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Appendix I - Excerpts From the Settlement

APPENDIX I – EXCERPTS FROM THE SETTLEMENT

Appendix I contains excerpts from the June 20, 1997 tobacco settlement cited by the authors of the articles. The full document is available at <http://www.stic.neu.edu/settlement/6-20-settle.htm>. Portions of the settlement contained in Appendix I are indicated in the Table of Contents in bold typeface. Omitted text is indicated by "* * *".

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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)) (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)

— 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))

— 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 ongoing 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 nonsmokers"

— "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 (897.1 4(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 (897.1 6(c)(2)(ii))

[Source/precedent: FDA Rule]

* * *

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.

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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 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): Year 1 2 3 4 5 6-8 9 after

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 multimedia 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. maintained only against companies, their assigns, any future fraudulent transferee, and/or entity for suit designated to survive defunct manufacturer. Actions may be manufacturing successors and
b. Manufacturers of agents agencies and liable vicariously for acts (including advertising 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, ap-

plications for compensation from persons, including nonsubrogation 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.

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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]

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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), 96.1 30(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 noncomplying 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.