

NLWJC - Kagan

DPC - Box 049 - Folder-003

**Tobacco-Settlement: New
Legislation-Hatch Bill**

Tobacco - new legislation -
Hatch bill

EK

From your
new friend

Senator Orrin G. Hatch
Section-by-Section Analysis
S. 1530
"PROTECT" Act

Section 1. SHORT TITLE; TABLE OF CONTENTS. Entitles the bill "Placing Restraints on Tobacco's Endangerment of Children and Teens" Act ("PROTECT") and lists a table of contents.

Section 2. FINDINGS. Makes a series of congressional findings with respect to tobacco, its harmful health effects on children and adults, and the role of government in regulating tobacco products.

Section 3. GOALS AND PURPOSES. Sets forth the goals and purposes of the legislation, including decreasing tobacco use by youth and adults, enhancing biomedical research efforts, setting forth Federal standards for smoking in public establishments, establishing the authority of the Food and Drug Administration to regulate tobacco products, providing transitional assistance to farmers, and reforming tobacco litigation practices.

Section 4. NATIONAL GOALS FOR THE REDUCTION IN UNDERAGE TOBACCO USE. Sets out national goals for reduction in youth tobacco use. For cigarettes, the national goals, measured from the baseline year, will be a 30% reduction in use in 2003 and 2004; a 50% decrease in 2005, 2006 and 2007; and a 60% reduction thereafter. For smokeless tobacco, the national goals, measured from the baseline year, will be a 25% reduction in use in 2003 and 2004; a 35% reduction in 2005, 2006, and 2007; and a 45% reduction thereafter.

Section 5. DEFINITIONS. Defines pertinent terms used in the bill.

TITLE I - NATIONAL TOBACCO SETTLEMENT TRUST FUND

Section 101. ESTABLISHMENT OF TRUST FUND. Creates a National Tobacco Settlement Trust Fund that will receive payments from tobacco manufacturers according to a schedule set out in the bill. Over the next 25 years, deposits will be \$398 billion, of which \$95 billion are considered punitive damages and will be used to fund a biomedical research trust fund.

The National Tobacco Settlement Trust Fund will be administered by the Attorney General, the Secretary of Health and Human Services, and the Secretary of Treasury,

and will be advised by a board composed of the Trustees and representatives of State attorneys general, public health experts, the *Castano* plaintiffs, and the tobacco industry. The initial \$10 billion down payment from the tobacco industry, the continued annual payments, and any look-back or surcharge payments or penalties will be deposited into the Settlement Trust Fund.

The Settlement Trust Fund consists of a State Account and a Federal Account. Generally, as specified in section 101(c), the funds are distributed as follows: First, a portion of the total funds are set aside in the Federal Account for a transitional agriculture assistance program, a limited fund for asbestos-related litigation (where it can be proven that tobacco use was a cause of injury), and a new program to enhance Native American health. The remaining funds are divided equally with one-half provided to the States and one-half to the Federal government. In addition to the set aside funds for tobacco farmers, tobacco/asbestos plaintiffs, and Native American activities, the remaining funds from the Federal Account will be essentially divided equally between tobacco-related biomedical research and public health activities as provided in sections 521 and 522, respectively.

Funds from the State Account may be used by the states for both general purposes and for tobacco-related programs as specified in sections 501 and 502, respectively. The Trustees are precluded from making an expenditure for programs which are currently being funded at either the Federal or State levels, so that the funds provided in this Act are supplemental to any on-going activities and not a substitution.

Section 102. PAYMENT SCHEDULE. As a condition of receiving the liability provisions contained in Title II, participating manufacturers must execute a protocol with the Secretary of Health and Human Services, each respective state attorney general, and *Castano* litigants, sign consent decrees with States and *Castano* plaintiffs, and deposit an initial \$10 billion payment into the Trust Fund. In addition, to be eligible for the liability protections, manufacturers must make payments according to a schedule listed in the bill. The Trustees are authorized to adjust those continuing payments for: 1) an annual inflation adjustment; 2) a volume adjustment which could either increase or reduce the base payments; 3) a credit for judgments paid; and 4) the incentive system described in section 307. The amount that each participating manufacturer will pay will be determined under the Protocol appended to the agreement.

Section 103. ADMINISTRATIVE PROVISIONS. The Attorney General will hold the Trust Fund and will report annually to the relevant congressional committees on the financial condition of the Trust Fund. The Trustees will invest excess balances of the Fund in interest-bearing obligations of the U.S. and proceeds therefrom will become a part of the account. Members of the Trustees' advisory board shall serve without compensation, although travel expenses will be reimbursed, and overall costs of the advisory board are capped. Receipts and disbursements from the Trust Fund will not be included in the annual budget, and cannot be transferred to the general fund of the

Treasury.

Section 104. ENFORCEMENT. Any participating manufacturer which fails to make payments required by the Act will be subject to daily fines. If the manufacturer has not made the required payment within one year, the manufacturer will be considered non-participating, will lose the liability protections contained in the Act, and will be ineligible from becoming a participating manufacturer in the future.

TITLE II - NATIONAL PROTOCOL AND LIABILITY PROVISIONS

Subchapter A - Protocol Restrictions on Advertising

Section 201. REQUIREMENT. To be eligible for the liability protections contained in Subtitle C, each tobacco manufacturer shall enter into a binding and enforceable contract ("the Protocol") in each state, with the Attorney General on behalf of the Chief Executive Officer of the state and representatives of the *Castano* litigants. As part of the protocol, a participating manufacturer shall agree, in any contract entered into with a distributor and retailer, to require the distributor and retailer to comply with the applicable terms of the protocol.

