those whose readership is no less than 85% adult.

- **Outdoor advertisements:** Billboards and other outdoor ads for cigarettes or smokeless tobacco are prohibited within 1,000 feet of public playgrounds, elementary schools, or secondary schools.
- **Promotional items and services:** Tobacco companies may not sell or distribute promotional items --such as tee shirts, caps, and sporting goods -- that are identified with tobacco products through the use of a brand name, logo, or other identifier. Companies may run contests, lotteries, and games of chance (all of which are restricted by law to adults over 18), but such promotions must follow the rules for text-only advertising.
- **Logos, brand names, and other identifiers of tobacco products:** These cannot be used in the sponsorship of cultural and sporting events, or on teams or entries in such events. Companies may continue to use a corporate name in the sponsorship of events, teams, or entries.

III. FDA's Assertion of Jurisdiction Over Tobacco

A. A Reversal of Prior Agency Findings of No Jurisdiction

The Food, Drug, and Cosmetic Act (and subsequent legislation amending the FDCA) gives FDA the authority to regulate products meeting the statutory definition of a drug or a medical device. Yet the text of the FDCA does not specifically mention tobacco, and for many years FDA administrators have declined to exercise regulatory jurisdiction over tobacco products. Under the Supreme Court's holding in Chevron, U.S.A. v. Natural Resources Defense Council, Inc., an agency is granted expansive discretion to determine its own jurisdiction. 5/ Within the scope of this discretion, two prior FDA commissioners have, in fact, maintained that the agency lacked any jurisdiction over tobacco products, unless such products were to be labeled with health claims.

An agency retains the discretion to reassess its jurisdiction, however, and in 1995, on the basis of new scientific evidence and newly-disclosed industry documents, FDA determined that its jurisdiction does extend to tobacco products under both the drug and the medical device provisions of the FDCA.6/ As the

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5/ 467 U.S. 837 (1984).

6/ Under the statutory definitions of both drugs and medical devices, products must either: (1) be used in the diagnosis or treatment of a disease; or (2) be "intended" by a manufacturer to affect the structure or function of the body.

preamble to the 1996 final rule indicates, in reaching this determination FDA relied in part upon the 1990 Safe Medical Devices Act (SMDA), which expanded the definition of medical devices and created a regulatory process for "combination" products (e.g., products combining a drug and a medical device).

B. The Regulation of Tobacco as a Medical Device

Separate legal authorities govern the FDA's review of drugs and of medical devices. In accordance with these statutes, FDA has determined that nicotine is a drug, and that both cigarettes and smokeless tobacco are "drug delivery" devices designed to introduce measured doses of nicotine into the human body. As "drug delivery" devices, cigarettes and smokeless tobacco are also combination products, and FDA maintains that in regulating a combination product the agency may select the most appropriate regulatory pathway from among the available authorities (i.e., drug, device, or biological product). FDA asserts that it chooses between regulating a combination product as either a drug, device or biological product based upon the most reasonable course of action to protect the public health, and in view of the particular scientific and safety concerns raised by a given product.

For the regulation of cigarettes and smokeless tobacco, the medical device provisions offer FDA the most flexibility, and, under the agency's interpretation of the relevant statutes, the greatest latitude to restrict tobacco advertisements. Thus, FDA is choosing to regulate cigarettes and smokeless tobacco products as medical devices. Tobacco products, like all regulated medical devices, will be subject to the following general controls:

- prohibitions against adulteration and misbranding;
- labeling requirements;
- the requirement that a manufacturer list all products and manufacturing establishments with FDA and undergo FDA's premarket notification process when introducing new versions of a product
- requirements governing recordkeeping and reporting (of product-related deaths and injuries); and

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Researchers now agree that cigarettes and smokeless tobacco deliver a pharmacologically active dose of nicotine to the body, and that nicotine is physiologically addictive at typical dosages. The FDA maintains that the industry's documented awareness of nicotine's addictive properties, coupled with manufacturers' conscious manipulation of nicotine levels in tobacco products, is sufficient to establish, for purposes of the statutory definition, that manufacturers intend tobacco products to be nicotine delivery devices.

- a requirement to conform to manufacturing standards (known as good manufacturing practices, or GMPs).

Additionally, FDA has determined that cigarettes and smokeless tobacco are "restricted devices." Under the Medical Device Amendments of 1976, FDA has the discretion to limit access to a device when restrictions are necessary to provide reasonable assurances of safe and effective use. In the 1996 Final Rule, FDA asserts this discretionary authority as a basis for limiting the marketing, sale, distribution, and advertising of cigarettes and smokeless tobacco to children and adolescents under the age of 18.

IV. FDA's Analysis of the Adequacy of the Rulemaking Procedures and the Constitutionality of the Rule

A. Rulemaking Procedures

In 1995, prior to publishing a Federal Register notice of the proposed rule, the FDA published a legal analysis of the agency's jurisdiction over tobacco, at the same time placing over 210,000 pages of supporting documents in the public docket. The agency responded to the comments regarding this jurisdictional analysis in the preamble to the final rule. The comment period for the final rule itself extended from August 1995 to January 1996, with a one month extension for comments on additional documents placed in the public docket. This public comment period generated over 700,000 pieces of mail -- the greatest volume in the history of federal rulemaking.

FDA maintains that during the course of this rulemaking the agency provided unprecedented public disclosure, supplementing the record to a degree far beyond that which courts have held the Administrative Procedures Act requires for notice and comment rulemaking. Contradicting FDA's assertion, the tobacco industry made the following procedural objections to the rulemaking:

- FDA failed to provide a complete and impartial discussion of the issues as is required in a notice of proposed rulemaking;
- FDA inappropriately relied on confidential documents that were not placed in the public docket; and
- FDA failed to provide the necessary "reasoned explanation" for its proposed rule; in particular, the agency did not explain its departure from prior findings of no jurisdiction over tobacco products.

The FDA addressed each of these objections in the preamble to the final rule. As additional evidence of the sufficiency of its public notice, the agency points to the unprecedented volume of comments it received in response to the proposed rule. FDA notes that these comments address all aspects of the rulemaking and the administrative record, including issues that the agency allegedly failed to adequately describe in the public notice.

B. Constitutional Objections

Comments received from the tobacco industry, the media, and retail trade associations raised a number of constitutional objections to the final rule, including the following:

- FDA's action violates the Separation of Powers doctrine and the Nondelegation doctrine;
- FDA's regulation impermissibly invades regulatory functions traditionally reserved to the States under the Tenth Amendment;
- FDA's access restrictions limit fundamental personal freedoms under the Ninth Amendment; and
- FDA's regulation of a manufacturer's use of copyrights and trademarks without a formal hearing violates the Due Process Clause of the Fifth Amendment.

In the preamble to the Final Rule, FDA dismisses each of these claims, arguing that prior Supreme Court precedents in analogous rulemaking contexts have upheld broad agency discretion to regulate in the interest of the public health. These precedents also uphold the use of notice and comment procedures in rulemakings that are not ajudicatory actions (i.e., notice and comment is sufficient where a rule will apply to a general class of persons or entities, as opposed to specific parties).

By far the most significant objection on constitutional grounds, however, has been to the limitations FDA places on the commercial speech of tobacco manufacturers and retailers. The tobacco industry and other interested parties claim that restrictions on truthful advertisements promoting legal activities abridge the First Amendment rights of manufacturers and consumers alike.

In the preamble to the final rule, FDA counters this First Amendment claim by asserting that the advertising regulations are narrowly drawn to directly advance a compelling governmental interest under the applicable Central Hudson test. 7/ Furthermore, FDA concludes that tobacco ads directed at minors are inducements to an illegal activity, and as such, are not entitled to constitutional protection under the Supreme Court's holding in Virginia State Board. 8/

7/ See Central Hudson Gas and Electric Corp. v. Public Service Commission of New York, 447 U.S. 557 (1980).

8/ Virginia State Board of Pharmacy v. Virginia Citizen's Consumer Council, Inc., 425 U.S. 748 (1976).

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LEGAL ANALYSIS OF *COYNE BEAHM, ET AL. V. FDA ET AL.*

Introduction

The Food and Drug Administration ("FDA") published "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (the "Regulations") in August 1996.[1] The Regulations attempted to reduce children's use of tobacco products by establishing federal age requirements, requiring minimum package sizes, restricting access to vending machines, prohibiting the distribution of free samples, restricting advertising, forbidding the use of promotional items and services, and barring logos and brand names for sponsorship of events. Following the promulgation of the Regulations, numerous tobacco companies challenged the FDA's authority to issue such Regulations in the case, *Coyne Beahm v. FDA*,[2] filed in United States District Court for the Middle District of North Carolina. In *Coyne Beahm*, the plaintiffs claimed that the FDA did not have jurisdiction under the Food, Drug, and Cosmetic Act ("FDCA" or the "Act")[3] to regulate tobacco products and that such rule making went beyond the scope of the authority granted to the FDA by Congress.

Rejecting most of the plaintiffs' arguments, the court in *Coyne Beahm* held that "tobacco products fit within the FDCA's definitions of 'drug' and 'device,'" and that the FDA can regulate cigarettes and smokeless tobacco as drug delivery devices. The court also upheld the FDA's prohibitions on sales of cigarettes and tobacco products to minors as well as access and labeling requirements. The court invalidated the FDA's restrictions on advertising and promoting tobacco products, however, finding these regulations to be outside the scope the FDA's authority.

Judicial Deference to an Administrative Agency

In determining the scope of the FDA's authority, the *Coyne Beahm* court undertook a two-step analysis, which was first set forth in the United States Supreme Court case, *Chevron v. Natural Resources Defense Council*.[4] Under

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1 61 Fed. Reg. 44,396 (1996).

2 958 F. Supp. 1060 (M.D.N.C. 1997).

3 21 U.S.C. § 321 *et. seq.*

4 467 U.S. 837 (1984).

Chevron, the first issue a court must consider is whether Congress has "directly spoken to the precise question at issue."[5] If the intent of Congress is unambiguous, then the court and the agency must follow Congress' policy decision.

