NLWJC - Kagan

DPC - Box 043 - Folder 001

Tobacco-Settlement - Agreement [2]

Tobacco - settlement agreement

FOR SETTLEMENT DISCUSSION
PURPOSES ONLY 6/20/97 3:00 p.m.

PROPOSED RESOLUTION

PREAMBLE

This legislation would mandate a total reformation and restructuring of how tobacco products are manufactured, marketed and distributed in this country. The nation can thereby see real and swift progress in preventing underage use of tobacco, addressing the adverse health effects of tobacco use and changing the corporate culture of the tobacco industry.

The Food and Drug Administration ("FDA") and other public health authorities view the use of tobacco products by our nation's children as a "pediatric disease" of epic and worsening proportions that results in new generations of tobacco-dependent children and adults. There is also a consensus within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease and other serious adverse health effects.

The FDA and other health authorities have concluded that virtually all new users of tobacco products are under legal age. President Clinton, the FDA, the Federal Trade Commission ("FTC"), state Attorneys General and public health authorities all believe that tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents. These officials have concluded that, because past efforts to restrict advertising and marketing have failed to curb adolescent tobacco use, sweeping new restrictions on the sale, promotion and distribution of such products are needed.

Until now, federal and state governments have lacked many of the legal means and resources they need to address the societal problems caused by the use of tobacco products. These officials have been armed only with crude regulatory tools which they view as inadequate to achieve the public health objectives with which they are charged.

This legislation greatly strengthens both the federal and state governments' regulatory arsenal and furnishes them with additional resources needed to address a public health problem that affects millions of Americans, including most importantly underage tobacco use. Further, it is contemplated that certain of the obligations of the tobacco companies will be implemented by a binding, enforceable contractual protocol.

The legislation reaffirms individuals' right of access to the courts, to civil trial by jury and to full compensatory damages. Resolution through the Act of potential punitive damages liability of the tobacco industry for past conduct is only made in the context of the comprehensive settlement proposed by the legislation. It is not intended to have precedential effect, nor does it express any position adverse to the imposition of punitive damages in general or as applied to any other specific industry, case, controversy or product and does not provide any authority whatsoever regarding the propriety of punitive damages.

Among other things, the new regime would:

- Confirm FDA's authority to regulate tobacco products under the Food, Drug and Cosmetic Act, making FDA not only the preeminent regulatory agency with respect to the manufacture, marketing and distribution of tobacco products but also requiring the tobacco industry to fund FDA's oversight out of on-going payments by the manufacturers pursuant to the new regime ("Industry Payments").

- Go beyond FDA's current regulations to ban all outdoor tobacco advertising and to eliminate cartoon characters and human figures, such as *Joe Camel* and the *Marlboro Man*, two tobacco icons which the public health community has long assailed as advertising appealing to our nation's youth.

- Impose and provide funding out of the Industry Payments for an aggressive federal enforcement program, including a State-administered retail licensing system, to stop minors from obtaining tobacco products, while in no way preventing the States from enacting additional measures.

- Ensure that the FDA and the States have the regulatory flexibility to address issues of particular concern to public health officials, such as youth tobacco usage and tobacco dependence.

- Subject the tobacco industry to severe financial surcharges in the event underage tobacco use does not decline radically over the next decade.

- Empower the federal government to set national standards controlling the manufacturing of tobacco products and the ingredients used in such products.

- Provide new and flexible regulatory enforcement powers to ensure that the tobacco industry works to develop and introduce "less hazardous tobacco products," including, among other things, vesting FDA with the power to regulate the levels of nicotine in tobacco products.

- Require the manufacturers of tobacco products to disclose all previously non-public internal laboratory research and all new internal laboratory research generated in the future relating to the health effects or safety of their products.

- Establish a minimum federal standard with tough restrictions on smoking in public places with enforcement funding from the Industry Payments, while preserving the authority of state and local governments to enact even more severe standards.

- Authorize and fund from Industry Payments a $500 million annual, national education-oriented counter-advertising and tobacco control campaign seeking to discourage the initiation of tobacco use by children and adolescents and to encourage current tobacco product users to quit use of the products.

- Authorize and fund from Industry Payments the annual payment to all States of significant, on-going financial compensation to fund health benefits program expenditures and to establish and fund a tobacco products liability judgments and settlement fund.

- Authorize and fund from Industry Payments a nationwide program, administered through State governments and the private sector, of smoking cessation.

The sale of tobacco products to adults would remain legal but subject to restrictive measures to ensure that they are not sold to underage purchasers. These measures respond directly to concerns voiced by federal and state public health officials, the public health community and the public at large that the tobacco industry should be subject to the strictest scrutiny and regulatory oversight. This statute imposes regulatory controls, including civil and criminal penalties, equal to, and in many respects exceeding, those imposed on other regulated industries. Further, it imposes on tobacco manufacturers the obligation to provide funding from Industry Payments for an array of public health initiatives.

The sale, distribution, marketing, advertising and use of tobacco products are activities substantially affecting interstate commerce. Such products

are sold, marketed, advertised and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the nation's economy. The sale, distribution, marketing, advertising and use of such products are also activities substantially affecting interstate commerce by virtue of the health care and other costs that federal and State governmental authorities have attributed to usage of tobacco products.

Various civil actions are pending in state and federal courts arising from the use, marketing or sale of tobacco products. Among these actions are cases brought by some 40 state Attorneys General, cases brought by certain cities and counties, the Commonwealth of Puerto Rico, and other third-party payor cases seeking to recover monies spent treating tobacco-related diseases and for the protection of minors and consumers. Also pending in courts throughout the United States are various private putative class action lawsuits brought on behalf of individuals claiming to be dependent upon and injured by tobacco products. Additionally, a multitude of individual suits have been filed against the tobacco products manufacturers and/or their distributors, trade associations, law firms and consultants.

All of these civil actions are complex, slow-moving, expensive and burdensome, not only for the litigants but also for the nation's state and federal judiciaries. Moreover, none of those litigations has to date resulted in the collection of any monies to compensate smokers or third-party payors. Only national legislation offers the prospect of a swift, fair, equitable and consistent result that would serve the public interest by (1) ensuring that a portion of the costs of treatment for diseases and adverse health effects linked to the use of tobacco products is borne by the manufacturers of these products, and (2) restricting nationwide the sale, distribution, marketing and advertising of tobacco products to persons of legal age. The unique position occupied by tobacco in the nation's history and economy, the magnitude of actual and potential tobacco-related litigation, the need to avoid the cost, expense, uncertainty and inconsistency associated with such protracted litigation, the need to limit the sale, distribution, marketing and advertising of tobacco products to persons of legal age, and the need to educate the public, especially young people, of the health effects of using tobacco products all dictate that it would be in the public interest to enact this legislation to facilitate a resolution of the matters described.

Public health authorities believe that the societal benefits of this legislation, in human and economic terms, would be vast. In particular, FDA has found that reducing underage tobacco use by 50% "would prevent well over 60,000 early deaths." FDA has estimated that the monetary value of its present regulations will be worth up to $43 billion per year in reduced medical costs, improved productivity and the benefit of avoiding the premature death of loved

ones. This statute, which extends far beyond anything FDA has previously proposed or attempted, can be expected to produce human and economic benefits many times greater than such existing regulations.

As part of this settlement, the tobacco companies recognize the historic changes that will be occurring to their business. They will fully comply with increased federal regulation, focus intense efforts on dramatic reductions in youth access and youth tobacco usage, recognize that the regulatory scheme encourages the development of products with reduced risk and acknowledge the predominant public health positions associated with the use of tobacco products.

[Source/precedent: FDA Rule]

Contents

Appendices:

TITLE I: Reformation Of The Tobacco Industry

Title I of the legislation would incorporate and expand upon FDA's recent regulation of nicotine-containing tobacco products. The following rules would apply to all tobacco products sold in the U.S. (including all its territories and possessions, as well as duty-free shops within U.S. borders). The new regime would be allowed to operate as described below for five years. FDA would have authority to make revisions even within this period under extraordinary circumstances. Thereafter, the FDA would be authorized to review and revise the rules under applicable Agency procedures.

A. Restrictions on Marketing and Advertising

The advertising and marketing of tobacco products would be drastically curtailed, including in ways that exceed the FDA rule as originally promulgated and in ways that have previously been challenged on First Amendment grounds. As in the FDA rule, the new regime would:

- Prohibit the use of non-tobacco brand names as brand names of tobacco products except for tobacco products in existence as of January 1, 1995 (897.16(a))[1]

- Restrict tobacco product advertising to FDA specified media (897.30(a)(1)-(2))

- Restrict permissible tobacco product advertising to black text on a white background except for advertising in adult-only facilities and in adult publications (897.32(a)-(b))

- Require cigarette and smokeless tobacco product advertisements to carry the FDA-mandated statement of intended use ("Nicotine Delivery Device") (897.32(c))

- Ban all non-tobacco merchandise, including caps, jackets or bags bearing the name, logo or selling message of a tobacco brand (897.34(a))

- Ban offers of non-tobacco items or gifts based on proof of purchase of tobacco products (897.34(b))

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1 The citations in this and in the next section are to Part 897 of the FDA's tobacco regulations, 61 Fed. Reg. 44396 (August 28, 1996).

- Ban sponsorships, including concerts and sporting events, in the name, logo or selling message of a tobacco brand (897.34(c))

Further, building on and going beyond the FDA rule, the new regime would:

- Ban the use of human images and cartoon characters – thereby eliminating *Joe Camel* and the *Marlboro Man* – in all tobacco advertising and on tobacco product packages

- Ban all outdoor tobacco product advertising, including in enclosed stadia as well as brand advertising directed outside from a retail establishment (modifies 897.30(a)(1) and extends 897.30(b))

- Prohibit tobacco product advertising on the Internet unless designed to be inaccessible in or from the United States

- Establish nationwide restrictions in non adult-only facilities on point of sale advertising with a view toward minimizing the impact of such advertising on minors. These provisions, which are detailed in Appendix VII, restrict point of sale advertising that was otherwise permitted in retail establishments by the FDA rule.

- Ban direct and indirect payments for tobacco product placement in movies, television programs and video games

- Prohibit direct and indirect payments to "glamorize" tobacco use in media appealing to minors, including recorded and live performances of music

- Without limiting the FDA's normal rulemaking authority in this area, require that the use, in both existing and future brand styles, of words currently employed as product descriptors (e.g., "light" or "low tar") be accompanied by a mandatory disclaimer in advertisements (e.g., "Brand X not shown to be less hazardous than other cigarettes"); exemplars of all new advertising and tobacco products labeling shall be submitted to FDA concurrently with their introduction into the marketplace for FDA's on-going review.

[Source/precedent: FDA Rule; 21 C.F.R. 101.70]

B. Warnings, Labeling and Packaging

The federally-mandated warning labels on cigarettes were last changed in 1984. Since then a number of countries, including Canada and members of the

European Union, have imposed new warning labels. Further, the Federal Trade Commission's methodology to measure the "tar" and nicotine yields of cigarettes has been criticized as producing misleading information.

