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Tobacco: McCain S. 1415: McCain 1415 [2]

Stack:	Row:	Section:	Shelf:	Position:
S	66	4	4	1

OCL COMMENTS ON S.1415

As a general matter, we question the need to superimpose a new statutory scheme on top of the Federal Food, Drug, and Cosmetic Act (FDCA) to deal with tobacco products that deliver nicotine to the human body. We, instead, favor an approach like that taken in Title II of Senator Conrad's bill, S.1638, which simply modifies the FDCA to expressly allow for the regulation of nicotine and tobacco products as the Food and Drug Administration has already done and to permit such future regulation as the agency may find necessary and appropriate under the FDCA.

On September 17, 1997, President Clinton announced five principles that he said should be the cornerstones of any legislative proposal to implement that settlement. (See White House document, "President's Plan for Comprehensive Tobacco Legislation to Protect America's Children" which is attached.): Point 2. was "Provide full statutory authority for the FDA to regulate nicotine without any conditions." To follow the approach established for FDA regulation in S. 1415 would contradict one of the President's principles.

Section 907(a) of the bill allows FDA to adopt a performance standard requiring the modification of a tobacco product to reduce gradually the nicotine yield of the product and to reduce or eliminate other constituents or harmful components of the product. Under Section 907(d), however, FDA is absolutely barred, for a period of twelve years, from adopting any performance standard that "requires the complete elimination of nicotine yields in a tobacco product." Moreover, Sections 907(b)(1) and 907(e)(2) of the bill prohibit FDA from adopting any performance standard with respect to nicotine yield, whether before or after the expiration of the 12-year grace period, unless the agency makes three specific findings: that the standard "will result in a significant overall reduction in the health risks associated with the use of the tobacco product," that the standard is "technologically feasible," and that the standard "will not result in the creation of a significant demand for contraband products." Overlaying these restrictions on the agency's regulatory authority, Sections 907(b)(2) and 907(e)(3) of the bill specify additional factors (e.g., number of nicotine-dependent tobacco users, availability of alternative products and tobacco cessation techniques) that FDA must consider in making its determinations with respect to demand for contraband products and the health risks of reducing or eliminating nicotine yield.

The absolute 12-year "prohibition" of any performance standard that would eliminate the nicotine yield of any tobacco product bars FDA from taking into account scientific and technological advances, societal changes and any other factors that may evolve during that period. Although, FDA has concluded that, at the present time, the public health harms that could flow from completely eliminating nicotine outweigh any potential benefit to be derived from such an action, the agency should not be foreclosed from reaching a different conclusion based on changing circumstances. Furthermore, while the various findings and factors that the bill imposes as preconditions to any performance standard may well be appropriate and, indeed, were carefully considered by FDA in adopting its current tobacco regulations, the ultimate decision as to what factors are most relevant, what weight they are to be given, and what findings will support a given standard should be left to the agency and not limited by statute.

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Provisions necessary to expressly acknowledge FDA's jurisdiction

A statement validating the regulations enacted by FDA--

The regulations promulgated by the Secretary in the rule dated August 28, 1996 (Vol. 61, No. 168 F.R.), adding part 897 to title 21, Code of Federal Regulations, shall be deemed to have been properly promulgated under the Food, Drug and Cosmetic Act as amended by this title.

Amendments to the definitions of drug and device to specifically include nicotine in tobacco as a drug and tobacco products as devices--

Drug-Section 201(q) (1) is amended by striking"; and (D)" and inserting ";(D) nicotine in tobacco products; and (E)"

Devices- Section 201(h) is amended--in paragraph (2) by striking "or" at the end; in paragraph (3), by striking "and" at the end and inserting "or"; and by inserting after paragraph (3), "(4) a delivery component of a tobacco product; and"

In order to clarify the agency's authority amend section 520(e) as follows:

Section 520(e) (1) is amended by striking "or use-" and inserting "or use, including restrictions on the access to and the advertising and promotion of, tobacco products-"

Codify the approach explained in the preamble to the FDA Tobacco Rule, 61 Fed. Reg. 44412-13:

Section 513(a) is amended in paragraph (1)(B), by inserting after the first sentence "For a device which is a tobacco product, the assurance in the previous sentence need not be found if the Secretary finds that special controls achieve the best public health result."; and in paragraph (2) by redesignating subparagraphs (A), (B) and (C) as clauses (i), (ii), and (iii), respectively; by striking "(2) For" and inserting "(2) (A) For"; and by adding at the end "(B) For purposes of paragraph (1)(B); subsections (c) (2) (C),

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(d) (2) (B), (e) (2) (A), (f) (3) (B) {i}, and (f) (3) (C) {i}, and sections 514, 519(a), 520(e), and 520(f), the safety and effectiveness of a device that is a tobacco product need not be found if the Secretary finds that the action to be taken under any such provision would achieve the best public health result. The finding as to whether the best public health result has been achieved shall be determined with respect to the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account- [i] the increased or decreased likelihood that existing customers of tobacco products will stop using such products; and (ii) the increased or decreased likelihood that those who do not use tobacco products will start using such products."

Recall Authority: Section 518(e) (1) is amended by inserting after "adverse health consequences or death," the following, "and for tobacco products that the best public health result would be achieved,"

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Antitrust Division Comments on Section 155 of S.1415 McCain Tobacco Legislation

March 12, 1998

Proposed section 155 would require the dissolution of the two existing tobacco industry trade associations and would set the requirements for any new tobacco industry trade association. Those requirements include complete independence for directors and officers from any association member; the hiring of a legal advisor who is likewise independent from any association member; the adoption of by-laws that prohibit meetings among association members who are competitors of each other except under association sponsorship; strict adherence of every meeting to an agenda pre-approved by legal counsel and circulated in advance; and maintenance of minutes of every meeting in the association's records for five years following the meeting. The provision also requires the Department of Justice and the state attorneys general to oversee the association, with access, for the first ten years of the association's existence, to all its directors, officers, employees, and records. Any trade association established under section 155 would be exempt from the antitrust laws.

The Antitrust Division has a number of concerns about this proposal. First, and most important, exempting the association from the antitrust laws would likely have the effect of immunizing a wide range of anticompetitive conduct from the antitrust laws. While trade associations generally engage in many procompetitive activities, it must be remembered that an important incentive for them to do so is that they are subject to the antitrust laws. Historically, trade associations have been a significant source of antitrust problems; indeed, as gatherings of firms who are competing against one another, trade association meetings can be a breeding ground for anticompetitive conduct. Over the years, antitrust enforcement actions against trade associations have led to greater awareness of the dangers involved, and trade associations are generally very careful to educate their members on what conduct is and is not appropriate. Indeed, a major element of most remedial decrees against trade associations is the institution of an antitrust education program for directors, officers, employees, and members.

We would be very concerned about an antitrust exemption for the association. The risks of anticompetitive conduct would not be eliminated by the various requirements set forth in the proposed section 155.

Second, we would strongly urge that the law not give the Department of Justice the kind of oversight envisioned in the proposed section. Such a role would impose on the Antitrust Division the duties of a regulator, necessitating the construction of a regulatory apparatus in order for those duties to be performed. We do not believe it is appropriate for the Antitrust Division to be essentially a taxpayer-supported antitrust counsel for any particular trade association. This is foreign to the law enforcement mission of the Antitrust Division, and would impose significant costs and burdens on the Division as well as on the private parties involved.

Indeed, such an oversight role would be especially unwise if the association were exempt from the antitrust laws. If the Antitrust Division would no longer have any authority to bring an enforcement action against even the most serious antitrust violations, what would be the utility in the Division having access to the association's records and its directors, officers, and employees?

It is much less burdensome, and more in keeping with our nation's free enterprise traditions, to give trade associations latitude to make their own decisions regarding their conduct, subject to traditional antitrust proscriptions, than to require trade associations to seek government approval for each activity through some kind of petition or oversight.

If the association remains subject to the antitrust laws, the other parts of proposed section 155 are likely to be unnecessary. The independence from individual members, adherence to agendas approved by legal counsel, and discouragement of meetings among competitors except openly and through association aegis are all typical hallmarks of a trade association operated with careful regard for the strictures of the antitrust laws. The access by antitrust enforcement authorities to association records is already available under current law whenever there is reason to believe an antitrust violation may have taken place. Nevertheless, if Congress believes -- either for reasons unrelated to competition policy or because it wants to implement specific procompetitive relief -- that the historical tobacco industry trade associations should be terminated or that it is important to mandate independence of the association's directors,

officers, and legal advisors, and to require the new trade association to keep certain records and to make them more readily available to the Antitrust Division outside of normal investigatory procedures, the Antitrust Division would have no objection.

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Memo To: Jerry Mande, Cynthia Rice
From: Jon Gruber
Re: Comments on Jeffords & McCain lookback provisions

All of the comments below apply to both provisions, with the exception of the last two comments which apply only to McCain:

1) The penalties apply only to the industry, and not to individual companies. As we have emphasized, it is crucial to have a mix of industry and company-specific penalties, to provide both price and non-price insurance against missing youth targets. In particular, using only an industry penalty provides no incentives for individual companies to change their behavior, since the penalty can simply be passed on to price. We are happy to provide detailed specifications of a preferred structure for lookback penalties.

2) The penalties are too small. On a cents/pack basis, these penalties amount to only 0.3 cents-2.2 cents per percentage point for Jeffords, and only 0.3 cents for McCain. Since the penalties are on the entire industry and will be passed on to price, these levels are much too low. The level should be at least 3 cents (if deductible, or 2 cents if non-deductible) to start, and should rise from there.

3) The penalties apply to daily smoking, rather than 30 day smoking. At this point, administration consensus is that a 30 day measure is more appropriate for public health reasons (e.g. catching children who are experimenting with smoking), and does not raise larger measurement problems.