If Congress has not "directly addressed the precise question at issue," however, a court may not simply "impose its own construction on the statute."[6] Instead, a court must determine if the agency's action is "based on a permissible construction of the statute."[7] An agency interpretation is given controlling weight unless it is arbitrary, capricious, or manifestly contrary to law.[8] A court "may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency."[9]

Summary of the *Coyne Beahm* Decision

The *Coyne Beahm* court analyzed the FDA's authority using the two-step analysis outlined in *Chevron*, inquiring: 1) whether Congress clearly intended to withhold from the FDA jurisdiction to regulate tobacco products, and 2) if not, whether the FDA's interpretation of the FDCA was reasonable. In answer to the first question, the court found that Congress *did not* clearly intend to withhold such jurisdiction from the FDA. The court then concluded that, except for the restrictions on advertising and promotion, the FDA regulations regarding cigarettes and smokeless tobacco were based on a permissible interpretation of the FDCA.

1. Congressional Intent

Plaintiffs contended that Congress clearly intended to withhold from the FDA federal jurisdiction to regulate tobacco products. To demonstrate this, plaintiffs first looked to the language and legislative history of the FDCA and argued that if Congress had intended the FDA's jurisdiction to include tobacco products, the legislative history would have referenced this subject, which it did not.

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5 *Id.* at 842.

6 *Id.* at 843.

7 *Id.*

8 *Id.* at 844.

9 *Id.* In *Chevron*, the Supreme Court examined the Environmental Protection Agency's ("EPA") interpretation of the term "stationary source" in the Clean Air Act Amendments of 1977. *Id.* at 840-41. The Supreme Court upheld the EPA's definition of "stationary source," finding that Congress had not defined the term and that the EPA's use of that concept was a "reasonable policy choice for the agency to make." *Id.* at 845.

In addition, plaintiffs argued that prior FDA representations to Congress and remarks of certain members of Congress indicated that Congress believed that the FDA lacked the authority to regulate tobacco. Finally, plaintiffs stated that a series of unenacted bills on the subject indicated Congress' intention to withhold from the FDA jurisdiction to regulate tobacco products.

Each of these arguments was rejected by the court, which held that Congress did not evidence a clear intent to withhold jurisdiction from the FDA. The court reasoned that since tobacco products were included in the definition of "drug" and "device" under the FDCA, they could only be excluded from FDA jurisdiction if Congress clearly stated that these products were to remain outside the scope of FDA authority. The fact that the FDCA's legislative history was silent concerning tobacco products was not sufficient to show that Congress clearly intended to exempt such products from the Act. Similarly, because unenacted bills generally provide unpersuasive evidence of Congressional intent, Congress' previously unsuccessful attempts to explicitly grant the FDA authority over tobacco products did not demonstrate that such authority did not exist. In addition, because an agency is entitled to adapt its policies and revise previous statutory interpretations on the basis of new evidence, the FDA was not bound by its previous representations to Congress that it did not have jurisdiction over tobacco products.

Plaintiffs also argued that Congress had reserved to itself the authority to set tobacco policy by passing three federal statutes regulating the sale and advertising of tobacco products.[10] The court held, however, that despite the enactment of those statutes, narrow preemptive language contained therein evidenced Congress' intent to permit other agency action in this area, as well.

In summary, in answer to the first *Chevron* question, the court found that Congress did not clearly express an intent to withhold from the FDA jurisdiction over tobacco products and, therefore, the FDA was not precluded from acting in this area so long as the agency's interpretation of the statute was reasonable.

2. The FDA's Interpretation of the FDCA

Without a finding of clear Congressional intent to withhold jurisdiction from the FDA, the court proceeded to the second prong of *Chevron* and inquired whether the FDA's interpretation of its jurisdiction was reasonable. Thus, the *Coyne Beahm* court applied this deferential standard in analyzing whether tobacco

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[10] Federal Cigarette Labeling & Advertising Act, 15 U.S.C. §§ 1331-40; Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. §§ 4401-08; Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992, 42 U.S.C. § 300x-26.

products fall within the definition of "drug" and "device" in the FDCA and whether the application of device authority was appropriate.

The FDCA defines "drug" and "device," in relevant part, to include articles "intended to affect the structure or any function of the body."[11] Plaintiffs contended that the requirement of "intent" must be established by examining the manufacturer's own representations about the product, and, in the case of tobacco products, no such representations were made. The court agreed with the FDA, however, that "intended use" may be established by evidence other than manufacturer representations, including foreseeability, consumer use, and internal manufacturer memoranda. The court found that nothing in the legislative history prohibited consideration of such evidence; therefore, the FDA's interpretation was found to be reasonable.

The court also deferred to the FDA's determination that tobacco products are "combination products" consisting of the *drug* nicotine and *device* components which are intended to deliver nicotine to the body. Because Congress did not define the term "combination product" with specificity, the FDA's interpretation of this concept was controlling. To this end, the court accepted the FDA's determination that a combination product consists of a combination of a drug, device and/or biological product and that the total product need only contain components that meet two of those definitions.[12] Furthermore, the court deferred to the FDA's conclusion that the device component of the combination product need only have an indirect effect on the structure or function of the body to meet the definition of "device." Finally, the court accepted the FDA's argument that although the definition of "device" specifically *excludes* products which achieve their primary intended purposes through chemical actions within or on the body – as do tobacco products – this definitional exception does not apply to the device component of a *combination product.*

With respect to the regulatory authority of the FDA, the court held that the FDA has discretion to apply the regulatory authority of its choice to combination products. Hence, even though the FDA determined that the primary mode of action of tobacco products is that of a *drug*, the FDA could regulate tobacco products pursuant to its *device* authorities.

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[11] 21 U.S.C. §§ 321(g)(1) & (h)(3).

[12] This definition was in contrast to the plaintiffs' assertion that a combination product must consist of two products, *each* of which could be *separately* regulated and that tobacco products did not meet that definition.

3. *Application of FDA Authority to Tobacco Products*

The final portion of the decision addressed the specific Regulations promulgated by the FDA under the 1996 rulemaking, which can be classified into three categories: (1) promotional and advertising restrictions, (2) access restrictions, and (3) labeling requirements. The rule was promulgated pursuant to the FDA's authority to govern "restricted devices," which provides that the Secretary may by regulation require that a device be restricted to "sale, distribution, or use" upon such conditions as the Secretary may prescribe "if, because of its potentiality for harmful effect . . . the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness."[13]

The FDA determined that tobacco products are restricted devices within the meaning of section 360j(e) because, due to the unique circumstances of these products, the only way to provide a reasonable assurance of safety was to prevent children and adolescents from using and becoming addicted to them. To this end, the FDA asserted that it could restrict the "sale, distribution, or use" of tobacco products as expressed in the Regulations.

With respect to the promotional and advertising restrictions, the court accepted the plaintiffs' arguments and held that these restrictions went beyond the FDA's jurisdiction to regulate devices. These regulations would have limited certain advertising to a black-and-white, text-only format, restricted the brand name of certain tobacco products, prohibited the sale or distribution of brand-identified promotional non-tobacco items such as hats and tee shirts, and prohibited use of a brand name of a tobacco product to sponsor entries, teams, sporting, and other events.

In striking down the promotional and advertising restrictions, the court held that the ability to regulate the *sale* of a product does not include the ability to regulate the *advertising or promotion* of the product. The court determined that FDA's authority to impose "other conditions" on the sale, distribution, or use of restricted devices to assure safety and effectiveness was simply not broad enough to authorize advertisement restrictions. Furthermore, the fact that Congress specifically granted the FDA authority to regulate advertising of certain restricted devices in a separate section of the FDCA demonstrated that it did not intend to grant such authority under section 360j(e). Because the court determined that the advertising restrictions were not within the FDA's authority, the court did not reach the First Amendment issues raised by these restrictions.

Although the court struck down the restrictions on tobacco promotions and advertising, it upheld the FDA's authority to restrict access to tobacco products.

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[13] 21 U.S.C. § 360j(e).

These access restrictions prohibit the sale of tobacco products to individuals under the age of 18, require retailers to verify a purchaser's age by photographic identification, prohibit the sale of tobacco products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not permitted, prohibit the distribution of free samples, and prohibit the sale of cigarette packages containing fewer than 20 cigarettes. These restrictions were found by the court to be a direct regulation of the "sale" or "distribution" of a restricted device and were, therefore, within the FDA's regulatory authority.

Lastly, the court upheld the FDA's labeling requirements, which require tobacco product packages, cartons, and boxes to bear the established name of the product and a statement of intended use. The court reasoned that the FDCA clearly authorizes the FDA to require such labeling, and it clearly possessed the authority to promulgate these restrictions.

Legal Implications of *Coyne Beahm*

Although *Coyne Beahm* is significant for its landmark holding that the FDA has authority under the FDCA to regulate tobacco products as a combination product with both drug and device characteristics, there are several elements of the decision which limit its precedential value. First, the court held that the FDA *did not have* the authority to promulgate restrictions limiting the format and scope of tobacco advertising and promotions. These restrictions are viewed by many as essential to curtailing youth smoking.

Second, although the court's reasoning appears to have been deliberative and thorough, the decision has been appealed to the United States Court of Appeals for the Fourth Circuit, and this appellate court will scrutinize anew the legal issues raised before the district court. If a majority of the Fourth Circuit's three-judge panel disagrees with the district court's determinations, the FDA's authority to regulate tobacco could be short-lived.

Third, the district court decision is limited in scope in that it is not binding on other courts around the nation. Although *Coyne Beahm* certainly provides persuasive authority which other courts may choose to follow, it does not even bind other courts in the Middle District of North Carolina, much less courts in other visinages and venues. Moreover, even if the case is affirmed by the Fourth Circuit, the plaintiffs could still bring challenges in other Circuits, which courts would not be bound by the Fourth Circuit's determination.