1. The legislation, through amendments to the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, would mandate new rotating warnings, to be introduced concurrently into the distribution chain on all tobacco product packages and cartons, and to be rotated quarterly in all advertisements. For cigarettes, the warnings would be:

- "WARNING: Cigarettes are addictive"
- "WARNING: Tobacco smoke can harm your children"
- "WARNING: Cigarettes cause fatal lung disease"
- "WARNING: Cigarettes cause cancer"
- "WARNING: Cigarettes cause strokes and heart disease"
- "WARNING: Smoking during pregnancy can harm your baby"
- "WARNING: Smoking can kill you"
- "WARNING: Tobacco smoke causes fatal lung disease in non-smokers"
- "WARNING: Quitting smoking now greatly reduces serious risks to your health"

For smokeless tobacco products, the warnings would be:

- "WARNING: This product can cause mouth cancer"
- "WARNING: This product can cause gum disease and tooth loss"
- "WARNING: This product is not a safe alternative to cigarettes"
- "WARNING: Smokeless tobacco is addictive"

For cigarettes, the warnings would occupy 25% of the front panel of the package (including packs and cartons) and would appear on the upper portion thereof. The legislation would contain a grandfather provision for existing brands with flip-top

boxes comprising less than 25% of the front panel. For smokeless tobacco products, the warnings would appear on the principal display panel (e.g., a band around the can for moist smokeless tobacco products) and would occupy 25% of the display panel. The warnings would be printed in line with current Canadian standards (e.g., 17 point type with appropriate adjustments depending on length of required text) and in an alternating black on white and white on black format. The size and placement of warnings in advertisements would follow the requirements set forth in the existing United Kingdom standards. As described in Appendix I, the warning text and, where relevant, "tar" and nicotine (or other constituent) yield information would occupy 20% of press advertisements.

Cigarette and smokeless tobacco product packages would also carry the FDA mandated statement of intended use ("Nicotine Delivery Device") on the side of pack.

2. The FDA would be required to promulgate a rule governing the testing, reporting and disclosure of tobacco smoke constituents that the Agency determines the public should be informed of to protect public health, including, but not limited to "tar," nicotine and carbon monoxide. This authority would be transferred from the FTC and would include the authority to require label and advertising disclosures relating to "tar" and nicotine, as well as disclosures by other means relating to other constituents.

[Source/precedent: Canadian warning regulations; FDA Rule; FDCA, 21 U.S.C. Sec. 360h, with conforming amendment in light of FCLAA]

C. Restrictions on Access to Tobacco Products

Preventing youth access to tobacco products is a major objective of this legislation and the FDA Rule. Without preventing state and local governments from imposing stricter measures, the legislation would incorporate every access restriction of the FDA Rule, and more. As in the FDA Rule, the legislation would:

- Set a minimum age of 18 to purchase tobacco products (897.14(a))
- Require retailers to check photo identification of anyone under 27 (897.14(b)(1)-(2))
- Establish the basic requirement of face-to-face transactions for all sales of tobacco products (897.14(c))
- Ban the sale of tobacco products from opened packages (897.14(d))

- Establish a minimum package size of 20 cigarettes (897.16(b))

- Impose retailer compliance obligations to ensure that all self-service displays, advertising, labeling and other items conform with all applicable requirements (897.14(e))

- Ban the sampling of tobacco products (897.16(d))

- Ban the distribution of tobacco products through the mail, including redemption of coupons, except for sales subject to proof of age, with a review after 2 years by FDA to determine if minors are obtaining tobacco products through the mail (goes beyond 897.16(c)(2)(i))

Building on and going beyond the FDA Rule, the legislation would:

- Ban all sales of tobacco products through vending machines (goes beyond 897.16(c)(2)(ii))

- Ban self-service displays of tobacco products except in adult-only facilities. In all other retail outlets, tobacco products must be placed out of reach of consumers (i.e., behind the counter or under lock-and-key) or, if on the counter, not visible or accessible to consumers (goes beyond (897.16(c)(2)(ii))

[Source/precedent: FDA Rule]

D. Licensing of Retail Tobacco Product Sellers

The legislation would mandate minimum federal standards for a retail licensing program that the federal government and state and local authorities would enforce through funding provided by the Industry Payments. Any entity that sells directly to consumers – whether a manufacturer, wholesaler, importer, distributor or retailer – would require a license.

Elements of the licensing program would include:

- Mandating compliance with the Act as a condition to obtain and hold a license

- Penalties for violations (See Appendix II)

- Suspension or revocation of licenses (on a site-by-site basis) for certain violations (see Appendix II)

- A requirement that distribution of tobacco products for resale to consumers be made only to licensed entities

- Licensing fees to cover the administrative costs of issuing state licenses (all other costs covered as noted above)

- Comparable federal licensing programs (with federal enforcement) for military facilities, U.S. government installations abroad, and other U.S. territories and possessions not otherwise under the jurisdiction of the States (including duty-free shops within U.S. borders)

- Comparable licensing programs to govern tobacco product sales on Indian lands (see Appendix III)

[Source/precedent: Various state laws governing sales of tobacco products and alcoholic beverages]

E. Regulation of Tobacco Product Development and Manufacturing

This legislation, for the first time, would impose a regulatory regime to govern the development and manufacturing of cigarettes and smokeless tobacco products, including FDA approval of the ingredients used in such products and imposition of standards for reducing the level of certain constituents, including nicotine.

Elements of the regulatory regime would include:

1. Tobacco products shall have the same definition as contained in the FDA Rule. Jurisdiction shall also cover Roll Your Own, Little Cigars, Fine Cut, etc.

2. Tobacco will continue to be categorized as a "drug" and a "device" under the Food, Drug and Cosmetic Act ("FDCA"). The Agency's authority to regulate the products as "restricted medical devices" will be explicitly recognized and tobacco products will be classified as a new subcategory of a Class II device pursuant to 21 U.S.C. section 360c. FDCA shall apply to these products as provided by the Act and the amendments to FDCA contained herein.

3. The Class II classification shall permit FDA to require product modification of tobacco products, including the regulation of nicotine content, and shall provide that the sale of tobacco products to adults in the form that conforms to Performance Standards established for tobacco products pursuant to Section 514 ("Section 514") of the

FDCA (21 U.S.C. Section 360d) shall be permitted notwithstanding 21 U.S.C. Sections 360f, 352(j) and 360h(e)

4. Reduced Risks Products

Products sold that an objective, reasonable consumer would believe pose less of a health risk:

- Tobacco product manufacturers will be barred from making claims that could reasonably be interpreted to state or imply a reduced health risk unless the manufacturer demonstrates to FDA that the product scientifically does in fact "significantly reduce the risk to health" from ordinary tobacco products. Currently employed product descriptors such as "light" and "low tar" will be regulated as described in I(A) above.

- FDA would have to approve all health claims (direct or implied), as well as the content and placement of any such claims in advertisements, to prevent the public from being misled and to prevent the advertisement from being used to expand, or prevent the contraction of, the marketplace.

- For "less hazardous tobacco products", FDA will be authorized to permit scientifically-based specific health claims and to permit exceptions to the advertising restrictions that apply to other products if FDA determines that such advertising would reduce harm and promote the public health. The FDA will promulgate a rule to govern how these determinations will be made.

- The manufacturers will be required to notify FDA of any technology that they develop or acquire and that reduces the risk from tobacco products and, for a commercially reasonable fee, to cross license all such technology, but only to those companies also covered by the same obligations. Procedural protections will be built in to resolve license fee disputes, if the private parties cannot agree among themselves first. If the technology reported to the FDA is in the early development stages, the manufacturer will be provided confidentiality protection during the development process.

- The Agency shall also have the authority to mandate the introduction of "less hazardous tobacco products" that are technologically feasible, after a formal rule making subject to the Administrative Procedures Act ("APA"), with the right of judicial review. In doing so,

the Agency shall have the authority to mandate that a manufacturer subject to this Act who owns such technology (at such manufacturer's election) either introduce such products, or, at a commercially reasonable market rate, license such technology to a manufacturer who agrees to bring the technology to market in a reasonable time frame. In the event that no manufacturer or licensee introduces such "less hazardous tobacco products," within a reasonable time frame set by FDA, then the U.S. Public Health Service may produce either itself, or through a licensing arrangement, any such product.

- The goal of any rule mandating the introduction into the marketplace of "less hazardous tobacco products" for which the technology exists is to guarantee that a mechanism exists to ensure that products which appear to hold out the hope of reducing risk are actually tested and made available in the marketplace and not held back.

5. Performance Standards

To further the public health, to promote the production of "reduced risk" tobacco products, and to minimize the harm to consumers of tobacco products by insuring that the best available, feasible safety technology becomes the industry standard, FDA will have the authority to promulgate Performance Standards pursuant to Section 514 that 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 in the basic form as described in the August 28, 1996 FDA Rule at 61 Fed. Reg. at 44616 (to be codified at 21 C.F.R. Section 897.3). Specifically:

A. For a period of no fewer than twelve years following the effective date of the Act, the product Performance Standards will be governed by the following: The Agency shall be permitted to 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, based upon a finding that the modification: (a) will result in a significant reduction of the health risks associated with such products to consumers thereof, (b) is 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. In determining the risk of the demand for a market

in contraband products, the FDA shall take into account the number of dependent tobacco product users and the availability, or lack thereof, of alternative products then on the market and such other factors as the Agency may deem relevant.

The authority to require such product modification can be exercised upon a showing of "substantial evidence," based upon an administrative record developed through a formal rule making subject to the Administrative Procedures Act, with the right of judicial review, and any such modification shall be subject to the current procedures of the Regulatory Reform Act of 1996 to provide time and a process for Congress to intervene should it so choose. In the event a party subsequently files a petition seeking an administrative review of whether a modification has, in fact, resulted in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard and FDA denies the petition, the petitioner shall have the right to seek judicial review of the denial of the petition.

Additionally:

- Within one year of the effective date of this Act, the FDA shall establish a Scientific Advisory Committee to examine and determine the effects of the alteration of nicotine yield levels and to examine and determine whether there is a threshold level below which nicotine yields do not produce drug dependence and, if so, to determine that level, and also review any other safety, dependence or health issue so designated by FDA.

- Separate from and without detracting from the Agency's authority under the requirements of the Section 514 Performance Standard noted above, effective three years from the date of enactment of this Act, no cigarette shall be sold in the United States which exceeds a 12 mg "tar" yield, using the testing methodology now being used by the Federal Trade Commission.

B. After the initial twelve year period, the Agency will be permitted to set product safety standards that go beyond the standards it is authorized to set pursuant to the above noted provisions and, if it does so, any such product Performance Standards shall be governed by the following: The Agency will be

permitted to require the alteration of tobacco products then being marketed, including the elimination of nicotine and the elimination of other constituents or other demonstrated harmful components of the tobacco product,[1] based upon a finding that: (a) the safety standard will result in a significant overall reduction of the health risks to tobacco consumers as a group,[2] (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. In determining the overall health benefit of a change, the Agency shall consider the number of dependent tobacco users then in existence, the availability and demonstrated market acceptance of alternate products then on the market, and the effectiveness of smoking cessation techniques and devices then on the market and such other factors as the Agency may deem relevant.

Given the significance of such an action, the Agency will be permitted to require the elimination of nicotine or take such other action that would have an effect comparable to the elimination of nicotine 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 review. Any such action shall be phased in, and no such phase-in shall begin in less than two years, to permit time for a meaningful Congressional review pursuant to the current procedures of the Regulatory Reform Act of 1996. In the event a party subsequently files a petition seeking an administrative review of whether a modification has, in fact, resulted in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard and the FDA denies the petition, the petitioner shall have the right to seek judicial review of the denial of the petition.