Section 211. APPLICATION OF SUBCHAPTER. The following provisions will be considered part of the Protocol.

Section 212. AGREEMENT TO PROHIBIT ADVERTISING. Parties to the executed Protocol agree that they will not use any form of outdoor product advertising, nor will they advertise in any arena or stadium whether athletic, musical, artistic or other social or cultural events or activities occur. Parties also agree not to use human images or cartoon characters in tobacco-related advertising, labeling or promotional materials, and not to advertise tobacco products on the Internet. Parties also agree to limit point of sale advertising of tobacco products both in terms of number of advertisements and format, except in adult-only stores and tobacco outlets.

Section 213. GENERAL RESTRICTIONS. Parties agreeing to the Protocol will not use a trade or brand name of a non-tobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for products sold in the United States before January 1, 1995. Parties further agree to limit the media in which tobacco products will be advertised and will not make payments for placement of tobacco products in television programs, motion pictures, videos or video game machines.

Section 214. AGREEMENT ON FORMAT AND CONTENT REQUIREMENTS FOR LABELING AND ADVERTISING. Those signing the Protocol agree to limit tobacco-related advertising to black text on white background, except in certain cases such as vending areas not visible from the outside and adult publications. Further, parties using audio or video formats agree to certain limits, such as restrictions on music or sound.

Section 215. AGREEMENT TO BAN NON-TOBACCO ITEMS AND SERVICES, CONTESTS AND GAMES OF CHANCE, AND SPONSORSHIP OF EVENTS. Parties to the Protocol agree to ban all non-tobacco merchandise bearing the brand name, logo or other identifier of tobacco products. They also agree not to offer any gift or item in connection with the purchase of a tobacco product. Parties agree not to sponsor any athletic, musical, artistic or other social/cultural event in which identifiers of tobacco products are used, although the use of a corporate number in use in the United States prior to January 1, 1995 would be permissible.

Subchapter B - Provisions relating to Lobbying

Section 220. APPLICATION OF SUBCHAPTER. The provisions of this subchapter will be considered part of the Protocol.

Section 221. AGREEMENT TO PROVISIONS RELATING TO LOBBYING. A manufacturer signing the Protocol must require that any lobbyists it retains will sign an agreement consenting to comply with applicable laws and regulations governing tobacco products, including this Act and the consent decree under this Act, and agreeing not support or oppose any Federal or State legislation without express consent from the manufacturer.

Section 222. AGREEMENT TO TERMINATE CERTAIN ENTITIES. Parties to the Protocol agree that, within one year of enactment, the Tobacco Institute and the Council for Tobacco Research, U.S.A. will be terminated, and that any successor organizations will meet strict guidelines with respect to membership and activities and will be subject to oversight by the Department of Justice.

Subchapter C -- Other Provisions

Section 225. APPLICATION OF SUBCHAPTER. The provisions of this subchapter will be considered part of the Protocol.

Section 226. DETERMINATION OF PAYMENT AMOUNT. Manufacturers agreeing to the Protocol will determine the percentages each specific manufacturer must pay.

Section 227. ATTORNEY'S FEES AND EXPENSES. Within 30 days of enactment, an arbitration panel will be appointed by the Trustees, the participating manufacturers, and State Attorneys General participating in the June 20, 1997 memorandum of understanding and the *Castano* litigants. The arbitration panel will establish procedures for its operation, receive petitions for attorneys' fees and expenses, and make awards based on enumerated criteria subject to an annual cap which is equal to 5% of the amount paid to the Trust Fund for the applicable year. Awards made by the panel will be paid by the participating manufacturers and will not be paid from the Trust Fund.

Section 228. LIMITATIONS WITH RESPECT TO INDIAN COUNTRY. Participating manufacturers will agree not to conduct any activity within Indian country that is otherwise prohibited under this Act, and agrees to sell or otherwise distribute tobacco products to an Indian tribe or tribal organization under the same terms and conditions as the manufacturer imposes on others.

Section 231. FEDERAL ENFORCEMENT OF THE PROTOCOL. Sets forth the terms and conditions under which the Attorney General may bring civil actions, including imposition of stiff penalties, to enforce the Protocol. The Attorney General may enter into contracts with state agencies to assist in enforcement. The Attorney General is authorized to utilize funds from the Trust Fund for performance of her duties under this section.

Section 232. STATE ENFORCEMENT OF THE PROTOCOL. The chief law enforcement officer of a state may bring actions to enforce the protocol if the alleged violation is the subject of a proceeding within that State. However, the State must first give the Attorney General 30 days' notice before commencing such a proceeding, and the State may not bring a proceeding if the Attorney General is diligently prosecuting or has settled a proceeding relating to the alleged violation.

Section 233. PRIVATE ENFORCEMENT OF PROTOCOL. A participating manufacturer may also seek a declaratory judgment in Federal District Court to enforce its rights and obligations under the Act, and may also bring a civil action against other participating manufacturers to enforce or restrain breaches of the contract. In general, no such actions may be commenced, however, if the Attorney General or applicable State is already pursuing an action on the same alleged breach.

Section 234. REMOVAL. The Act allows removal to Federal court of state claims which seek to enforce the Protocol.