Finally and, perhaps, most importantly, the legal basis of *Coyne Beahm* – the *Chevron* decision – leaves the future regulation of tobacco products subject to uncertainty. Under *Chevron*, a court must defer to an agency's reasonable interpretation of its enabling statute if Congress has not already spoken to the issue. Hence, just as the court in *Coyne Beahm* deferred to the FDA's

determination that it had the authority to regulate tobacco products under the FDCA, a court would, likewise, be required to defer to a future determination by the FDA that it *did not have* – or did not wish to exercise – such jurisdiction, so long as this decision was reasonable. Thus, the court's holding in *Coyne Beahm* may be applicable only so long as the FDA asserts its jurisdiction in the field of tobacco regulation. If a President is elected who is less sympathetic to FDA regulation of tobacco, the deferential standard of *Chevron*, as applied in *Coyne Beahm*, would provide little support for the continued regulation of tobacco products.

The Proposed Resolution would require the enactment of legislation clearly granting the FDA authority to regulate tobacco products. Under the Proposed Resolution, such authority would encompass the FDA's ability to regulate tobacco advertising and promotion. Furthermore, it would evidence clear Congressional intent to grant the FDA jurisdiction over tobacco, thereby eliminating the potentially problematic deference to an agency interpretation which may vacillate over time.

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SUMMARY OF PROPOSED TOBACCO SETTLEMENT AGREEMENT

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SUMMARY OF PROPOSED TOBACCO SETTLEMENT AGREEMENT

Preamble

The Preamble to the proposed settlement describes the purpose of the settlement and outlines its basic tenets. Specifically, the agreement confirms the authority of the Food and Drug Administration (FDA) to regulate and control tobacco products, places restrictions on marketing and advertising, imposes financial penalties on the tobacco industry as an incentive to curb underage consumption, authorizes funds from the industry to establish a national education campaign, and creates federal standards to restrict smoking in public places.

Title I: Reformation of the Tobacco Industry

A. Restrictions on Marketing and Advertising

The agreement significantly curtails the ability of the tobacco industry to advertise and market tobacco products. In addition to adopting the provisions promulgated by the FDA, the settlement agreement adds new restrictions. The new provisions incorporated in the settlement include the following:

- A ban on *all* outdoor advertising as well as a ban on advertising indoors when the ad is directed outside;
- A ban on the use of human images and cartoon characters in tobacco advertising (e.g. Joe Camel and the Marlboro Man);
- A ban on all Internet advertising that is accessible from the U.S.;
- A restriction on point of sale advertising in non-adult-only facilities;[1]
- A ban on direct and indirect payments for tobacco images in movies, television programs and video games;
- A prohibition on payments to "glamorize" tobacco use in media appealing to minors, including recorded and live performances of music;

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[1] Point of sale advertising was otherwise permitted in retail establishments under the FDA rule.

- A provision authorizing the FDA to approve the use of product descriptors in advertising such as "light" or "low tar;"

Provisions that were part of the FDA Rule and incorporated into the settlement agreement include:

- A ban on the use of non-tobacco brand names on tobacco products;
- A limitation on billboard advertisements;
- A requirement that tobacco product advertising be limited to black text on a white background except in adult publications and adult-only facilities;
- A ban on brand-name sponsorships, including concerts and sporting events;
- A ban on all non-tobacco merchandise, including caps, jackets and bags;
- A prohibition on offers of non-tobacco items or gifts based on proof-of-purchase of tobacco products;
- A requirement that cigarette and smokeless tobacco product advertisements carry a statement of intended use (e.g. "nicotine delivery device").

B. Warnings, Labeling and Packaging

The proposed agreement requires a series of new, updated warning labels for all cigarette and smokeless tobacco products, which would rotate on all advertisements on a quarterly basis. These warnings, required by the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, have not been updated since 1984.

In addition to the new warning labels, the agreement grants authority to the FDA to promulgate rules on testing, reporting and disclosure of tobacco smoke ingredients. Possible subject matter for these rules includes, but is not limited to, "tar," nicotine, and carbon monoxide.

C. Restrictions on Access to Tobacco Products

Building on the provisions included in the FDA Rule, the proposed settlement agreement seeks to prevent access to tobacco products by minors through strict regulatory measures. These measures include the following:

- A ban on sales of tobacco products to children under 18 years old;
- A requirement that retailers check photo identification for anyone under 27;
- A ban on the vending machine sales of cigarettes and other tobacco products;
- A requirement that all sales of tobacco products must be face-to-face;
- A ban on the sale of tobacco products from open packages;
- Establishment of a minimum package size of 20 cigarettes;
- Imposition of new retailer compliance obligations to ensure that all self-service displays, advertising, labeling and other items conform with applicable requirements;
- A ban on tobacco product samples;
- A ban on the distribution of products through the mail, including coupon redemption offers where sales are not subject to proof of age;
- A ban on self-service displays of cigarettes and smokeless tobacco products.

D. Licensing of Retail Tobacco Product Sellers

The provisions to eliminate youth access to cigarettes and smokeless tobacco are enhanced by a requirement that the Federal government establish minimum standards for a retail licensing program financed through funding provided by industry payments. The licensure program would apply to all manufacturers, distributors, wholesalers, retailers, and importers of tobacco products. It would be enforced by Federal, state and local authorities. The new licensing program:

- Prohibits the sale of tobacco products to consumers without a license;
- Requires that applicants and holders of a license comply with all federal statutes and regulations governing tobacco products;

- Imposes licensing fees to cover costs incurred by states to administer the licensing program;

- Establishes comparable Federal licensing provisions for the military and other U.S. Government operations and for Indian tribes.

The settlement also specifies penalties for violation of the licensing laws. Any person who sells tobacco products without a license is subject to criminal sanctions, including a $1,000 fine, six months imprisonment, or both. For corporations, the settlement calls for a maximum fine of $50,000.

States may impose more severe penalties than those set forth under federal law. Civil sanctions for violating state licensing laws governing the sale of tobacco to minors could result in fines and license suspension or revocation, depending on the number of offenses committed within a two-year period.

E. Regulation of Tobacco Product Development and Manufacturing

The agreement sets forth a regulatory framework to govern the development and manufacturing of cigarettes and smokeless tobacco products. The agreement addresses FDA jurisdiction over tobacco as a "drug" and a "device" under the Food, Drug, and Cosmetic Act (FDCA) and recognizes FDA authority to regulate tobacco products as "restricted medical devices." More specifically, tobacco products are classified as a new subcategory of a Class II device. As a result of this reclassification, the FDA may require "product modification" of tobacco products, including the regulation of nicotine content. Other aspects of the regulatory framework are as follows.

1. *Reduced Risks Products*

The proposed agreement would bar tobacco product manufacturers from making claims that state or imply a reduced health risk, unless it can demonstrate to the FDA that the product in fact "significantly reduces the risk to health" compared to ordinary tobacco products. Additionally, the FDA has authority to approve all health claims made in advertisements in order to "prevent the public from being misled."

With regard to tobacco products that the agreement refers to as "less hazardous," the FDA may permit scientifically-based health claims. In addition, the FDA can provide exceptions to the advertising restrictions that apply to other products if it determines that to do so would "reduce harm and promote the public health."

The FDA also would have the authority, under the agreement, to mandate the introduction of "less hazardous tobacco products" that are technologically feasible. Alternatively, the FDA can mandate that the technology to develop such products be licensed to other manufacturers that agree to bring the technology to market within a reasonable time frame. If no manufacturer is identified, then the FDA is authorized to produce the product itself.

2. *Performance Standards*

For *twelve years*, the FDA is permitted to adopt performance standards that require the modification of existing tobacco products, including a gradual reduction (but not the elimination) of nicotine and the possible elimination of other harmful components of tobacco products. These modifications may be required based on a finding that such changes:

(a) will significantly reduce health risks;
(b) are technologically feasible, and
(c) will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard.

The authority to require any product modification during this initial twelve-year period must be based on a showing of "substantial evidence" that is documented in an administrative record and developed through a formal rulemaking process, including a hearing. Manufacturers of tobacco products that would be affected by any proposed modification have a right of judicial review. Congress also may intervene if it so chooses.

After the initial twelve year period, the FDA is permitted to set product safety standards that go beyond the standards it is authorized to set during the first twelve years. Specifically, the FDA is permitted to require the alteration of tobacco products, including the elimination of nicotine or other harmful components of tobacco products based on a finding that:

(a) the safety standard will result in a *significant* overall reduction of the health risks to tobacco consumers as a group,
(b) the modification is technologically feasible, and
(c) the modification will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard.

According to the agreement, given the significance of such an action, the FDA may require the elimination of nicotine based on a "preponderance of the evidence" pursuant to, at a manufacturer's election, a hearing or notice and comment rulemaking with a right of judicial review. Furthermore, any such action must be

phased in, and the phase-in period may not begin for two years in order to permit Congressional review.

Importantly, in any judicial review of the FDA's action, deference to the FDA's findings will depend on the extent to which the matter at issue is within the agency's field of expertise.

3. *Manufacturing Oversight*

The proposed agreement would subject tobacco product manufacturers to "good manufacturing practice standards" (GMPs) comparable to those applicable to medical device manufacturers, food companies and other FDA regulated industries. The GMPs included in the agreement are tailored specifically to tobacco products, however, and include:

- Implementation of a quality control system (e.g. to prevent contamination);
- Inspection of tobacco product materials (e.g. to ensure compliance with quality standards);
- Requirements for proper handling of finished products;
- Tolerances for pesticide chemical residues;
- Inspection authority comparable to the FDA's authority over other regulated products (e.g. the ability to enter manufacturing plants and demand certain records); and
- Record keeping and reporting requirements.

4. *Access to Company Information*

The agreement ensures that previously non-public or confidential documents from the files of the tobacco industry, including internal health research documents, are disclosed to the FDA, private litigants and the public. Any unresolved disputes regarding access to trade secrets and documents considered privileged will be decided by a panel of three federal judges.

F. Non-Tobacco Ingredients

The proposed agreement requires manufacturers to disclose to FDA all additives in tobacco products by brand. Manufacturers would be prohibited from

using non-tobacco ingredients unless they could demonstrate that the ingredient is not harmful. Furthermore, manufacturers would be required to disclose all ingredients, substances and compounds added to tobacco to the FDA on a confidential basis and identify whether each item is exempt from public disclosure.