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[1] The elimination of nicotine or other harmful constituent shall not be deemed to violate the prohibition on the sale of traditional tobacco products to adults, even if it results in a reduction of the number of the consumers who use the tobacco products then remaining on the market.

[2] This includes the reduction in harm which will result from decreased drug dependence from the reduction and/or elimination of nicotine from (a) those who continue to use tobacco products, but less often, and (b) those who stop using tobacco products.

In any judicial review, the deference accorded to the Agency's findings shall depend upon the extent to which the matter at issue is then within the Agency's field of expertise.

6. Manufacturing Oversight

The legislation 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, but tailored specifically to tobacco products. In this regard there would be:

- 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 product
- Tolerances for pesticide chemical residues in or on commodities in the possession of the manufacturer; existing EPA authority and oversight is retained
- Inspection authority comparable to FDA's authority over other FDA regulated products, including the ability to enter manufacturing plants and demand certain records
- Record keeping and reporting requirements

Tobacco farmers will face no greater regulatory burden than the producers of other raw products regulated by the federal government.

[Source/precedent: FDA Rule; FDCA, 21 U.S.C. Sections 346a; 360]

7. Access to Company Information

- The Act would ensure that previously non-public or confidential documents from the files of the tobacco industry – including internal health research documents – are disclosed to FDA, private litigants and the public. The details of the arrangement are set forth in Appendix VIII.

- Any subpoena authority FDA has with respect to manufacturers of medical devices generally would also apply to tobacco product manufacturers.

F. Non-tobacco Ingredients

Currently, at the federal level, tobacco manufacturers are required only to submit aggregated ingredient information (not by brand or company) to HHS for monitoring and review. Nor do tobacco products manufacturers currently disclose to consumers ingredients information for each of the tobacco products they sell.

The legislation would supersede the current often-criticized federal ingredient law and confirm FDA's authority to evaluate all additives in tobacco products. No non-tobacco ingredient could be used in manufacturing tobacco products unless the manufacturer can demonstrate that such ingredient is not harmful under the intended conditions of use. Further, the legislation would require the manufacturers to disclose to FDA the ingredients and the amounts thereof in each brand. In addition, it would require manufacturers to disclose ingredient information to the public under regulations comparable to what current federal law requires for food products, reflecting the intended conditions of use.

Under this proposed legislation:

- Manufacturers would be required to provide FDA on a confidential basis a list of all ingredients, substances and compounds (other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco) which are added by the manufacturer to the tobacco, paper or filter of the tobacco product by brand and by quantity in each brand. For each such item, the manufacturer would identify whether or not it believes that the item would be exempt from public disclosure under the legislation.

- Manufacturers would be required to submit, within 5 years of the enactment of the Act, for each ingredient currently added to the tobacco product, a safety assessment, based on the best available evidence, that there is a reasonable certainty in the minds of competent scientists that the ingredient (up to a specified amount) is not harmful under the intended conditions of use. FDA shall promulgate applicable regulations within 12 months.

    - Within a statutory time period FDA must review assessment(s) in accordance with the applicable standard; within 90 days, FDA shall approve or disapprove an

ingredient's safety, and if FDA takes no action, the ingredient is deemed approved. FDA may also challenge any manufacturer's assertion that an ingredient would be exempt from disclosure to consumers under applicable regulations comparable to what current federal law requires for food products.

- New ingredients or use of current ingredients beyond the specified maximum amount are subject to a comparable process prior to use.

- FDA would be required to protect as strictly confidential ingredient information not otherwise subject to public disclosure. If not subject to such disclosure, this information will be treated as trade secrets under federal law, exempt from FOIA requests and protected by procedures which shall include the designation of an agent who will store it in a locked cabinet, maintain a record of any person who has access to the information and require a written confidentiality commitment from any such person.

° Manufacturers would be required to disclose to the public ingredients information pursuant to regulations comparable to what current federal law requires for food products. During an initial 5 year period, each ingredient that would be exempt from disclosure under the food regime would be presumed not to be subject to disclosure unless FDA disproves its safety. However, manufacturers would be required to disclose all ingredients which they have been compelled to publicly disclose with respect to a particular brand in order to comply with a statute or regulation (e.g., MA Ch 94 §307B).

° Manufacturers would be required to have procedures for the selection, testing, purchase, storage and use of ingredients. The Act would:

- Provide for record keeping regarding ingredients

- Allow FDA access to such records, with protection of proprietary information

[Source/precedent: MA Chapter 94, §307B; 21 C.F.R. §§101.4, 101.105, and 101.170; 18 U.S.C. §1905; 5 U.S.C. §552(b)(4); MA proposed reg. 105 C.M.R. §660.200(G)]

G. Compliance and Corporate Culture.

A key element in achieving the Act's goals will be forcing a fundamental change in the way the tobacco industry does business. Accordingly, the Act will provide for means to ensure that the industry will not only comply with the letter of the law but will also have powerful incentives to prevent underage usage of tobacco products and to strive to develop and market less hazardous tobacco products.

First, manufacturers would be required to create plans, with an annual review and update, to:

- Ensure compliance with all applicable laws and regulations
- Identify ways to achieve the goals of reduced youth access to and incidence of underage consumption of tobacco products and provide internal incentives for doing so
- Provide internal incentives to develop products with reduced risk

Second, with a special emphasis on laws and regulations that make it unlawful to sell tobacco products to underage persons and other laws directed at the issue of underage tobacco use, the manufacturers must implement compliance programs that include, at a minimum, the following elements:

- Compliance standards and procedures to be followed by employees and agents that are reasonably capable of reducing the prospect of violations
- Assignment to specific individual(s) within high-level personnel of the organization of overall responsibility to oversee compliance with the relevant standards and procedures, especially in regard to preventing underage tobacco use
- Use of due care not to delegate substantial discretionary authority to individuals who the organization knows, or should have known through the exercise of due diligence, had a propensity to disregard corporate policy
- Steps to communicate relevant standards and procedures to all employees and other agents (including lobbyists), e.g., by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required
- Internal audits, hotlines and other measures to promote compliance

- Appropriate disciplinary mechanisms and measures (e.g., discipline of employees who violate marketing restrictions)

- Reasonable steps to respond appropriately to a violation and to prevent further similar violations

Furthermore, the Act would provide "whistleblowers" in the tobacco industry with the maximum protection available under current federal statutes.

Beyond compliance with the letter of the law, manufacturers would be required to take affirmative steps in furtherance of the spirit of the new regime, including:

- Promulgating corporate principles that express and explain the company's commitment to compliance, reductions of underage tobacco use, and development of reduced risk tobacco products

- Designating a specific individual within high-level personnel of the organization with appropriate responsibility and authority to promote efforts to attain these new standards

- Providing reports to shareholders on compliance as well as progress toward meeting these new standards

Manufacturers would also be required to work with retail organizations on compliance, including retailer compliance checks and financial incentives for compliance.

Third, each tobacco manufacturer would require all contract lobbyists (and any other third-parties who may engage in lobbying activities on behalf of a manufacturer) to agree that they will not support or oppose any state or federal legislation, or seek or oppose any governmental action on any matter, without the manufacturer's express authorization. Manufacturers would also require anyone lobbying on their behalf to agree in writing that a) they are aware of and will fully comply with all applicable laws and regulations; b) they have reviewed and will fully comply with the Act as it applies to them; c) they have reviewed and will fully comply with the Consent Decree as it applies to them; and d) they have reviewed and will fully abide by the manufacturer's business conduct policies and any other policies and commitments as they apply, especially those related to prevention of youth tobacco usage.

Fourth, within ninety days after the Act's effective date, the Tobacco Institute and the Council for Tobacco Research, U.S.A. would be dissolved and disbanded. Tobacco product manufacturers would be permitted to form new trade associations only in accordance with strict procedures and federal oversight

designed to ensure compliance with antitrust and other applicable laws. (See Appendix IV)

Finally, companies would be subject to fines and penalties (including "Scarlet Letter" advertising) for breaching their obligations vis-à-vis the development, implementation and enforcement of compliance plans and corporate principles. These penalties shall follow the scheme set forth in the Clean Air Act, up to $25,000 per day per violation with a total not to exceed $200,000. In addition, each manufacturer's employees shall be directed to report to that manufacturer's compliance officer any known or alleged violations of this Act by retailers or distributors. In accordance with procedures established by FDA, the compliance officer shall be required to furnish all such reports to FDA for reference to appropriate federal or state enforcement authorities. The manufacturer shall be subject to fines or penalties in the event its compliance officer fails to furnish any such reports to FDA.

[Source/precedent: Federal Organizational Sentencing Guidelines; various federal consent decrees; various corporate environmental programs]

H. Effective Dates

Many of the foregoing requirements relating to the reformation of the tobacco industry will become effective shortly after the Act is signed by the President; including the following categories of new rules, which will be implemented on the dates indicated:

Category	Effective Dates on Final Passage
Retail Product Displays	9 months
Retail signage	5 months
Advertising	9 months
Package Labeling	1/3 in 90 days 1/3 in 120 days 1/3 in 180 days
Sponsorships	12/31/98
Vending machines	12 months
Sampling	3 months
GMPs	24 months or in accordance with rulemaking, whichever is later
Corporate compliance	12 months
Face-to-face transactions	3 months
Ban on sales of open packs	3 months
20 cigarettes per pack minimum	3 months
Puerto Rico pack size	12 months

TITLE II: "Look Back" Provisions/State Enforcement Incentives

A central aim of this legislation is to achieve dramatic and immediate reductions in the number of underage consumers of tobacco products. The legislation accordingly contains a "look-back" provision giving tobacco product manufacturers significant economic incentives to take every possible step to ensure that the advertising, marketing and distribution requirements of this Act are met, and imposing substantial surcharges on the manufacturers in the event that underage tobacco-use reduction targets are not achieved.

The "look-back" provision sets targets for the dramatic reduction of current levels of underage tobacco use (as measured by the University of Michigan's National High School Drug Use Survey "Monitoring the Future"). Underage use of cigarette products must decline by at least 30% from estimated levels over the last decade by the fifth year after the legislation takes effect, by at least 50% from estimated levels over the last decade by the seventh year after the legislation takes effect, by at least 60% from estimated levels over the last decade by the tenth year after the legislation takes effect, and remain at such reduced levels or below thereafter. (These required reductions amount to even steeper declines from current levels of underage smoking.) Underage use of smokeless tobacco products must decline by at least 25% from current levels by the fifth year after the legislation takes effect, by at least 35% from current levels by the seventh year after the legislation takes effect, by at least 45% from current levels by the tenth year after the legislation takes effect, and remain at such reduced levels or below thereafter. FDA will annually assess the prevalence of underage tobacco use (based on the methodology employed by the University of Michigan survey) to determine whether these targets have been met.

If a target has not been met, FDA will impose a mandatory surcharge on the relevant industry (cigarette or smokeless tobacco) based upon 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 (subject to an annual cap of $2 billion for the cigarette industry (adjusted each year for inflation) and a comparably derived cap for the smokeless tobacco industry). Tobacco product manufacturers could receive a partial abatement of this surcharge (up to 75%) only if they could thereafter prove to FDA that they had fully complied with the Act, had taken all reasonably available measures to reduce youth tobacco use and had not taken any action to undermine the achievement of the required reductions.

