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U.S. SENATE COMMITTEE ON

Commerce, Science, and Transportation

JOHN McCAIN, Chairman

www.senate.gov/~commerce

CC: EK
Tom
JTRM
+ return

FAX

TO: Bruce Reed

OFFICE:

FAX NO: 456-2878

DATE: 2/2/98 TIME: 1:23 pm

PAGE 1 OF: 11

FROM: John Raidt (202) 224-1251

SUBJECT:

United States Senate
COMMITTEE ON COMMERCE, SCIENCE,
AND TRANSPORTATION
WASHINGTON, DC 20510-6125

February 2, 1998

The Honorable William Clinton
The White House
Washington, DC 20500

Dear Mr. President:

As you know, Congress intends to consider comprehensive tobacco legislation during the upcoming legislative session.

The issues raised by the global tobacco settlement and involved in the crafting of legislation to implement responsible national tobacco policy, are extremely diverse and intensely complex.

As I stated in my letter to you of six weeks ago, it's imperative that Congress and the administration work together in a cooperative and bi-partisan fashion if we are to craft a bill that will gain public support, Congressional approval and your signature.

In that regard, it will be particularly important for the Administration to exercise its executive responsibilities by providing Congress with detailed assessment of the provisions of pending tobacco legislation, and your specific policy and legislative recommendations.

The Senate Commerce Committee which I chair, and which has jurisdiction over key components of tobacco legislation, will hold hearings on the issue early this year. To assist with these deliberations I would like to request the administration's answers to the attached tobacco related questions.

These are the first in a series of questions to which we must have answers if we are to properly assess global tobacco settlement legislation, and move forward with the most effective and appropriate bill.

With the advice and expertise of the executive branch, we can ensure that federal tobacco legislation is based on a firm understanding of the facts, grounded in a solid understanding of the true consequences of our actions, and formulated by consensus. Most importantly, these disciplines will enhance our ability to achieve our most important goal of dramatically reducing youth smoking.

Thank you for your assistance in providing the Committee and Congress with the information requested. With regards,

Sincerely,

John McCain
Chairman

JM/jr

QUESTIONS REGARDING GLOBAL TOBACCO SETTLEMENT LEGISLATION

THE FOLLOWING IS THE FIRST SET IN A SERIES OF QUESTIONS PERTAINING TO S. 1415, LEGISLATION IMPLEMENTING THE GLOBAL TOBACCO SETTLEMENT PROPOSAL AGREED TO BY THE ATTORNEYS GENERAL OF THE VARIOUS STATES AND THE TOBACCO INDUSTRY.

QUESTIONS RELATED TO SPECIFIC LEGISLATIVE LANGUAGE SHOULD USE S. 1415 AS THE REFERENCE. ADDITIONAL QUESTIONS WILL FOLLOW.

I. BAN ON OUTDOOR ADVERTISING, INCLUDING IN STADIA AND ARENAS

The agreement (bill page 15) bans outdoor tobacco product advertising, and tobacco advertising in stadia and arena.

1. What data does the administration have to substantiate that a ban on outdoor advertising, including stadia and arenas will reduce smoking and, in particular, youth smoking?

2. To what extent do you believe such restrictions be expected to reduce smoking?

3. Does the administration support such a ban. If so, why? If not, why not?

4. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.

II. BAN ON HUMAN FIGURES AND CARTOON FIGURES IN ADVERTISING

The agreement (bill page 15) bans the use of human figures and cartoons in tobacco advertising.

1. What data does the administration have to substantiate that barring the use of human figures and cartoon advertising will reduce smoking, in particular, youth smoking?

2. To what extent do you believe such restrictions can be counted on to reduce smoking?

3. What entity would you propose to determine what constitutes a human image or cartoon character?

4. What penalty do you believe is appropriate and should accrue for a violation of the prohibition on material containing figures deemed to be human or cartoon?

5. Does the administration support this ban. If so, why? If not why not?

6. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.

III. BAN ON INTERNET ADVERTISING

The agreement (bill page 16) bans tobacco advertising on the internet.

1. Does the administration support such a ban? If so, why? If not, why not?

2. How can and should a ban on internet advertising of cigarettes be enforced?

3. What, if any, concerns does the administration have regarding Constitutional free speech issues raised by any such ban?

4. What specific changes, if any, in the legislative language implementing the ban would the administration propose?

IV. BAN ON POINT-OF-SALE ADVERTISING

The agreement (bill page 16) bans point-of-sale tobacco except for advertisements which comply with that certain restrictions.

1. What data does the administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?

2. Does the administration support such a ban? If so, why? If not, why not?

3. Is the exemption of point-of-sale advertisement for adult stores and tobacco outlets appropriate?

4. Is it appropriate to grant companies with greater cigarette market share additional point-of-sale advertising rights? If so, why? If not, why not?

5. Does such a privilege constitute a statutorily granted competitive advantage? Please discuss.

6. Does the administration support this grant? If so, why? If not, why not?

7. What specific changes, if any, in the legislative language implement the ban would the administration propose? Please provide specifics.

V. LIMITATIONS ON POINT-OF-SALE ADVERTISING

The agreement (bill page 17) specifies the size and design of permissible point-of-sale advertising.

1. What data does the administration possess to suggest that such limitations will reduce smoking, particularly among youth?

2. Does the administration support this provision? If so, why? If not, why not?

3. If so, what is the justification for statutorily determining a particular size limitation and for the particular size and restrictions proposed?

4. What specific changes in legislative language, if any, does the administration propose? Please provide specifics.

VI. BAN ON ADVERTISING RESTRICTION AGREEMENTS

The agreement (bill page 17) includes a prohibition on arrangements to limit the ability of a retailer to display permissible point-of-sale advertisement or promotional material originating with another manufacturer or distributor.

1. Are such agreements currently against federal or state law? If so, is such a provision necessary?

2. Does the administration support such a provision? If so, why? If not, why not?

3. Does the administration support the limitation. If so, why? If not, why not?

4. What specific changes, if any, in the legislative language implement the ban would the administration propose? Please provide specifics.

VII. GLAMORIZATION OF TOBACCO

The agreement, (bill page 20) prohibits payments to glamorize or promote the image or use of tobacco through pint, films or live performance that appeals to individuals under 18 years of age.

1. What data does the administration possess to indicate whether and to what extent this provision will reduce smoking, particularly among youth?

2. What entity does the administration propose will determine what activity constitutes promoting the image or use of a tobacco produce?

3. How does the administration envision such a ban will be enforced?

4. Does the administration support such limitations?

5. What specific changes, if any, in the legislative language would the administration propose? Please provide specifics.

VIII. RESTRICTION ON COLOR ADVERTISEMENTS

The agreement (bill page 21) prohibits the use of color advertising except in adult publications.

1. What data does the administration have to substantiate that a ban on color ads, except in publications with limited youth readership, will reduce smoking, particularly youth smoking?

2. Does the administration believe that the threshold for the restriction of two million readers is the appropriate threshold?

3. How does the administration envision readership demographics being determined?

4. How would this restriction be enforced?

5. Does the administration support this restriction? If so, why? If not, why not?

6. What specific changes, if any, in the legislative language implementing the restriction does the administration propose? Please provide specifics.

IX. GENERAL QUESTION REGARDING MARKETING/ADVERTISING BAN

1. Can the marketing and advertising restrictions envisioned in the settlement be constitutionally imposed, with or without the industry's consent? Please discuss.

X. WARNING LABELS

The agreement, (bill page 26- 28), authorizes a variety of new warning labels for tobacco products.

1. Does the administration believe that these are appropriate warning labels?

2. Does the administration possess data suggesting that these warning will effectively reduce smoking, particularly youth smoking?