Within five years, the manufacturers must submit to FDA a safety assessment. The assessment must be based on the best available evidence, and must demonstrate that "there is a reasonable certainty in the minds of competent scientists that the ingredient is not harmful under intended conditions of use." Manufacturers would be required to disclose ingredients information to the public under regulations comparable to current Federal requirements for food. Ingredient information not subject to disclosure would be treated as confidential by FDA. Also within five years, any tobacco ingredient that is exempt under the FDCA is presumed to be exempt from FDA scrutiny.

G. Compliance and Corporate Culture

The proposed settlement attempts to force a fundamental change in the corporate culture of the tobacco industry. To achieve this objective, the agreement requires manufacturers to establish plans to ensure compliance with all applicable laws and regulations. In addition, tobacco manufacturers must create a mandatory "compliance program" that includes the following elements:

- Compliance standards and procedures must be followed by employees and agents;

- High-level personnel of tobacco organizations must oversee compliance with standards and procedures, especially with regard to preventing underage tobacco use;

- Due care must be exercised in order to avoid delegating substantial discretionary authority to individuals that the organization knows to have a propensity to disregard corporate policy;

- Relevant standards and procedures must be communicated to all employees and other agents (e.g. by requiring participation in training programs or by disseminating publications);

- Internal audits, hotlines and other measures to promote compliance should be considered;

- Appropriate disciplinary mechanisms and measures should be established for violations of agreement provisions, and reasonable steps should be taken to respond appropriately to violations.

The agreement also provides that "whistleblowers" in the tobacco industry should have maximum protection available under current federal standards. In addition, manufacturers must work with retail organizations for compliance.

The agreement calls for the dissolution of the Tobacco Institute and the Council for Tobacco Research. Any new trade association created by tobacco manufacturers would be subject to certain requirements governing, for example, who may serve on its board of directors. In addition, manufacturers would be required to ensure that all contract lobbyists do not seek or oppose state or federal legislation on any matter without express authorization from the manufacturer. Manufacturers would require anyone lobbying on their behalf that they will comply with applicable provisions of law, the new provisions resulting from enactment of the legislation, the Consent Decrees and the manufacturers' business conduct policies. Breach of any corporate obligations set forth in this section can result in a fine of up to $25,000 per day per violation with a maximum fine of $200,000.

Title II: "Look Back" Provisions and State Enforcement Incentives

A. Reducing Underage Tobacco Use

The "look-back" provision sets specific targets for the reduction in current levels of underage smoking and use of smokeless products over the next ten years. These targets are as follows:

Smoking Reduction	Smokeless Reduction	Year
30%	25%	5th
50%	35%	7th
60%	45%	10th

Thus, according to these targets, use of cigarette products must decline by at least 30% from estimated levels over the last decade by the fifth year after the settlement agreement becomes effective.

If the targets are not met, the FDA may impose a mandatory surcharge on the relevant industry (i.e., cigarette or smokeless tobacco) based on an approximation of the present value of the profit the industry would earn over the lives of all underage users in excess of the target. The surcharge is subject to an annual cap of $2 billion for the cigarette industry and a comparably derived cap for the smokeless tobacco industry. Manufacturers are eligible to receive a partial abatement of the surcharge (up to 75%) if they can prove that they fully complied with the terms of the settlement agreement and that they took all reasonably available measures to reduce tobacco use by minors.

B. State Enforcement Incentives

Under the agreement, states are required to have a "no sales to minors" law. Additionally, each state must conduct 250 random, unannounced inspections per one million population annually to ensure retailer compliance with the law. The FDA must determine, on an annual basis, whether each state has "pursued all reasonably available measures" to enforce the ban on tobacco sales to minors. Further, the FDA must presume that a state has not met this standard if the following compliance rate targets are not met:

Year	Retail Compliance Rate
5th	75%
7th	85%
10th	90%

State enforcement efforts are funded by industry payments. If a state fails to meet its enforcement targets, it will lose funds designated to cover public health care programs.

Title III: Penalties and Enforcement; Consent Decrees; and Non-Participating Companies

A. Penalties and Enforcement

The settlement agreement would be enforceable both by the Federal government, including the FDA and the Department of Justice, and by the states. In addition, the FDA is given authority to contract directly with state agencies to assist with enforcement.

States with consumer protection laws or comparable statutes governing conduct that is the subject of the agreement are permitted to proceed under that law. State enforcement actions, however, whether brought under the settlement provisions or under a state's own consumer protection law, could not impose obligations or requirements on tobacco manufacturers beyond those imposed by the settlement agreement. Further, state penalties would be limited to the civil and criminal penalties established by the agreement and by the prohibition on duplicative penalties. State enforcement proceedings arising under the settlement agreement are removable to federal court.

Civil and criminal penalties for violation of the agreement are comparable to those imposed under the FDCA for violation of laws relating to devices. In addition, tobacco manufacturers may face civil penalties of up to $10 million per violation for failure to disclose to the FDA research about tobacco-product health effects and

information regarding the toxicity of non-tobacco ingredients in their products. This penalty is ten times larger than the penalty faced by other device manufacturers for similar violations.

B. Consent Decrees

The proposed settlement identifies those aspects of the agreement that must be translated into Consent Decrees in order to protect states that are not signatories to the agreement. The provisions that are *not* included in the Consent Decrees include the following:

- product design, performance or modification;
- manufacturing standards and GMPs;
- testing and regulation with respect to toxicity and ingredients approval; and
- the national FDA "look back" provisions.

State proceedings to enforce provisions of the Consent Decrees may be brought in state court, subject to an acceptable procedure to ensure consistent rulings with respect to conduct on the part of tobacco manufacturers that is not exclusively "local" in character. State proceedings to enforce the Consent Decrees may seek injunctive relief only and are precluded from seeking criminal or monetary sanctions. The agreement does not, however, prevent a state from seeking criminal or other sanctions for a tobacco company's subsequent violation of an injunction entered by a court in an action brought to enforce the Consent Decree.

The parties to the agreement would expressly waive any claim that the provisions of the Consent Decrees or the agreement violate the federal or state constitutions. Further, the Consent Decrees will also state that if a provision of the settlement is subsequently declared unconstitutional, the provision nevertheless remains an enforceable term.

C. Non-Participating Companies

To ensure that tobacco manufacturers participating in the settlement will not be disadvantaged relative to non-participating manufacturers, and to avoid potential constitutional problems that might arise if the settlement were simply imposed on non-participating manufacturers, the agreement requires the creation of

a separate statutory and regulatory framework for non-participating tobacco companies.

First, the access restrictions and regulatory oversight provisions under Title I of the settlement would apply to non-participants as well as participants. Furthermore, statutory provisions would require non-participating manufacturers to place certain funds into a reserve escrow account each year. This account would insure the availability of funds for the satisfaction of judgments and settlements of tort claims against non-participants. Any unused funds in the escrow account could be reclaimed by the non-participants after 35 years.

Neither the non-participating manufacturers, nor their distributors and retailers would be eligible for the civil liability protections afforded participating companies under Title VIII.

Title IV: Nationwide Standards to Minimize Involuntary Exposure to Environmental Tobacco Smoke

The proposed settlement agreement restricts indoor smoking in "public facilities"[2] to ventilated areas with systems that: (a) exhaust the air directly to the outside; (b) maintain the smoking area at "negative pressure" compared with adjoining areas; and (c) do not recirculate the air inside the public facility. Restaurants, bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants and prisons are exempted.[3]

These provisions do not preempt or otherwise affect any other state or local law or regulation that imposes the same or more stringent restrictions on smoking in public facilities. Similarly, the agreement does not preempt or otherwise affect any Federal rules that restrict smoking in federal facilities.

Title V: Scope and Effect

The settlement agreement confirms the FDA's authority to regulate tobacco products within the U.S., while preserving the authority of individual states and local governments to take additional tobacco control measures.

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[2] "Public facility" is defined as any building regularly entered by 10 or more individuals at least one day per week.

[3] "Fast food" restaurants are not included in the term "restaurants" and are therefore *not* exempt from the restrictions on indoor smoking.

A. Scope of FDA Authority

The agreement reaffirms the FDA's authority to regulate all tobacco products sold in interstate commerce, including new products entering the market, imports into the United States and products sold in U.S. duty free shops. The Bureau of Alcohol Tobacco and Firearms (ATF), the Federal Trade Commission (FTC), and the United States Department of Agriculture, however, will retain their existing authority to regulate tobacco.

B. State Authority

The settlement preserves the authority of state and local governments to further restrict accessibility to and use of tobacco among minors. In addition, state and local governments retain the authority to regulate smoking in the workplace and other public places, to restrict or eliminate the sale or distribution of tobacco products, and to impose taxes on such products.

The settlement also retains federal laws requiring states to adopt uniform requirements with respect to warning labels, packaging, advertising, and manufacturing of tobacco products.

Similarly, the FDCA's uniform manufacturing and design requirements for medical devices will apply to tobacco products. The FDA may permit states and local governments to impose different requirements only if those requirements would not "unduly burden" interstate commerce. For five years after the effective date of the settlement, however, no exemptions relating to ingredient requirements may be granted.

Title VI: Programs Funding

The settlement requires tobacco companies to pay $368.5 billion over 25 years to fund public health and smoking cessation programs. This amount includes a lump sum payment of $10 billion due immediately upon signing of the settlement, followed by annual base payments that range between $8.5 and $15 billion.

The amount of each year's scheduled base payment will be increased over the previous year's payment by the greater of 3% or the Consumer Price Index ("CPI"). In addition, the base payments will be adjusted according to fluctuations in the volume of tobacco product sales.[4] In order to further reduce youth smoking, the

[4] Annual adjustments will be made on the basis of the ratio of the domestic tobacco product sales volume for a given year to the base year volume. The base year is 1996. The amount of any reduction in the annual payment, however, will be

settlement requires tobacco companies to pass on the costs of these payments to tobacco consumers in increased product prices.

Through statutory provisions, these payment requirements will apply to all sellers of tobacco products, not merely the signatories to the settlement. The settlement permits tobacco companies to deduct these payments from their federal income tax liabilities as "ordinary and necessary business expenses."