4) The penalties should be based on a new, 1999 survey done to be done by CDC (and there should be funding for such a survey). This will be required to do company-specific penalties. The Secretary should be empowered with proper authority to carry out and adjust this survey as necessary. This survey should cover all children age 12-17, as well as other age groups; this is as opposed to the Michigan survey, which covers only 8th, 10th, and 12th grades.

5) There should be no abatement process. This makes the entire penalty structure very uncertain and adds a degree of uncertainty to the penalties which greatly weakens the incentives for companies to reduce teen smoking. Moreover, after abatement the levels of the penalties are sufficiently low to provide little incentives for reductions in youth smoking, particularly when they can simply be passed on to price (as in the case of an industry penalty).

6) (McCain only) The penalty should be increasing, either at a point in time (for missing the targets more severely, as in Jeffords), or over time (multiplying if you miss the targets for a number of consecutive years). An advantage of the latter over the former is that, even at a given performance (e.g. missing targets by 10%), higher prices will be needed in later years to obtain a given reduction in youth smoking (since the youths who are still smoking after large price increases are less price sensitive).

7) (McCain only). The cap on industry penalties should not be at such a low level (NOTE: \$2 billion is less than 10 cents/pack).

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Memorandum

To: Jim O'Hara

From: Gary Claxton and Christy Schmidt

Subject: Comments on lookback penalty section of S. 1415

For the most part, the lookback provisions of S. 1415 resemble provisions in the industry settlement which the Administration has criticized as being largely ineffective. Specific concerns include:

The bill establishes an industry penalty for missing reduction targets. This may not provide appropriate incentives for individual firms to reduce youth tobacco use. There should be penalties assessed on individual companies as well based on their success in meeting the reduction targets.

Cigar and like products are not included among the tobacco products for which reduction targets would be established.

The baseline for the reduction targets in youth smoking is based on estimates of "daily smokers" rather than youth who have used tobacco products within the previous month which is the more appropriate goal. There is a further measurement problem because the baseline is based on the average number of youth smokers over the past 5-10 years. These two factors tend to understate youth smoking, because many youth smoke but are not daily users and the prevalence of youth smokers has been increasing over the last decade (which means that averaging over the period results in a low estimate of youth smokers).

The bill locks us into using a methodology for measuring youth smoking that is identical to the current University of Michigan survey. The methodology for this survey is not generally available to the public so we do not know if it is sufficient to accurately measure youth smoking. The survey also has not collected information about the prevalence of youth smoking on a brand- or company-specific basis.

The reduction targets are based on daily smokers; they should be based on the prevalence of youth that use tobacco products in the previous month.

The reduction targets are relatively modest as compared to other bills. In addition,

because the bill uses a baseline that averages the percentage of youth smokers over the previous 5-10 years, the reduction targets should be higher (e.g., a 60 percent reduction from current levels would translate into about a 65 percent reduction from the average levels). The bill has a lower target for smokeless tobacco than for cigarettes; there is no reason to use a different target reduction percentage.

The level of surcharge is very low compared to the cost of tobacco products, and so is unlikely to have a significant impact on company behavior or on the costs of tobacco products.

A double counting adjustment is inappropriate, because the penalty should provide a continuing incentive for the industry and for companies to reduce youth smoking.

The abatement procedures should be eliminated because they would largely eliminate any reason to have a lookback penalty system.

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Draft Specifications 3/6/98

Note: This follows the language of Conrad bill with some clarifications and some differences in policy.

PURPOSE.

The purpose of this title is to achieve reductions in the proportion of underage consumers of tobacco products through the imposition of financial deterrents relating to the use of tobacco products if certain underage tobacco-use reduction targets are not met.

CHILD TOBACCO USE SURVEYS.

Annual Performance Survey. Not later than 1 year after the date of the enactment of this Act and annually thereafter the Secretary shall conduct a survey to determine

- ▶ The percentage of all young individuals who used a type of tobacco product within the past 30 days; and
- ▶ the percentage young individuals who identify each brand of each type of tobacco product as the usual brand smoked or used within the past 30 days.

Young Individuals. For the purposes of this title, the term "young individuals" means individuals who are over 12 years of age and under 18 years of age.

Baseline Level. For the purposes of this title, the term "baseline level" is, with respect to each type of tobacco product, the percentage of young individuals determined to have used such tobacco product in the first annual performance survey for 1999.

Manufacturers Baseline Level. For the purposes of this title, the term "manufacturers baseline level" is, with respect to each type of tobacco product, the percentage of young individuals determined to have identified a brand of such tobacco product of such manufacturer as the usual brand smoked or used in the first annual performance survey for 1999.

Tobacco product. For the purposes of this title, the following are considered separate types of tobacco products: cigarettes, cigars, little cigars, smokeless tobacco, and roll-your-own tobacco.

Participation in survey. Notwithstanding any other provision of law, the Secretary may conduct a survey relating to tobacco use involving minors if the results of such survey with respect to such minors are kept confidential and are not disclosed.

REDUCTION IN UNDERAGE TOBACCO PRODUCT USAGE.

Annual Determination. The Secretary shall annually determine, based on the annual performance

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survey, whether the required percentage reductions in underage use of tobacco products for a year have been achieved for the year involved. Such determination shall be based on the average annual percentage prevalence of the use of tobacco products by young individuals (as determined by the surveys conducted by the Secretary) for the year involved as compared to the baseline levels.

Required Percentage Reduction in Underage Use of Tobacco Products. For purposes of this section, the required percentage reduction from the baseline level in the percentage underage use of tobacco products by young individuals with respect to each tobacco product shall be as follows:

- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2001 and 2002;
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2003 and 2004;
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2005 through 2007; and
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for calendar year 2008 and each subsequent calendar year.

Actual Percentage Reduction in Underage Use of Tobacco Products. For purposes of this section, "actual percentage reduction in underage use" means, for a type of tobacco product for a year, the percentage reduction, as determined by the Secretary through the annual performance survey, in the use of such tobacco product by young individuals measured from the baseline level for such tobacco product.

Application to Manufacturers. With respect to the average percentage prevalence of the use of each manufacturer's brands of tobacco product by young individuals (as determined on the basis of the annual performance survey conducted by the Secretary) for a year --

- ▶ Each manufacturer which manufactured a brand or brands of tobacco product on or before the date of the enactment of this Act shall reduce the percentage of young individuals who use such manufacturer's brand or brands as their usual brand in accordance with the percentage reductions described under (above).
- ▶ Each manufacturer of a tobacco product which begins to manufacture a tobacco product after the date of the enactment of this Act shall ensure that the percentage prevalence of young individuals who use the manufacturer's tobacco products as their usual brand is equal to or less than the de minimis level (for a firm).

Target Reduction Level for A Manufacturer. For purposes of this section, the target reduction level for each type of tobacco product for a year for a manufacturer is the product of the manufacturers baseline level for such tobacco product and an amount that is equal to 100 minus

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the required percentage reduction for such tobacco product for such year.

NONCOMPLIANCE.

Industry-Wide Penalty. If, with respect to a year, the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___, the Secretary shall impose an industry-wide penalty on the manufacturers of such product which shall be applied to each unit of the tobacco product involved that is manufactured and distributed for consumer use in the year following the year in which the noncompliance occurs.

- ▶ **Penalty for noncompliance.** The amount of the industry-wide penalty for such type of tobacco product for a year shall be equal to [] for each percentage point by which the required percentage reduction in underage use for a type of tobacco product for a year exceeds the actual percentage reduction in underage use for such product for such year.
- ▶ **Increased penalty for at least three consecutive years of noncompliance.** If the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___ for at least three consecutive years but less than five consecutive years, the amount of the industry-wide penalty described (above) shall be [] instead of [].
- ▶ **Increased penalty for five or more consecutive years of noncompliance.** If the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___ for five or more consecutive years, the amount of the industry-wide penalty described (above) shall be [] instead of [].

De Minimis Rule. The Secretary shall not impose an industry-wide penalty with respect to a type of tobacco product for a year if the Secretary determines that the average percentage prevalence of young individuals using such tobacco product is less than [] percentage points.

Manufacturer-Specific Penalty. With respect to each manufacturer for a year, if the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved by such manufacturer, the Secretary shall impose a penalty on such manufacturer which shall be paid by such manufacturer within ___ days of assessment.

- ▶ **Penalty for noncompliance.** The amount of the manufacturer-specific penalty for a type of tobacco product for a year shall be equal to [] for each young individual for which such firm is in noncompliance with respect to its target reduction level.

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- ▶ The number of young individuals for which a manufacturer is in noncompliance for a year shall be determined by the Secretary from the annual performance survey and shall be calculated based on the estimated total number of young individuals in such year and the actual percentage prevalence of young individuals identifying a brand of such tobacco product of such manufacturer as the usual brand smoked or used in such year as compared to such manufacturer's target reduction level for the year.

De Minimis Rule. The Secretary shall not impose a penalty on a manufacturer for a type of tobacco product for a year if the Secretary determines that actual percentage prevalence of young individuals identifying a brand of such tobacco product of such manufacturer as the usual brand smoked or used for such year is less than __ percentage points.

Prohibition on Single-Pack Sales in Cases of Repeated Noncompliance. The Secretary shall establish regulations to prohibit the sale of single packs of a manufacturer's tobacco products in cases of repeated noncompliance with the reductions required under []. Such regulations shall require that, if a manufacturer fails to comply with such reductions in 4 or more consecutive years, the manufacturer's tobacco products may be sold in the following year only in packages containing not less than 10 units of the product per package (200 cigarettes per package in the case of cigarettes, and a corresponding package size for other tobacco products).

Required Generic Packaging in Severe Cases of Repeated Noncompliance. The Secretary shall establish regulations to require units and packages of a manufacturer's tobacco products to have generic packaging in severe cases of repeated noncompliance with the reductions required under []. Such regulations shall require that, if a manufacturer fails to comply with such reductions in 6 or more consecutive years, the manufacturer's tobacco products may be sold in the following year only in units and packages whose packaging contains no external images, logos, or text (other than any required labels), except that the brand name and the identifier 'tobacco' may appear on the packaging in block lettering in black type on a white background.