3. What data suggests that the various new warnings will

be as or more effective than the current warning requirements?

4. Does the administration support the provisions authorizing specific new labels? If so, why? If not, why not?

5. What specific changes, if any, in the legislative language implementing this provision would the administration propose? Please provide specifics.

IX. WARNING LABEL SIZE AND LOCATION REQUIREMENTS

The agreement (bill page 28-29) specifies, the size, placement and print type of the various tobacco warning labels.

1. What data does the administration have to suggest that these specifications will reduce smoking, particularly youth smoking?

2. Does the administration support these particular specifications? If so, why? If not why not?

3. Does the administration support the exception (page 29) provided for flip-top cigarette packages? If so, why? If not, why not?

4. What specific changes, if any, in the legislative language to implement these restrictions would the administration propose? Please provide specifics.

X. SMOKELESS TOBACCO ALTERNATIVE LABELS

The agreement (bill page 34) provides for various new warning label options for smokeless tobacco

1. What data does the administration have to suggest that the various new warning labels will effectively reduce the use of smokeless tobacco, particularly among youth?

2. Does the administration support the use of these alternative labels?

3. What changes, if any, to the legislative language implementing this provision would the administration propose? Please provide specifics.

XI. ENFORCEMENT OF ADVERTISING, MARKETING AND LABELING RESTRICTIONS

The agreement (bill page 36-37)provides for the enforcement of advertising, marketing and labeling restrictions.

1. Does the administration support the enforcement provisions regarding advertising, marketing and labeling? If so why? If not, why not?

2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specific language.

XII. PREEMPTION OF STATE AND LOCAL ACTION

The agreement (bill page 38) prohibits state and local requirements related to the packaging or advertising of cigarettes or smokeless tobacco.

1. Does the administration support such preemption? If so, why? If not, why not?

2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specific language.

XIII. EXEMPTION OF EXPORTS

The agreement (bill page 40) exempts exports from the packaging, labeling and advertising requirements.

1. Does the administration support this exemption? If so, why? If not, why not?

2. What ramifications does this provision have in the area of foreign relations?

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XIV. RESTRICTION ON ACCESS TO TOBACCO PRODUCTS

The agreement (bill page 40-41), prohibits the sale of tobacco products to individuals under 18 years of age; requires that retailers verify the age of individuals purchasing tobacco; and exempts individuals 27 years of age or older from the photo identification requirement.

1. Does the administration support these provisions? If so, why? If not, why not?

2. How does the administration envision that this provision will be enforced and can it be enforced effectively?

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XV. PROHIBITION ON SALE OF LESS THAN A FULL PACK OF CIGARETTES

The agreement (bill page 41) prohibits the sale of less than a full pack of cigarettes.

1. Does the administration support this prohibition? If so, why? If not, why not?

2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XVI. STATE LICENSURE TO SELL TOBACCO

The agreement, (bill page 44) requires states to license sellers of tobacco products.

1. What data, if any, does the administration have to indicate that licensure will effectively reduce access to tobacco by minors?

2. What entity does the administration envision would enforce the licensure requirement if a state should be unable or unwilling to implement the licensure program?

3. Has the administration developed or formulated the cost of a licensure program?

4. Does the administration support the licensure program? If so, why? If not, why not?

5. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XVII. ANTI-TRUST EXEMPTION

The agreement, (bill page 94), provides anti-trust exemption for the tobacco industry.

1. Does the administration support such an exemption? If so, why? If not, why not?

2. Could such an exemption be used to set prices beyond those necessary to deter youth smoking, but to increase profits for the industry?

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

XVIII. APPLICABILITY TO NEW ENTRANTS IN TOBACCO INDUSTRY

1. Under the agreement, and the implementing legislation, what is the assurance that new entrants into the tobacco industry will comply with the statute and any related consent agreements not to challenge the legality of the agreement implementation legislation.

###

United States Senate

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION
WASHINGTON, DC 20510-6125

Tom/BRM
What response?
BR

December 15, 1997

The Honorable William Clinton
The White House
Washington, DC 20500

Dear Mr. President:

Shortly before adjournment of the congressional session last November, Senator Hollings and I, among others, introduced legislation, S. 1414 and S. 1415, which would implement the proposed global tobacco settlement reached between the State Attorneys General and the tobacco industry.

The legislation will serve as a vehicle for analysis, debate and action on how to best achieve federal tobacco policy goals. The Senate committees which have jurisdiction over tobacco policy issues will be holding extensive hearings on the legislation and relevant matters in the coming session.

The Senate Committee on Commerce, Science and Transportation has a large portion of the jurisdiction on issues touched by the settlement. As Chairman of the panel I intend to hold a series of hearings in February and March on the tobacco settlement issues within the Committee's jurisdiction, and we envision the Administration playing a key role in those hearings.

We're confident that you will agree, consensus is critical if we are to enact a bill that will win public support and best serve the interests of the nation.

In order to build such consensus, and to properly develop the best possible legislation, we believe it's essential that the Administration be prepared to testify with detail and specificity on the terms of the pending tobacco bill, and to make specific proposals regarding whether and how bill language should be modified to most appropriately and effectively achieve federal tobacco policy goals.

I would like to ensure that the appropriate administration representative is prepared to testify at those hearings and to provide the Committee with the Administration's analysis, specific policy positions and legislative proposals. We respectfully request your assistance and leadership in ensuring that the Administration takes what actions are necessary to fully prepare for that effort.

Thank you for your consideration and assistance. I'm confident that, working together, Congress and the Administration can produce a bill that will help us meet federal tobacco policy goals--the most vital of which is to reduce, dramatically, the number of children and youth who smoke.

Sincerely,

John McCain
Chairman

JM/jr

U.S. SENATOR • ARIZONA
JOHN McCAIN
www.senate.gov/~mccain

PRESS RELEASE

FOR IMMEDIATE RELEASE
MONDAY, DECEMBER 15, 1997

CONTACT: PIA PIALORSI 202-224-2670
NANCY IVES 202-224-7130

McCAIN CALLS FOR "SPECIFICS" FROM WHITE HOUSE AT TOBACCO HEARINGS

WASHINGTON, D.C. – Senator John McCain (R-AZ), Chairman of the Committee on Commerce, Science, and Transportation, today requested that the Administration participate in a series of tobacco hearings to be held early next year to provide detailed analysis and specifics of the tobacco settlement. McCain believes that the Administration's input is critical to build congressional consensus and public support on the issue, in addition to effectively achieving federal tobacco policy goals.

"I want to ensure that an Administration representative is prepared to testify at our hearings, and provide the Committee with the Administration's analysis, specific policy position and legislative proposals," McCain said in a letter to President Clinton today.

"There's little to be gained from another recitation of the problem or reiteration of general goals by the Administration," McCain said. "What Congress and the public need are specific comments and recommendations on the terms of the global tobacco settlement and to what extent they should be amended to best meet our public health objectives."

In November, Senators McCain, Ernest Hollings (D-SC), Slade Gorton (R-WA), and John Breaux (D-LA) introduced legislation, S.1414 and S.1415, which would implement the proposed global tobacco settlement reached between the State Attorneys General and the tobacco industry.

"I fear the White House may simply opt to provide general observations, and evade the tougher, specific direction we need," McCain said. "In order to gain the public support necessary to move such sweeping legislation, the Administration's leadership and expertise is absolutely necessary."

The Senate Committee on Commerce, Science and Transportation has a large area of jurisdiction including marketing, advertising, labeling and liability issues. To date, the Committee has held three hearings including the Global Settlement of Tobacco Litigation on July 29, Tobacco Marketing and Youth on September 16, and the Public Health Benefits of a Global Settlement of Tobacco Litigation on October 9.