Title VII: Public Health Funds from Tobacco Settlement

The payments received from tobacco companies will be used fund a variety of public health programs, as follows:

- The Secretary of HHS will receive $125 million for the first three years, and $225 million annually thereafter to fund programs aimed at reducing public use of tobacco products (e.g. education, prevention and cessation campaigns, as well as research efforts aimed at developing methods to reduce tobacco dependency).
- The FDA will receive $300 million annually to carry out its obligations and to enforce the provisions of this settlement.
- State and local governments will receive $75 million for the first two years, $100 million the third year, and $125 million annually thereafter to fund community-based programs aimed at reducing tobacco use.
- million per year will be dedicated to fund research and development of tobacco prevention and cessation methods.
- For the first 10 years following the effective date of the settlement, $75 million per year will be used to compensate organizations, events and teams that lose sponsorship by the tobacco industry as a result of the settlement. After 10 years, these funds will be reallocated to other public health programs.
- An independent, non-profit organization will be formed and will receive $500 million per year to fund multi-media public education campaigns designed to "discourage and de-glamorize" the use of tobacco products.
- A trust fund also will be established to assist existing smokers in their efforts to quit smoking. The fund, which will be managed by the Secretary of HHS, will receive $1 billion per year for the first four years and $1.5 billion per year thereafter.

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reduced to account for any increase in the tobacco industry's profitability above its base year net operating profits.

- A Public Health Trust Fund under the control of a Presidential Commission will receive $25 billion to fund specific tobacco-related medical research. Representatives from the public health community and state Attorneys General will serve on the Commission.

Title VIII: Civil Liability

A. General Provisions

The proposed agreement will "legislatively settle" all current and pending state Attorney General actions, *parens patriae* actions, and class action lawsuits, and will bar future prosecution of all such actions. With the exception of individual claims based on tobacco addiction and dependence, the settlement agreement will not affect the rights of individuals to litigate personal injury claims. In addition, the agreement does not settle third-party payor actions that were pending as of June 9, 1997, however, these actions are governed by the provisions regarding past conduct.

B. Provisions Addressing Civil Liability for Past Conduct

Under the settlement agreement, the following provisions would apply to all personal injury and damage claims arising from the conduct of tobacco companies that occurred prior to the effective date of the settlement:

- Plaintiffs in individual tort actions are barred from seeking punitive damages;
- Individuals are required to pursue their claims through individual trials only and are thus barred from joining their claims or initiating class actions. Defendants may remove any such action filed in state court to a federal court;
- The Federal Cigarette Labeling and Advertising Act and related case law remain unchanged;
- The five tobacco companies participating in the settlement negotiations will enter a liability-sharing agreement and will not be held "jointly and severally liable" for claims against non-participating companies;
- Only individuals suffering injury (or their heirs), third party payors bringing non-subrogation claims pending as of June 9, 1997, and third party payors bringing claims based on subrogation are eligible to bring claims against manufacturers. In addition, plaintiffs may bring claims only against tobacco product manufacturing companies, including their

successors, assigns and any future fraudulent transferee, and manufacturers that are vicariously liable for the acts of their agents, such as advertising agents and attorneys;

- Actions are removable to federal courts only by defendants.
- Evidence regarding the development of "reduced risk" tobacco products after the effective date of the settlement is neither admissible nor discoverable;
- State laws governing statutes of limitations apply;
- The tobacco industry's aggregate annual payments in a given year resulting from individual judgments and settlements are limited to a maximum of 33% of the "annual industry base payment" under Title VII. The tobacco companies may make any payments in excess of that amount in the following year. In addition, for each dollar paid by tobacco companies in satisfaction of such judgments or settlements, the tobacco industry receives an 80-cent reduction in the annual industry base payment due for that year.
- Tobacco companies are required to pay their own litigation costs.

C. Provisions as to Civil Liability for Future Conduct

With respect to legal actions based on the *future* conduct of tobacco companies, all paragraphs in Section B of this Title (except for paragraphs 1 and 4) apply. In addition, third party payor claims that are not based on subrogation are not permitted.

Title IX: Board Approval

The terms of the proposed settlement are subject to the approval of the Boards of Directors of the participating tobacco companies.

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MEMORANDUM

July 10, 1997

TO: American Cancer Society

FROM: Stephan E. Lawton

This memorandum summarizes and offers an initial evaluation of the provisions of the proposed settlement with the tobacco companies as it applies to the regulation of nicotine. We conclude that the proposed enactment of legislation explicitly recognizing FDA's authority to regulate tobacco products represents a major advantage to the public. There are, however, unwise barriers to FDA regulation of nicotine included in the proposed settlement.

We recommend that the American Cancer Society seek five changes or clarifications to the agreement. They are as follows:

- The document apparently contemplates that the type of administrative proceeding to be conducted by FDA in developing the Performance Standards for tobacco products during the first twelve years following the enactment of the proposed legislation would involve a hearing on the record -- a protracted trial-type proceeding -- which would give tobacco companies the ability to delay the imposition of standards. The legislation should instead specify that the standards be developed after notice and opportunity for comment, pursuant to 5 U.S.C. § 553.

- It would be preferable for the legislation to be silent on the standard to be applied by a court reviewing any FDA regulation during the initial twelve year period. As noted below, requiring review under a "substantial evidence" standard could pose some difficulties for FDA.

- Requiring that FDA demonstrate that any modification in tobacco products (including the reduction of nicotine yields) must be based, inter alia, on a finding that the modification will not result in significant demand for contraband is unreasonable.

- The basis by which FDA could require elimination of nicotine from tobacco products -- preponderance of the evidence -- poses a significant barrier to effective FDA action.

- Acknowledging that Congress has the right to review and block any proposed FDA action before it becomes applicable raises concerns. Encouraging such review by Congress invites an unnecessary "second bite at the apple" on Capitol Hill by opponents of Performance Standards.

THE FDA RULE

Background

On August 28, 1996, the Food and Drug Administration ("FDA") issued final regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents. See 61 Fed. Reg. 44,396-45,318 (1996). The regulations prohibit the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18; require manufacturers, distributors, and retailers to comply with certain conditions regarding the sale and distribution of these products; require retailers to verify a purchaser's age by photographic identification; prohibit all free samples; prohibit the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time; limit the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format; prohibit the sale or distribution of brand-identified promotional non-tobacco items such as hats and tee shirts; prohibit sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permit such sponsorship in a corporate name; and require manufacturers to provide intended use information (i.e., "Nicotine-Delivery Device for Persons 18 or Older") on all cigarette and smokeless tobacco product labels and in cigarette advertising.

Jurisdiction

FDA asserted jurisdiction over cigarettes and smokeless tobacco under the drug and medical device provisions of the Federal Food, Drug, and Cosmetic Act (FDC Act). Specifically, FDA concluded that cigarettes and smokeless tobacco are

"combination products" consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body. Id. at 44,628. A United States District Court has affirmed that FDA has the authority to regulate tobacco products as medical devices and to impose access restrictions and labeling requirements on tobacco products. The court found, however, that FDA lacks authority under the FDC Act to restrict the advertising and promotion of tobacco products. The court also ordered FDA not to implement any of the agency's regulatory requirements, other than those prohibiting the sale of tobacco products to minors, pending further orders by the court. 1/

Regulatory Requirements

FDA intends to regulate cigarettes and smokeless tobacco products under the device authorities of the FDC Act. For example, manufacturers will be required to: 1) submit medical device reports for serious adverse reactions that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing procedure; 2) register their establishment and submit device listing information; and 3) comply with the applicable device good manufacturing practice ("GMP") requirements. FDA's current regulations, however, would not control the development or manufacturing of tobacco products or impose any limitations on the nicotine content of these products.

PROPOSED RESOLUTION APPLICABLE TO REGULATION OF NICOTINE

A 64-page Proposed Resolution would resolve lawsuits brought by 40 states against the tobacco industry through enactment of legislation that, among other things, would confirm FDA's authority over tobacco products and advertising of such products. Unlike FDA's regulations, the proposed legislation would for the first time authorize the agency to regulate the development and manufacturing of cigarettes and smokeless tobacco products and the ingredients used in these products. In addition, the legislation would authorize FDA to take steps to ensure that the tobacco industry works to develop and introduce less hazardous tobacco products and to regulate the levels of nicotine in tobacco products.

Under this regulatory regime, the FDA's authority to regulate tobacco products "will be explicitly recognized and tobacco products will be classified as a

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1/ Coyne Beahm, Inc. v. FDA, 958 F. Supp 1060 (M.D.N.C. 1997).

new subcategory of a Class II device." 2/ The Class II classification would permit FDA to require modification of tobacco products, including the regulation of nicotine content, as well as permit the regulation of the sale of tobacco products to adults in accordance with Performance Standards.

Under the proposal, these Performance Standards may "require the modification of tobacco products to reduce the harm caused by those products (including the components that produce drug dependence), provided that the standard shall not require the prohibition on the sale to adults of traditional tobacco products." During the first twelve years following the effective date of the legislation, FDA may adopt Performance Standards that "require the modification of existing tobacco products, including the gradual reduction, but not the elimination, of nicotine yields, and the possible elimination of other constituents or other harmful components of the tobacco product." The Performance Standards must be based upon a finding that the modification:

- will result in a significant reduction of the health risks associated with such products to consumers thereof,
- is technologically feasible, and
- will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard.

Any such modification must be based upon a "showing of 'substantial evidence,' based upon an administrative record developed through a formal rule making subject to the Administrative Procedure[ ] Act ('APA'), with the right of judicial review." Such a modification would also be subject to the "Regulatory Reform Act of 1996 to provide time and a process for Congress to intervene should it so choose."

After the initial twelve year period, FDA may set product safety standards that go beyond the standards established previously, including the elimination of nicotine and other constituents or other demonstrated harmful components of the tobacco product. These additional modifications must be based upon the same findings listed above. Any modification that would eliminate nicotine or have an effect comparable to the elimination of nicotine must be based upon a "preponderance of the evidence" pursuant to, "at a manufacturer's election, a Part 12 hearing, or notice and comment rule making, with a right of judicial

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2/ The medical device provisions of the FDC Act authorize classification of devices into one of three classes. Devices classified into Class II -- Special Controls -- may be required to meet Performance Standards.

review." 3/ Any such action must be phased-in over a span of at least two years and would be subject to Congressional review under the "Regulatory Reform Act of 1996."