Procedures. In assessing penalties under this section, the Secretary may apply such statistical methods, including sampling, as may be appropriate to increase the accuracy of the estimates from the annual performance survey.



FACSIMILE

Date: 03-06-98

**PLEASE NOTIFY OR HAND CARRY THIS TRANSMISSION
TO THE FOLLOWING PERSON(S) AS SOON AS POSSIBLE:**

NAMES

FAX NUMBER

Richard Turman	202-395-5648
Jon Gruber	202-622-1294
Cynthia Rice	202-456-7431 (1028)
Gary Giovino	770-488-5848
Dan Chinok	202-395-6974

FROM: *Ariel Winter/Gary Claxton*
Assistant Secretary for Planning and Evaluation
202-690-6870
202-401-7321

Number of pages being transmitted (including fax sheet): 11

COMMENTS:

Attached are revised draft specifications and talking points on the lookback penalty system. The revisions to the specifications include:

(1) Adding "five or more consecutive years of noncompliance" to the third bullet point under noncompliance on page 3.

(2) Adding "including sampling" to the last paragraph on page 4.

The talking points have been revised to include a bullet mentioning a \$1 per pack cap on the industry penalty on page 2.

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Draft Specifications 3/6/98

Note: This follows the language of Conrad bill with some clarifications and some differences in policy.

PURPOSE.

The purpose of this title is to achieve reductions in the proportion of underage consumers of tobacco products through the imposition of financial deterrents relating to the use of tobacco products if certain underage tobacco-use reduction targets are not met.

CHILD TOBACCO USE SURVEYS.

Annual Performance Survey. Not later than 1 year after the date of the enactment of this Act and annually thereafter the Secretary shall conduct a survey to determine

- ▶ The percentage of all young individuals who used a type of tobacco product within the past 30 days; and
- ▶ the percentage young individuals who identify each brand of each type of tobacco product as the usual brand smoked or used within the past 30 days.

Young Individuals. For the purposes of this title, the term "young individuals" means individuals who are over 12 years of age and under 18 years of age.

Baseline Level. For the purposes of this title, the term "baseline level" is, with respect to each type of tobacco product, the percentage of young individuals determined to have used such tobacco product in the first annual performance survey for 1999.

Manufacturers Baseline Level. For the purposes of this title, the term "manufacturers baseline level" is, with respect to each type of tobacco product, the percentage of young individuals determined to have identified a brand of such tobacco product of such manufacturer as the usual brand smoked or used in the first annual performance survey for 1999.

Tobacco product. For the purposes of this title, the following are considered separate types of tobacco products: cigarettes, cigars, little cigars, smokeless tobacco, and roll-your-own tobacco.

Participation in survey. Notwithstanding any other provision of law, the Secretary may conduct a survey relating to tobacco use involving minors if the results of such survey with respect to such minors are kept confidential and are not disclosed.

REDUCTION IN UNDERAGE TOBACCO PRODUCT USAGE.

Annual Determination. The Secretary shall annually determine, based on the annual performance

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survey, whether the required percentage reductions in underage use of tobacco products for a year have been achieved for the year involved. Such determination shall be based on the average annual percentage prevalence of the use of tobacco products by young individuals (as determined by the surveys conducted by the Secretary) for the year involved as compared to the baseline levels.

Required Percentage Reduction in Underage Use of Tobacco Products. For purposes of this section, the required percentage reduction from the baseline level in the percentage underage use of tobacco products by young individuals with respect to each tobacco product shall be as follows:

- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2001 and 2002;
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2003 and 2004;
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2005 through 2007; and
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for calendar year 2008 and each subsequent calendar year.

Actual Percentage Reduction in Underage Use of Tobacco Products. For purposes of this section, "actual percentage reduction in underage use" means, for a type of tobacco product for a year, the percentage reduction, as determined by the Secretary through the annual performance survey, in the use of such tobacco product by young individuals measured from the baseline level for such tobacco product.

Application to Manufacturers. With respect to the average percentage prevalence of the use of each manufacturer's brands of tobacco product by young individuals (as determined on the basis of the annual performance survey conducted by the Secretary) for a year --

- ▶ Each manufacturer which manufactured a brand or brands of tobacco product on or before the date of the enactment of this Act shall reduce the percentage of young individuals who use such manufacturer's brand or brands as their usual brand in accordance with the percentage reductions described under (above).
- ▶ Each manufacturer of a tobacco product which begins to manufacture a tobacco product after the date of the enactment of this Act shall ensure that the percentage prevalence of young individuals who use the manufacturer's tobacco products as their usual brand is equal to or less than the de minimis level (for a firm).

Target Reduction Level for A Manufacturer. For purposes of this section, the target reduction level for each type of tobacco product for a year for a manufacturer is the product of the manufacturers baseline level for such tobacco product and an amount that is equal to 100 minus

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the required percentage reduction for such tobacco product for such year.

NONCOMPLIANCE.

Industry-Wide Penalty. If, with respect to a year, the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___, the Secretary shall impose an industry-wide penalty on the manufacturers of such product which shall be applied to each unit of the tobacco product involved that is manufactured and distributed for consumer use in the year following the year in which the noncompliance occurs.

- ▶ **Penalty for noncompliance.** The amount of the industry-wide penalty for such type of tobacco product for a year shall be equal to [] for each percentage point by which the required percentage reduction in underage use for a type of tobacco product for a year exceeds the actual percentage reduction in underage use for such product for such year.
- ▶ **Increased penalty for at least three consecutive years of noncompliance.** If the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___ for at least three consecutive years but less than five consecutive years, the amount of the industry-wide penalty described (above) shall be [] instead of [].
- ▶ **Increased penalty for five or more consecutive years of noncompliance.** If the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___ for five or more consecutive years, the amount of the industry-wide penalty described (above) shall be [] instead of [].

De Minimis Rule. The Secretary shall not impose an industry-wide penalty with respect to a type of tobacco product for a year if the Secretary determines that the average percentage prevalence of young individuals using such tobacco product is less than [] percentage points.

Manufacturer-Specific Penalty. With respect to each manufacturer for a year, if the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved by such manufacturer, the Secretary shall impose a penalty on such manufacturer which shall be paid by such manufacturer within ___ days of assessment.

- ▶ **Penalty for noncompliance.** The amount of the manufacturer-specific penalty for a type of tobacco product for a year shall be equal to [] for each young individual for which such firm is in noncompliance with respect to its target reduction level.

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- ▶ The number of young individuals for which a manufacturer is in noncompliance for a year shall be determined by the Secretary from the annual performance survey and shall be calculated based on the estimated total number of young individuals in such year and the actual percentage prevalence of young individuals identifying a brand of such tobacco product of such manufacturer as the usual brand smoked or used in such year as compared to such manufacturer's target reduction level for the year.

De Minimis Rule. The Secretary shall not impose a penalty on a manufacturer for a type of tobacco product for a year if the Secretary determines that actual percentage prevalence of young individuals identifying a brand of such tobacco product of such manufacturer as the usual brand smoked or used for such year is less than __ percentage points.

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Required Generic Packaging in Severe Cases of Repeated Noncompliance. The Secretary shall establish regulations to require units and packages of a manufacturer's tobacco products to have generic packaging in severe cases of repeated noncompliance with the reductions required under []. Such regulations shall require that, if a manufacturer fails to comply with such reductions in 6 or more consecutive years, the manufacturer's tobacco products may be sold in the following year only in units and packages whose packaging contains no external images, logos, or text (other than any required labels), except that the brand name and the identifier 'tobacco' may appear on the packaging in block lettering in black type on a white background.

Procedures. In assessing penalties under this section, the Secretary may apply such statistical methods, including sampling, as may be appropriate to increase the accuracy of the estimates from the annual performance survey.

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INTERNAL USE ONLY

Draft: March 6, 1998

Talking Points on Lookback Penalty System

Purpose of Lookback

The purpose of a system of lookback penalties is to provide an incentive for tobacco companies to meet the youth reduction targets. The lookback penalties act as insurance in case fixed payments do not sufficiently reduce youth tobacco use.

Structure of Lookback System

A lookback system works by assessing additional payments on tobacco firms if the specified youth tobacco use reduction targets are not achieved. Penalties can be assessed on the industry as a whole, on specific firms that fail to reduce youth use of their brands, or a combination of industry and firm-specific penalties can be developed. A combination of these approaches would appear to provide the best guarantees that youth tobacco use reduction targets are achieved.

- ▶ Industry penalties would provide price insurance by increasing prices of tobacco products further if the fixed payments or excise taxes do not sufficiently reduce youth tobacco use. Industry-wide penalties should be fully passed on by each of the firms to consumers as higher prices, as has traditionally been the case with common charges to the entire industry.
- ▶ Firm-specific penalties would provide non-price insurance by inducing individual companies to reduce youth use of their brands. It would be difficult for a firm to pass on firm-specific penalties to consumers as higher prices because a large price increase on its brands relative to the brands of its competitors would make the firm less competitive. As a result, firm-specific penalties have a more direct effect on a firm's bottom line.

There are clear arguments for pursuing both types of insurance, price and non-price, through a mix of industry and company-specific penalties. While firm-specific penalties are better targeted to firms and brands that continue to be used by youth tobacco users, they will not necessarily result in price increases because there are incentives for firms to absorb the penalty without passing it on to price. Firm-specific penalties also present greater (but certainly manageable) difficulties in measuring compliance and may be difficult to apply if the composition of the tobacco industry changes significantly. At the same time, industry-wide penalties that can be passed through to price do not provide sufficient incentives for each individual tobacco firm to reduce youth use of its own brands. Without holding specific firms accountable for youth use of their products, achieving a real change in the behavior and culture of the industry will be very difficult. If specific firms are held accountable, it will cause them to take other actions to reduce

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youth use of their products.