A fuller description is provided in Appendix V.

In addition, the proposed Act goes well beyond the provisions of the Synar Amendment's "no tobacco sales to minors" law and related regulations, 42 U.S.C. § 300X-26, and the Final Rule promulgated thereunder, which became effective February 20, 1996 (61 Fed. Reg., June 19, 1996). The proposed Act requires the several States to undertake significant enforcement steps designed to dramatically reduce the incidence of youth smoking, and youth access to tobacco products. These enforcement obligations are funded by Industry Payments. Each state must maintain specific levels of enforcement effort, or the state risks the loss of a significant portion of the health care program funds otherwise payable to the state under the Act. Amounts withheld from states not doing an adequate enforcement job will be reallocated to states with a superior "no sales to minors" enforcement record. No state will be held responsible for sales to underage consumers outside that state's jurisdiction.

The details of these state enforcement incentives are set forth in Appendix VI.

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

A. Penalties and Enforcement

- This legislation will be enforceable both by the federal government, including FDA and civil and criminal divisions of the Department of Justice, and by the several States. FDA will also have the authority to contract directly with state agencies to assist with enforcement. If conduct is subject to a particular State's consumer protection law or similar statute, such state may proceed under that law.

- State enforcement actions – whether brought under the Act or a State's consumer protection law – could not impose obligations or requirements beyond those imposed by the legislation (except where the legislation does not specifically preempt additional state-law obligations), and would be limited to the civil and criminal penalties established by the legislation and by the prohibition on duplicative penalties. State enforcement proceedings under the Act (or predicated on conduct violating the Act), except those exclusively local in nature, would be removable to federal court. Nothing in the Act precludes a State from enforcing its laws in the ordinary fashion as to matters not covered by the Act or Protocol.

- Civil and criminal penalties for violations of the legislation based on those governing other drugs or devices regulated under the Food, Drug and Cosmetic Act and, where applicable, under Title 18 of the U.S. Code.

- In addition, the industry faces civil penalties of up to $10 million per violation for any violations of the obligations to disclose to the FDA research about tobacco-product health effects and information regarding the toxicity of non-tobacco ingredients and constituents used in their products. This penalty is ten times the largest penalty faced by other drug or device manufacturers for similar violations.

- To reflect the fact that not all States have filed lawsuits against the tobacco industry, but that the intent of the negotiators is to provide the benefits of the settlement to all States, the industry also will enter into a binding and enforceable national tobacco control

Protocol embodying certain terms of the proposed resolution. As an enforceable contract, which would not be subject to facial constitutional challenge, this Protocol will provide benefits and enforcement rights to the federal government and all states.

B. Consent Decrees

- Certain terms of the agreement will also be reiterated in consent decrees between the tobacco industry and the states that will not take effect until after enactment of the Act. These consent decrees will be identical to, and will reiterate, the terms of the agreement with respect to: (1) restrictions on advertising, marketing and youth access to tobacco products; (2) trade associations; (3) restrictions on lobbying; (4) disclosure of tobacco smoke constituents; (5) disclosure of non-tobacco ingredients; (6) disclosure of existing and future industry documents relating to health, toxicity and addiction; (7) compliance and corporate culture; (8) obligations to make monetary payments to the States reflecting their reasonable share of the total provided by the Act; (9) obligations of the industry to deal only with distributors and retailers that operate in compliance with applicable provisions of law respecting the distribution, sale and marketing of tobacco products; (10) warnings, labeling and packaging (to the extent noted below); and (11) dismissal of other pending litigation specified by the parties.

- The consent decrees will not contain provisions as to: (1) product design, performance or modification; (2) manufacturing standards and good manufacturing practices; (3) testing and regulation with respect to toxicity and ingredients approval; and (4) the national FDA "look back" provisions.

- The consent decrees will provide that their terms are to be construed in conformity with the Act and the Protocol and with each other. State proceedings to enforce the provisions of the consent decrees may be brought in state court, subject to an acceptable procedure to ensure consistent rulings with respect to conduct that is not exclusively local in character. State proceedings to enforce the consent decrees may seek injunctive relief only, and may not seek criminal or monetary sanctions. A State shall not be limited from seeking criminal or other sanctions for a company's

subsequent violation of an injunction entered by the court in an action brought to enforce the consent decree

- The provisions of the consent decrees will remain enforceable regardless of whether subsequent changes in the Act or in any other provision of law diminish the obligations of the companies in the areas covered by the consent decrees, except: (1) where such changes create federal requirements that produce obligations in conflict with those contained in the consent decrees; (2) with respect to the allocation of funds; and (3) with respect to warnings, labeling and packaging. With respect to warnings, labeling and packaging, if the requirements of the Act are later modified, or if Congress subsequently prohibits warnings on tobacco products, the consent decrees will be modified to conform to such requirements. However, if Congress later eliminates altogether the warning requirement in the Act, the warnings originally set forth in the Act (the so-called Canadian warnings) shall be mandated and enforceable under the consent decrees.

- In addition, the parties recognize that certain provisions of the consent decrees and the agreement may require them to act (or refrain from acting) in a manner that they might otherwise claim would violate the federal or state constitutions. They will therefore in the consent decrees expressly waive any claim that the provisions of the consent decrees or the agreement violate the federal or state constitutions. The consent decrees will also state that if a provision of the Act covered by the decrees is subsequently declared unconstitutional, the provision remains an enforceable term of the consent decrees.

C. Non-participating companies

- The regime envisioned by the resolution would be substantially undercut if certain companies were free to ignore the limitations it imposes, and were instead able to sell tobacco products at lower prices (because they were not making the payments described above) and through less restricted advertising and marketing activities. The resolution accordingly anticipates the possibility that some manufacturers of tobacco products may not consent to the institution of this regime. Rather than seeking to impose on such manufacturers the advertising restrictions, full required payments and corporate culture changes set forth above, the resolution

avoids constitutional questions that might otherwise be raised by establishing a separate regime for non-participating manufacturers.

- Non-participating manufacturers would be subject to the access restrictions and regulatory oversight set forth above. They would receive none of the civil liability protections described in Title VIII. Their product would be subject to a user fee equal to the portion of the payments by participating manufacturers allocated to fund public health programs and federal and state enforcement of the access restrictions.

- The resolution further recognizes that – unlike the participating manufacturers -- non-participating manufacturers will not have made consensual payments to settle governmental actions for health care costs, to settle class actions and in to provide consideration for the partial settlement of individual tort actions (including punitive damages claims). Because such actions would remain wholly unsatisfied, it is vital that the claimants be ensured that funds will be available to satisfy any judgments that may be obtained. Accordingly, the resolution requires that each non-participating manufacturer place into an escrowed reserve fund each year an amount equal to 150% of its share of the annual payment required of participating manufacturers (other than the portion allocated to public health programs and federal and state enforcement). These escrowed funds would be earmarked for potential liability payments, and the manufacturer would reclaim them with interest 35 years later to the extent they had not been paid out in liability.

- Moreover, the resolution also recognizes that – because non-participating manufacturers are not subject to the corporate culture commitments requiring manufacturers to monitor distributor and retailer compliance with the underage access restrictions – distribution and retail sales of those manufacturers' products present a particularly great obstacle to the achievement and enforcement of the access restrictions. Accordingly, the resolution provides that the exemption from civil liability applicable to distributors and retailers of the products of participating manufacturers will not apply to distributors and retailers who handle tobacco products of non-participating manufacturers.

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

Until now, there has been no minimum or other federal standard governing smoking in public places or at work. The legislation would:

- Restrict indoor smoking in "public facilities" (i.e., any building regularly entered by 10 or more individuals at least one day per week) to ventilated areas with systems that:
  - Exhaust the air directly to the outside;
  - Maintain the smoking area at "negative pressure" compared with adjoining areas; and
  - Do not recirculate the air inside the public facility.
- Ensure that no employee shall be required to enter a designated smoking area while smoking is occurring. Cleaning and maintenance work in a designated smoking area shall be conducted while no smoking is occurring.
- Exempt restaurants (but not "fast food" restaurants)[1] and bars (including those in hotels), private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants and prisons.
- Direct OSHA to issue, not later than one year after the effective date of the legislation, regulations implementing and enforcing the preceding standards, with enforcement costs paid out of the Industry Payments. The smoking restrictions outlined in this Title would take effect on the first anniversary of the enactment of the legislation

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[1] "Fast food" restaurant means any restaurant or chain of restaurants which primarily distributes food via customer pick-up (either at a counter or drive-through window). In addition, OSHA would be authorized to issue regulations clarifying this definition to the extent necessary to ensure that the intended inclusion of establishments catering largely to minors is achieved. Any such regulation may consider such factors as whether a restaurant either has attached playgrounds or play areas for children, uses ad campaigns that feature or prominently include cartoon characters and/or toy giveaways or advertises "happy meal" or other comparable kids-combination platters, and other factors OSHA deems relevant.

irrespective of whether the implementing regulations have been promulgated.

The legislation would not preempt or otherwise affect any other state or local law or regulation that restricts smoking in public facilities in an equal or stricter manner. Nor would the legislation preempt or otherwise affect any federal rules that restrict smoking in federal facilities.

[Source/precedent: H.R. 3434, as reported out of committee; WISHA workplace smoking rule; state law exemptions for the "hospitality sector"]

TITLE V: Scope and Effect

A. Scope of FDA Authority

- All product sold in U.S. commerce
- Covers new entrants; imports; U.S. duty free, etc.
- BATF to retain fiscal authority over tobacco products
- FTC to retain existing authority, except for "tar", nicotine, and carbon monoxide testing
- Grower Limitation: FDA jurisdiction does not extend to the growing, cultivation or curing of raw tobacco (USDA has exclusive authority).

B. State Authority

1. Preservation of State and Local Government Laws and Legal Authority

- While setting a federal "floor" for tobacco control measures in many substantive areas, this legislation preserves, to the maximum extent, state and local government authority to take additional tobacco control measures that further restrict or eliminate the product's use by and accessibility to minors.
- This legislation also permits state and local governments to enact measures that further restrict or eliminate employee and general public exposure to smoking in workplaces and in other public and private places and facilities.
- The legal authority of a state or local government to further regulate, restrict or eliminate the sale or distribution of tobacco products, and to impose state or local taxes on such products, also remains unchanged.
- The legislation retains similar flexibility for Indian tribes, military facilities and other federal agencies.

2. Uniformity of Warning Labels, Packaging, Labeling and Other Advertising Requirements; Manufacturing Requirements

- Current federal law providing for national uniformity of warning labels, packaging and labeling requirements, and advertising and promotion requirements related to tobacco and health, is preserved, except that this legislation gives FDA express authority to require changes in the language of the warnings, subject to the standard requirement that it provide public notice and a hearing opportunity prior to making such changes.

- Similarly, the provisions of FDCA designed to provide uniformity in product manufacturing and design requirements relating to medical devices will apply to tobacco products, except that any application by a State or locality for an exemption permitting it to adopt additional or different requirements relating to performance standards or good manufacturing practices may only be granted if the requirement would not unduly burden interstate commerce. Further, to ensure that FDA has an adequate opportunity to evaluate non-tobacco ingredients as described in Title I(F), no exemption relating to ingredients may be applied for until the fifth anniversary of the effective date of the Act.