Under the proposed settlement, FDA may also regulate all direct or implied health claims regarding tobacco products. FDA may also require manufacturers either to introduce "less hazardous tobacco products" that are technologically feasible or to license such technology at a commercially reasonable rate. Any such action would take place "after a formal rule making subject to the Administrative Procedure[ ] Act, with the right of judicial review."

ANALYSIS

Benefits of the Proposed Settlement

One of the primary benefits of the proposed settlement is that the FDA's authority to regulate tobacco products as restricted medical devices "will be explicitly recognized." The proposed settlement clearly suggests that FDA's authority to regulate tobacco will be embodied in legislation. 4/

Statutory recognition of the FDA's authority to regulate tobacco would strengthen one of the major potential weaknesses in the campaign to regulate tobacco products. The Coyne Beahm decision is, of course, the principal authority supporting the FDA's jurisdiction to regulate tobacco. It carefully reviews and discards industry arguments that, with limited exceptions, FDA has no authority to regulate tobacco products as drugs or devices. It is dangerous, however, to place too great a reliance on Coyne Beahm -- like any District Court decision, it remains

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3/ A Part 12 hearing refers to a formal evidentiary public hearing under FDA regulations found at Code of Federal Regulations, Title 21, Part 12. Such hearings involve written and oral presentations, opportunity for cross-examination, submission of briefs and other trial-type procedures.

4/ Part E of the proposed settlement begins by stating that "[t]his legislation, for the first time would impose a regulatory regime to govern the development and manufacturing" of tobacco products, and then goes on to list "[e]lements of the regulatory regime" that would be included. The reference to a "regulatory regime" imposed by "legislation" probably indicates that, under the proposed settlement, Congress will go beyond mere silent acquiescence in FDA's assertion that it has the authority to regulate tobacco products and will explicitly recognize FDA's authority to do so in a statute. ACS should confirm that Congress will affirmatively embody such authority in a statute before it agrees to support the proposed settlement.

subject to reversal on appeal and has no binding authority on any other court. Indeed, even the Fourth Circuit's decision on appeal will not foreclose similar challenges being brought in other Circuits.

In reviewing the FDA's assertion that the FDC Act granted it the authority to regulate tobacco the Coyne Beahm court applied the deferential standard laid out in Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), in which the Supreme Court held that so long as Congress has not spoken directly to the precise question at issue, courts should defer to reasonable agency interpretations of statutes. The Coyne Beahm court concluded that Congress had not expressed any clear intent with regard to FDA's authority to regulate tobacco products. Therefore, the court deferred to FDA's construction of the FDC Act asserting such regulatory authority.

The reasoning of the Coyne Beahm case indicates that its conclusion would potentially be in jeopardy as soon as an Administration were elected that was less sympathetic to FDA regulation of tobacco. Since, under the reasoning of Coyne Beahm, Congress has not clearly expressed any clear intent on the issue, courts would be obligated to defer to any reasonable interpretation advanced by FDA, even if that interpretation represented a reversal of current policy. 5/ Thus, should a subsequent FDA Commissioner interpret the scope of FDA's authority under the FDC Act differently than the current Administration has and conclude that the FDA does not possess the authority to regulate tobacco under current law, under the reasoning of Coyne Beahm a reviewing court would defer to that interpretation and hold that the FDA lacks such authority. The enactment of legislation clearly granting to FDA the authority to regulate tobacco products would eliminate this concern.

POTENTIAL PROBLEMS WITH THE PROPOSED SETTLEMENT

1. The Requirement of Formal Rulemaking Procedures

Under the proposed settlement, FDA would have the authority to adopt Performance Standards and mandate the introduction of "less hazardous tobacco products" only after a "formal rule making" subject to the Administrative Procedure Act ("APA"). Under the APA, in order to promulgate a rule, in most cases

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5/ As the Coyne Beahm court explicitly recognized, under Supreme Court precedent agencies are allowed to alter their interpretations of the statutes they administer. 958 F. Supp. at 1070 (slip op. at 17-18) (citing Chevron, 467 U.S. at 863-884; Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983); and Rust v. Sullivan, 500 U.S. 173 (1991)).

agencies are required to publish a notice of proposed rule making in the Federal Register, permit interested persons to submit comments, and to incorporate in the rules a concise statement of the rule's basis and purpose. 5 U.S.C. § 553(b)-(c). When the rules are required by statute to be made on the record after opportunity for an agency hearing, however, more extensive procedural protections apply. Id. § 553(c). The proponent of the rule has the burden of proof. Id. § 556(d). The parties are entitled to present their case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct cross examination. Id. Before any decision is rendered, parties are entitled to a reasonable opportunity to submit proposed findings and conclusions or exceptions to decisions or recommended decisions issued by subordinate agency officials, along with supporting reasons. Id. § 557(c). Thus the requirement of a "formal rule making" has the potential of enabling the tobacco companies to complicate and encumber the administrative process.

Use of the formal hearing process to develop rules has been widely criticized in administrative law circles as unnecessarily cumbersome and time consuming. Indeed, twenty-five years ago the Administrative Conference of the United States recommended that

> in future grants of rulemaking authority to administrative agencies, Congress ordinarily should not impose mandatory procedural requirements other than those required by 5 U.S.C. § 553 . . . . Congress should never require trial-type procedures for resolving questions of policy or of broad or general fact. 6/

Two FDA rulemaking proceedings involving formal hearings illustrate the basis for the recommendation of the Administrative Conference. A hearing on Foods for Special Dietary Uses consumed over 200 days of testimony and a transcript of over 32,000 pages. A proceeding to establish the standard of identity for peanut butter (largely involving the issue of whether the product should consist of 90 percent peanuts or 87 1/2 percent peanuts) developed a transcript of over 7,700 pages. In both instances, more than ten years elapsed between the first proposal and the final order. 7/

6/ Administrative Conference of the U.S., Recommendation 72-5, Procedures for Adoption of Rules of General Applicability (Adopted Dec. 14, 1972).

7/ See, generally, Hamilton, Robert W., Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking, California Law Review, Vol. 60 (Spring, 1972).

The proposed settlement appears to contemplate that Performance Standards for tobacco products may be adopted during the initial twelve-year period only after a trial type hearing and other procedures. 8/ ACS should insist on the traditional "notice and comment" rulemaking in these situations.

2. The Application of the "Preponderance of the Evidence" Test After the First Twelve Years

After the initial twelve-year period, FDA will be permitted to require the limitation of nicotine based upon a " 'preponderance of the evidence' pursuant to, at a manufacturer's election, a Part 12 hearing, 9/ or notice and comment rulemaking." 10/ This provision is problematic. Requiring that an agency base an action upon the preponderance of the evidence is extremely unusual and runs contrary to the tenets of agency expertise and accountability that underlie most of administrative law. The extent to which courts would accord deference to an agency's policy judgments under preponderance of the evidence review is simply unclear.

Furthermore, in referring to "a manufacturer's election," the proposed settlement appears to give every single tobacco manufacturer the ability to dictate the type of procedures that must be followed before nicotine can be eliminated. It is unclear how any conflicts between the different manufacturers would be resolved.

We thus strongly recommend elimination of the preponderance of the evidence test as inappropriate in the context of administrative law. Moreover, authorizing manufacturers to select the type of administrative procedure should be eliminated.

8/ The Supreme Court has restricted the applicability of procedural requirements of 5 U.S.C. §§ 556-557 to situations in which the statute clearly indicates that the rule must be made "on the record after opportunity for an agency hearing." The use of similar, less stringent language in a statute is not sufficient. United States v. Florida E. Coast Ry., 410 U.S. 224 (1973). Thus unless the legislation states on its face that rule must be made "on the record after opportunity for a agency hearing," it is unclear whether agencies are obligated to follow the §§ 556-557 procedures.

9/ See Footnote 3.

10/ It should be noted that the preponderance of the evidence standard appears to apply only to FDA action to eliminate nicotine. It would not apply to FDA efforts to restrict nicotine unless that restriction would have an effect comparable to the elimination of nicotine.

3. The "Negative" Finding with Respect to Contraband

It should not prove difficult to establish two of the factual bases required for FDA regulation of tobacco products. There is significant scientific evidence that modifications of existing tobacco products "will result in a significant reduction of the health risks associated with such products to consumers thereof," and there can be little doubt that potential modifications exist that are "technologically feasible." The other finding -- that the modification "will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard -- could be more difficult to establish. Factual data needed to establish that regulating tobacco products will not create a significant demand for contraband tobacco products may not exist at the time of rulemaking. Indeed, the provision can appropriately be characterized as requiring "proof of the negative." It would be far preferable if the statute were clarified or deleted requirements concerning demand for contraband products altogether.

4. The Application of the "Substantial Evidence" Test During the First Twelve Years

The proposed settlement specifies that the FDA may impose Performance Standards that require the modification of existing tobacco products upon a showing of "substantial evidence." This means that a reviewing court would uphold an agency's action if it were supported by substantial evidence. In the absence of a hearing or special statutory provision, a court would overturn agency action if it was "arbitrary or capricious." 11/

On its face, the substantial evidence standard appears to be somewhat more stringent than the arbitrary or capricious standard. Under the case law, however, the proposed use of the substantial evidence standard poses few concerns. The substantial evidence standard has been held to require great deference to an expert agency. As the Supreme Court has held, the evidence needed to constitute substantial evidence need only be "enough to justify if the trial were to a jury a refusal to direct a verdict." Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-490 (1951) (citing NLRB v. Colombian Enameling & Stamping Co., 306 U.S. 292, 300 (1939)); see also Illinois Central R.R. v. Norfolk & Western Ry., 385 U.S. 57, 66 (1966). 12/

11/ The APA requires that courts set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

12/ Although the substantial evidence standard is more restrictive than the extremely deferential standard that governs review of jury verdicts, it is only

Furthermore, courts have interpreted these two standards as being largely the same. Indeed, with regard to factual determinations, courts have concluded that under "the emerging consensus of the Courts of Appeals" the difference between the substantial evidence test and the arbitrary or capricious test was "largely semantic" and held that there is "no substantive difference" between the substantial evidence test and the arbitrary or capricious standard. Association of Data Processing Serv. Orgs. v. Board of Governors, 745 F.2d 677, 683-684 (D.C. Cir. 1984) (Scalia, J.) (citing cases). Thus, the "quantum of factual support . . . demanded by the substantial evidence provision of the APA . . . is . . . no different from that demanded by the arbitrary or capricious standard." Id. at 686. Moreover, courts have drawn similar conclusions with regards to policy determinations, recognizing that to the extent that agency's decisions "depend to a greater extent upon policy judgments and less upon purely factual analysis," those decisions "are not susceptible to the same type of verification or regulation by reference to the record as are some factual questions." Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467, 474-475 (D.C. Cir. 1974). Accordingly, even when the governing statute purports to subject policy decisions to substantial evidence review, courts review such decisions under the arbitrary or capricious standard. Id. at 476. Thus the use of the substantial evidence standard should not appreciably affect the manner in which an agency makes factual or policy determinations.