Industry Penalties

- Industry-wide penalties would be best expressed as cents per unit of tobacco product for each percentage point by which the target percentage reduction in underage use exceeds the actual percentage reduction in underage use.
- The amount of the penalty per product unit should be determined by the required price increase per percentage point of youth users to meet a given youth reduction target. A surcharge of about 3 cents per pack of cigarettes appears to be needed to reduce youth tobacco use by one percentage point, relative to baseline use.
- The surcharge could be capped at \$1.00 per pack.
- The penalty per unit could increase with each additional year in which the industry fails to meet reduction targets to account for declining price sensitivity as the number of youth tobacco users falls. The reduction in price sensitivity suggests that the appropriate penalties for very steep youth reduction targets should be 2-3 times as large as those for mild targets.
- These penalties should be tax-deductible so that the full amount will be passed on to consumers as higher prices. If the penalties are not tax deductible, then a 33% lower surcharge would achieve the same price effect because firms would pass through both the surcharge and the cost of paying the tax on the surcharge to consumers.
- In the absence of a firm-specific penalty, it may be appropriate to increase the surcharge per unit as the industry misses the target by a larger amount in order to compound the penalty's punitive effect on the industry.
- It is not appropriate for either the industry or firm-specific penalties to include a "double-counting adjustment" of the type proposed by the June 20 settlement. This adjustment would be very difficult to carry out in practice and would reduce industry and firm incentives to meet the reduction targets. All of the figures noted for either the industry or firm-specific penalty assume no such adjustment.

Firm-specific Penalties

- Because industry penalties likely will be passed on fully to prices, individual companies may not have incentives to combat teen use of their specific products. Firm-specific penalties would provide incentives to companies to use their own resources to reduce underage use of their products.

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- Firm-specific penalties should be based on a dollar amount per youth tobacco user in excess of the reduction targets. A penalty of \$1,500 per youth appears to be appropriate. In developing a penalty amount, we should consider the expected lifetime profits that a firm would derive from hooking a youth smoker on its brand of tobacco product and assess a penalty per youth smoker that is well in excess of anticipated profits to ensure that firms have strong incentives to discourage youth use.
- To maximize the effectiveness of the firm-specific penalty, this penalty could increase as the firm misses its target by a larger amount.
- The firm-specific penalty should be non-tax-deductible because firms should bear the costs of the penalty directly as lower after-tax profits. If the penalty is deductible, the penalty per youth should be increased by roughly one-third.
- This penalty should be uncapped because capping it would limit its effectiveness.
- Repeated failure to meet youth tobacco use reduction targets could trigger additional, noneconomic, penalties on a firm. For instance, repeated failure to meet targets could result in the firm being required to sell their products only by the carton (making the brands much less attractive to price sensitive youth) or being required to use generic packaging.
- [An alternative approach would be to express the penalty as a cents per unit of tobacco product surcharge, based on the number of percentage points by which the reduction target is missed (paralleling the industry penalty). But this approach has three disadvantages in the context of the firm-specific penalty:
 - ▶ The relation of the penalty to foregone profits will actually change as total cigarette demand (primarily determined by adults) changes.
 - ▶ This approach will penalize relatively less those firms that have a relatively high share of the youth market; firms with a smaller share of the youth than adult market will pay disproportionately more of the penalty.
 - ▶ If all firms achieve the same percentage point reduction in youth smoking, this penalty can be passed on to price, since it will operate effectively as an industry penalty; this will minimize its impact on actual firm behavior.]
- There should be a de minimis level of youth use of a firm's brands that does not trigger a penalty. Establishing such a level would recognize that there will always be some amount of youth tobacco use that no firm can prevent. A level of 0.5-1

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percent of youth may be an appropriate level.

Measuring Youth Tobacco Use

To impose a lookback penalty, it is necessary to measure current levels of youth tobacco use and changes to those levels over time. If a portion or all of the penalty scheme is applied on a firm-specific basis, then the measurements must be made by brand (and then aggregated to the firm level). These measurements would need to be made by surveying a sufficient number of youth to get reliable measures of youth tobacco use. Current surveys of youth smokers are not sufficient for this purpose for a variety of reasons, including insufficient sample size, failure to ask for brand-specific information, and failure to release methodology to the public.

A new survey that measures youth tobacco use would provide both point-in-time estimates of the prevalence of youth tobacco users (annually beginning with a base year of 1999) and estimates of the percent reduction in youth prevalence between the base year and later years (e.g., between the baseline in 1999 and 2003). In either case, confidence intervals of less than ± 1 percent could be obtained from a sample of 25,000 youths of age 12-17 in households. Given a sample of this size, very precise point estimates could be made down to a prevalence level of 0.5 percent (the confidence interval would be approximately ± 0.15 percent). An ongoing survey of this type would permit the determination of shortfalls in the reduction of prevalence rates at any point in time and could be used to develop smoothed and statistically more robust estimates in trends over time in the deviation from specified targets.

There are several specific issues involved in designing such a survey:

All Brands v. Usual Brand

Youth tobacco users can use more than one tobacco brand or product. A survey could attempt to identify all of the brands and types that each respondent uses or could focus on the usual brand used.

- Respondents would be better able to recall usual brand than all tobacco products used so the information on usual brand should be more reliable. Unpublished survey data from California indicate that about 90% of youth who smoked on 1 to 5 days in the past 30 days were able to identify a usual brand.

- Information on all types and brands may not be very useful without attempting to identify the quantity used of each identified brand and type. Information relating to quantity used is more difficult to obtain and may be less reliable.

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Use in Past Month v. Daily Use

The most common methods of analyzing youth tobacco use are to measure (1) the percentage of youth who use tobacco products on a daily basis or (2) the percentage of youth who have used tobacco products [at least a specified number of times] within the past month. Each approach has advantages and disadvantages for use in a lookback penalty system.

- Basing measurements on daily tobacco use is likely to produce the most accurate information on brand use. Daily tobacco users are more likely than less frequent users to be able to accurately identify the brand of tobacco product they use most often.
- Daily use also may be a more defensible basis for a penalty system. Daily smokers are addicted smokers for which the tobacco industry and specific firms may surely be held accountable. The broader measure of minimum number of uses within a month would also bring in some respondents who are experimenting with tobacco products, which may provide the industry with a basis to challenge the system.
- The daily use measure, however, would omit valid information about tobacco use by youths that occurs regularly (e.g., 2-3 times per week) but that is less than daily use. Data on youth tobacco use indicate that a significant percentage of youths who are occasional users will become addicted smokers, some while they are still teens and others in early adulthood. For example, survey data shows that 31% of 12-17 year olds who smoked just 2-9 times in the previous 30 days had become everyday smokers 4 years later. If these youth are not captured in the measurement, tobacco companies would have little incentive to discourage experimentation and occasional use; in fact, they might find it profitable to encourage occasional use by older teens on the assumption that these teens will not progress to daily use until after age 17.
- The daily use measure also may omit other patterns of tobacco use that should be captured by a penalty system. For example, it is possible that some tobacco products, such as cigars and smokeless tobacco, are used by some youth on a routine but not daily basis. There also are instances in which youth may use several different brands or types of products on a routine basis, but none of them on a daily basis. Data indicate that youth who have established a usual brand, even if they use other brands or products on an occasional basis, are likely to remain with that brand into the future. Failure to capture this data could omit important patterns of tobacco use from the penalty system.
- Tobacco firms may have an easier time complying with targets based on daily use

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than on targets based on minimum number of uses within a month. Although daily smokers are presumably more addicted, any movement from daily use to periodic use will count towards meeting a target based on daily use. To meet a target based on minimum number of uses within a month, firms must essentially discourage youth from any tobacco use.

Measuring change relating to targets based on minimum number of uses within a month can be done more accurately than change relating to targets based on daily use, because the baseline prevalence rates for minimum number of uses within a month are larger than those for daily use. Measuring change from higher prevalence levels can be done more accurately.

Capturing Information on Quantity

One option in measuring youth tobacco use is to attempt to measure the quantity of product that is actually used. This approach would more comprehensively determine each firm's share of the youth market because it asks about every product consumed and the amount of each product consumed in the past month. For example, a user who only smoked cigarettes would be asked to identify all the brands smoked in the past month and of each brand the number of cigarettes smoked. Surveys have not asked these questions in this way before, so work would have to be done to test whether or not a youth user could recall for the past month all the brands of all the tobacco products they used and the quantity of each used. For youth who switched brands often this might be particularly difficult to assess. Using a measure of quantity would delay the collection of baseline data until 2001.

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Draft Specifications 3/6/98

Note: This follows the language of Conrad bill with some clarifications and some differences in policy.

PURPOSE.

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CHILD TOBACCO USE SURVEYS.

Annual Performance Survey. Not later than 1 year after the date of the enactment of this Act and annually thereafter the Secretary shall conduct a survey to determine

- ▶ The percentage of all young individuals who used a type of tobacco product within the past 30 days; and
- ▶ the percentage young individuals who identify each brand of each type of tobacco product as the usual brand smoked or used within the past 30 days.

Young Individuals. For the purposes of this title, the term "young individuals" means individuals who are over 12 years of age and under 18 years of age.

Baseline Level. For the purposes of this title, the term "baseline level" is, with respect to each type of tobacco product, the percentage of young individuals determined to have used such tobacco product in the first annual performance survey for 1999.

Manufacturers Baseline Level. For the purposes of this title, the term "manufacturers baseline level" is, with respect to each type of tobacco product, the percentage of young individuals determined to have identified a brand of such tobacco product of such manufacturer as the usual brand smoked or used in the first annual performance survey for 1999.

Tobacco product. For the purposes of this title, the following are considered separate types of tobacco products: cigarettes, cigars, little cigars, smokeless tobacco, and roll-your-own tobacco.

Participation in survey. Notwithstanding any other provision of law, the Secretary may conduct a survey relating to tobacco use involving minors if the results of such survey with respect to such minors are kept confidential and are not disclosed.