TITLE VI: Programs/Funding

TOTAL 25 YEAR PACKAGE FACE VALUE -- $368.5 Billion

A. Up Front Commitment -- Lump Sum Cash Payment -- $10 Billion

1. Payable on Statute Signing Date.

B. Base Annual Payments -- 25 Year Total Face Value is $358.5 Billion (Figures Subject to Inflation Protection and Market Volume Adjustments)

1. Duration -- annual payments in perpetuity

2. Commencement -- 12/31 of first **full** year after statute signing

3. Face Amounts (includes payments from all industry sources):

Payment Year	1	2	3	4	5	6-8	9	→ ∞
Total Payments	$8.5B	$9.5B	$11.5B	$14B	$15B	$15B	$15B	$15B
Base Amount:	$6B	$7B	$8B	$10B	$10B	$12.5B	$15B	$15B
Public Health Trust	$2.5B	$2.5B	$3.5B	$4B	$5B	$2.5B		

4. Inflation Protection for Annual Payments

   - Greater of 3% or CPI applied each year on previous year, beginning with first annual payment.

5. Adjustment for Volume Decrease (Adult Volume Only) or Total Volume Increase

   - Beginning in year 1; payment made equal to scheduled annual payment times the ratio of actual relevant domestic tobacco product unit sales volume to relevant base volume. In the event of a decline in volume, relevant actual volume and relevant base volume are adult volume figures; in the event of an increase in volume, relevant actual volume and

relevant base volume are total volume figures. Base volume is 1996 volume.

- Any reduction in an annual payment will be reduced by 25% of any increase above the industry's base year net operating profits (after application of inflator discussed above) from domestic sales of tobacco products.

6. Payment Protection

- Provide for payment priority/continuation during bankruptcy/ reorganization proceedings. Protocol cannot be rejected in bankruptcy. Obligation for annual payments responsibility only of entities selling into domestic market.

7. Pass-Through

- In order to promote maximum reduction in youth smoking, the statute would provide for the Annual Payments to be reflected in the prices manufacturers charge for tobacco products.

C. Applicability

1. Applicable to All Sellers of Tobacco Products

- Through protocol and statute to protocol signatories.

- Through alternative statutory provisions to non-signatories.

D. Tax Treatment

All payments pursuant to this Agreement (including those pursuant to Title II) shall be deemed ordinary and necessary business expenses for the year of payment, and no part thereof is either in settlement of an actual or potential liability for a fine or penalty (civil or criminal) or the cost of a tangible or intangible asset.

TITLE VII: Public Health Funds From Tobacco Settlement
As Recommended By The Attorneys General For Consideration By The President And The Congress

BASED ON THE PREMISE OF $ 1 BILLION FOR THE FIRST YEAR AND GRADUALLY INCREASING TO $1.5 BILLION THEREAFTER, ADJUSTED FOR INFLATION AFTER THE FIRST YEAR.

BASED ON THE PREMISE OF $1 BILLION FOR SMOKING CESSATION FOR THE FIRST 4 YEARS AND $1.5 BILLION THEREAFTER, ADJUSTED FOR INFLATION.

(A) · ALLOCATION OF GRANT MONIES AMONG PROGRAMS – The use of moneys under this Section shall be limited to programs established under this Section, shall be adjusted for inflation annually from the effective date, and shall be allocated among such programs as follows:

(1) $125,000,000 for the first three years and $225,000,000 annually thereafter to the Secretary of HHS to accomplish the purposes described in Paragraph (B) of this Section (Reduction in Tobacco Usage);

(2) $300,000,000 annually for the FDA to carry out its obligations under and to enforce the terms of this Act, including for grants to the states to assist in the enforcement of the provisions of the Act;

(3) $75,000,000 for the first two years, $100,000,000 in the third year, and $125,000,000 annually thereafter to fund state and local tobacco control community based efforts modeled on the ASSIST program, designed to encourage community involvement in reducing tobacco use and the enactment and implementation of policies designed to reduce the use of tobacco products;

(4) $100,000,000 annually to fund research and the development of methods for how to discourage individuals from starting to use tobacco and how to help individuals to quit using tobacco;

(5) Beginning in the second year, $75,000,000 annually for a period of ten (10) years to compensate events, teams or entries in such events, who lose sponsorship by the tobacco industry as a result of this Act, or who currently receive tobacco industry funding to sponsor events and elect to replace that

funding, provided that the event, team, or entry is otherwise unable to replace its tobacco industry sponsorship during those given years. Funds used for this purpose shall promote a Quit Tobacco Use theme. After a ten year period, no additional funds shall be used for this purpose and the funds previously allocated to this purpose shall be used as follows: 50% to supplement funding of the multi-media campaigns in paragraph (1) of this subsection; 25% to supplement the funding of the enforcement provisions of paragraph (2) of this subsection; and 25% to supplement the funding of community action programs in paragraph (3) of this subsection.

(B) ESTABLISHMENT OF PROGRAMS BY THE SECRETARY – The Secretary shall establish programs to accomplish the following purposes—

(1) the reduction of tobacco product usage, both by seeking to discourage the initiation of tobacco use by persons under the age of 18 and by encouraging current tobacco users to quit through media-based and non-media based education, prevention and cessation campaigns. The Secretary may make grants to state health departments to assist in carrying out the purposes of this provision.

(2) the research into and development and public dissemination of technologies and methods to reduce the risk of dependence and injury from tobacco product usage and exposure;

(3) the identification, testing and evaluation of the health effects of both tobacco and non-tobacco constituents of tobacco products;

(4) the promulgation of such other rules and regulations as are necessary and proper to carry out the provisions of this Act, as well as the development of such other programs as the Secretary determines are consistent with the goals of the Act.

(C) Public Education Campaign - $500,000,000 shall be spent annually in such multi-media campaigns designed to discourage and de-glamorize the use to tobacco products. To carry out such efforts, an independent non-profit organization with a Board made up of prestigious individuals and the leaders of the major public health organizations shall be created which shall contract or make grants to non-profit private entities who are unaffiliated with tobacco manufacturers or tobacco importers, who have a demonstrated record of working effectively to reduce tobacco product use and expertise in multi-media communications campaigns. The independent body shall be authorized to contract with state health departments, where appropriate, to run campaigns for

their states and communities. In creating the program the Secretary or independent body shall also take into account the needs of particular populations. The goal shall be the reduction of tobacco product usage, both by seeking to discourage the initiation of tobacco use by persons under the age of 18 and by encouraging current tobacco users to quit.

(D) Tobacco Use Cessation - For the first 4 years, $1 billion, and thereafter, $1.5 billion of the total amount paid by the tobacco industry shall be paid into a Trust Fund to be used to assist individuals who want to quit using tobacco to do so. Within 12 months the Secretary shall promulgate regulations to govern (1) the establishment of criteria for and a procedure for the approval of cessation programs and devices for which payment may be made under the program, (2) the eligibility requirements for individuals seeking to use moneys from the trust to fund the tobacco cessation efforts, and (3) the procedures to govern the tobacco cessation program.

The goal of the tobacco cessation program shall to enable the most tobacco users possible to receive assistance in their effort to quit using tobacco by providing financial assistance and identifying the programs, techniques, and devices that have been shown to be safe and effective. Benefits to individuals should not be limited to a single effort, but should be tailored to the needs of individual smokers according to standards established by the Secretary using the best available scientific guidelines.

(E) Public Health Trust Fund Presidential Commission – A Presidential commission will be appointed to include representatives of the public health community, Attorneys General, Castano attorneys and others to determine the specific tobacco-related medical research for which the $25 Billion Public Health Trust Fund will be used.

TITLE VIII: Civil Liability

The following provisions would govern actions for civil liability related to tobacco and health.

A. General

1. Present Attorney General actions (or similar actions brought by or on behalf of any governmental entity), parens patriae and class actions are legislatively settled. No future prosecution of such actions. All "addiction"/dependence claims are settled and all other personal injury claims are reserved. As to signatory States, pending Congressional enactment, no stay applications will be made in pending actions, based upon the fact of this resolution, without mutual consent of the parties.

2. Third-party payor (and similar) actions pending as of 6/9/97 are not settled, but governed by provisions regarding past conduct set forth in Section B below.

B. Provisions as to Civil Liability for Past Conduct

The following provisions apply to suits for relief arising from past conduct – i.e., suits by persons claiming injury or damage caused by conduct taking place prior to the effective date of the Act.

1. All punitive damages claims resolved as part of overall settlement. No punitive damages in individual tort actions.

2. Individual trials only: i.e., no class actions, joinder, aggregations, consolidations, extrapolations or other devices to resolve cases other than on the basis of individual trials, without defendant's consent.

   Action removable by defendant to federal court upon receipt of application to, or order of, state court providing for trial or other procedure in violation of this provision.

3. Except as expressly provided in the Act, FCLAA and applicable case law unchanged by the Act.

4. Provided that the five negotiating companies enter into the Protocol: Protocol manufacturers to enter into joint sharing

agreement for civil liability. Protocol manufacturers not jointly and severally liable for liability of non-Protocol manufacturers. Trials involving both protocol and non-Protocol manufacturers to be severed.

5. Permissible parties:

Plaintiffs –

a. Claims of individuals, or claims derivative of such claims, must be brought either by person claiming injury or heirs.

b. Third-party payor (and similar) claims not based on subrogation that were pending as of 6/9/97.

c. Third-party payor (and similar) claims based on subrogation of individual claims; no extrapolations, etc.

Defendants –

a. Actions may be maintained only against manufacturing companies, their successors and assigns, any future fraudulent transferee, and/or entity for suit designated to survive defunct manufacturer.

b. Manufacturers liable vicariously for acts of agents (including advertising agencies and attorneys).

6. No removal except under paragraph 2 above.

7. The development of "reduced risk" tobacco products after the effective date of the Act is neither admissible nor discoverable.

8. Statute of limitations: for all actions, individual state laws governing time periods from injury, discovery, notice or contamination/violation.

9. Annual aggregate cap for judgments/settlements: 33% of annual industry base payment (including any reductions for volume decline). If aggregate judgments/settlements for a

year exceed annual aggregate cap, excess does not have to be paid that year and rolls over.

Any judgments/settlements run against defendant, but give rise to 80-cent-on-the-dollar credit against annual payment in year paid. Suitable provision for settlement consultation and permission. Manufacturers control insurance claims, and any insurance recovery obtained by manufacturers (net of cost) on account of judgment and/or settlement covered by above sharing arrangement allocated 80% to annual payments. Manufacturers retain any insurance proceeds on account of defense costs.

Provision with respect to individual judgments above $1 million: amount in excess of $1 million not paid that year unless every other judgment/settlement can be satisfied within the annual aggregate cap. Excess rolls forward without interest and is paid at the rate of $1 million per year, until the first year that the annual aggregate cap is not exceeded (at which time the remainder is paid in full). For purposes of this provision, a third-party payor (or similar) action not based on subrogation is treated as having been brought by a single plaintiff and is subject to the $1 million rollover on that basis.

10. In the event that the annual aggregate cap is not reached in any year, a Commission appointed by the President will determine the appropriate allocation of the amount representing the unused amount of the credit. The Commission will be entitled to consider, among public health, governmental entities, and other uses of the funds, applications for compensation from persons, including non-subrogation claims of third party payors, not otherwise entitled to compensation under the Act.