SUBTITLE B--CONSENT DECREES

Section 241. CONSENT DECREES. For a State to receive funding under Title V, for a manufacturer to receive liability protections under subtitle C, and for settlement of the *Castano* claims, consent decrees must be signed effective on the date of enactment. The consent decrees shall include provisions relating to restrictions on tobacco advertising and youth access, restrictions on trade associations and lobbying, disclosure on tobacco smoke constituents, disclosure of nontobacco ingredients in tobacco products, disclosure of all documents relating to health, toxicity, and addiction, the obligation of manufacturers to make payments for the benefit of States, the obligation of manufacturers to deal only with distributors and retailers that comply with all laws regarding tobacco products, requirements for warnings, labeling, and packaging, the dismissal of pending litigation as required under this Act, and any other matters deemed appropriate by the Secretary.

The consent decrees shall not include information on tobacco product design, performance, or modification, manufacturing standards and good manufacturing practices, testing and regulation with respect to toxicity and ingredients, and the national goals relating to reductions in underage use of tobacco. Constitutional claims shall be waived and the provisions are severable. The decree must be approved by the Attorney General. The decree shall remain in effect regardless of amendments to the Act, except as superseded by said amendments. A state may only seek injunctive enforcement of the consent decree in state court. The Attorney General will regulate to ensure consistency of state court rulings regarding consent decrees which are not exclusively local.

Section 242. STATE ENFORCEMENT OF CONSENT DECREES. A State may bring an injunctive action to enforce the terms of a consent decree which falls within its jurisdiction. It can only seek criminal or monetary relief for a subsequent violation of an injunction previously granted.

Section 243. NON-PARTICIPATING MANUFACTURERS. Provides an incentive for manufacturers to participate in the national tobacco control protocol. Non-participating firms will not be protected by the civil liability protections of this bill. A non-participating company will be required to transfer funds to the National Tobacco Settlement Trust Fund in an amount based on the proportion of the market share of the sales of the firm. Each non-participating manufacturer shall place into an escrow reserve fund each year an amount equal to 150% of its share of the annual payment required of participating manufacturers.

SUBTITLE C--LIABILITY PROVISIONS

Section 251. DEFINITIONS. Defines pertinent terms used in Subtitle C.

CHAPTER 1--IMMUNITY AND LIABILITY FOR PAST CONDUCT

Section 255. APPLICATION OF CHAPTER. This chapter is the sole enforcement mechanism and exclusive remedy for any claims against any participating manufacturer which have not reached final judgment or settlement by the effective date of this act. Any court judgment entered subsequent to this bill's enactment shall include express language subjecting the judgment to the act. No bond, penalty, or increased interest shall be required in connection with appeal of any judgment arising under this act.

Section 256. LIMITED IMMUNITY. All pending actions against participating manufacturers whether brought by a State or local government entity, as a class action, or as a civil action based on addition to or dependence, are hereby terminated. All participating manufacturers are hereby immune from any future action brought by a State or local governmental entity, as a class action, or as a civil action based on tobacco addiction or dependence. Individual personal injury claims arising from the use

of tobacco are preserved.

Section 257. CIVIL LIABILITY FOR PAST CONDUCT. This section applies to all actions permitted under section 256 for conduct *before* enactment. Punitive damages are prohibited.

All actions must be brought by individuals and may not be consolidated without consent of defendants. The only means to remove an action is if a defendant removes it to Federal court. Participating manufacturers must jointly share in civil liability for damages; they shall not be jointly and severally liable with non-participating manufacturers; and actions involving participating and non-participating manufacturers shall be severed. Permissible plaintiffs are individuals, their heirs, and third-party payers who are bringing individual claims for tobacco-related injuries and third-party payers whose claims are not based on subrogation that were pending on June 9, 1997. Defendants under this section are participating manufacturers, their successors or assigns, any future fraudulent transferees, or any entity for suit designated to survive a defunct signatory. Vicarious liability for agents applies. Subsequent development of reduced risk tobacco is not admissible or discoverable.

Aggregate annual cap is 1/3 of annual payments required of all signatories for the year involved. Excess amounts shall be paid in the following year. Signatories shall receive credit of 80% of amounts paid under judgments or settlements for the year involved, up to one-third of annual payments. Any amount awarded over \$1,000,000 may be paid in the following year. Each annual payment shall not exceed \$1,000,000, unless all judgments in the first year can be paid without exceeding the aggregate annual cap. Defendants shall bear their own attorneys' fees and costs.

Section 258. CIVIL LIABILITY FOR FUTURE CONDUCT. This section applies to all actions permitted under section 256 for conduct *after* enactment. Sections 257(c) and (e) through (l) shall apply to actions under this section. Third-party payor claims not based on subrogation shall not be commenced under this section. There is no prohibition for punitive damages under this section.

Section 259. NON-PARTICIPATING MANUFACTURERS. This title shall not apply to non-signatories to the Protocol and participating manufacturers who are 12 months delinquent in payments due pursuant to the act.

Section 260. PAYMENT OF JUDGMENTS AND SETTLEMENTS. A participating manufacturer may seek injunctive relief in federal court to stop a state court from enforcing a judgment which is unenforceable under this chapter. The federal court shall issue an injunction if the participating manufacturer demonstrates that the judgment or settlement is unenforceable under this chapter.

Section 261. STATE ELIGIBILITY. A state shall be eligible to receive funds under this

act if (1) (by the effective date of the act) it adopts sections 256 through 259 as unqualified state law and any defendant in a civil action under this act shall have a right to a prompt interlocutory appeal to the highest court of the state to enforce the requirements of state law; and (2) it withdraws and dismisses any claims required to be dismissed under section 256.