REDUCTION IN UNDERAGE TOBACCO PRODUCT USAGE.

Annual Determination. The Secretary shall annually determine, based on the annual performance

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survey, whether the required percentage reductions in underage use of tobacco products for a year have been achieved for the year involved. Such determination shall be based on the average annual percentage prevalence of the use of tobacco products by young individuals (as determined by the surveys conducted by the Secretary) for the year involved as compared to the baseline levels.

Required Percentage Reduction in Underage Use of Tobacco Products. For purposes of this section, the required percentage reduction from the baseline level in the percentage underage use of tobacco products by young individuals with respect to each tobacco product shall be as follows:

- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2001 and 2002;
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2003 and 2004;
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2005 through 2007; and
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for calendar year 2008 and each subsequent calendar year.

Actual Percentage Reduction in Underage Use of Tobacco Products. For purposes of this section, “actual percentage reduction in underage use” means, for a type of tobacco product for a year, the percentage reduction, as determined by the Secretary through the annual performance survey, in the use of such tobacco product by young individuals measured from the baseline level for such tobacco product.

Application to Manufacturers. With respect to the average percentage prevalence of the use of each manufacturer's brands of tobacco product by young individuals (as determined on the basis of the annual performance survey conducted by the Secretary) for a year --

- ▶ Each manufacturer which manufactured a brand or brands of tobacco product on or before the date of the enactment of this Act shall reduce the percentage of young individuals who use such manufacturer's brand or brands as their usual brand in accordance with the percentage reductions described under (above).
- ▶ Each manufacturer of a tobacco product which begins to manufacture a tobacco product after the date of the enactment of this Act shall ensure that the percentage prevalence of young individuals who use the manufacturer's tobacco products as their usual brand is equal to or less than the de minimis level (for a firm).

Target Reduction Level for A Manufacturer. For purposes of this section, the target reduction level for each type of tobacco product for a year for a manufacturer is the product of the manufacturers baseline level for such tobacco product and an amount that is equal to 100 minus

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the required percentage reduction for such tobacco product for such year.

NONCOMPLIANCE.

Industry-Wide Penalty. If, with respect to a year, the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ____, the Secretary shall impose an industry-wide penalty on the manufacturers of such product which shall be applied to each unit of the tobacco product involved that is manufactured and distributed for consumer use in the year following the year in which the noncompliance occurs.

- ▶ **Penalty for noncompliance.** The amount of the industry-wide penalty for such type of tobacco product for a year shall be equal to [] for each percentage point by which the required percentage reduction in underage use for a type of tobacco product for a year exceeds the actual percentage reduction in underage use for such product for such year.
- ▶ **Increased penalty for at least three consecutive years of noncompliance.** If the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ____ for at least three consecutive years but less than five consecutive years, the amount of the industry-wide penalty described (above) shall be [] instead of [].
- ▶ **Increased penalty for five or more consecutive years of noncompliance.** If the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ____ for five or more consecutive years, the amount of the industry-wide penalty described (above) shall be [] instead of [].

De Minimis Rule. The Secretary shall not impose an industry-wide penalty with respect to a type of tobacco product for a year if the Secretary determines that the average percentage prevalence of young individuals using such tobacco product is less than [] percentage points.

Manufacturer-Specific Penalty. With respect to each manufacturer for a year, if the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved by such manufacturer, the Secretary shall impose a penalty on such manufacturer which shall be paid by such manufacturer within ____ days of assessment.

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Prohibition on Single-Pack Sales in Cases of Repeated Noncompliance. The Secretary shall establish regulations to prohibit the sale of single packs of a manufacturer's tobacco products in cases of repeated noncompliance with the reductions required under []. Such regulations shall require that, if a manufacturer fails to comply with such reductions in 4 or more consecutive years, the manufacturer's tobacco products may be sold in the following year only in packages containing not less than 10 units of the product per package (200 cigarettes per package in the case of cigarettes, and a corresponding package size for other tobacco products).

Required Generic Packaging in Severe Cases of Repeated Noncompliance. The Secretary shall establish regulations to require units and packages of a manufacturer's tobacco products to have generic packaging in severe cases of repeated noncompliance with the reductions required under []. Such regulations shall require that, if a manufacturer fails to comply with such reductions in 6 or more consecutive years, the manufacturer's tobacco products may be sold in the following year only in units and packages whose packaging contains no external images, logos, or text (other than any required labels), except that the brand name and the identifier 'tobacco' may appear on the packaging in block lettering in black type on a white background.

Procedures. In assessing penalties under this section, the Secretary may apply such statistical methods, including sampling, as may be appropriate to increase the accuracy of the estimates from the annual performance survey.

Draft Specifications 2/28/98

Note: This follows the language of Conrad bill with some clarifications and some differences in policy.

PURPOSE.

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REDUCTION IN UNDERAGE TOBACCO PRODUCT USAGE.

Annual Determination. The Secretary shall annually determine, based on the annual performance survey, whether the required percentage reductions in underage use of tobacco products for a year has been achieved for the year involved. Such determination shall be based on the average

annual percentage prevalence of the use of tobacco products by young individuals (as determined by the surveys conducted by the Secretary) for the year involved as compared to the baseline levels.

Required Percentage Reduction in Underage Use of Tobacco Products. For purposes of this section, the required percentage reduction from the baseline level in the percentage underage use of tobacco products by young individuals with respect to each tobacco product shall be as follows:

- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2001 and 2002;
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2003 and 2004;
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for each of the calendar years 2005 through 2007; and
- ▶ the percentage reduction in the percentage use shall be at least ___ percent for calendar year 2008 and each subsequent calendar year.

Actual Percentage Reduction in Underage Use of Tobacco Products. For purposes of this section, "actual percentage reduction in underage use" means, for a type of tobacco product for a year, the percentage reduction, as determined by the Secretary through the annual performance survey, in the use of such tobacco product by young individuals measured from the baseline level for such tobacco product.

Application to Manufacturers. With respect to the average percentage prevalence of the use of each manufacturer's brands of tobacco product by young individuals (as determined on the basis of the annual performance survey conducted Secretary) for a year —

- ▶ Each manufacturer which manufactured a brand or brands of tobacco product on or before the date of the enactment of this Act shall reduce the percentage of young individuals who use such manufacturer's brand or brands as their usual brand in accordance with the percentage reductions described under (above).
- ▶ Each manufacturer of a tobacco product which begins to manufacture a tobacco product after the date of the enactment of this Act shall ensure that the percentage prevalence of young individuals who use the manufacturer's tobacco products as their usual brand is equal to or less than the de minimis level (for a firm).

Target Reduction Level for A Manufacturer. For purposes of this section, the target reduction level for each type of tobacco product for a year for a manufacturer is the product of the manufacturers baseline level for such tobacco product and an amount that is equal to 100 minus the required percentage reduction for such tobacco product for such year.

NONCOMPLIANCE.

Industry-Wide Penalty. If, with respect to a year, the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___, the Secretary shall impose an industry-wide penalty on the manufacturers of such product which shall be applied to each unit of the tobacco product involved that is manufactured and distributed for consumer use in the year following the year in which the noncompliance occurs.

- ▶ **Penalty for noncompliance.** The amount of the industry-wide penalty for such type of tobacco product for a year shall be equal to [] for each percentage point by which the required percentage reduction in underage use for a type of tobacco product for a year exceeds the actual percentage reduction in underage use for such product for such year.
- ▶ **Increased penalty for at least three consecutive years of noncompliance.** If the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___ for at least three consecutive years but less than five consecutive , the amount of the industry-wide penalty described (above) shall be [] instead of [].
- ▶ **Increased penalty for more than five consecutive years of noncompliance.** If the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved as required under section ___ for five or more consecutive years, the amount of the industry-wide penalty described (above) shall be [] instead of [].

De Minimis Rule. The Secretary shall not impose an industry-wide penalty with respect to a type of tobacco product for a year if the Secretary determines that the average percentage prevalence of young individuals using such tobacco product is less than [] percentage points.

Manufacturer-Specific Penalty. With respect to each manufacturer for a year, if the Secretary determines that the required percentage reduction in use of a type of tobacco product has not been achieved by such manufacturer, the Secretary shall impose a penalty on such manufacturer which shall be paid by such manufacturer within ___ days of assessment.

- ▶ **Penalty for noncompliance.** The amount of the manufacturer-specific penalty for a type of tobacco product for a year shall be equal to [] for each young individual for which such firm is in noncompliance with respect to its target reduction level.
- ▶ **The number of young individuals for which a manufacturer is in noncompliance for a year shall be determined by the Secretary from the annual performance survey and shall be calculated based on the the estimated total number of young individuals in such year and the actual percentage prevalence of young individuals identifying a brand of such tobacco product of such manufacturer as the usual brand smoked or used in such year as compared to such manufacturer's target reduction level for the year.**

De Minimis Rule. The Secretary shall not impose a penalty on a manufacturer for a type of tobacco product for a year if the Secretary determines that actual percentage prevalence of young individuals identifying a brand of such tobacco product of such manufacturer as the usual brand smoked or used for such year is less than ___ percentage points.

Prohibition on Single-Pack Sales in Cases of Repeated Noncompliance. The Secretary shall establish regulations to prohibit the sale of single packs of a manufacturer's tobacco products in cases of repeated noncompliance with the reductions required under []. Such regulations shall require that, if a manufacturer fails to comply with such reductions in 4 or more consecutive years, the manufacturer's tobacco products may be sold in the following year only in packages containing not less than 10 units of the product per package (200 cigarettes per package in the case of cigarettes, and a corresponding package size for other tobacco products).

Required Generic Packaging in Severe Cases of Repeated Noncompliance. The Secretary shall establish regulations to require units and packages of a manufacturer's tobacco products to have generic packaging in severe cases of repeated noncompliance with the reductions required under []. Such regulations shall require that, if a manufacturer fails to comply with such reductions in 6 or more consecutive years, the manufacturer's tobacco products may be sold in the following year only in units and packages whose packaging contains no external images, logos, or text (other than any required labels), except that the brand name and the identifier 'tobacco' may appear on the packaging in block lettering in black type on a white background.