11. Defense costs paid by manufacturers.

C. Provisions as to Civil Liability for Future Conduct

The following provisions apply to suits for relief arising from future conduct – i.e., suits claiming injury or damage caused by conduct taking place after the effective date of the Act.

1. Paragraphs 2, 3, 5, 6, 7, 8, 9,10 and 11 in Section B apply.

2. No third-party payor (or similar) claims not based on subrogation.

Title IX: Board Approval

The terms of this resolution are subject to approval by the Boards of Directors of the participating tobacco companies.

Appendix I - Warnings in Advertisements

The space in press and poster advertisements for tobacco products that is to be devoted to the warning and, where relevant, the "tar," nicotine and any other constituent yield statements will be 20% of the area of the advertisement. The size of the printing of the warning and the yield statements shall be pro rata to the following examples:

a) Whole page broadsheet newspaper - 45 point type
b) Half page broadsheet newspaper - 39 point type
c) Whole page tabloid newspaper - 39 point type
d) Half page tabloid newspaper - 27 point type
e) DPS magazine - 31.5 point type
f) Whole page magazine - 31.5 point type
g) 28 cm X 3 columns - 22.5 point type
h) 20 cm X 2 columns - 15 point type

FDA may revise the required type sizes within the 20% requirement.

Appendix II - Retail Tobacco Product Seller Penalties

1. The sale of tobacco products to consumers by an unlicensed seller shall be a criminal violation, and be subject to minimum penalty of $1,000, or imprisonment, for 6 months, or both, if an individual, or in the case of a corporation, by a maximum penalty of $50,000. Any State or local jurisdiction may provide by statute or code more severe penalties.

2. In addition to any criminal penalties which may be imposed under any applicable state or local law, a tobacco product licensee may be subjected to civil sanctions, including penalties, or license suspension or revocation (on a site-by-site basis), or a combination thereof, for any violation of the provisions of the State licensing laws regarding sales to minors. Such sanction shall not exceed the following:

   (a) For the first offense within any two year period, $500 or a 3 day license suspension or both.

   (b) For the second offense within any two year period, $1,000 or a 7 day license suspension or both.

   (c) For the third offense within any two year period, $2,000 or a 30 day license suspension or both.

   (d) For the fourth offense within any two year period, $5,000 or a 6 month license suspension or both.

   (e) For the fifth offense within any two year period, $10,000 or 1 year license suspension or both.

   (f) For the sixth and any subsequent offenses within any two year period, $25,000 or a revocation of license with no possibility of reinstatement for a period of three years.

   (g) Permanent license revocation is mandatory for the tenth offense within any two year period.

Each state must enact a statutory or regulatory enforcement scheme that provides substantially similar penalties to the minimum federal standards for a retail licensing program.

[Source/Precedent: Washington State Alcohol Licensing Act]

Appendix III - Application to Indian Tribes

A. Application Of Act

1. The provisions of the FDCA, the regulations of the FDA, and the Act relating to the manufacture, distribution and sale of tobacco products shall apply on Indian lands as defined in 18 U.S.C §1151 and on any other trust lands subject to the jurisdiction of an Indian tribe. To the extent that an Indian tribe engages in the manufacture, distribution or sale of tobacco products, the provisions of this Act shall apply to such tribe.

2. Any federal tax or fee imposed on the manufacture, distribution or sale of tobacco products shall be paid by any Indian tribe engaged in such activities, or by persons engaged in such activities on such Indian lands, to the same extent such tax or fee applies to other persons under the law.

B. Tribal Programs And Authority

1. For the purposes of the provisions of this Act, FDA is authorized to treat any federally-recognized Indian tribe as a state, and is authorized to provide any such tribe grant and contract assistance to carry out the licensing and enforcement functions provided by this section.

2. Such treatment shall be authorized only if:

   (a) the Indian tribe has a governing body carrying out substantial governmental powers and duties;

   (b) the functions to be exercised by the Indian tribe under this section pertain to activities on trust lands within the jurisdiction of the tribe; and

   (c) the Indian tribe is reasonably expected to be capable of carrying out the functions required under this Act.

[Source/precedent: Clean Air Act, 42 U.S.C. §7601(d)]

3. FDA regulations which establish a retail licensing program shall apply on Indian trust lands, and each tribe's program shall be no less strict than the program of the State in which the tribe is located.

4. If FDA determines that an Indian tribe does not qualify for treatment as a state, FDA will directly administer the retailer licensing program, or may delegate such authority to the state.

C. Tobacco Compensation And Public Health Grants

1. A portion of the settlement funds to which a state is otherwise entitled shall be paid to HHS for distribution to the Indian tribes which have been certified by FDA for treatment as states. The funds to be paid for such purposes on behalf of Indian tribes shall be determined by the proportion of registered tribal members resident on the reservation to the total population of the state in which the tribe is located. The funds to be distributed to Indian tribes shall be used for the same purposes as those funds are to be used by the states and be subject to the same compliance requirements for retail sales to minors as are the states under the Act.

2. The Department of Health and Human Services will annually pay to the governing body of each Indian tribe its share of the funds for use under an FDA-approved plan after annual certification by FDA, under the same standards that apply to the States, that the Indian tribe is in compliance with the requirements of the Act and any applicable regulations.

3. If HHS does not distribute all, or a portion, of an Indian tribe's share of the funds in any given year because the tribe has not qualified under the terms of this section or has not met the compliance requirements for retail sales to minors, those funds will be distributed to other qualified tribes in the same state for the same purposes and on the same proportional basis, less the non-qualified tribe's population, as other settlement funds are to be distributed to the tribes.

D. Obligations of Tobacco Manufacturers

1. Tobacco manufacturers shall not engage in any activity on Indian lands subject to this Act which activity the manufacturers may not otherwise do within a State.

2. Tobacco manufacturers also agree not to sell tobacco products for manufacture, distribution, or sale to an Indian tribe, or to a manufacturer, distributor, or retail seller subject to the jurisdiction of an Indian tribe, except under the same terms and conditions as the

tobacco manufacturers impose under other manufacturers, distributors and retail sellers under the Act, or any applicable regulations.

Appendix IV – Industry Associations

Within 90 days of the effective date of the Act, the tobacco product manufacturers shall disband and dissolve the Council for Tobacco Research, U.S.A. and the Tobacco Institute. In addition, with respect to any new trade associations:

A. Tobacco product manufacturers may form or participate in any new tobacco industry trade association. Any such new trade association shall have an independent board of directors, in accordance with the following requirements. For at least 10 years after the formation of the new association, a minimum of 20 percent of the directors, but at least one director, shall be other than a current or former director, officer or employee of any association member or affiliated company. No other director of a new trade association may be, at the same time, a director of any association member or affiliated company. The officers shall be appointed by the board and shall be employees of the association, and during their term shall not be employed by any association member or affiliated company. Legal counsel for any such association shall be independent and not serve as legal counsel to any association member or affiliated company while counsel to the association.

B. Any new tobacco product manufacturers' trade association shall adopt by-laws governing the association's procedures and the activities of its members, board, employees, agents and other representatives. The by-laws shall include, among other things, provisions that:

(1) members who are competitors in the tobacco industry shall not meet on the association's business except under sponsorship of the association;

(2) every board of directors meeting, board sub-committee meeting, general association or committee meeting, and any other association sponsored meeting, shall proceed under and strictly adhere to an agenda, approved by legal counsel and circulated in advance; and

(3) minutes describing the substance of the meetings shall be prepared for all such meetings, and shall be maintained by the association for a period of 5 years.

C. Moreover, under the new regime:

1. The structure, by-laws, and activities of tobacco industry trade associations shall be subject to continuing oversight by the U.S. Department of Justice and by state antitrust authorities. For a period of 10 years from the creation of a new trade association, such authorities may, without limitation on whatever other rights to access they may be permitted, upon reasonable prior notice:

   (a) have access during regular office hours to inspect and copy all books, records, meeting agenda and minutes, and other association documents; and

   (b) interview the association's directors, officers and employees, who may have counsel present.

   The inspection and discovery rights provided in (a) and (b) above shall be exercised through a multi-state States' Attorneys General oversight committee. Any documents and information provided to any state pursuant to (a) and (b) above shall be kept confidential by and among the states and shall be utilized only for governmental purposes of enforcing the Act and ancillary documents.

2. In order to achieve the goals of this Agreement and the Act relating to tobacco use by children and adolescents, the tobacco product manufacturers may, notwithstanding the provisions of the Sherman Act, the Clayton Act, or any other federal or state antitrust law, act unilaterally, or may jointly confer, coordinate or act in concert, for this limited purpose. Manufacturers must obtain prior approval from the Department of Justice of any plan or process for taking action pursuant to this section; however, no approval shall be required of specific actions taken in accordance with an approved plan. Approval or non-approval of a plan shall not be grounds for abatement of any surcharge to a manufacturer for failure to meet the reductions in underage tobacco use contemplated in this resolution and the Act.

Appendix V – "Look Back"

A summary of the "look-back" provision is as follows:

A. The Reduction Requirements.

1. The required reductions in underage tobacco use are measured against a base percentage. For underage use of cigarettes, the base percentage is the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Census Bureau, of (a) the average of the percentages of 12th graders (ages 16 and 17) from 1986 to 1996 who used cigarette products on a daily basis; (b) the average of the percentages of 10th graders (ages 14 and 15) from 1991 to 1996 who used cigarette products on a daily basis; and (c) the average of the percentages of 8th graders (age 13) from 1991 to 1996 who used cigarette products on a daily basis. The percentages are those measured by the University of Michigan's National High School Drug Use Survey "Monitoring the Future" or by such comparable index using identical methodology as is chosen by FDA after notice and hearing.

   For underage use of smokeless tobacco products, the base percentage is the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Census Bureau, of (a) the percentage of 12th graders (ages 16 and 17) in 1996 who used smokeless tobacco products on a daily basis; (b) the percentage of 10th graders (ages 14 and 15) in 1996 who used smokeless products on a daily basis; and (c) the percentage of 8th graders (age 13) in 1996 who used smokeless tobacco products on a daily basis. These percentages are to be derived from the same source as are the percentages with respect to use of cigarette products.

2. After the fifth year after enactment of the Act and annually thereafter, the FDA will calculate the incidence of daily use of tobacco products by those under 18 years of age as follows:

   For cigarette product use, the FDA will calculate the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Bureau of Census, of the percentages of 12th graders (ages 16 and 17), 10th graders (ages 14 and 15) and 8th graders (age 13) who used cigarette products on a daily basis during the preceding year. The percentages used in this calculation are to be those measured (a) by the University of Michigan Survey;

or (b) by such comparable index using identical methodology as is chosen by the FDA after notice and hearing. If the methodology of the University of Michigan Survey is hereafter changed in a material manner from that employed in 1986-96 (including by changing the states or regions on which that Survey is based), the FDA shall use the percentages measured by an index chosen by it after notice and hearing having a methodology identical to that employed by the University of Michigan Survey in 1986-96.

For smokeless tobacco product use, the FDA will calculate the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Bureau of Census, of the percentages of 8th (age 13), 10th (ages 14 and 15) and 12th graders (ages 16 and 17) who used smokeless tobacco products on a daily basis during the preceding year. This calculation is to be made using the same methodology as with respect to cigarette product use.