Within 6 months of the effective date of this act (with special provision for states whose legislature do not meet within that time frame), and annually thereafter, the AG shall certify that each state eligible to receive funds has complied with this section -- states not certified shall not receive funds. No state claim may be maintained in any court of that state if it does not comply with subsection (a)(1) herein. This chapter governs any action by a state which is not in compliance with subsection (a)(1) herein but is otherwise maintainable in the state.

Section 262. REMOVAL. This section amends the existing code to enact the removal provisions and give the federal court jurisdiction.

Section 263. CONFORMING AMENDMENTS. The section conforms existing code sections with this act.

TITLE III -- REDUCTION IN UNDERAGE TOBACCO USE

Subtitle A -- State Laws Regarding the Sale of Tobacco Products to Minors

Section 301. STATE LAWS REGARDING SALE OF TOBACCO PRODUCTS TO INDIVIDUALS UNDER THE AGE OF 18. Expands upon what is popularly known as the "Synar amendment" (relating to the sale or distribution of tobacco products to individuals under the age of 18) P.L 102-321.

Effective in FY 1999 (or FY 2000 for States with legislatures which do not convene in 1999) and thereafter, a State which wishes to receive funding under Title V of this Act must have in effect a State law consistent with the provisions contained in the model law described in section 302. A State must enforce the law systematically and conscientiously and in a manner which can reasonably be expected to reduce the extent to which tobacco products are available to individuals under age 18. A State must also certify that enforcement of the law is a priority, conduct random, unannounced inspections to ensure compliance, and annually transmit to the Trustees a report describing its operation of the program. As a funding source for the program, States may use payments from the Trust Fund, grants under sections 1901 and 1921 of the Public Health Service Act, license fees or penalties collected pursuant to this Act, or any other funding authorized by the State legislature. The Trustees are authorized to reduce payments to States for noncompliance.

Section 302. MODEL STATE LAW. Describes the provisions of the model state law. Under that model, a series of conditions are placed on the sale of tobacco to restrict use

by persons under age 18. It will be unlawful for a person to distribute a tobacco product to an individual under age 18. Persons who violate this section, and employers of employees who violate the section, are liable for civil penalties. Under the model, it is also unlawful for an individual under age 18 to purchase, smoke or consume (or attempt such acts) in a public place. Penalties are imposed for violations of this provision. Law enforcement agencies are required to notify promptly the parent(s) or guardians about such violations. Persons who sell tobacco products at retail must post signs communicating that the sale to individuals under 18 is prohibited. It is also unlawful for product samples or opened packages to be provided to anyone under 18, or for packages to be displayed so that individuals have direct access. Civil penalties for violations of these requirements apply.

The model law also requires employers who distribute tobacco products at retail to implement a program to ensure that employees are not distributing tobacco products to minors in violation of the preceding requirements. The model also requires appropriate state and local law enforcement officials to enforce the Act in a manner reasonably expected to reduce the extent to which individuals under age 18 have access to tobacco products. Under certain conditions, states are authorized to use individuals under age 18 to test compliance with this act. The Act also sets forth requirements for states to license persons engaged in the distribution of tobacco products, and describes the procedures which will be used for suspension, revocation, denial and non-renewal of licenses. States are required to report annually on compliance with the Act.

Subtitle B -- Required Reduction in Underage Usage

Section 311. PURPOSE. Encourages achievement of dramatic and immediate reductions in the number of underage consumers of tobacco through substantial financial surcharges on manufacturers if targets are not met.

Section 312. DETERMINATION OF UNDERAGE USE BASE PERCENTAGES. Sets forth a methodology for the Secretary of HHS to set base percentages for the calculation by age group of children who use tobacco products.

Section 313. ANNUAL DAILY INCIDENCE OF UNDERAGE USE OF TOBACCO PRODUCTS. Five years after enactment, and annually thereafter, the Secretary shall make a determination according to the methodology set out in this section of the average annual incidence of daily tobacco use by individuals under age 18.

Section 314. REQUIRED REDUCTION IN UNDERAGE TOBACCO USE. Requires the Secretary to determine if the annual incidence of the daily use of tobacco products exceeds the national goals set forth in section 4.

Section 315. APPLICATION OF SURCHARGES. If the Secretary determines that the national goals have not been met in any year following year five, she will make a report

to Congress outlining changes to the national program established in this act that she believes must be undertaken to move the country toward achievement of the national goals. The Secretary is authorized to impose a surcharge on cigarette manufacturers of \$100 million per percentage point for each of the first five percentage points by which the goal is not met; the surcharge will be \$200 million for each of the next five percentage points by which the goal is not met, and \$300 million per percentage point for the amount that the goal is not met by eleven or more percentage points. In the case of smokeless tobacco products, which represent one-seventh of youth use of tobacco products, the potential lookback penalties will be \$15 million per applicable percentage point for each of the first five points by which the goal is not met. The potential surcharge that could apply would be \$30 million and \$45 million for the next two five percentage point increments, respectively.

Five years after the surcharge provisions are applicable (the eleventh year after passage), the surcharge payments will be increased. For cigarettes, the surcharge payment will be \$250 million for each of the first five percentage points that the goal is not met and \$500 million for each additional percentage point by which the goal is not met. (E.g., If cigarette usage failed to meet the applicable target by 6 percentage points, in year 6 the surcharge assessment is \$700 million, and in year 11 is \$1.75 billion.) For smokeless tobacco products, the corresponding surcharge amounts will be \$30 million and \$60 million, respectively. This section provides an annual cap on surcharge payments for cigarettes of \$5 billion for the first five years in which the surcharges apply under the Act (the sixth year after passage) and \$10 billion thereafter. For smokeless tobacco products, the analogous caps are, \$500 million and \$1 billion, respectively.