Procedures. In assessing penalties under this section, the Secretary may apply such statistical methods as may be appropriate to increase the accuracy of the estimates from the annual performance survey.

OSHA COMMENTS ON MCCAIN BILL, S1415

We think that this bill would be an excellent amendment for Sen. Kennedy to offer to the Jeffords bill, S 1648.

On page 113, line 16:

strike "residential purposes" and add "private residences"

line 20

add "or children's restaurant" between "restaurant" and ")"

On page 114, line 2

strike "The Administrator.... achieved"

line 3

add: (D) CHILDREN'S RESTAURANT.---Any restaurant a majority of whose patrons are under 18 years of age.

On page 115, change (1), (2) and (3) to:

(1) the area is subject to direct exhaust ventilation to ensure that air from the area is directly exhausted to the outside of the building and does not recirculate or drift to other areas within the public facility. Direct exhaust ventilation handles contaminated exhaust air from a designated smoking room in such a way that it is transported to the outside of the building, through exhaust ducts under negative pressure to avoid leakage into nonsmoking areas that the duct passes through.

(2) the area is maintained at negative pressure as compared to adjacent nonsmoking areas. Negative pressure is achieved by exhausting more air from the space than is supplied to the space. Transfer air must enter the designated smoking room to make-up the volumetric flowrate differential between supply and exhaust air. It may be necessary to provide a tight architectural enclosure so as to achieve negative pressure and containment. Negative pressure will induce airflow into the room through the entrance door undercut. Containment may be checked by using smoke-trails at the door undercut to verify direction of airflow.

(3) nonsmoking individuals are fully advised that the area is a smoking area and such individuals do not have to enter the area for any purpose while smoking is occurring in such area, and for an additional period that allows for at least 3 air exchanges to occur in the room

Cleaning and maintenance work shall be conducted in such area only while no smoking is occurring in the area, following an additional period that allows for at least 3 air exchanges to occur in the room."

On page 117, line 14

new "SEC.304.OSHA.

Violations of this title that cause the exposure of covered employees to environmental tobacco smoke are subject to citation under section 9 of the OSH Act."

line 14

renumber "304" to "305"

line 16

add "equal or greater" between "provides" and "protection"

line 19

renumber "305" to "306"

On page 118, line 1

renumber "306" to "307"

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Title III -- Standards to Reduce Involuntary Exposure to Tobacco Smoke

Sec. 301. Definitions. (p.113-114)

Amend (2)(B) Exclusions

Amend (2)(C) Fast Food Restaurant

Amend (3) Responsible Entity

Suggestion: Delete (2)(B) and (2)(C). Renumber remaining paragraph.

There is no public health basis for subjecting workers and patrons in one occupational setting to the adverse health effects of ETS exposure. Lung cancer, heart disease, and asthma should not be conditions of employment in the hospitality industry. The only allowable exclusion from protections should be those facilities with “specially designated smoking areas” defined in Sec.302.(b)(2).

Creating a special category of restaurant which is subject to the “Smoke-Free Environment Policy” (so-called “Fast Food Restaurant”) reduces but does not eliminate the health risks posed to workers and the public by the original exclusion. The definition of “fast food restaurant” is subject to wide interpretation and possible litigation that would jeopardize the protections promised. Again, there is no scientific justification for protecting workers and customers in one segment of the hospitality industry while denying similar protections to workers and customers in others. ETS protections are intended to protect children as well as adults. Indeed, adults can be severely affected by ETS exposure and deserve full protection in the workplace and public facilities.

Sec. 302. Smoke-Free Environment Policy (p. 114-116)

Amend subsection (b) (1) (A)

Suggestion: After “vicinity of” in line 4 (Page 115) add
“air intake ducts and”

Amend subsection (c) Specially Designated Smoking Areas.

Suggestion: Defer to Department of Labor on the level of detail
 necessary and the nature of the Administrator’s
 responsibility to issue regulations. With greater clarity
 provided in statute, it may not be necessary to condition
 the exemption on the issuance of regulations.

Sec. 303. Citizen Actions. (p. 116-117)

Amend subsection (c) Notice

Suggestion: Clarify that the requirement for 60 day notice to alleged
 violators applies to an “aggrieved person” as well as
 “any State or local government agency.”

Amend (e) Penalties by deleting the last sentence.

Suggestion: As currently drafted (p. 117; lines 11-13) the court is required
to obtain the view of the OSHA Administrator in exercising
discretion to require that assessed civil penalties be used for
projects which further the purposes of this title. It may be more
appropriate to make this report language or to authorize the
Administrator to file an amicus brief with the court.

Sec. 304. Preemption. (p. 117)

Suggestion: The section title (line 14) should be revised to read: “**Affect on Federal, State or local law.**” It is critical that the preemption language be retained. We urge that DoLabor and DoJustice review the proposed language and confirm that it is unambiguous and would sustain challenge from those who would support preemption.

Sec. 305. Regulations. (p. 117)

Suggestion: Legislative history should make clear that the effective date of the protections is not contingent upon the Administrator issuing regulations.

1 **TITLE III—STANDARDS TO RE-**
2 **DUCE INVOLUNTARY EXPO-**
3 **SURE TO TOBACCO SMOKE**

4 **SEC. 301. DEFINITIONS.**

5 In this title—

6 (1) **ADMINISTRATOR.**—The term “Adminis-
7 trator” means the Administrator of the Occupational
8 Safety and Health Administration.

9 (2) **PUBLIC FACILITY.**—

10 (A) **IN GENERAL.**—The term “public facil-
11 ity” means any building regularly entered by 10
12 or more individuals at least 1 day per week, in-
13 cluding any such building owned by or leased to
14 a Federal, State, or local government entity.
15 Such term shall not include any building or
16 portion thereof regularly used for residential
17 purposes.

18 (B) **EXCLUSIONS.**—Such term does not in-
19 clude a building which is used as a restaurant
20 (other than a fast food restaurant), bar, private
21 club, hotel guest room, casino, bingo parlor, to-
22 bacco merchant, or prison.

23 (C) **FAST FOOD RESTAURANT.**—The term
24 “fast food restaurant” means any restaurant or
25 chain of restaurants that primarily distributes

1 food through a customer pick-up (either at a
 2 counter or drive-through window). The Admin-
 3 istrator of the Occupational Safety and Health
 4 Administration may promulgate regulations to
 5 clarify this subparagraph to ensure that the in-
 6 tended inclusion of establishments catering
 7 largely to individuals under 18 years of age is
 8 achieved.

9 **2 RESPONSIBLE ENTITY.**—The term “respon-
 10 sible entity” means, with respect to any public facil-
 11 ity, the owner of such facility except that, in the
 12 case of any such facility or portion thereof which is
 13 leased, such term means the lessee.

14 **SEC. 302. SMOKE-FREE ENVIRONMENT POLICY.**

15 (a) **POLICY REQUIRED.**—In order to protect children
 16 and adults from cancer, respiratory disease, heart disease,
 17 and other adverse health effects from breathing environ-
 18 mental tobacco smoke, the responsible entity for each pub-
 19 lic facility shall adopt and implement at such facility a
 20 smoke-free environment policy which meets the require-
 21 ments of subsection (b).

22 (b) **ELEMENTS OF POLICY.**—

23 (1) **IN GENERAL.**—Each smoke-free environ-
 24 ment policy for a public facility shall—

1 (A) prohibit the smoking of cigarettes, ci-
2 gars, and pipes, and any other combustion of
3 tobacco within the facility and on facility prop-
4 erty within the immediate vicinity of the en-
5 trance to the facility; and

Air intake ducts and

6 (B) post a clear and prominent notice of
7 the smoking prohibition in appropriate and visi-
8 ble locations at the public facility.

9 (2) EXCEPTION.—The smoke-free environment
10 policy for a public facility may provide an exception
11 to the prohibition specified in paragraph (1) for 1 or
12 more specially designated smoking areas within a
13 public facility if such area or areas meet the require-
14 ments of subsection (c).

15 (c) SPECIALLY DESIGNATED SMOKING AREAS.—A
16 specially designated smoking area meets the requirements
17 of this subsection if—

18 (1) the area is ventilated in accordance with
19 specifications promulgated by the Administrator that
20 ensure that air from the area is directly exhausted
21 to the outside and does not recirculate or drift to
22 other areas within the public facility;

23 (2) the area is maintained at negative pressure,
24 as compared to adjoining nonsmoking areas, as deter-

1 mined under regulations promulgated by the Admin-
2 istrator; and

3 (3) nonsmoking individuals do not have to enter
4 the area for any purpose while smoking is occurring
5 in such area.

6 Cleaning and maintenance work shall be conducted in such
7 area only while no smoking is occurring in the area.

8 **SEC. 303. CITIZEN ACTIONS.**

9 (a) IN GENERAL.—An action may be brought to en-
10 force the requirements of this title by any aggrieved per-
11 son, any State or local government agency, or the Admin-
12 istrator.

13 (b) VENUE.—Any action to enforce this title may be
14 brought in any United States district court for the district
15 in which the defendant resides or is doing business to en-
16 join any violation of this title or to impose a civil penalty
17 for any such violation in the amount of not more than
18 \$5,000 per day of violation. The district courts shall have
19 jurisdiction, without regard to the amount in controversy
20 or the citizenship of the parties, to enforce this title and
21 to impose civil penalties under this title.

22 (c) NOTICE.—An aggrieved person shall give any al-
23 leged violator notice of at least 60 days prior to commenc-
24 ing an action under this section. No action may be com-
25 menced by an aggrieved person under this section if such

OR ANY State or local government AGENCY

1 alleged violator complies with the requirements of this title
2 within such 60-day period and thereafter.