(letter attached)

United States Senate
COMMITTEE ON COMMERCE, SCIENCE,
AND TRANSPORTATION
WASHINGTON, DC 20510-6125

December 15, 1997

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The White House
Washington, DC 20500

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Sincerely,

John McCain
Chairman

JM/jr

U.S. SENATOR • ARIZONA
JOHN McCAIN
www.senate.gov/~mccain
PRESS RELEASE

FOR IMMEDIATE RELEASE
MONDAY, DECEMBER 15, 1997

CONTACT: PIA PIALORSI 202-224-2670
NANCY IVES 202-224-7130

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(letter attached)

Congress of the United States
JOINT COMMITTEE ON TAXATION
1015 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6453
(202) 225–3621

Honorable Pete V. Domenici
United States Senate
Washington, DC 20510

JUN 0 1 1998

Dear Senator Domenici:

This letter is in response to your request of May 26, 1998, for a revenue estimate of a possible amendment to S. 1415.

The amendment would provide an above-the-line deduction for joint returns equal to the excess of the standard deduction amount for single individuals plus the standard deduction amount for heads of households over the standard deduction amount for joint returns. The deduction amount would be phased in as follows:

Taxable years	Phase in percentage
1999	35%
2000	40%
2001	45%
2002-2005	50%
2006	75%
2007 and thereafter	100%

Taxpayers with modified adjusted gross income in excess of $50,000 would be ineligible for the deduction. The $50,000 amount would be indexed for inflation beginning in taxable year 2000 with rounding down to the next lowest multiple of $5,000.

The deduction allowed above the line would also be allowed against earned income for the purpose of the earned income credit phase-out calculation.

This amendment, effective for taxable years beginning after December 31, 1998, would have the following effect on Federal fiscal year budget receipts.

Fiscal Years [Billions of Dollars]										
1999	2000	2001	2002	2003	2004	2005	2006	2007	99-02	03-07
-0.9	-4.7	-5.3	-6.0	-6.6	-7.3	-7.4	-8.4	-13.1	-16.8	-42.8

NOTE: Details may not add to totals due to rounding.

I hope this information is helpful to you. If we can be of further assistance, please let me know.

Sincerely,

Lindy L. Paull

Lindy L. Paull

1850

Table 1. CBO and JCT scoring of S. 1415 as Modified

($ billions)	1999	2000	2001	2002	2003	1998-2002	1999-2003	2003-2007	2004-2008	10-year
Revenues										
Industry payments	15	11	13	13	13	52	65	71	74	139
Look-back fees	---	---	---	---	---	---	---	9	12	12
Revenues	**15**	**11**	**13**	**13**	**13**	**52**	**65**	**81**	**87**	**152**
Direct Spending										
State allocation	5	5	5	5	5	20	25	28	29	54
Farmer assistance	2	2	2	2	2	8	10	10	11	21
Other mandatory	1	1	1	1	1	4	5	5	5	10
Spending	**8**	**8**	**9**	**9**	**8**	**34**	**42**	**45**	**47**	**89**
PAYGO Effect	**7**	**3**	**4**	**4**	**5**	**18**	**23**	**36**	**40**	**63**
						12				
Discretionary										
Public health*	1	2	3	3	3	9	12	21	25	17
Health Research*	1	2	3	3	3	9	12	15	15	27
Discretionary	**2**	**5**	**5**	**5**	**6**	**17**	**23**	**37**	**41**	**64**
						10				
NET EFFECT	**-5**	**+2**	**+1**	**+1**	**+1**	**+9**	**0**	**+1**	**+1**	**+1**
Payments/pack	*$0.76*	*$0.89*	*$1.06*	*$1.11*	*$1.24*	---	---	---	---	---

*Authorization of appropriations.

8416679

Congress of the United States

JOINT COMMITTEE ON TAXATION

Washington, DC 20515–6453

Honorable Daniel Patrick Moynihan
United States Senate

Fiscal Years
[Billions of Dollars]

	1999	2000	2001	2002	2003	2004	2005	2006	2007	1999-02	2003-07
1. General industry payments.....	15.4	11.0	12.5	12.7	13.2	13.8	14.3	14.8	15.4	51.5	71.5
2. Look-back assessment [1]	--	--	--	--	--	1.0	0.6	4.0	3.1	--	8.7
3. Total of S. 1415 as amended.....	15.4	11.0	12.5	12.7	13.2	14.8	14.9	18.8	18.5	51.5	80.2
General industry payments per pack.....[2]	$0.76	$0.89	$1.06	$1.11	$1.24	$1.28	$1.32	$1.36	$1.40		

Note: Details may not add to totals due to rounding.

[1] This net revenue reflects the effect of reduced excise tax receipts because of the assumption that the penalty excise tax payments are passed through in the price of tobacco products.

[2] Presented on a calendar year basis and without regard to look-back assessments.

I hope this information is helpful to you. If we can be of further assistance, please let me know.

Sincerely,

Lindy L. Paull

Lindy L. Paull

Key to Comments:

DoJ	red
FDA	blue
Inserts	green

S.1415

Universal Tobacco Settlement Act

Sec. 1. Short title; table of contents.

Sec. 2. Findings. [pp. 4-7]

In light of the provisions contained in Title I that would restrict the marketing and advertising of tobacco products, the legislation should adopt and incorporate the findings that support the Food and Drug Administration's analogous restrictions on marketing and advertising. See 61 Fed. Reg. 44,396 (1996).

Stating that "FDA found . . ." may negate the helpfulness of these findings; need to make it clear that Congress recognizes and adopts the particular findings.

Need to have more extensive findings on advertising issues. The following findings should be added (essentially what's in the Conrad bill with minor edits):

- In 1995, the tobacco industry spent close to $4,900,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

- Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful.

- Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.

- Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

- Children are exposed to substantial and unavoidable tobacco advertising, that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

- Tobacco advertising increases the size of the tobacco market by increasing consumption of tobacco products including increasing tobacco sales to young people.

- Children are more influenced by tobacco advertising than adults, they smoke the most advertised brands, and children as young as 3 to 6 can recognize a character associated with smoking at the same rate that they recognize cartoons and fast food characters.

- Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market.

- Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

- Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

- International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones. Text only requirements, while not as stringent as a ban, will accomplish this purpose while preserving the informational function of advertising.

Sec. 3. Purposes. [pp. 7-9]

Subsection (2) provides that it is a purpose of the bill to "ban all outdoor tobacco advertising and ban all cartoon figures and human figures used in connection with tobacco advertising." As discussed below, such categorical restrictions would go beyond the FDA's rule limiting the advertising of tobacco products and would therefore raise significant constitutional concerns that are not presented by the FDA rule. Accordingly, subsection (2) should be amended to accord with our suggested amendments to the substantive provisions of S.1415 that would ban all outdoor tobacco advertising and ban all cartoon figures and human figures used in connection with tobacco advertising.

(2) FDA's current position is that specific advertising restrictions should not be in legislation; also, FDA's restrictions do not ban all outdoor advertising, and its black and white text only requirements encompass limits on cartoon characters and human figures.

(3) This is a reference to a state-administered licensing program. The working group seems to support the concept of a federal registration system. Required state licensing programs may be unnecessary.

Subsection (4) provides that it is a purpose of the bill to "subject the tobacco industry to severe

financial penalties in the event that underage tobacco usage does not decline radically over the next 10 years[.]" However, the relevant substantive provisions of S.1415 refer to the payments that manufacturers would be required to make as "surcharges." See, e.g., Section 205. The purpose section should be amended to accord with the substantive provisions, which would minimize the risk of constitutional challenge.

(5) is unnecessary because the concept is encompassed by general FDA authority.