Any surcharge imposed under this section is the joint and several obligation of all participating manufacturers (subject to the abatement provisions contained in section 316) as allocated by the market share of each manufacturer. Any funds generated under this section will be available to the Trust Fund.

Section 316. ABATEMENT PROCEDURES. A manufacturer who becomes subject to any surcharge that might be imposed under section 315 must first pay the surcharge, and then may petition the Secretary for abatement of the surcharge. The Secretary is required to hold a hearing on the abatement petition, during which the burden will be on the participating manufacturer to prove by a preponderance of the evidence that the manufacturer should be granted the abatement. The Secretary will make her decision based on criteria described in this section. She may abate all or part of the surcharge, but this is totally at her discretion. Judicial review of the Secretary's decision may be sought.

Section 317. INCENTIVES FOR EXCEEDING THE NATIONAL TOBACCO PRODUCTS USE REDUCTION GOALS. In any year, including the first five program years, that the ultimate national tobacco product use reduction goals are exceeded (a 60% reduction for cigarettes and a 45% reduction for smokeless tobacco products,

tobacco manufacturers will be assessed reduced payments. This section provides that for payments related to cigarettes, for each percentage point by which the 60% reduction goal has been exceeded payments will be reduced by a factor of 1/80 per percentage point. (E.g., if cigarette use dropped by 80% from the base year in a given year, the payment would be reduced by 20/80th's, or 25%). The corresponding factor for smokeless tobacco products is 1/110 per percentage point that the 45% goal is exceeded.

TITLE IV -- HEALTH AND SAFETY REGULATION OF TOBACCO PRODUCTS

Subtitle A -- General Authority

Section 401. Amendments to Definitions Contained in the Federal Food, Drug, and Cosmetic Act. This title grants clear jurisdiction over tobacco products and establishes the framework for the Secretary of Health and Human Service, acting through the Food and Drug Administration, to oversee a new comprehensive regulatory system for tobacco products. "Tobacco product" and other relevant terms are defined for the first time in the FDA's basic regulatory statute, the Federal Food, Drug, and Cosmetic Act. This section adds two important new prohibited acts to the FD&C statute that make it illegal to manufacture and market tobacco products that do not comply with the new Tobacco Products chapter, Chapter IX. The bill amends the definition of "drug" to give FDA authority to regulate tobacco products as unapproved drugs if they do not comply with new Chapter IX. No change is made in the definition of "medical device" and this bill does not contemplate that tobacco products shall be regulated as restricted medical devices.

Adds a new Chapter IX to the Federal Food, Drug and Cosmetic Act, which will be entitled "Health and Safety Regulatory Requirements Relating to Tobacco Products. It will contain the following new sections.

Section 900. Definitions. Definitions of the term "cigarette," "cigarette tobacco," "nicotine," "smokeless tobacco," "tar," "tobacco additive," and "tobacco product" will be added to the FD&C Act.

Sec. 901. Statement of General Duties. The Secretary of HHS is directed to undertake a number of regulatory activities, detailed in section 902 through section 908, in furtherance of the comprehensive health promotion and disease prevention program that the PROTECT Act establishes for tobacco products.

Sec. 902. Tobacco Product Health Risk Management Standards. This section directs the Secretary to issue regulations, through routine notice and comment rulemaking procedures and in consultation with public health experts, that establish rigorous controls over the composition of tobacco products. These regulations will include provisions relating both to the protection of confidential commercial information and for the public disclosure of the ingredients of tobacco

products.

Such regulations will grant the Secretary the authority to issue regulations to assess and manage the risks presented by nicotine and reduce or eliminate constituents of tobacco products, or to ban tobacco products after the Secretary considers relevant factors. These factors include: reduction of public health risks; capacity of the health care system to provide effective and accessible treatments to current consumers of tobacco products; the potential creation of a significant market for contraband tobacco products; and, the technological feasibility of manufacturers to modify existing products. Secretarial actions to ban tobacco products will require a joint resolution of approval from both chambers of the United States Congress.

Sec. 903. Good Manufacturing Practice Standards for Tobacco Products.

The Secretary shall issue regulations that specify the good manufacturing practices (GMP) for tobacco products. Such regulations will prescribe the methods used in, and the facilities and management controls used for, the manufacturing of tobacco products. The GMP regulations will contain requirements for registration and inspection of the tobacco product manufacturing establishments.

The GMP regulations promulgated by the Secretary shall contain provisions relating to pesticide residue levels and will provide for an advisory committee to recommend to the Secretary whether to approve, consistent with the public health, petitions for variances to the established residue level standards. The GMP requirements established by the Secretary shall include record keeping and reporting standards for tobacco products.

Sec. 904. Tobacco Product Labeling, Warning, and Packaging Standards.

Section 904 stipulates new warning statements for both cigarettes and smokeless tobacco products. Section 904 provides format and type-size requirements and stipulates rotation schedules for tobacco product labels. Section 904 grants the Secretary the authority to issue regulations to revise tobacco product labeling statements and exempts tobacco product exports from these labeling requirements.