3 (d) COSTS.—The court, in issuing any final order in
4 any action brought pursuant to this section, may award
5 costs of litigation (including reasonable attorney and ex-
6 pert witness fees) to any prevailing plaintiff, whenever the
7 court determines such award is appropriate.

8 (e) PENALTIES.—The court, in any action under this
9 section to apply civil penalties, shall have discretion to
10 order that such civil penalties be used for projects which
11 further the policies of this title. The court shall obtain the
12 view of the Administrator in exercising such discretion and
13 selecting any such projects.

14 **SEC. 304. PREEMPTION.**

15 Nothing in this title shall preempt or otherwise affect
16 any other Federal, State or local law which provides pro-
17 tection from health hazards from environmental tobacco
18 smoke.

19 **SEC. 305. REGULATIONS.**

20 The Administrator is authorized to promulgate such
21 regulations as the Administrator deems necessary to carry
22 out this title.

1 **SEC. 306. EFFECTIVE DATE.**

2 The provisions of this title shall take effect on the
3 date that is 1 year after the date of enactment of this
4 Act.

5 **TITLE IV—PUBLIC HEALTH AND**
6 **OTHER PROGRAMS**

7 **Subtitle A—Public Health Block**
8 **Grant Program**

9 **SEC. 401. PUBLIC HEALTH TRUST FUND.**

10 (a) **ESTABLISHMENT.—**

11 (1) **IN GENERAL.—**The Secretary shall estab-
12 lish, as a separate fund within the Trust Fund es-
13 tablished under section 401, a trust fund to be
14 known as the “Public Health Trust Fund”, consist-
15 ing of such amounts as may be appropriated or cred-
16 ited to the Trust Fund.

17 (2) **TRUSTEES.—**The trustees of the Trust
18 Fund shall be the Commissioner and the Secretary.

19 (b) **TRANSFERS.—**There are hereby appropriated and
20 transferred to the Trust Fund the amounts described in
21 section 401(d)(1) with respect to the year involved.

22 (c) **EXPENDITURES FROM TRUST FUND.—**Amounts
23 in the Public Health Trust Fund shall be available in each
24 calendar year, as provided by appropriations Act, for block
25 grants under section 502.

Title III -- Standards to Reduce Involuntary Exposure to Tobacco Smoke

Sec. 301. Definitions. (p.113-114)

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Amend (2)(C) Fast Food Restaurant

Amend (3) Responsible Entity

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Subtitle B -- Other Programs

Sec. 411. National Smoking Cessation Program

Amend the Section title (p. 125; line 9) to read: "National **Tobacco** Cessation Program." which more accurately reflects the purpose of the program. Smokeless tobacco is a major source of nicotine addiction.

Amend subsection (a) Establishment (lines 10-14) to read as follows:

① **"(a) ESTABLISHMENT.-- There is established a program to be known as the "National Tobacco Cessation Program." The Secretary is authorized to make grants to, and enter into contracts and cooperative agreements with public and nonprofit entities for the purpose of expanding the availability and utilization of cessation services.**

The amendment revises the title of the program, clarifies the Secretary's authority to issue contracts and cooperative agreements, and deletes authority to make awards to "individuals." Given funding limitations, cessation awards should be concentrated on making structural reforms which will enhance the availability of effective cessation services rather than providing a reimbursement mechanism for individuals seeking treatment.

Amend subsection (b) Eligibility by striking lines 3-13 on page 126 and making a necessary conforming amendment.

Amend subsection (c) Use of Funds (p. 126-127) to read as follows:

② **"(c) USE OF FUNDS. --- Funds made available under subsection (a) may only be used for the planning, establishment and administration to tobacco use cessation programs approved in accordance with subsection (d)."**

These amendments are necessary to remove references to the award of grants to individuals and to clarify the purpose of the cessation program.

Amend subsection (d) Approval of Cessation Program or Devices (p. 127)
to read as follows:

③ **“(d) APPROVAL OF CESSATION PROGRAM.--- Programs receiving assistance under subsection (a) shall provide a range and quality of services consistent with the most current cessation service guidance issued by the Agency for Health Care Policy Research. In addition, using the best available scientific information, the Secretary shall promulgate such additional guidelines as are necessary to assure the quality, accessibility and cost effectiveness of services receiving funds under this section.”**

1 (c) AVAILABILITY OF INFORMATION.—Each State,
 2 and each entity which has received funds from an allot-
 3 ment made to a State under this subtitle, shall make avail-
 4 able to the Secretary, for examination, copying, or me-
 5 chanical reproduction on or off the premises, appropriate
 6 books, documents, papers, and records of the entity upon
 7 a reasonable request therefore.

8 Subtitle B—Other Programs

9 SEC. 411. NATIONAL ^{Tobacco}~~SMOKING~~ CESSATION PROGRAM.

10 (a) ESTABLISHMENT.—The Secretary shall establish
 11 a program to be known as the “National ^{Tobacco}~~Smoking~~ Ces-
 12 sation Program” under which the Secretary may award
 13 grants to eligible public and nonprofit entities and individ-
 14 uals for smoking cessation purposes.

15 (b) ELIGIBILITY.—

16 ~~OF ENTITIES~~ OF ENTITIES.—To be eligible to receive a
 17 grant under this section an entity shall—

18 (A) be a public or nonprofit private entity;

19 (B) prepare and submit to the Secretary
 20 an application at such time, in such manner,
 21 and containing such information as the Sec-
 22 retary may require;

23 (C) provide assurances that amounts re-
 24 ceived under the grant will be used in accord-
 25 ance with subsection (c)(1); and

1 (D) meet any other requirements deter-
2 mined appropriate by the Secretary.

3 (2) OF INDIVIDUALS.—To be eligible to receive
4 a grant under this section an individual shall—

5 (A) prepare and submit to the Secretary
6 an application at such time, in such manner,
7 and containing such information as the Sec-
8 retary may require;

9 (B) provide assurances that amounts re-
10 ceived under the grant will be used only in ac-
11 cordance with subsection (c)(2); and

12 (C) meet any other requirements deter-
13 mined appropriate by the Secretary.

14 (c) USE OF FUNDS.—

15 (1) BY ENTITIES.—An entity that receives a
16 grant under this section shall use amounts provided
17 under the grant to establish or administer tobacco
18 product use cessation programs that are approved in
19 accordance with subsection (d).

20 (2) BY INDIVIDUALS.—An individual that re-
21 ceives a grant under this section shall use amounts
22 provided under the grant to enroll in a tobacco prod-
23 uct use cessation program or to purchase a tobacco
24 product cessation device that has been approved in
25 accordance with subsection (d). Grants to individuals

1 under this section may be in the form of vouchers
2 that may be used to pay the costs of enrollment in
3 an approved program or to purchase an approved
4 device.

5 (d) APPROVAL OF CESSATION PROGRAM OR DE-
6 VICES.—Using the best available scientific information,
7 the Secretary shall promulgate regulations to provide for
8 the approval of tobacco product use cessation programs
9 and devices. Such regulations shall be designed to ensure
10 that tobacco product users, if requested, are provided with
11 reasonable access to safe and effective cessation programs
12 and devices. Such regulations shall ensure that such indi-
13 viduals have access to a broad range of cessation options
14 that are tailored to the needs of the individual tobacco
15 user.

16 (e) FUNDING.—The Secretary shall use amounts
17 available under section 401(d)(2) to carry out this section.

18 **SEC. 412. NATIONAL REDUCTION IN TOBACCO USAGE PRO-**
19 **GRAM.**

20 (a) ESTABLISHMENT.—The Secretary shall establish
21 a program to be known as the “National Reduction in To-
22 bacco Usage Program” under which the Secretary may
23 award grants to eligible public and nonprofit entities to
24 carry out activities designed to reduce the use of tobacco
25 products.

Subtitle B -- Other Programs
Sec. 411. National Smoking Cessation Program

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U. S. Department of Justice
Office of the Attorney General

Washington, D.C. 20530

DATE: March 10, 1998

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TRANSMISSION CONTAINS 7 SHEETS INCLUDING THIS COVERSHEET

SPECIAL NOTE(S) Draft document disclosure provisions.

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DOJ

PUBLIC DISCLOSURE OF TOBACCO INDUSTRY DOCUMENTS

FINDINGS. — The American tobacco industry has made claims of attorney-client privilege, attorney work product, and trade secrets to protect from public disclosure thousands of internal documents sought by civil litigants. A number of courts have found that these claims of privilege were not made in good faith. To promote understanding by the public of the tobacco industry's research and practices, Congress finds that a prompt and full exposition of tobacco documents will further the purposes of this Act.

(a) **APPLICABILITY.** — This Title shall apply to all manufacturers of tobacco products as a necessary requirement of participation in the American tobacco market.

(b) **NATIONAL TOBACCO DOCUMENT DEPOSITORY.** — Manufacturers of tobacco products shall, within __ days after the enactment of this Act, establish and maintain a National Tobacco Document Depository (the Depository) in the Washington, D.C. area.

(1) **DOCUMENT CATEGORIES.** — Within __ days after the enactment of this Act, each manufacturer of a tobacco product shall submit to the Depository every existing document in the manufacturer's possession, custody, or control —

(A) relating, referring, or pertaining to —

(i) any health effects in humans or animals, including addiction, caused by the use of tobacco products or components of tobacco products;

(ii) the engineering, manipulation or control of nicotine in tobacco products;

(iii) the sale or marketing of tobacco products;

(iv) any research involving safer or less hazardous tobacco products;

(v) studies of smoking habits of minors;

(vi) the relationship between advertising or promotion and youth smoking;

(B) produced, or ordered to be produced, by the tobacco product manufacturer in any health-related civil or criminal proceeding, judicial or administrative; or

(C) that the National Tobacco Documents Review Board, as described in subsection (c) below, determines is appropriate for submission to the Depository.