(6) contains an unnecessary clause, "including the power to regulate the level of nicotine in such products," which is encompassed in general FDA authority.

Subsection (7) provides that it is a purpose of the bill to "require the manufacturers of tobacco products to disclose all present and future non-public internal laboratory research regarding tobacco products." (Emphasis added). The substantive provisions of the bill regarding the disclosure of documents are not as broad as the statement suggests. The relevant provisions would permit manufacturers to assert privileges against the disclosure of certain documents that fall within this category. See Title VII. Accordingly, we recommend deleting the word "all" from subsection 7.

(7) A final decision has not been made as to whether companies will be required to publically disclose future laboratory research.

In addition, we note that although subsections (9) through (12) make reference to the National Tobacco Settlement Trust Fund, which S.1414, 105th Cong. (1997), would have established, S.1415 does not establish such a fund.

TITLE I--REGULATION OF THE TOBACCO INDUSTRY

Sec. 100. Definitions. [pp. 9-14]

Relation of these definitions to the Federal Food, Drug, and Cosmetics Act (FDCA) is unclear; some of the definitions are more narrow than FDCA usage. For example, under FDCA, "commerce" includes movement from a foreign country to the United States. The definitions could be a problem if FDA wished to adopt a broader definition of a particular term with respect to tobacco (such as manufacturer).

Subtitle A--Restriction on Marketing and Advertising [pp. 15-26]

Subtitle A contains a number of provisions that would impose restrictions on the advertising and marketing of tobacco products. Many of these provisions track those set forth in the recently promulgated FDA regulations. The Administration believes, as the Department of Justice has

explained in the Coyne-Beahm litigation, that the FDA's regulations are consistent with the First Amendment, under the framework for First Amendment review of restrictions on commercial speech, set out by the Supreme Court in Central Hudson Gas & Elec. Corp v. Public Serv. Comm'n, 447 U.S. 557 (1980), and subsequent cases. The FDA restrictions are appropriately tailored to serve the government's wholly legitimate and compelling interest in curtailing demand for and use of tobacco products by those who may not lawfully purchase the product, by reducing minors' exposure to tobacco product advertising. As a result, the advertising restrictions contained in S.1415 that track the FDA regulations are constitutional. Other provisions in S.1415, however, would impose restrictions on the advertising of tobacco products that are broader than those contained in the FDA regulations. These broader provisions raise significant constitutional concerns -- i.e., that they are not appropriately tailored to serve the government's interest in curtailing minors' tobacco use through restricting minors' exposure to tobacco product advertising.

Sec. 101. Prohibitions on advertising. [pp. 15-18]

Codifies restrictions expressly into legislation. Constitutional concerns regarding advertising restrictions that go beyond FDA restrictions have been discussed with McCain staffers. To retain flexibility, it would be preferable to simply affirm FDA's authority to issue advertising restrictions rather than include specific restrictions in statute. In order to clarify the agency's authority in this regard, 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-"

To ensure that 1996 FDA regulations do not need to be re-promulgated, the legislation should include the following 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."

Specific comments on the particular restrictions

Section 101(a)(1) [p. 15] provides that "[n]o manufacturer, distributor, or retailer may use any form of outdoor tobacco product advertising, including bill boards, posters, or placards." This restriction would go beyond the FDA regulation restricting the outdoor advertising of tobacco products. The FDA regulation bans all outdoor advertising of tobacco products within 1000 feet of a school or playground but otherwise requires only that such outdoor advertising be confined to so-called "tombstone advertising," i.e., black letters on a white background. 21 C.F.R. § 897.30(b) (1997); id. § 897.32(a). The FDA regulation's outdoor advertising restriction is appropriately tailored to serve the government's wholly legitimate and compelling interest in preventing underage consumers' exposure to advertising about products that may not lawfully be

sold to them.

The greater breadth of the ban on outdoor advertising contained in section 101(a)(1) gives rise to significant constitutional concerns that are not presented by the FDA regulation. The provision should be redrafted to alleviate these concerns. Instead of imposing a complete ban, the provision could simply confirm the FDA's authority to regulate the outdoor advertising of tobacco products. In addition to confirming the FDA's regulatory authority, the bill could also enact the existing FDA restriction on outdoor advertising or extend the FDA restriction in a more tailored manner. For example, the provision could impose a general requirement that outdoor advertising appear in a tombstone format and then extend the FDA's ban on such outdoor advertising to include geographic areas, in addition to schools and playgrounds, that are frequented by children.

Section 101(b) of S.1415 [p. 15] provides that "[n]o manufacturer, distributor, or retailer may use a human image or a cartoon character or cartoon-type character in its advertising, labeling, or promotional material with respect to a tobacco product." This restriction would go beyond the FDA regulation restricting the use of images in the advertising of tobacco products. That regulation provides that, in general, tobacco advertising must take the form of tombstone advertising but permits images to be used without restriction in certain circumstances, for example, in an "adult publication," one that has a readership that is at least eighty-five percent adult and that includes less than two million children. 21 C.F.R. § 897.32(a)(2)(i)-(ii).

Section 101(b)'s broader restriction on the use of images in the advertising of tobacco products would raise significant constitutional concerns that the FDA regulation does not present. These concerns could be alleviated by confirming the FDA's authority to regulate in this area, enacting the FDA regulation, or extending the FDA restriction in a more tailored manner. For example, the bill could adjust the definition of an "adult publication" by lowering the threshold number of child readers for such publications to less than two million and then adopting the newly defined "adult publication" exception. We also note that the imposition of a restriction on the use of "human images" alone might raise constitutional concerns because the use of image advertising depicting animals would not be restricted, even though it would appear that such image advertising would be likely to appeal to children. See Rubin v. Coors Brewing Co., 514 U.S. 476, 488-90 (1995) (explaining concerns raised by underinclusive restrictions on commercial speech). This concern could be alleviated by extending the restriction to include images of both human and animal figures.

Section 101(c) [p. 15] provides that "[n]o manufacturer, distributor, or retailer may use the Internet to advertise tobacco products unless such an advertisement is inaccessible in or from the United States." Insofar as the complete ban on Internet advertising would be for the purpose of diminishing minors' exposure to such advertising, it would raise significant constitutional concerns, because there might be more narrowly tailored means of achieving such a governmental objective. Cf. Reno v. ACLU, 117 S.Ct. 2329, 2346-48 (1997) (discussing less restrictive alternatives to a ban on Internet transmission of indecency in a manner available to minors). Congress should consider whether, in light of available technology, there may be means short of a

complete ban that would serve the government's interest in protecting underage consumers from advertising about products that may not lawfully be sold to them. In order to ensure that the government retains necessary flexibility to regulate the advertising of tobacco products on the Internet, however, we recommend that the bill simply provide express statutory confirmation of the FDA's existing authority to regulate such advertising. This approach would ensure that any future regulatory restrictions are targeted at appropriate forms of Internet advertising and are fashioned in a manner that is appropriately sensitive to First Amendment concerns.

Section 101(d) [pp. 15-17] would, in general, limit each manufacturer of tobacco products to the display of not more than two separate point-of-sale advertisements in any location at which tobacco products are sold, and would limit each retailer to the display of one point-of-sale advertisement relating to the retailer's or wholesaler's contracted retailer or private label brand product. The bill would also require that these point-of-sale advertisements consist only of black letters on a white background, and not be larger than a prescribed size. However, the bill would include a significant exception to this limitation for "adult-only stores and tobacco outlets." Section 101(d)(2). Section 101(d)'s exception permitting manufacturers with a greater market share to engage in more point-of-sale advertising than their competitors raises significant constitutional concerns. It constitutes a speaker-based preference for certain manufacturers that appears inconsistent with the government's asserted interest in restricting such advertising because it would appear to be unrelated to the objective of reducing youth tobacco use. If the government imposes advertising constraints on some commercial speakers, but declines to impose those same restrictions on an analogous class of speakers, the disparate treatment can "undermine and counteract" the effects of the imposition, and suggest that the government is not truly or fully committed to advancing its claimed interest. See Coors Brewing, 514 U.S. at 488-90.