Sec. 905. Reduced Risk Tobacco Products. This section requires the Secretary to issue regulations that create incentives for the development and commercial distribution of reduced risks tobacco products. Under section 905 manufacturers of new technologies that reduce the negative health effects of using tobacco products notify, in confidence, the Secretary of such technology. Upon a determination that an innovation reduces the health risks of tobacco products and is technologically feasible, the Secretary may require that such risk reduction innovations be incorporated, through a licensing program, into other

tobacco products.

Section 906. Tobacco Product Marketing Restrictions. Section 906 prohibits the sale of tobacco products to persons under 18 years of age and generally requires retailers to conduct sales in a face-to-face manner and to verify the age of tobacco purchasers. Under this section, cigarettes must be sold in packages with no fewer than twenty cigarettes; no free samples may be distributed; the vending machine sales must be eliminated except in certain limited adult facilities; and mail order sales must be accompanied by age verification procedures.

Section 907. Tobacco Products Scientific Advisory Committee. This requires the Secretary to establish a Tobacco Products Scientific Review Committee to assist in the development and in an on-going assessment of the effectiveness of the tobacco product health risk management standards required by section 902, the tobacco product good manufacturing standards required by section 903, the tobacco product labeling, warning, and packaging standards required by section 904, the reduced risk tobacco product provisions of section 905, and the tobacco product marketing restrictions required by section 906. This committee will primarily consist of experts in science, medicine, and public health but will also include experts in law and ethics and include representatives of both pro-, and anti- tobacco use groups.

Section 908. Report to Congress. Section 908 requires the Secretary to report to Congress biennially on the effectiveness of new Chapter IX and the other relevant provisions of the PROTECT Act, and other relevant laws and policies that relate to the nation's effort to reduce use of, and the health risks associated with, tobacco products. Such report will contain information on current use patterns and health effects of tobacco products with a particular emphasis on use of these products by those under 18 years of age. The Secretary shall also report to the Congress on recommended changes in legislation that will increase the effectiveness

Section 909. Judicial Review Standards. This new section makes clear that in any judicial proceeding involving the regulations issued under Chapter IX, the courts will use procedures, apply standards of review, and grant the degree of deference that it normally accords the Secretary under the Federal Food, Drug, and Cosmetic Act.

Section 910. Preemption. This section permits state and local governments to enact requirements with respect to tobacco products so long as the state or local requirement does not conflict with a requirement of section 902, 903, 904, or 905.

Section 402. Technical Revisions. This section supersedes part of the Federal

Cigarette Labeling and Advertising Act and repeals the Comprehensive Smokeless Tobacco Health Education Act.

TITLE V -- PAYMENTS TO STATES AND PUBLIC HEALTH PROGRAMS
Subtitle A -- Payments to States

Section 501. Reimbursement for State Expenditures. The Trustees will make available to the states one-half of the Trust Fund amounts each year (after payments have been allocated for tobacco farmers, Native Americans, and certain combined asbestos/tobacco plaintiffs), apportioned state-by-state according to a table listed in the Act which is based on the State Attorney Generals' agreement. The funds will be utilized by the States under two sets of conditions. Utilizing the Medicaid matching percentage rates, the portion of the funds which would have been attributable to the state matching share shall be used by the State for any purpose it deems appropriate. Federal subrogation is waived, and the amount that otherwise would have been returned to the Federal government will be retained by the State, but may only be used for certain specified anti-tobacco-related purposes as outlined in section 502.

Section 502. Requirements for States' Use of Certain Funds. As a condition of receiving funds which otherwise would have been returned to the Federal government, a state must submit to the Trustees a plan that describes the anti-tobacco programs for which the funds will be used, the measurable objectives that will be used to evaluate the program outcome, the procedures which will be used for outreach, and efforts which are made to coordinate the new programs with existing Federal and State programs. The state must also collect necessary data and maintain records to allow the Trustees to evaluate the plan and its effectiveness. State plans and amendments thereto are deemed to be approved unless disapproved by the Trustee within 90 days of submission. Each year, the State must provide the Trustees with an assessment of the plan, including the effectiveness of the plan in reducing the number of children and adults who use tobacco products. In addition, the Trustees will provide an annual report on operations of the plan.

In order to retain the otherwise-Federal share, States must use the funds for anti-tobacco programs in coordination with existing Federal public health and social services programs, including child nutrition programs, maternal and child health, the State Children's Health Insurance Program, Head Start, school lunch, Indian Health Service, Community Health Centers, Ryan White, and social services block grant. States may also use these funds for smoking cessation programs that reimburse for medications or other therapeutic techniques, and anti-tobacco products public education programs, including counter-advertising campaigns.

Subtitle B -- Public Health Programs

Section 521. National Institutes of Health Trust Fund for Health Research. A

National Institutes of Health Trust Fund for Health Research is established which reflects the settlement of punitive damages for past reprehensible behavior of the tobacco industry. This punitive damages fund will be funded from the National Settlement Trust Fund, and overall funding will amount to \$95 billion over the first 25 years. In year 5 and thereafter, a total of \$4 billion annually will be available under this section, subject to any required adjustments due to inflation, sales volume adjustments, and look-back penalties.

Section 521(e) requires the Director of the National Institutes of Health, in consultation with leading experts, to devise a National Tobacco and Other Abused Substances Research Agenda. Funds provided under this section are expended as follows: NIH Director's Discretionary Fund, 2%; Research Facilities, 2%; health information communications, 1%; national cancer research and demonstration centers under section 414 of the Public Health Service Act, 10%; and, the remaining 85% shall be allocated to the established Institutes, Centers, and Divisions of NIH in the same proportion as the annual appropriations bill for NIH. Eligible research are stipulated in section 521(d)(2) and include diseases associated with tobacco use including cancer, cardiovascular diseases, and stroke.