Any data underlying the University of Michigan Survey shall be available by request from FDA.

3. The reduction requirements (expressed as reduction from the base percentage) for cigarette products are as follows:

Year After Enactment	Reduction Requirement
years 5-6	30% reduction
years 7-9	50% reduction
year 10 (and thereafter)	60% reduction

The reduction requirements (expressed as reduction from the base percentage) for smokeless tobacco products are as follows:

Year After Enactment	Reduction Requirement
years 5-6	25% reduction
years 7-9	35% reduction

year 10 (and thereafter)	45% reduction

B. The Surcharge

Where the FDA's calculation (per the procedure set forth above) shows that the reduction requirements with respect to underage use of cigarette products were not met in the preceding year, the FDA will impose a surcharge on the manufacturers of cigarette products. Where the FDA's assessment shows that the Reduction Requirements with respect to underage use of smokeless tobacco products were not met in the preceding year, the FDA will impose a surcharge on the manufacturers of smokeless tobacco products.

1. The surcharge with respect to the cigarette industry will be calculated as follows:

(a) The FDA will the determine the percentage point difference between:

(i) the required percentage reduction applicable to a given year, and

(ii) the percentage by which the percent incidence of underage use of cigarette products for that year is less than the base incidence percentage.

(In the event that the FDA's calculation of the percent incidence of underage use of cigarette products for that year is greater than the base incidence percentage, the number of percentage points used will be (i) the required percentage reduction for that year plus (ii) the percentage by which the actual percent incidence for that year is greater than the base incidence percentage.)

(b) The surcharge will be $80 million for each percentage point derived per the above procedure. This amount reflects an approximation of the present value of the profit the cigarette industry would earn over the life of underage smokers in excess of the required reduction (at current levels of population and profit). This calculation will be subject to the following:

(1) the $80 million will be adjusted proportionately for percentage increases or decreases compared with 1995 in the population of persons resident in the United States aged 13-17, inclusive.

(2) the $80 million will be adjusted proportionately for percentage increases or decreases compared with 1996 in the average profit per unit (measured in cents and weighted by annual sales) earned by the cigarette industry. (The average profit per unit in 1996 will be derived from the industry's operating profit as reported to the SEC; and the average profit per unit for the year in which the surcharge is being determined will be calculated and certified to the FDA by a major, nationally recognized accounting firm having no existing connection to the tobacco industry using the same methodology as employed in deriving the average profit per unit for 1996.)

(3) the surcharge will be reduced to prevent double counting of persons whose smoking had already resulted in the imposition of a surcharge in previous years (to the extent that there were not underage smokers of comparable age in those previous years on whom a surcharge was not paid because of the cap set forth in paragraph (d) below).

(4) the surcharge may not exceed $2 billion in any year (as adjusted for inflation).

2. The surcharge with respect to the smokeless tobacco industry will be derived through a comparable procedure based upon a base pe- percentage point amount and a cap specific to that industry.

3. The surcharge payable by cigarette manufacturers will be the joint and several obligation of those manufacturers, allocated by actual market share. The surcharge payable by smokeless tobacco product manufacturers will be the joint and several obligation of those manufacturers, as allocated in the same manner. Within each such respective product market, the FDA will make such allocations according to each manufacturer's relative market volume in the United States domestic cigarette or smokeless tobacco markets in the year for which the surcharge is being assessed, based on actual federal excise tax payments.

4. The surcharge for a given year, if any, will be assessed by the FDA by May 1 of the subsequent calendar year. Surcharge payments will be paid on or before July 1 of the year in which they are assessed by the FDA. The FDA may establish, by regulation, interest at a rate up

5. After payment of its share of the surcharge, a tobacco product manufacturer may seek return of up to 75% of that payment through the abatement procedures described below.

C. Use of the Surcharge

The Surcharge funds would be used in an manner designed to speed the reduction of the levels of underage tobacco use.

Upon final completion and review of any abatement petition, the FDA would transfer as grants to state and local government public health agencies, without further appropriation, 90% of all monies paid as Surcharge amounts.

- As a condition of such transfers, the recipients of the transferred funds would be required to spend them on additional efforts by state and local government agencies, or by contract between such agencies and private entities, to further reduce the use of tobacco products by children and adolescents.

- The FDA may retain up to 10 percent of such Surcharge amounts for Administrative Costs – the administration of the Surcharge provisions of the Act and related proceedings, and for other administrative requirements imposed on the FDA by the Act.

- If 10 percent of the Surcharge amounts exceeds the Administrative Costs, the FDA may (1) transfer any portion of the excess to other federal agencies, or to state and local government agencies, to meet the objective of reduction of youth tobacco usage, or (2) may expend such amounts directly to speed the reduction of underage tobacco use.

D. Abatement Procedures

Upon payment of its allocable share of any Surcharge, a tobacco product manufacturer may petition the FDA for an abatement of the surcharge, and shall give timely written notice of such petition to the attorneys general of the several states.

1. The FDA shall conduct a hearing on an abatement petition pursuant to the procedures set forth in sections 554, 556 and 557 of Title 5 of the United States Code.

2. The attorneys general of the several states shall be entitled to be heard and to participate in such a hearing.

3. The burden shall be on the manufacturer to prove, by a preponderance of the evidence, that the manufacturer should be granted an abatement.

4. The FDA's decision on whether to grant an abatement, and the amount thereof, if any, shall be based on whether:

   (a) The manufacturer has acted in good faith and in full compliance with the Act, and any FDA rules or regulations promulgated thereunder, and all applicable federal, state or local laws, rules or regulations;

   (b) In addition to full compliance as set forth in (a) above, the manufacturer has pursued all reasonably available measures to attain the required reductions;

   (c) There is evidence of any action, direct or indirect, taken by the manufacturer to undermine the achievement of the required reductions or other terms and objectives of the Act; and

   (d) Any other relevant evidence.

5. Upon a finding by the FDA that the manufacturer meets the grounds for an abatement under the standards set forth above, it shall order an abatement of up to 75% of the Surcharge with interest at the average United States 52-Week Treasury Bill rate for the period between payment and abatement of the surcharge. The FDA may consider all relevant evidence in determining what percentage to order abated.

6. Any manufacturer or state attorney general aggrieved by an abatement petition decision of the FDA may seek judicial review thereof within 30 days in the United States Court of Appeals for the District of Columbia Circuit. Unless otherwise specified in this Act, judicial review under this section shall be governed by sections 701-706 of Title 5 of the United States Code.

7. Notwithstanding the foregoing, a tobacco product manufacturer

may neither file an abatement petition or seek judicial review of a decision denying an abatement if it has failed to pay the surcharge in a timely fashion.

8. No stay or other injunctive relief enjoining imposition and collection of the surcharge amounts pending appeal or otherwise may be granted by the FDA or any court.

[Source/precedent: 5 U.S.C. Sections 554, 556-57, 701-06]

Appendix VI: State Enforcement Incentives

The details of the state enforcement incentives are as follows:

In addition to FDA and other federal agency, state attorney general and other existing state and local law enforcement authority under current law, the proposed Act requires the following:

A. States must have in effect a "no sales to minors" law providing that it is unlawful for any manufacturer, retailer or distributor of tobacco products to sell or distribute any such products to any persons under the age of 18. (42 U.S.C. §300X-26(a)(1); 45 C.F.R. §96.130(b)). This state statutory requirement remains in addition to the federal regulatory prohibitions on retail sales of tobacco products to children and adolescents (also defined as persons under the age of 18) adopted by the FDA in its August 28, 1996 Final Rule (to be codified at 21 C.F.R. §897.14 et seq.);

B. States must conduct random, unannounced inspections at least monthly, and in communities geographically and statistically representative of the entire state and its youth population to ensure compliance with the "no sales to minors" law, and implement "any other action which the state believes are necessary to enforce the law." (goes further than 45 C.F.R. §96.130(c), 96.130(d)(1),(d)(2);

C. States must conduct at least 250 random, unannounced inspections of retailer compliance with the "no sales to minors" law per year for each 1 million of resident population, as determined by the most recent decennial census. In the case of tribes, tribes must conduct no fewer than 25 such inspections per location of point of sale to consumers per year, conducted throughout the year.

Annual State Reporting Requirements

As a condition to receiving any moneys due and payable pursuant to the Act, States must annually submit a report to the FDA and the States must make their reports public (except as provided in (C) below) within the state. Such state reports must include at least the following:

A. A detailed description of enforcement activities undertaken by the state and its political subdivisions during the preceding federal fiscal year;

B. A detailed description of the state's progress in reducing the availability of tobacco products to individuals under the age of 18, including the detailed statistical results of the mandated compliance checks;

C. A detailed description of the methods used in the compliance checks, and in identifying outlets which were tested, with the FDA providing the state appropriate confidentiality safeguards for information provided to the agency regarding the timing and investigative techniques of state compliance checks that depend for their continued efficacy upon such confidentiality;

D. A detailed description of strategies the state intends to utilize in the current and succeeding years to make further progress on reducing the availability of tobacco products to children and adolescents; and

E. The identity of the "single state agency" responsible for fulfilling the Synar Amendment and the Act's requirements, including the coordination and report of state efforts to reduce youth access to tobacco products sold or offered for sale in the state.

(strengthens and extends beyond 45 C.F.R. §96.130(e) by adding greater detail to the requirements and transferring reporting obligation of states to FDA from HHS)

Required Attainment Goals for State Enforcement

The FDA is required to make an annual determination, prior to allocating any moneys allocated to the states under the proposed Act for the purposes of defraying public health care program expenditures (but not including or conditioning moneys made available under the Act for the payment of private claims), as to whether each state has "pursued all reasonably available measures to enforce" the prohibition on sales of tobacco products to children and adolescents.

In addition to the criteria set forth in 45 C.F.R. §96.130, the proposed Act will require the FDA to find presumptively that the state has not "pursued all reasonably available measures to enforce" the "no sales to minors law" unless the state has achieved, in the following years, the following compliance rate results for the retail compliance checks required by the Act:

Federal Fiscal Year Under Review	Retail Compliance Check Performance Target
5th Year after year of enactment of Act	75%

7th Year after year of enactment of Act	85%
10th Year after year of enactment of Act and annually thereafter	90%

These compliance percentages are expressed as the percentage of the random, unannounced compliance checks conducted pursuant to the Act for which the retailer refused sale of tobacco products to the potential underage purchaser. (note: these performance targets are far more stringent on the states than those in the Synar Amendment, which sets as a "final goal" a target of no less than 80% (i.e., an inspection failure rate of no more than 20%) within "several years." See 45 C.F.R. §96.130. In addition, the proposed Act's targets are mandatory, uniform national minimum performance requirements, while the Synar Amendment calls for HHS simply to "negotiate" an "interim performance target" beginning in 1998).

Reduction of Money Allocated to State Not Meeting Performance Targets

If a state does not meet the Act's "no sales to minors" performance targets for retail compliance checks, then the FDA may refuse to pay to that non-complying state certain moneys otherwise payable to that state under the proposed Act. No state shall be held responsible for sales to underage consumers outside that state's jurisdiction. Specifically, the FDA may withhold from such state an amount equal to 1% of moneys otherwise payable to that state under the Act to defray health care expenditures of public programs of medical assistance for each percentage point by which the state's performance on its mandatory compliance checks fails to meet the required performance targets for that year. In no event may the FDA withhold more than 20% of the money otherwise allocable to such state under the Act for such purposes.