Section 101(d)(3)(B) [p. 16]: The provision allowing the manufacturer with at least a 25% market share to have another sign at point-of-sale serves no public health interest, and would only further strengthen market leaders.

Section 101(d)(4)(B) [p. 17] permits audio and video materials to be distributed (but not played) at point of sale. These materials will make their way to children. The FDA rule limits audio or video formats to words only with no music or sound effects and, for video, static black text only on a white background. Any audio with the video is limited to words only with no music or sound effects. Materials may not be taken from the store. (These restrictions do not apply in adult-only facilities; the audio/visual materials may not, however, leave the adult-only facility).

The enforcement authority for these provisions is unclear. This was discussed in the 2/27 letter. Advertising restrictions similar to the FDA tobacco rule restrictions can be enforced under FDCA enforcement provisions. If the language discussed above is enacted, the FDCA enforcement provisions would be operative.

Sec. 102. General restrictions. [pp. 18-20]

First two comments on Section 101 also apply here.

Section 102(c)(1) [p. 20] provides that "[n]o payment shall be made by any manufacturer, distributor, or retailer for the placement of any tobacco product or tobacco product package or advertisement . . . as a prop in any television program or motion picture produced for viewing by the general public; . . . or in a video or on a video game machine." This provision could reach forms of expression other than commercial speech; to the extent that it does, it must be narrowly tailored to serve a compelling governmental interest. See Board of Trustees of SUNY v. Fox, 492 U.S. 469, 473-74, 482 (1989) (describing commercial speech). To ensure that this restriction does not impermissibly limit fully protected, non-commercial speech, the provision should be redrafted to prohibit the placement of "any brand-name tobacco product or brand-name tobacco product package or any tobacco product advertisement."

Section 102(d) [p. 20] provides that "[n]o direct or indirect payment shall be made by any manufacturer, distributor or retailer to any entity for the purpose of promoting the image or use of a tobacco product through print or film media that appeals to individuals under 18 years of age or through a live performance by an entertainment artist that appeals to such individuals." The scope of the restriction is unclear. For example, is the provision intended only to restrict attempts to promote brand names of tobacco products or is it intended to restrict the promotion of smoking generally? If the latter were the case, the provision would appear to restrict some non-commercial speech, raising significant constitutional concerns. In addition, the phrase "appeals to individuals under 18 years of age" is unclear and could be subject to challenge on vagueness grounds. These concerns could be alleviated by limiting the provision's scope to commercial speech and substituting a more objective definition of the media or types of entertainment that would appeal to underage consumers. For example, the provision could be amended to read: "No direct or indirect payment shall be made by any manufacturer, distributor or retailer to any entity for the purpose of advertising a tobacco product or of promoting the image or use of a brand-name tobacco product through an adult publication, film media that has been rated G through R, or their equivalent, by the motion picture industry, or through a live performance by an entertainment artist that persons under the age of 18 are permitted to attend."

Restriction on glamorization, Sec. 102(d) [p. 20], goes beyond FDA rule; would be difficult to enforce; may raise constitutional issues.

Sec. 103. Format and content requirements for labeling and advertising. [pp. 21-22]

First two comments on Section 101 also apply here.

Section 103(b)(1)(A)(ii), advertising in adult only locations [p. 21]: FDA rule requires items to be affixed to the facility. It is not sufficient to be attached to a fixture (this could include banners, etc. that could be removed easily by patrons). Should delete "or fixture."

Sec. 104. Statement of intended use. [pp. 22-24]

These provisions are in FDA rule; unnecessary if FDA's jurisdiction to regulate products as drug delivery devices is affirmed.

In addition, the statements of intended use in the FDA rule employ BATF terms of reference for smokeless tobacco products. As a result, only two intended use statements for smokeless tobacco products should be permitted—

> Chewing Tobacco--A Nicotine-Delivery Device for Persons 18 or Older.
>
> Snuff--A Nicotine-Delivery Device for Persons 18 or Older.

> Sec. 105. Ban on nontobacco items and services, contests and games of chance, and sponsorship of events. [pp. 105-26]

First two comments on Section 101 also apply here.

> Sec. 106. Use of product descriptors. [p. 26]

FDA may find, based on available information, that it is not in the interests of public health to permit usage of the terms "light" and "low tar" even with disclaimers. FDA should retain existing authority to prohibit the use of such terms. Section 106(b) would permit FDA to continue to do this.

Subtitle B--Warnings, Labeling and Packaging [pp. 26-40]

> Sec. 111. Cigarette warnings. [pp. 26-33]

Not clear what part of government is responsible for these provisions; "[FDA] Commissioner" is supposed to do some things; FTC is to approve compliance plans; "Commission" is to do other actions. The language changes below refer to the HHS Secretary.

Section 111(a)(2) [p. 27, lines 15-16], modify as follows (add words in bold)—

- (2) ADVERTISING- It shall be unlawful for any manufacturer, or importer, ***distributor, or retailer*** of cigarettes to advertise or cause to be advertised . . .

ADD at the end of Section 111(a)(2) [p. 28, line 11], the following—

- "(3) ADDITIONAL WARNINGS.--Beginning on the date that is 18 months after the date of enactment of this subchapter, the Secretary may substitute for, or require warnings in addition to, those otherwise required under subparagraphs (1) and (2) if the Secretary determines that such warnings would be more effective in deterring the use of cigarettes."

Section 111(b)(1) [p. 28, lines 12-16], modify as follows (add words in bold)—

(1) LOCATION- Each label statement required by paragraph (1) of subsection (a) shall be located on the upper portion of the front ***and rear*** panel of the cigarette package (or carton) ***directly on the package underneath the cellophane or other clear wrapping*** and occupy not less than 25 percent of such ~~front~~ panel.

Section 111(b)(3) [p. 29, lines 5-8], modify as follows (add words in bold)—

(3) EXCEPTION—The provisions of paragraph (1) shall not apply in the case of a flip-top cigarette package (offered for sale on the date of enactment of this Act) ***manufactured or distributed prior to January 1, 2000*** where the front portion . . .

Section 111(c)(1) [p. 29, lines 14-17], modify as follows (add words in bold)—

(1) LOCATION- Each label statement required by paragraph (2) of subsection (a) shall ***appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area and shall*** occupy not less than 20 percent of the area of the advertisement involved.

Section 111(d) [p. 31, line 6, - p. 33, line 15], DELETE and replace with—

"(3) FORMAT.--The label statements under paragraph (2) of subsection (a) shall be black when the background is white and white when the background is black, and shall be in the point size required under this subparagraph. The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first down stroke of the capital 'W' of the word 'WARNING' in the label statements."

"(4) LANGUAGE REQUIREMENT.--The label statements required under paragraph (2) of subsection (a) shall be in English, except that—

"(i) in the case of an advertisement that appears in a newspaper, magazine, periodical or other publication that is not in English, such statements shall appear in the predominant language of the publication; or
"(ii) in the case of any other advertisement that is not in English, such statements shall appear in the same language as that principally used in the advertisement."

"(d) ROTATION OF LABEL STATEMENTS.--

"(1) LABELING.--The label statements specified in paragraph (2) of subsection (a) shall be randomly displayed in each 12 month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which such product is marketed in accordance with a

plan submitted by the manufacturer, importer, distributor or retailer and approved by the Secretary."