Section 522. National Anti-Tobacco Product Consumption and Tobacco Product Cessation Public Health Program. Under this section, with the funds specified in section 101(c)(3)(C) of Title I of this Act, the Secretary shall establish and implement a national anti-tobacco product consumption and tobacco product cessation program. This program will be coordinated by the Office on Smoking and Health of the Centers for Disease Control and Prevention. In year 6 and thereafter, a total of \$4 billion annually will be available under this section, subject to any required adjustments due to inflation, sales volume adjustments, and look-back penalties.

The Secretary may use funds under this section to offset HHS' administrative costs in carrying out the public health components of the PROTECT Act, including the additional costs attributable to the new regulatory responsibilities placed on the Food and Drug Administration under this Act. In carrying out this section, the Secretary may act under the general authorities provided under section 301 of the Public Health Service Act. In carrying out this program the Secretary must act in concert with state and local public health officials and non-governmental organizations and will consider, as appropriate, the public health recommendations made by the *Castano* class action plaintiffs.

This section requires the Secretary to undertake a substantial public education program, including the development and dissemination of materials that alert the public to the risks of tobacco use, with a special emphasis on materials and techniques that are targeted to the young. The Secretary is also directed to make a special effort to inform current adult users of tobacco products of the health benefits of ceasing use of these products. Among the public education and information techniques authorized by this section is a publicly financed nationally directed counter-advertising campaign. The Secretary is also directed to develop and make available a model state anti-tobacco use

and tobacco cessation program.

Section 522 directs the Secretary to make available at least one half the funds available under this section through section 101(c)(3)(C) to states in the form of voluntary anti-tobacco use and tobacco cessation program block grants. Eligible activities for this block grant will be the same as those specified under 502(e). To the extent possible, the Secretary will harmonize the program management requirements under sections 502 and 522.

TITLE VI - STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO TOBACCO SMOKE

Section 601. DEFINITIONS. Defines pertinent terms used in this section.

Section 602. SMOKE-FREE ENVIRONMENT POLICY. Requires a public facility to implement a smoke-free environment policy, which prohibits tobacco use within the facility and on facility property within the immediate vicinity of the facility's entrance. Requires the policy to be posted in a clear and prominent manner. Exceptions are granted to facilities which meets the requirements of a Specially Designated Smoking Area and to bars. No exception would be granted for restaurants, prisons, and congressional office buildings and the Capitol Building. There are special rules for schools and other facilities serving children.

Section 603. PREEMPTION. Precludes preemption of any other Federal, State, or local law in this area.

Section 604. REGULATIONS. Sets a 6-month period to promulgate the title's regulations.

Section 605. EFFECTIVE DATE. Sets an effective date of 6 months after the date the rules are promulgated, or 1 year after date of Act's enactment, whichever is later.

TITLE VII - PUBLIC DISCLOSURE OF HEALTH RESEARCH

Section 701. PURPOSE. Sets the purpose of this title to disclose previously nonpublic or confidential documents by tobacco product manufacturers.

Section 702. NATIONAL TOBACCO DOCUMENT DEPOSITORY. Establishes a National Tobacco Document Depository which will be used as a resource for litigants, public health groups, and other interested parties and which will contain documents described in the statute. The section also creates a Tobacco Documents Dispute Resolution Panel, to be composed of 3 Federal Judges appointed by the Congress, and outlines the Panel's structure, including its basis for determining a dispute, its final decision rule, and its assessment of fees policy. Provides for the Panel to establish a procedure for accelerated review and for special masters.

Section 703. ENFORCEMENT. Allows the Attorney General to bring a proceeding

before the Tobacco Documents Dispute Resolution Panel with appropriate notice requirements and civil penalty levels.

TITLE VIII--AGRICULTURAL TRANSITION PROVISIONS

Section 801. SHORT TITLE: "Tobacco Transition Act"

Section 802. PURPOSES. Terminates the federal tobacco program while making compensation to quota owners and tobacco farmers. Provides economic assistance to affected counties through block grants to affected states.

Section 803. DEFINITIONS. Defines pertinent terms used in Title VIII.

Subtitle A--Tobacco Production Transition

CHAPTER 1--TOBACCO TRANSITION CONTRACTS

Section 811. TOBACCO TRANSITION ACCOUNT. Establishes the Tobacco Transition Account within the Trust Fund. Through this account, compensation will be made to quota owners and tobacco farmers. Economic assistance block grants to affected states will also be provided through the Transition Account.

Section 812. OFFER AND TERMS OF TOBACCO TRANSITION CONTRACTS. The Secretary of Agriculture shall offer to buy tobacco quotas from owners through a three-year payment period. All restrictions on the production and marketing of tobacco will be lifted in 1998, ending the tobacco quota program.

Section 813. ELEMENTS OF CONTRACTS. Within 90 days of enactment of this legislation, the Secretary to offer contracts to quota owners until June 31, 1999. Buyout payments and transition payments shall start at the beginning of the 1999 marketing year and end at the end of the 2001 marketing year.

Section 814. BUYOUT PAYMENTS TO OWNERS. During the three-year phaseout period, buyout payments will be made to quota owners as a compensation for the lost value they experience associated with the ending of the quota program. The payments will be determined by multiplying \$8.00 by the average annual quantity of quota owned during the 1995-1997 crop years.