(2) **DOCUMENT IDENTIFICATION AND INDEX.** — Documents shall be sequentially numbered and marked to identify the tobacco manufacturer. Within __ days of submission of documents to the Depository, each tobacco manufacturer shall supply the Depository with a comprehensive document index which references the applicable

document categories contained in section (b)(1)(A) of this subtitle.

(3) **PRIVILEGE AND TRADE SECRET CLAIMS.** — Any document that is subject to a claim by a tobacco manufacturer of privilege or trade secret protection shall be so marked and shall be submitted separately to the Depository. Compliance with this section shall not be deemed to be a waiver of any applicable claim of privilege or trade secret protection.

(A) **PRIVILEGE AND TRADE SECRET LOGS.**— Within __ days after the enactment of this Act, each manufacturer shall submit to the Depository a comprehensive log which identifies on a document-by-document basis all documents produced to the Depository for which the manufacturer asserts attorney-client privilege, attorney work-product, or trade secrecy. The determination of privilege shall be the result of the manufacturer's good faith de novo review of all documents for which it previously has asserted one or more of the aforementioned privileges or trade secret protection. In making such a claim, the manufacturer shall adopt the standards set forth in subsection (c)(2) below.

(i) The log shall be organized in numerical order based upon the document identifier assigned to each document. For each document, the log shall contain:

- (a) a description of the document, including type of document, title of document, name and position or title of each author, addressee and other recipient (e.g., cc's), document date, document purpose and general subject matter; (b) an explanation why the document or a portion of the document is privileged or subject to trade secret protection; and (c) a statement whether any previous claim of privilege or trade secret was denied and, if so, in what proceeding. Within __ days of receipt of such a log, the Depository shall make it available for public inspection and review.

(ii) Each manufacturer shall submit a declaration, pursuant to 28 U.S.C. Section 1746, by an individual with responsibility for the de novo review of documents, preparation of the privilege log and knowledge of its contents. The declarant shall attest to the manufacturer's compliance with the requirements of this Title pertaining to the review of documents and preparation of a privilege log.

(4) **DISCLOSURE BY THE DEPOSITORY.** — Within __ days of receipt of a document that is not subject to a claim of attorney-client privilege, attorney work product, or trade secret protection, the Depository shall make the document available to the public using the Internet and other means.

(c) **NATIONAL TOBACCO DOCUMENTS REVIEW BOARD.** — There shall be a National Tobacco Documents Review Board (the Board) consisting of __ members each of whom shall be appointed by the President and confirmed by the Senate. Any person who is a citizen of the United States and who has attained the age of thirty years shall be eligible to serve as a member of the Board. Each Board member shall be appointed for a term of seven years and shall be

eligible for reappointment. The Board shall have the power, not subject to judicial review, to hire such staff and establish such operating procedures as it deems necessary to carry out its functions as specified hereunder.

(1) **RESPONSIBILITY FOR DEPOSITORY.** — The Board, in consultation with the General Services Administration, shall establish guidelines and procedures for the establishment and operation of the Depository, including guidelines for the immediate disclosure of documents that are not subject to unresolved claims of privilege or trade secrecy. The Depository shall be open to the public and maintained in a manner that permits it to be used as a resource for litigants, public health groups, and persons with an interest in tobacco industry records and research concerning smoking and health, addiction or nicotine dependency, safer or less hazardous cigarettes, and underage tobacco use and marketing.

(2) **RESOLUTION OF DISPUTED PRIVILEGE AND TRADE SECRET CLAIMS.** — The Board shall determine whether to uphold or reject disputed claims of attorney client privilege, attorney work product, or trade secret protection with respect to documents submitted to the Depository. Any person may petition the Board to resolve a claim that a document submitted to the Depository may not be disclosed to the public. Such determination shall be made by a single member of the Board, in writing, and shall be subject to judicial review as specified in this Title. All such determinations shall be made solely on consideration of the subject document and written submissions from the person claiming that the document is privileged and/or protected by trade secrecy and from any person seeking disclosure of the document.

(A) **PRIVILEGE.**-- The Board shall apply the attorney-client privilege and the attorney work-product doctrine in a manner consistent with federal law.

(B) **TRADE SECRET.**-- The Board shall define "trade secret" as "any commercially valuable plan, formula, process or device that is used for making or preparing trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process."

(3) **FINAL DECISION** — The Board may uphold a claim of privilege or protection in its entirety or, in its sole discretion, it may redact that portion of a document that it determines is protected from public disclosure under (C)(2) above. Any decision of the Board shall be final unless judicial review is sought as specified in subsection (c)(4) of this Title. In the event that judicial review is so sought, the Board's decision shall be stayed pending a final judicial decision.

(4) **PETITION; RIGHT OF APPEAL.** — Any interested person may obtain judicial review of a final decision of the Board by filing a petition for review with the United States Court of Appeals for the Federal Circuit within __ days after the entry of such decision. A copy of the petition shall be transmitted by the Clerk of the Court to the

Board. The Board shall file in the court the record of the proceedings on which the Board based its decision (including any documents reviewed by the Board *in camera*) as provided in section 2112 of Title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the Board's decision, except that until the filing of the record the Board may modify or set aside its decision.

(A) **ADDITIONAL EVIDENCE AND ARGUMENTS.** — If the petitioner applies to the court for leave to adduce additional evidence or arguments respecting the decision being reviewed and shows to the satisfaction of the court that such additional evidence or arguments are material and that there were reasonable grounds for the failure to adduce such evidence or arguments in the proceedings before the Board, the court may order the Board to provide additional opportunity for the presentation of evidence or arguments in such manner and upon such terms as the court deems proper. The Board may modify its findings or make new findings by reason of the additional evidence or arguments and shall file with the court such modified or new findings, and its recommendation, if any, for the modification or setting aside of the decision being reviewed.

(B) **STANDARD OF REVIEW; FINALITY OF JUDGMENTS.** — The Board's findings of fact, if supported by substantial evidence on the record taken as a whole, shall be conclusive. The court shall review the Board's legal conclusions *de novo*. The judgment of the court affirming or setting aside the Board's decision shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of Title 28.

(5) **PUBLIC DISCLOSURE AFTER FINAL DECISION.**-- Within __ days of a final decision by the Board that a document, as redacted by the Board or in its entirety, is not protected from disclosure by a claim of attorney-client privilege, attorney work product, or trade secret protection, the Board shall direct the Depository to make the document available to the public.

(d) **SANCTIONS.**--

(1) Each tobacco manufacturer must act in good faith and have a readily understood claim of privilege or trade secret protection based on fact and law as set out in subsection (c)(2) of this Title. If the Board determines that a tobacco manufacturer has not acted in good faith with full knowledge of the truth of the facts asserted and with a reasonable basis under existing law, the manufacturer shall be assessed costs, which shall include the full administrative costs of handling the claim of privilege, and all attorneys' fees incurred by the board and any party contesting the privilege. The Board may also impose civil penalties of up to \$ __ per violation if it determines that the manufacturer knowingly acted with the intent to delay, frustrate, defraud, or obstruct the Board's determination of privilege, attorney work product, or trade secret protection claims.

(2) A failure by a tobacco manufacturer to produce indexes and documents in

compliance with the schedule set forth in this Title shall be punished by a civil penalty of up to \$ _____ per violation. A separate violation occurs for each document the manufacturer has failed to produce in a timely manner. The maximum penalty under this subsection for a related series of violations is \$ _____. In determining the amount of any civil penalty, the Board shall consider the number of documents, length of delay, any history of prior violations, the ability to pay, and such other matters as justice requires. Nothing in this Title shall replace or supercede any criminal sanction under Title 18 or any other Title of the United States Code.

(e) FDA AUTHORITY. — No assertion that a document constitutes or contains trade secret material, and no determination by the Board that a document constitutes or contains trade secret material, shall limit in any way the ability of the Food and Drug Administration to obtain such a document from or through the Board. Provided that, unless and until it is finally determined pursuant to this Title, either through judicial review or because the time for judicial review has expired, that such a document does not constitute or contain trade secret material, the Food and Drug Administration shall treat the document as a trade secret in accordance with the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder. In no event shall the Food and Drug Administration disclose such a document, and the only recourse to obtain such a document shall be to the Board. Nothing herein shall limit the authority of the Food and Drug Administration to obtain and use, in accordance with any provision of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder, any document constituting or containing trade secret material.

(f) OTHER.-- For the purposes of this Title,

(1) the term "DOCUMENT" shall include originals and drafts of any kind of written or graphic matter, regardless of the manner of production or reproduction, of any kind of description, whether sent or received or neither, and all copies thereof that are different in any way from the original (whether by interlineation, receipt stamp, notation, indication of copies sent or received or otherwise) regardless of whether "confidential", "privileged", or otherwise, including any paper, book, account, photograph, blueprint, drawing, agreement, contract, memorandum, advertising material, letter, telegram, object, report, record, transcript, study, note, notation, working paper, intra-office communication, intra-department communication, chart, minute, index sheet, routing sheet, computer software, computer data, delivery ticket, flow sheet, price list, quotation, bulletin, circular, manual, summary, recording of telephone or other conversation or of interviews, or of conferences, or any other written, recorded, transcribed, punched, taped, filmed, or graphic matter, regardless of the manner produced or reproduced. Such term shall also include any tape, recording, videotape, computerization, or other electronic recording, whether digital or analog or a combination of the two;

(2) the term "MANUFACTURER OF A TOBACCO PRODUCT" also includes the Tobacco Institute, the Council for Tobacco Research, the Smokeless Tobacco Council, the Center for Indoor Air Research, or any other trade association or entity that is primarily funded by persons who manufacture a tobacco product;

(3) any action undertaken pursuant to this Title, including but not limited to, the search, indexing, and production of documents, is deemed to be a "proceeding" before the executive branch of the United States.

(4) the disclosure process in this Title is not intended to affect the Federal Rules of Civil or Criminal Procedure or any federal law which requires the disclosure of documents or which deals with attorney-client privilege, attorney work product, or trade secret protection.