"(2) ADVERTISING.--The label statements specified in paragraph (2) of subsection (a) shall be rotated quarterly in alternating sequence in advertisements for each such brand of cigarettes in accordance with a plan submitted by the manufacturer, importer, distributor or retailer and approved by the Secretary."

"(3) APPROVAL OF PLANS.--The Secretary shall review each plan submitted by a manufacturer, importer, distributor or retailer of cigarettes under this paragraph and approve such plan if the plan will provide for the equal distribution and display on packaging and the rotation required in advertising under this paragraph and if such plan assures that all of the labels required under subparagraphs (1) and (2) will be displayed by the manufacturer, importer, distributor or retailer at the same time."

DELETE Section 111(e) [p. 33, lines 16-19]. Exports are addressed in Section 117 [pp. 39-40].

Sec. 112. Smokeless tobacco warnings. [pp. 33-36]

Section 112(a)(2) [p. 34, lines 14-16], modify as follows (add words in bold)—

- (2) ADVERTISING- It shall be unlawful for any manufacturer, ~~or~~ importer, ***distributor, or retailer*** of smokeless tobacco products to advertise or cause to be advertised . . . .

ADD at the end of Section 112(a)(2) [p. 35, line 4], the following—

- "(3) ADDITIONAL WARNINGS.--Beginning on the date that is 18 months after the date of enactment of this subchapter, the Secretary may substitute for, or require warnings in addition to, those otherwise required under subparagraphs (1) and (2) if the Secretary determines that such warnings would be more effective in deterring the use of smokeless tobacco products."

Section 112(b)(1) [p. 35, lines 5-8], modify as follows (add words in bold)—

- (1) LOCATION- Each label statement required by paragraph (1) of subsection (a) shall be located on the ***two*** principal display panel of the product and occupy not less than 25 percent of ~~such~~ ***each*** panel.

Section 112(c) [p. 35, lines 22-24], delete (1) after (d) (conforms to changes above)—

- "(c) ADVERTISING AND ROTATION- The provisions of subsections (c) and (d)~~(1)~~ of section 111 shall apply to advertisements for smokeless tobacco products and the rotation of the label statements required under subsection (a)(1) on such products."

DELETE Section 112(d) [p. 36, lines 3-7]. Exports are addressed in Section 117 [pp. 39-40].

After 112(e) [p. 36, line 11], ADD the following—

(f) OTHER TOBACCO PRODUCTS—The Secretary may prescribe such regulations as may be appropriate to establish warning labels for other tobacco product packaging, labeling, and advertising.

Sec. 113. Ingredients. [p. 36]

[pp. 36, lines 12-17]

This refers to a proposed new provision of the FDCA; the requirements of proposed FDCA section 119 do not need to be repeated here. Should delete.

Sec. 114. Enforcement, regulations, and construction. [pp. 36-37]

At minimum, a violation of section 113 (a proposed new FDCA provision) should not be enforced by FTC but by FDA.

Suggest deleting sections 114(a)-(c), and have provisions be enforced under FDCA. Warning statements are a concept encompassed by FDCA. Given the public health purpose of these statements, they are appropriately administered and enforced by FDA.

Sec. 115. Preemption.

[p. 38, lines 1-14]

Delete "or in any advertisement" in subsections (a), (b) [lines 6 and 12-13].

Sec. 116. Reports.

Sec. 117. Exports. [p. 39]

Warning statement requirements would not be required for exports. Is there a policy issue?

Sec. 118. Repeals.

Subtitle C--Restriction on Access to Tobacco Products [pp. 40-44]

Sec. 121. Requirements relating to retailers.

Sec. 122. Manufacture, sale, and distribution.

Sec. 121. Requirements relating to retailers
Sec. 122. Manufacture, sale, and distribution

These provisions codify the FDA access restrictions. To retain flexibility (and simplify this legislation), it may be preferable to simply expressly affirm FDA authority to enact access restrictions and recognize the 1996 regulations. See comments on section 101, above.

Subtitle D--Licensing of Retail Tobacco Sellers [pp. 44-52] (see Insert A - registration proposal)

Sec. 131. Establishment of program.

Sec. 132. Requirements.

Sec. 133. Penalties, revocations and suspensions.

Sec. 134. Federal licensing of military and other entities.

Subtitle D would provide two incentives for states to establish licensing programs for retail distributors of tobacco products. States that establish satisfactory licensing programs (1) would qualify for block grants under section 402 (see §§ 131(a), (c), 402(c)); and (2) would retain control over the regulation of tobacco retailers within their borders instead of ceding regulatory authority in this area to the federal government (see § 131(b)). Congress possesses authority, under Spending Clause principles discussed in South Dakota v. Dole, 483 U.S. 203, 206-10 (1987), to require states to take regulatory action in order to receive federal funds. When Congress acts in areas where the Constitution permits direct federal regulation, Congress also possesses authority, under principles discussed in New York v. United States, 505 U.S. 144, 167-68 (1992), to offer States a choice between regulating in accordance with federal standards and having state law pre-empted by a federal regulatory scheme.

S. 1415's incentives for states to establish federally approved licensing programs, in our view, should survive any federalism-based constitutional challenge. The spending power, as elaborated in Dole, accommodates the bill's block grant provisions. The commerce power would support a general federal ban on sales of tobacco products and therefore, under the principles described in New York, authorizes a more limited ban -- one that applies only where states fail to take alternative regulatory action.

There is, nevertheless, some risk that courts would take a contrary view. The Court in South Dakota v. Dole, stated that "in some circumstances, the financial inducement offered by Congress might be so coercive as to pass the point at which 'pressure turns to compulsion.'" 483 U.S. at

211 (quoting Steward Machine Co. v. Davis, 301 U.S. 548, 590 (1937)).[1] S. 1415 does not indicate how much money states would receive for establishing and administering a satisfactory tobacco licensing program.[2] And we have no information as to the costs that states would have to incur to establish and administer acceptable licensing programs. Opponents of the bill's state licensing provisions might be able, depending on the size of the burden that a state was asked to bear and of the incentive for that state to bear it, to argue that the bill's spending power inducement for state licensing is impermissibly coercive.

The bill's reliance on a conditional exercise of the commerce power to encourage state to regulate tobacco sellers might also raise federalism-based concerns. The Supreme Court has not suggested a coercion test for conditional commerce power legislation. However, opponents of the licensure provisions might argue that Dole's anti-coercion principle ought to apply, as a logical matter, when Congress seeks to encourage state action through conditional commerce power legislation as well as when Congress exercises its conditional spending power.

To reduce the risk of a successful federalism-based challenge, Congress might consider revising the bill's incentives for state action. Options could include, but would not be limited to: (1) changing the block grant provisions to call for a reduction rather than a complete cutoff in federal payments to noncompliant states (compare, e.g., Dole, 483 U.S. at 211 (state refusal to establish

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[1] Courts have repeatedly rejected arguments that particular spending power inducements exert an impermissibly coercive influence on the states. See, e.g., Nevada v. Skinner, 884 F.2d 445, 448 (9th Cir. 1989) ("the difficulty if not the impropriety of making judicial judgments regarding a state's financial capabilities renders the coercion theory highly suspect as a method for resolving disputes between federal and state governments"), cert. denied, 493 U.S. 1070 (1990); South Dakota v. Adams, 506 F. Supp. 50, 57 (D. S.D. 1980) ("There is a vast difference between requiring a state to adopt certain regulations and denying funding to a state that refuses to adopt them."), aff'd sub nom. South Dakota v. Goldschmidt, 635 F.2d 698 (8th Cir. 1980), cert. denied sub nom. South Dakota v. Lewis, 451 U.S. 984 (1981). But cf. Virginia Dep't of Educ. v. Riley, 106 F.3d 559, 569-72 (4th Cir. 1997) (en banc) (suggesting, in dictum, that one particular piece of spending power legislation operates in an impermissibly coercive manner) (Luttig, J., writing for six of thirteen judges).