Section 815. TRANSITION PAYMENTS TO PRODUCERS. Provides assistance to farmers who do not own quotas but who leased from quota owners during three of the last four years. Transition payments only apply to the leased portion of the recipient's crop and will constitute a compensation to the producer for lost revenue caused by this act. The payments shall be determined by multiplying 40 cents by the average quantity of tobacco produced during the three years of the transition period.

Section 816. TOBACCO WORKER TRANSITION PROGRAM. Establishes a retraining program for displaced tobacco workers involved in the manufacture,

processing or warehousing of tobacco or tobacco products. Patterned after the NAFTA Trade Adjustment Assistance program, the Governor and then the Secretary of Labor shall determine a group's eligibility for the program. The total amount of payments for the Tobacco Worker Transition Program is capped at \$50,000,000 for any fiscal year, and after ten years the program will be terminated. Any individual receiving tobacco quota buyout payments are ineligible for this program.

Section 817. FARMER OPPORTUNITY GRANTS. Amends the Higher Education Act of 1965 to establish a grant payment for tobacco farmers and their families to pay for higher education. Grants will be made in the amount of \$1,700 per year, rising to \$2,900 annually by 2019. Academic eligibility requirements will mirror the standards regulating Pell Grants. Receipt of a Farmer Opportunity Grant will not affect a student's eligibility to receive other income-based assistance.

CHAPTER 2--RURAL ECONOMIC ASSISTANCE BLOCK GRANTS

Section 821. Rural Economic Assistance Block Grants. For each of the three years of the transition period, 1999 through 2001, the Secretary shall provide block grants to tobacco growing states to assist areas that are largely dependent on tobacco production. The grants will total \$100 million for each of the three years, with a total cost of \$300 million. The amount of each state's block grant will be based on (1) the number of counties within the state dependent on tobacco production and (2) the extent to which the counties are dependent on tobacco production. The Governor shall use a similar formula to apportion the state's grant to the counties. Use of the grants by the counties shall be approved by the Governor.

Subtitle B--Tobacco Price Support and Production Adjustment Programs

CHAPTER 1--TOBACCO PRICE SUPPORT PROGRAM

Section 831. INTERIM REFORM OF TOBACCO PRICE SUPPORT PROGRAM. Amends Section 106 of the Agricultural Act of 1949 to phase out the tobacco price support program over the four years following the enactment of this act. In 1999, the price supports will decline by 25% and then by 10% in 2000 and in 2001, after which the price support program will be terminated.

Section 832. TERMINATION OF TOBACCO PRICE SUPPORT PROGRAM. Amends Section 101 of the Agricultural Act of 1949 to repeal the tobacco price support program after 2001.

CHAPTER 2--TOBACCO PRODUCTION ADJUSTMENT PROGRAMS

Section 835. TERMINATION OF TOBACCO PRODUCTION ADJUSTMENT PROGRAMS. Amends the Agricultural Adjustment Act of 1938 to exclude tobacco from the provisions of the Act, effectively ending the Tobacco Production Adjustment Program.

Subtitle C--Funding

Section 841. TRUST FUND. Provides for the transfer of funds from Tobacco Transition Account (in the Trust Fund) to the Commodity Credit Corporation (CCC).

Section 842. COMMODITY CREDIT CORPORATION. Allows the Secretary to use the CCC in carrying out the provisions of this title.

TITLE IX -- MISCELLANEOUS PROVISIONS

Section 901. PROVISIONS RELATING TO NATIVE AMERICANS. Provides that the requirements of this Act relating to the manufacturer, distribution and sale of tobacco products will apply on Indian lands as defined in section 1151 of title 18 of the U.S. Code. Any federal tax or fee imposed on the manufacture, distribution or sale of tobacco products will 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 applies to other entities.

The Secretary, in consultation with the Secretary of the Interior, is authorized to treat Indian tribes as a state for purposes of this Act. The Secretary is authorized to provide any such tribe grant assistance to carry out the licensing and enforcement functions in accordance with a plan submitted and approved by the Secretary as in compliance with the Act.

A participating tobacco manufacturer shall not engage in any activity within Indian country that is prohibited under the Protocol. Recognizing that tobacco use remains a significant risk factor for Indians and that cigarette smoking is more than twofold for Indian men and more than fourfold for Indian women over non-Indians, a supplemental fund is established for the Indian Health Service to raise the health status of Indians. The fund is established at \$5 billion to be allotted to IHS at increments of \$200 million annually for 25 years.

Section 902. WHISTLEBLOWER PROTECTIONS. A tobacco manufacturer or distributor may not retaliate against an employee for disclosing a substantial violation of law related to this Act to the Secretary, the Department of Justice, or any State or local authority. Said employee may file a civil action in federal court if he believes such retaliation has occurred (within two years of the retaliation). The court may order reinstatement of the employee, order compensatory damages, or other appropriate remedies. Employees who deliberately participate in the violation or knowingly provide false information are excluded from this section.

Section 903. LIMITED ANTITRUST EXEMPTION. Federal and state antitrust laws shall not apply to certain actions by manufacturers, which are taken pursuant to this Act, including entering into the Protocol or consent decree, refusing to deal with non-complying distributors, or other actions meant to comply with plans or programs to reduce the use of tobacco by children. In order for the exemption to apply, such plans or programs must be approved by the Attorney General pursuant to a process set forth in this section.

Section 904. EFFECTIVE DATE. The effective date will be the date of enactment.