We assume that the draftsperson included a requirement for use of the substantial evidence standard because it is the standard for review when an agency hearing is required. Our recommendation for notice and comment rulemaking is, therefore, inconsistent with imposition of the substantial evidence standard and we recommend its deletion.

5. The Applicability of the "Regulatory Reform Act of 1996"

The settlement provides that any rule governing the modification of Performance Standards during the initial twelve-year period or the elimination of nicotine after the initial twelve year period would be subject to Congressional review under the "Regulatory Reform Act of 1996." This language presumably refers to Section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, which was enacted as part of the Contract with America Advancement Act of 1996, Pub. L. No. 104-121. Under this provision, Congress has sixty days to pass a joint resolution of disapproval of any "major rule" proposed by an agency. "Major

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marginally more restrictive. As the Supreme Court held, "'(s)ubstantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" Universal Camera, 340 U.S. at 477 (citing Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)).

rule" includes any rule that the Office of Management and Budget finds has resulted in or is likely to result in an annual effect on the economy of $100 million or more. It is certainly likely that Performance Standards requiring reduction in nicotine yields would have this effect on the economy. We thus question the basis for specifically authorizing Congressional Review. This provision should be deleted.

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SMOKING AND HEALTH

Health Effects of Smoking

Smoking is the most preventable cause of death in our society, accounting for nearly one in five deaths in the United States.

☐ Smoking is related to *over* 419,000 U.S. deaths each year -- more than alcohol, car accidents, fires, suicides, homicides, drugs and AIDS combined.

☐ Smoking-related cancer deaths continue to rise.

- Since 1987, more women have died each year from lung cancer than breast cancer, which, for over 40 years, was the major cause of cancer death in women.

☐ Approximately half of all continuing smokers die prematurely from smoking. Of these, about 50% die in middle age (35-69), losing an average of 20 to 25 years of life expectancy.

☐ Smoking accounts for 29% of all cancer deaths.

- 87% of lung cancers are caused by smoking.

  ✓ Lung cancer mortality rates are 23 times higher for male smokers and 11 times higher for female smokers compared to never smokers.

- Smoking is also associated with cancers of the mouth, pharynx, larynx, esophagus, pancreas, uterine cervix, kidney and bladder.

☐ Smoking is a major cause of heart disease, and is associated with conditions ranging from colds and gastric ulcers to chronic bronchitis, emphysema, and cerebrovascular disease.

Smoking Prevalence

☐ In 1994, an estimated 48 million adults (25 million men and 22.7 million women) were current smokers in the U. S.

☐ Smoking trends:

- Cigarette smoking among adults aged 18 and over declined 40% -- from 42% to 25% -- between 1965 and 1990 (National Health Interview Survey).

- Between 1990 and 1994, the overall smoking prevalence among adults was virtually unchanged, although smoking among adolescents increased.

- Between 1983 and 1994, smoking prevalence among males (older than 18) declined from 34% to 28% for white men and from 42% to 34% for African American men; smoking prevalence among women (older than 18) declined from 30% to 23% among white women and from 32% to 22% among African American women. During the same time period, smoking prevalence among college graduates declined from 21% to 12% and among adults without a high school education declined from 41% to 32%.

Smoking and Youth

☐ More than 3 million American children and teenagers smoke cigarettes.

☐ For the more than 80% of adults who have ever smoked, cigarette smoking was initiated by age 18 and more than half were already smoking regularly by that age. As a matter of fact, the average teen smoker starts at age 13 and is addicted by age 14½.

☐ The National Health Interview Survey (NHIS) data show that while adult smoking prevalence remained virtually unchanged between 1990 and 1994, with the exception of African American female students, the percentage of high school students who smoke frequently increased from 3% in 1991 to 5% in 1995 for all racial, ethnic and gender groups.

☐ The 1995 Youth Risk Behavior Survey (YRBS) data show that:

- Nationwide, 71% of high school students have tried cigarette smoking.

- About one-third of high school students are current cigarette smokers (smoked at least one cigarette in the past 30 days).

- 16% of high school students are frequent smokers, an increase from 14% in the 1993 YRBS.

- White students (20%) are more likely than African American students (5%) or Hispanic students (10%) to smoke frequently.

☐ According to the Centers for Disease Control and Prevention (CDC):

- Teen smoking has gone up five years in a row.
- If nothing is done, 5 million Americans *who are now* children will die prematurely from tobacco-related diseases and impose $200 billion in future health care costs.

Cost of Tobacco

☐ Tobacco costs to our society are best measured by the number of people who die or suffer illness because of its use.

☐ Tobacco use also drains the U.S. economy of more than $100 billion in health care costs and lost productivity *annually.*

- Health care expenditures caused directly by smoking totaled $50 billion in 1993 (Centers for Disease Control).
  - ✓ Forty-three percent of those costs were paid by government funds, including Medicare and Medicaid.
  - ✓ Tobacco costs Medicare more than $10 billion and Medicaid more than $5 billion per year.
- Lost economic productivity caused by smoking cost the U.S. economy $47.2 billion in 1990 (Office of Technology Assessment).
  - ✓ Adjusted for inflation, the total economic cost of smoking is more than $100 billion per year.
  - ✓ This does not include costs associated with diseases caused by environmental tobacco smoke, bum care resulting from cigarette smoking-related fires, or perinatal care for low-birthweight infants of mothers who smoke.

☐ Even though smokers die younger than the average American, over the course of their lives, current and former smokers generate an estimated $501 billion in excess health care costs.

☐ On average, each cigarette pack sold costs Americans more than $3.90 in smoking-related expenses.

Environmental Tobacco Smoke

In 1992, the U.S. Environmental Protection Agency (EPA) declared that environmental tobacco smoke (ETS), also called secondhand smoke, is a human carcinogen.

- ☐ Each year, about 3,000 nonsmoking adults die of lung cancer as a result of breathing the smoke of others' cigarettes.

- ☐ ETS causes an estimated 35,000 to 40,000 deaths from heart disease in people who are not current smokers, and can result in aggravated asthmatic conditions, impaired blood circulation, bronchitis and pneumonia.

- ☐ Children exposed to secondhand smoke have increased risks of respiratory illnesses and infections, impaired development of lung function, and middle ear infections.

- ☐ Secondhand smoke contains over 4,000 chemical compounds, including carbon monoxide, formaldehyde, ammonia, nickel, zinc, acetone, cholesterol, hydrogen cyanide, and formic acid.

- ☐ Four chemicals in secondhand smoke (benzene, 2-naphthylamine, 4-aminobiphenyl and polonium-210) are known human carcinogens, based on EPA standards.

- ☐ Ten other chemicals in secondhand smoke are classified by the EPA as probable human carcinogens.

Smokeless Tobacco

"Smokeless tobacco" is a phrase that is widely used by the tobacco industry in its advertising and promotion. It implies that snuff and chewing tobacco are safe alternatives to smoking. This is false. All tobacco products cause cancer and contain nicotine, a highly addictive drug.

- ☐ Smokeless tobacco causes cancer of the mouth, pharynx, esophagus and pancreas, and many other oral problems.

- ☐ Nearly 30,000 new cases of oral cancer are diagnosed each year in the U.S. Half of those diagnosed die within five years.

- ☐ There has been a resurgence in the use of all forms of smokeless tobacco - plug, leaf and snuff.

- From 1970 to 1985, the percentage of males aged 16-19 using snuff increased ninefold from 0.3% to 2.9%.

- For all smokeless tobacco products, prevalence of males aged 16-19 increased from 1.4% to 5.9%.

- About 11% of high school seniors had used smokeless tobacco during the previous 30 days (1994 Monitoring the Future Project survey).

Cigars

Because cigar smoke is rarely inhaled, there is a growing false sense of security that cigar smoking is safe. Congress did not explicitly include cigars in the 1984 law requiring health warnings on cigarettes. Yet most of the same carcinogens and cancer-producing chemicals found in cigarettes are found in cigars.

☐ The year 1994 marked the first annual increase in cigar consumption since 1970.

☐ Growing numbers of women are also participating in this unhealthy fad.

☐ According to the Centers for Disease Control, an estimated 6 million (26.7%) U.S. teenagers aged 14 to 19 -- 4.3 million males (37%) and 1.7 million females (16%) -- smoked at least one cigar within the past year.

☐ Overall cancer deaths among men who smoke cigars are 34% higher an among nonsmokers.

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NICOTINE DEPENDENCE

Nicotine

☐ Manufactured tobacco products facilitate and optimize the delivery of nicotine to the brain where the drug affects the central nervous system.

☐ Inhaled smoke carries the nicotine deeply into the lungs where it is quickly absorbed into the blood and carried to the heart and brain.

☐ Cigar smoke, snuff, and chewing tobacco present nicotine to the buccal mucosal and into the veins, where its effect does not produce the large, quick surges of inhaled nicotine.

☐ With continued use, nicotine is addictive because it changes the way information is transmitted in the brain.