[2] Under S. 1414, the previous version of this bill, states that established and enforced satisfactory licensing programs would have received a total of $2.5 billion in the first two years, increasing to $5.0 billion in the fifth year, before decreasing to $2.5 billion in the sixth and subsequent years. See S. 1414 §§ 401(d)(1)(A)-(E). The current bill omits all of the provisions that appeared as Title IV of S. 1414, which set forth the blueprint for payments into and out of the National Tobacco Settlement Trust Fund (NTSTF). As a result of this deletion, we are unsure how to interpret the current bill's apparent reliance on the NTSTF as the source of funding for the grants to states that satisfy the licensing requirement. See, e.g., S. 1415 §§ 401(a)(1), 401(a)(2) (referring to the Trust Fund established and controlled by (former) section 401).

21 years old as the minimum drinking age caused it to lose five percent of specified highway funds); and (2) substituting a federal regulatory scheme (such as a prohibition on retail tobacco sales except in adults-only locales) for S. 1415's outright federal ban on tobacco sales in noncompliant states. In addition, the risk of a successful federalism-based challenge would be further reduced if some significant portion of block grant funds to the states -- especially any portion that was identified as reimbursement for state expenditures under the Medicaid program for the treatment of tobacco-related illnesses -- were paid out unconditionally, without any requirement that states perform specified tasks in order to receive the money or that they spend the money in prescribed ways.[1]

Sec. 131. Establishment of program
Sec. 132. Requirements
Sec. 133. Penalties, revocations and suspensions
Sec. 134. Federal licensing of military and other entities

These provisions would, in effect, shift enforcement of the FDA access restrictions to individual state programs. FDA believes that a comprehensive federal enforcement strategy is necessary.

There have been extensive discussions within the administration (DPC, HHS/FDA, DOJ, Treasury) to finalize a federal approach to "licensing" that would achieve this goal as well as provide necessary controls over the chain of distribution. Legislative language is being drafted now.

The penalty scheme is based on violations within a 2 year period; FDA's current enforcement strategy does not impose any time restrictions on the schedule for escalating penalties.

Subtitle E--Regulation of Tobacco Product Development and Manufacturing [pp. 52-83] (see Insert B - OLC comments, and Insert C - proposed FDA language)

Sec. 141. Reference.

Sec. 142. Treatment of tobacco products as drugs.

[pp. 52-55]

Sec. 141. Reference
Sec. 142. Treatment of tobacco products as drugs

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[1] Payment of a significant portion of the block grants to the states on an unconditioned basis would undercut arguments that the bill impermissibly revised the federal-state bargain governing states' past participation in the Medicaid program by reducing states' rights to recoup their Medicaid outlays from parties, such as tobacco companies, whose actions increase health care costs.

These provisions should be deleted and replaced with the provisions for express affirmation of FDA authority.

- To express affirm FDA jurisdiction, and amend the definitions of drug and device to specifically include nicotine in tobacco as a drug and tobacco products as devices, the following is needed—

  Drug: Section 201(g)(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"

Consistent with the traditional FDCA approach of defining regulated products rather than specific products within the category, it would be only necessary to define "tobacco products," e.g.—

"201(kk) The term 'tobacco product' means any product made or derived from tobacco leaf made for human consumption."

- If desired, the following clause could also be included, but is not necessary:

", including, but not limited to, cigarettes, cigarillos, cigarette tobacco, cigars, little cigars, pipe tobacco, and smokeless tobacco, and roll-your-own tobacco."

Thus, p. 52, line 20, — p. 55, line 4, should be deleted and replaced with the above.

Sec. 143. Health and safety regulation of tobacco products. [pp. 55-83]

Should not create a separate chapter for tobacco products; tobacco products should be subject to regulation as drugs and devices. (Specific comments on proposed sections follow).

Section 901

Incorporates definitions of Sec. 100; some of the definitions are more narrow than current FDA provisions or interpretations. FDA could face unnecessary obstacles if it wished to promulgate a broader definition of a particular term (such as manufacturer).

Section 902; purpose

Unnecessary.

Section 903; regulations

FDA already has this authority under section 701.

Section 904: minimum requirements

Already have misbranding and adulteration authority in sections 501, 502.

Section 905: performance standards [pp. 57-60]

Already have this authority under section 514; may wish to include authority for FDA to issue performance standards prior to classification (because classification is a lengthy process and the issuance of performance standards requires notice and comment rulemaking).

- The following would provide such authority—

  "The Secretary may adopt a performance standard under section 514(a)(2) for a tobacco product regardless of whether the product has been classified under section 513."

- If there is a desire to specify what the standards could encompass, the following could be added, but is not necessary—

  "Such standards may include--
  "(1) the reduction or elimination of nicotine yields of the product;
  "(2) the reduction or elimination of other constituents or harmful components of the product; or
  "(3) standards relating to any other requirement pursuant to section 514(a)(2)."

  "(b) TOBACCO CONSTITUENTS.--The Secretary may require that a manufacturer test, report and disclose tobacco and tobacco smoke constituents, including labeling and advertising disclosures relating to such constituents, including, but not limited to, tar and nicotine."

In particular, the agency opposes the limitations on its authority in 905(f), (g) [p. 61]. Developments in nicotine replacement products or nicotine analogues may make these options appropriate at some point in the future.

Section 906: scientific advisory committee [pp. 61-63]

Already have provision under current FDCA section 904 to establish advisory committee (and there are requirements in various operational device provisions to consult with an advisory group). Not opposed to special provisions for a tobacco scientific advisory group, provided that there is no requirement of tobacco industry representation.

Section 907: nicotine and other constituents [pp. 63-68]

Unnecessary and unduly burdensome.

The approach that would be more consistent with the public health would be to codify the approach explained in the preamble to the FDA Tobacco Rule, 61 Fed. Reg. 44412-13, in the device provisions:

- 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), (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,"

Section 908: reduced risk [pp. 68-73]

Suggest deleting entire section.

The provision allowing reduced risk claims are very problematic. FDA has authority under FDCA to address these issue. If Congress wishes to make express this authority, the following provision would do so—

- MISBRANDING.--Section 502 (21 U.S.C. 360) is amended by adding at the end the following:

  "(u) The regulations promulgated in accordance with this chapter with respect to devices that are tobacco products shall, at a minimum, require that a tobacco product be deemed to be misbranded if the labeling of the package of the product, or any claim of the manufacturer in connection with the product, states or implies

(as determined by the Secretary) that the product presents a reduced health risk unless it is demonstrated to the satisfaction of the Secretary that the product will achieve the best public health result, taking into account all relevant factors including, but not limited to, the probability of the increased number of new users of tobacco products and the reduced probability that existing users of tobacco products will quit."

The provisions for development of reduced risk technology contain authority that FDA has under the FDCA and authority that goes beyond the FDCA. FDA is available to discuss these issues further. Mandatory cross-licensing would create disincentives to research and development efforts. At minimum, licensing should not be mandatory. In addition, FDA does not have experience in setting patent license fees. Commerce might be a more appropriate authority to set such fees.

The provision requiring the Secretary/PHS manufacture reduced risk products would require HHS involvement in an entirely new area, and could expose the government to tort liability.

Sections 908(c) and (d) [pp. 70-73] could give rise to takings claims involving the forced disclosure of two classes of propriety information: (1) trade secrets and patents involving risk-reducing technology and (2) trade secrets involving non-tobacco ingredients.[1] We believe that the risk of takings liability arising out of the operation of these disclosure provisions is relatively modest and that minor changes to the bill could reduce this risk still further.