The FDA shall reallot any Withhold Amounts, once final, to states that exceed the Act's Performance Targets, in amounts and by an allocation formula determined by the agency to reward those states with the best record of reducing youth access to tobacco products.

Appeal Following Withhold

Upon notice from the FDA of a withhold of moneys (the "Withhold Amount") allocable to the state under the Act, a state subject to such notice of

withhold may petition the agency for a release and disbursement of the Withhold Amount, and shall give timely written notice of such petition to the attorney general for that state and to all tobacco product manufacturers. The agency shall hold, and invest in interest bearing securities of the United States government or its agencies, any Withhold Amounts subject to a pending petition for release and disbursement or related appeal until final disposition of such petition and appeal.

In the case of petition by a state for a release and disbursement of a Withhold Amount, the agency's decision on whether to grant such a petition, and the amount thereby released and disbursed, if any, shall be based on whether:

(1) the state has acted in good faith and in full compliance with the Act, and any agency rules or regulations promulgated thereunder;

(2) the state has pursued all reasonably available measures to attain the Retail Compliance Check Performance Targets and Youth Smoking Reduction Goals of the Act;

(3) there is evidence of any action, direct or indirect, taken by the state to undermine the achievement of the Retail Compliance Check Performance Targets and Youth Smoking Reduction Goals or other terms and objectives of the Act; and

(4) any other relevant evidence.

The burden shall be on the state to prove, by a preponderance of the evidence, that the state should be granted a release and disbursement of the Withhold Amount or any portion thereof. Prior to decision, the agency shall hold a hearing on the petition, with notice and opportunity to be heard given to the attorney general of that state and to all domestic tobacco product manufacturers.

Upon a finding by the agency that the state meets the grounds, as set forth above, and the burden of proof for a release and disbursement of a Withhold Amount, then it shall order a release and disbursement of up to 75% of the Withhold Amount appealed, and it shall so release and disburse to the state that amount, with interest at the average United States 52-Week Treasury Bill rate for the period between notice and release of such Withhold Amount. The agency may consider all relevant evidence in determining that percentage of the Withhold Amount to order released and disbursed.

Any manufacturer or state attorney general aggrieved by a Withhold Amount decision of the agency may seek judicial review thereof within 30 days in the United States Court of Appeals for the District of Columbia Circuit. Unless

otherwise specified in this Act, judicial review under this Section shall be governed by Sections 701-706 of Title 5 of the United States Code.

No stay or other injunctive relief enjoining imposition of the withhold pending appeal or otherwise may be granted by the FDA or any court.

No appeal may be taken from an agency decision denying a petition to release and disburse a Withhold Amount unless filed within 30 days following notice of such decision. No stay or other injunctive relief, enjoining imposition of the withhold pending appeal or otherwise, may be granted, by any court or administrative agency. Appeals filed hereunder shall be made to the District of Columbia Circuit Court of Appeals and, on appeal, shall be governed by the procedural and evidentiary provisions of the Administrative Procedures Act, unless otherwise specified in this Act. The judgment of the District of Columbia Court of Appeals on appeal shall be final.

Appendix VII - Restrictions on Point of Sale Advertising

The details with respect to point of sale advertising restrictions are as follows:

1. There shall be no Point of Sale Advertising of tobacco products, excluding adult-only stores and tobacco outlets, except as provided herein:

   A. Each manufacturer of tobacco products may have not more than two separate point of sale advertisements in or at each location at which tobacco products are offered for sale, except any manufacturer with 25 percent of market share may have one additional point of sale advertisement. A retailer may have one sign for its own or its wholesaler's contracted house retailer or private label brand.

   No supplier of tobacco products may enter into any arrangement with a retailer that limits the retailer's ability to display any form of advertising or promotional material originating with another supplier and permitted by law to be displayed at retail.

   B. Point of Sale advertisements permitted herein each shall be of a display area not larger than 576 square inches (either individually or in the aggregate) and shall consist of black letters on white background or recognized typographical marks. Point of Sale advertisements shall not be attached to nor located within two feet of any fixture on which candy is displayed for sale. Display fixtures are permitted signs consisting of brand name and price, not larger than 2 inches in height.

2. Except as provided herein, Point of Sale Advertising shall mean all printed or graphical materials bearing the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco, which, when used for its intended purpose, can reasonably be anticipated to be seen by customers at a location at which tobacco products are offered for sale.

3. Audio and video formats otherwise permitted under the FDA Rule may be distributed to adult consumers at point of sale but may not be played or shown at point of sale (i.e., no "static video displays").

Appendix VIII - Public Disclosure of Past and Future Tobacco Industry Documents and Health Research

The legislation would ensure that previously non-public or confidential documents from the files of the tobacco industry – including the results of internal health research -- are disclosed to the federal government, the States, public and private litigants, health officials and the public. The legislation also would provide for binding, streamlined and accelerated judicial determinations with nationwide effect in the event that disputes remain over the legitimacy of claims of privileges or protections, including attorney-client privilege, and work product and trade secret protections.

1. Under the Act, the manufacturers and CTR and TI would establish a national tobacco document depository that is open to the public and located in the Washington, DC area. This depository would serve as a resource for litigants, public health groups, and anyone else with an interest in the tobacco industry's corporate records on the subjects of smoking and health, addiction or nicotine dependency, safer or less hazardous cigarettes and underage tobacco use and marketing. Specifically:

    - The depository would include all of the documents produced to the other side by the manufacturers, CTR and TI in the Attorneys General actions (including all documents selected by plaintiffs from the Guilford, U.K. repository), Philip Morris Companies Inc.'s defamation action against Capital Cities/ABC News, the FTC's investigation concerning Joe Camel and underage marketing, the Haines and Cipollone actions and the Butler action in Mississippi.

    - In the event there are additional existing documents discussing or referring to health research, addiction or dependency, safer/less hazardous cigarettes, studies of the smoking habits of minors and the relationship between advertising or promotion and youth smoking that the manufacturers or trade associations have not yet completed producing as agreed or required in the above actions, such additional documents shall be placed in the depository commencing within 90 days of the effective date of the Act, and concluding as soon as practicable thereafter.

- Except for privileged and trade secret materials (which shall be exempt from disclosure into the depository), all documents placed in the depository shall be produced without any confidentiality designations of any kind.

- Along with these document collections, the manufacturers and trade associations shall place into the depository all indices (as defined by the court's order in the Minnesota Attorney General action) of documents relating to smoking and health, including all indices identified by the manufacturers in the Washington, Texas and Minnesota Attorney General actions. Any computerized indices shall be produced in both a computerized and hard-copy form. (If redactions of any such indices are required in order to protect any privileged or trade secret information, such redactions shall be subject to the procedures set forth below for adjudicating any disputes over claims of privilege and trade secrecy.)

- All documents placed into the depository shall be deemed produced for purposes of any litigation in the United States. The court in each underlying action shall retain the discretion to determine the admissibility on a case-by-case basis of any such produced document.

- The tobacco industry shall bear the expense of maintaining the depository.

2. Immediately upon finalizing a resolution of these litigations with the Attorneys General, without waiting for Congress to embody these requirement in the proposed legislation, the manufacturers, CTR and TI shall:

   - Commence to conduct a good-faith, de novo, document-by-document review of all documents previously withheld from production in tobacco litigation on grounds of privilege. The purpose of this review shall be to identify documents which the reviewer concludes are not privileged. All documents so identified shall be placed in the depository as soon as practicable.

   - Prepare and place in the national depository as soon as practicable a comprehensive new privilege log of all

documents that the manufacturers, CTR and TI, based on their de novo review, continue to deem to be legitimately privileged against disclosure.

- Itemize on this new privilege log all of the descriptive detail that the court has required defendants to furnish document-by-document on their privilege logs in the Minnesota Attorney General action, thereby ensuring that there will be sufficient detail on the privilege logs to enable any interested person to determine whether he or she wishes to challenge claims of privilege or trade secrecy on any particular documents.

3. The Act also would establish a panel of three federal Article III judges, appointed by the Judicial Conference, to hear and decide all disputes over claims of privilege or trade secrets, except for those disputes that already have been determined by other federal or state courts at the time the Act is enacted or are pending in cases prior to the time the Court has had an opportunity to begin to review privilege claims.

   - The three-judge panel shall decide all privilege or trade secrecy challenges asserted by the federal government, the States, public and private litigants, health officials and the public with respect to tobacco industry documents.

   - The Act would vest exclusive federal jurisdiction for the three-judge panel to decide any such disputes in accordance with the ABA/ALI Model Rules and/or principles of federal law with respect to privilege and the Uniform Trade Secrets Act with respect to trade secrecy. Any such adjudication shall be reviewable only in the manner prescribed by 28 U.S.C. [Sec. 1254–certiorari].

   - The panel's adjudications shall be binding upon all federal and state courts in all litigation in the United States.

   - The panel shall be authorized to appoint Special Masters pursuant to Fed. R. Civ. P. 53, with the cost to be borne by the tobacco industry.

   - Once the Act becomes effective and the three-judge panel is appointed, all disputes that may arise concerning privilege

claims by the manufacturers or trade associations relating to smoking and health subjects must be resolved through this process, except for disputes in pending cases that can be resolved prior to the time the Court has had an opportunity to begin to renew privilege claims.

- If a claim of privilege is not upheld, the three-judge panel shall consider whether the claimant had a good faith factual and legal basis for an assertion of privilege and, if the claimant did not, shall assess against the claimant costs and attorneys' fees and may assess such additional costs or sanctions as the panel may deem appropriate.

4. In order to expedite the process of judicial review and to ensure that the federal government, the States, public and private litigants, health officials and the public no longer need to be concerned that claims of privilege and trade secrecy are being asserted improperly or without legal basis, the legislation would create an accelerated process by which any public or private person or entity, subject to a right of intervention by any other interested person or entity, may challenge any claims of privilege or trade secrecy before the three-judge panel. Under the Act, a person or entity filing such an action to challenge to privilege or trade secrecy will not need to make any prima facie showing of any kind as a prerequisite to in camera review of the document or documents at issue.

5. The manufacturers would also be subject to certain continuing disclosure obligations over and above the aforementioned provisions and whatever further judicial discovery may be required in pending or future civil actions. Specifically, for the first time ever, the manufacturers would be required to disclose all original laboratory research relating to the health or safety of tobacco products, including, without limitation, all laboratory research relating to ways to make tobacco products less hazardous to consumers.

   - Whenever such research is performed in the future, the manufacturers shall disclose its results to the FDA.

   - In addition, all such research (except for legitimate trade secrets) shall be produced to the national document depository described above. In addition, the manufacturers and trade

associations shall produce into the depository on an ongoing basis any future studies of the smoking habits of minors or documents discussing or referring to the relationship, if any, between advertising and promotion and underage smoking.

- No original laboratory research relating to the health or safety of tobacco products shall be withheld from either the FDA or the depository on grounds of attorney-client privilege or work product protection.

6. The tobacco manufacturers' and CTR's and TI's compliance with any of the provisions of this Act shall not be deemed a waiver of any applicable privilege or protection.

7. The Act will also incorporate reasonable and appropriate provisions to protect against the destruction of documents bearing on matters of public health or safety.