- As their nervous systems adapt to tolerate nicotine, tobacco users gradually increase the number of cigarettes they smoke, tobacco they chew, or snuff they use, and hence the amount of nicotine in their blood.

- Smokers and other tobacco users reach a target level of nicotine concentration in their blood and then maintain this level through continued use of tobacco products.

- Evidence shows that nicotine use can cause a drug dependence, that is, a lack of control over use and continued use despite the known consequences.

- The absence of nicotine leads to withdrawal symptoms, such as irritability, headache, change in appetite, and symptoms of depression. This may lead the addict to use enough nicotine to boost blood levels back to the target level.

☐ Nicotine also acts as a depressant by inhibiting the flow of information between nerve cells.

☐ Nicotine affects many parts of the body, including the cardiovascular system, the hormonal system, and the brain.

Children and Nicotine Dependence

☐ About 6,000 young people begin to experiment with tobacco each day, with two-thirds to three-quarters of children in the United States experimenting with tobacco at least once.

- Nearly half of these continue with experimentation.
- By the senior year of high school, about 20 percent of students report smoking every day.

☐ Many complications from tobacco use might not be apparent until decades after initiating use, but young people may experience effects such as persistent cough from smoking or gum recession and malignant oral lesions from chewing tobacco.

☐ Prolonged use of tobacco products will cause nicotine dependence in children.

- Children often start to smoke once their attitudes change so that smoking is "okay" and they find that tobacco products are fairly easy to obtain.
- Some concerns about children using cigarettes and moist snuff are that these often go along with alcohol abuse and may lead to other drug problems, such as heroin or cocaine use.
- Through smoking, children learn how to take a psychoactive drug and how to control their doses of nicotine to prevent adverse side effects, such as a cough or nausea.

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Divider Title: _____

TOBACCO AND SPECIAL POPULATIONS

The declining prevalence of smoking over the past few decades is the most important contributor to the sustained decline in cancer mortality in the US since 1991. In 1965, 42 percent of adults were smokers. By 1994, the smoking prevalence had decreased to 26 percent. However, over the years, the problem of tobacco use has become increasingly concentrated among Americans with lower socioeconomic status and some racial minority groups and, as a result, these populations suffer from a particularly severe burden of smoking-related disease.

Socioeconomic Status

- Lung cancer has consistently been associated with low socioeconomic status (SES). Much of the excess incidence and mortality from lung cancer is associated with higher rates of cigarette smoking among lower SES groups. In 1994, smoking prevalence among adults living below the poverty level was 35 percent, significantly higher than the prevalence among adults living at or above the poverty level (24 percent).

- The association between socioeconomic status and tobacco use exists among adolescents as well as adults. In 1992, when 20 percent of all adolescents aged 12 to 17 smoked cigarettes, cigarette smoking was significantly more prevalent among adolescents from lower-income families (25 percent) and from families in which the responsible adult had not completed high school (25 percent).

- Although there has been little, if any, evidence of a causal relationship between SES and tobacco use, a variety of explanations have been offered to explain the higher prevalence of smoking among lower SES groups.

    - ❖ The socioeconomically disadvantaged experience greater psychological stress in their lives because of the hassles of having to survive in difficult environments. This stress may result in increased tobacco use as a coping behavior. Stress may be a barrier to successful smoking cessation also.

    - ❖ Social support may promote the adoption or continuation of healthy behaviors such as not smoking. Lower SES persons are likely to have weaker social support networks because of less stability in their lives.

    - ❖ Generally, health education campaigns have shown to be less effective in producing behavior change in lower SES populations than in their higher

SES counterparts. Those with more education may be more aware of health risks and better prepared or more inclined to take action to reduce those risks. In addition to being generally less knowledgeable about the health effects of smoking, low SES populations are more likely to have fatalistic attitudes regarding their ability to prevent smoking-attributable diseases.

Race and Ethnicity

- Race/Ethnicity is a surrogate for a set of conditions and circumstances that influence behaviors that may impact health. As a predictor of conditions and circumstances that impact health, race and ethnicity are similar to SES, although SES may be a stronger factor in explaining variations in smoking prevalence among different groups of Americans.

Nonetheless, the relevance of race and ethnicity to tobacco use and smoking-attributable diseases is undeniable.

- There is considerable variation in smoking prevalence among racial and ethnic groups of Americans. In 1994, the prevalence of smoking was highest for American Indians/Alaska Natives (42 percent) and lowest for Asian Americans/Pacific Islanders (14 percent). Also, within racial and ethnic categories, there is considerable difference between genders and ethnic subgroups. Smoking prevalence is much higher among groups from Southeast Asia than other ethnic groups such as Chinese. Asian American Pacific Islander women in all ethnic subgroups are much less likely to smoke than their male counterparts. For American Indians and Alaska natives, cigarette smoking prevalence varies greatly in relation to tribal affiliations and regionally with prevalence lowest in the Southwest and highest in the Northern Plains.

- The prevalence of smoking among Hispanics has been consistently lower than among non-Hispanics. Hispanic women have the lowest rates of smoking among ethnic gender groups. In the Hispanic population, as well as other groups with significant numbers of recent immigrants, acculturation is a significant factor. Recent immigrants from Mexico and Central America are less likely to smoke than other Hispanics.

- The prevalence of cigarette smoking among African American adults was slightly higher than the national rate (27 percent versus 26 percent). However, African American adolescents were less likely to use tobacco in 1992 in comparison to their White counterparts (9 percent versus 23 percent). The prevalence of smoking among African American male adolescents has increased steadily in recent years however.

Targeted Marketing by the Tobacco Industry

- Marketing by the tobacco industry has been shown to target selectively minority and lower SES groups. Outdoor advertising in particular has been used in poor and minority neighborhoods to associate tobacco products with culturally-specific imagery and prosperous and glamorous lifestyles. Billboard advertising by the tobacco industry has been shown to be particularly ubiquitous in urban, minority communities.

- In addition to paid advertising, the tobacco industry has raised the visibility of its products in minority communities through the sponsorship of sports and cultural events, such as traditional festivals and concerts, that appeal to people of color. Also, targeted philanthropic activities create a financial dependency in communities of color that tends to inhibit organizations from addressing the tobacco-related problems of their communities.

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Divider Title: _____

SMOKING CESSATION

Over the past 30 years, smoking in the US has declined to about 25% of the population as the result of a massive public education program by the federal government and private organizations. Today's smoker, who has continued his or her habit in spite of clear information about its harmful effects, is largely a much heavier smoker and much more addicted. Today's average smoker smokes from 30 to 32 cigarettes a day. In spite of this heavier addiction, the 1988 Surgeon General's Report states that from 70 - 90% of these remaining smokers would quit if it were not for withdrawal symptoms.

Quitting smoking carries major and immediate benefits for men and women of all ages, even those in the older age groups. Benefits apply to healthy people and to those already suffering from smoking-related diseases.

Smoking Cessation in the U.S.

☐ More than 38 million American adults have quit smoking, and nearly half of all living adults who ever smoked cigarettes have quit.

- Women are more likely than men to try to quit smoking. However, an equal proportion of men and women have been off cigarettes for 1 to 4 years. Men are more likely than women to have been off cigarettes for 5 or more years.

- Blacks are more likely than whites to try to quit smoking. However, whites are more likely than blacks to have been off cigarettes for 1 or more years.

- Younger smokers (ages 20 to 44) are more likely than older smokers to try to quit smoking.

- People with any college education are more likely than those without to both try to quit and to stay off cigarettes for 1 or more years. Most ex-smokers cycle through the quitting process several times before becoming long-term quitters.

- At least one-third of smokers who stay off cigarettes for one or more years may eventually relapse. However, relapse becomes less likely as ex-smokers stay off cigarettes for longer periods of time.

- Additional research and assessment is needed into the impact of cessation programs on various population groups particularly children and adolescents.

Smoking Cessation and Life Expectancy

☐ People who quit smoking live longer than those who continue to smoke.

- After 15 years off cigarettes, the risk of death for ex-smokers returns to nearly the level of persons who have never smoked.

- Male smokers who quit between ages 35 to 39 add an average of 5 years to their lives. Female quitters in this age group add 3 years.

- Men and women who quit at ages 65 to 69 increase their life expectancy by one year.

Smoking Cessation and Health

☐ Quitting smoking decreases the risk of lung cancer, heart disease, stroke, chronic lung diseases, and respiratory illnesses.

- After 10 years, the risk of lung cancer for ex-smokers drops to as much as 1/2 that of continuing smokers.

- In 10 to 15 years, the risk of stroke for ex-smokers returns to the level of those who have never smoked.

- Ex-smokers who have been off cigarettes for many years are less likely to die of chronic lung diseases, such as emphysema, than those who continue to smoke.

- Ex-smokers have fewer days of illness, fewer health complaints, better self-reported health status, and reduced rates of bronchitis and pneumonia.

- For people with heart disease, quitting smoking reduces the risk of repeat heart attacks and death from heart disease by 50% or more.

- For people with poor circulation to the legs, quitting smoking improves the ability to exercise and increases overall survival.

- For people with ulcers, quitting smoking reduces the risk of recurrence and improves short-term healing.

Smoking Cessation and Women

☐ There are unique benefits for women who quit smoking.

- If all women quit smoking during pregnancy, about 5% of deaths among newborn infants could be prevented.
- Women who stop smoking before becoming pregnant or during the first trimester of pregnancy reduce their risk of having a low birthweight baby to that of women who have never smoked.
- It takes female smokers longer to get pregnant than nonsmokers.
- Women who quit smoking before trying to get pregnant are as likely to get pregnant as women who have never smoked.

Nicotine Substitutes

☐ Nicotine substitutes, in the form of transdermal patches, chewing gum and nasal sprays, can double the successful quit rate among smokers. Yet treatment of withdrawal symptoms is only part of a smoking cessation effort.

- All over-the-counter products currently include a behavior modification program.
- Studies have shown that a combined approach to smoking cessation that pairs treatment of withdrawal symptoms and behavioral counseling can double the quit rate achieved by one or the other approach alone.
- In carefully controlled clinical trials, nicotine patches combined with behavioral programs resulted in 22 - 24% quit rates.