Disclosures of information concerning risk-reducing technology would be governed by newly added section 908(c). This provision would require manufacturers to notify the FDA of newly developed or newly acquired technology that was capable of reducing the health risks of tobacco products. After establishing the viability of the new technology, the FDA could ask the notifying company to manufacture and market the product. If the company declined, the FDA could require the company to license the new technology to other manufacturers for a "commercially reasonable fee." Section 908(c)(1)(B). Finally, if no manufacturer agreed to manufacture the new product, the FDA, acting through the U.S. Public Health Service, could provide for the manufacture and marketing of the new product, either directly or through grants and contracts.

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[1] The takings issues addressed here and at various later points in this memorandum do not implicate the constitutionality of S. 1415. Successful takings claims would increase the cost of the proposed legislation to federal taxpayers. However, unless the bill unambiguously withdrew the Tucker Act remedy, there would be no taking without just compensation and, therefore, no basis for a judgment invalidating any part of the statute as violative of the Fifth Amendment. See Ruckleshaus v. Monsanto, 467 U.S. 986, 1016-19 (1984) (refusing to enjoin EPA disclosure of pesticide trade secrets where the Tucker Act provided compensation for any taking of trade secrets); accord, e.g., Preseault v. ICC, 494 U.S. 1, 8 (1990). In this respect, the risk of successful takings claims differs in kind from the risks posed by other constitutional claims discussed here.

Disclosures of the ingredients found in tobacco products would be governed by newly added FDCA section 910. This provision would require the FDA to establish rules governing ingredient labels for tobacco products, patterned on existing ingredient labelling requirements for food products (see 21 U.S.C. § 343 (1994)).[3]

Trade secrets are among the "intangible property rights protected by state law [that] are deserving of the protection of the Taking Clause." Monsanto, 467 U.S. at 1003. Accordingly, if the bill's provisions concerning risk-reducing technology and ingredients labelling required a tobacco company to disclose information to the public or its competitors that would have been protected from disclosure under otherwise applicable state trade secret law, the company could claim a federal taking. Patents, which could also be affected by the reduced risk provisions, also represent a form of property, the contours of which are defined by federal rather than state law. See U.S. Const. art. I, § 8; 35 U.S.C. §§ 101-261 (1994). Although Congress could presumably alter the rights conferred by future patents for risk-reducing tobacco products without paying compensation, retrospective alteration of the terms of an existing patent could well invite takings litigation. Cf. Jacobs Wind Elec. v. Florida Dep't of Trans., 919 F.2d 726, 728 & n.2 (Fed. Cir. 1990) (because patents are property, a state's infringement can constitute a taking actionable under the Fifth and Fourteenth Amendments) (dictum).

Takings claims arising under the risk-reducing technology provisions would most likely be based on alleged disparities between the "commercially reasonable fee" that a company received under FDA regulations and the quantum of compensation that the company was entitled to receive under the Fifth Amendment, an amount often referred to as "fair market value." "Commercially reasonable fees," determined under the FDA's section 908 regulations, might approximate fair market value. Alternatively, licensing might be set below fair market value in order to attract licensees (and to sustain direct development efforts by the Public Health Service where no private licensee steps forward).

If licensing fees are expected to fall short of fair market value, supporters of S. 1415 might want to minimize potential takings liability by adding provisions that would secure tobacco companies' consent to below-market licensing fees. For example, the obligation to share risk-reducing technology could be tied to a separate, newly created governmental benefit -- a right, which could be implemented through a permit or registration requirement, to continued access to the U.S. market for tobacco products. This approach would conform to the analysis of Monsanto. There, the Supreme Court ruled that EPA's use and disclosure of pesticide data that Monsanto had

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[3] Section 910 also would require tobacco companies to provide the FDA with brand-by-brand lists of non-tobacco ingredients. (Current law only requires tobacco manufacturers to submit ingredient data to the FDA in aggregated form -- without any indication of which companies or products use particular ingredients. See 15 U.S.C. § 1335a (1994)). Because the FDA would maintain the confidentiality of these submissions, except for information covered by the ingredients labelling provision, these provisions would not add to the risk of successful takings claims.

voluntarily submitted, under conditions of non-confidentiality, "in exchange for the economic [benefit] of [legally required] registration [could] hardly be called a taking." Monsanto, 467 U.S. at 1007.

We think it unlikely that the ingredients disclosure provisions of S. 1415 would give rise to successful takings claims. We are unaware of any takings challenge to the food ingredients disclosure requirements that the bill identifies as the model for tobacco ingredients disclosure. Moreover, the Supreme Court has rejected claims that state ingredient-disclosure requirements deprived manufacturing companies of property without due process. See, e.g., Corn Prod. Ref. Co. v. Eddy, 249 U.S. 427, 431-32 (1919) ("The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the state, in the exercise of [the] police power and in promotion of fair dealing, to require that the nature of the product be fairly set forth."). On the other hand, tobacco companies have argued, with some preliminary success, that information concerning the ingredients found in tobacco products is more sensitive than information on the ingredients in food.[4] As in the reduced risk technology context, takings risks could be reduced by provisions that would make company consent to ingredients disclosure a precondition to receipt of statutory benefits.

Section 909: good manufacturing practices [pp. 73-78]

Have gmp authority in device provisions, section 520(f). Already have regulations for device gmps that were the result of several years of rule-making. Industry could comply with these existing regulations (in fact, industry has been consultations with private gmp consultations on this issue). At some later date, FDA will likely promulgate tobacco-specific gmp regulations for some areas. But that is not the same as starting with a new statutory provision.

If there is a concern about agricultural producers, see proposed 909(d) [p. 77], the FDCA could be amended to include the following—

> "AGRICULTURAL PRODUCERS. The Secretary may not promulgate any regulation directed towards devices that are tobacco products under this chapter that has the effect of placing regulatory burdens on tobacco producers (as such term is used for purposes of the

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[4] Massachusetts and Minnesota recently enacted ingredients disclosure laws for tobacco companies doing business within those states. See Mass. Gen. L. Ann. ch. 94, § 307B (West 1996); 1997 Minn. Laws c. 227, § 5 (to be codified at Minn. Stat. Ann. § 461.17). Tobacco companies have sued to block implementation of these laws, arguing, among other things, that disclosure would result in uncompensated takings. In the Massachusetts litigation, the companies have obtained a preliminary injunction against implementation of the Massachusetts statute. Philip Morris, Inc. v. Harshbarger, Civ. No. 11599-GAO (D. Mass. Dec. 10, 1997). There, the district court found that the companies had shown a sufficient likelihood of success on the merits of their claim that the Massachusetts statute would effect an uncompensated taking of their trade secrets to warrant preliminary injunctive relief.

Agricultural Adjustment Act of 1938 (7 U.S.C. 1281 et seq.) and the Agricultural Act of 1949 (7 U.S.C. 1441 et seq.)) in excess of the regulatory burdens generally placed on other agricultural commodity producers. This section shall not be construed to limit the regulatory requirements that may be imposed on producers who are also manufacturers under this Act."

Section 910: Ingredients [pp. 78-82]

FDA has authority under FDCA to issue regulations related to ingredient review and regulation. The agency is available to work with the Committee to develop appropriate statutory provisions, similar to those proposed, that would eliminate need for rulemaking. Appropriate changes are discussed below.

Section 910(a)(1)(A): the exclusion of reconstituted tobacco from submission requirements is a significant omission; the fact that the tobacco is reconstituted can reveal information concerning the nicotine content and delivery of a product. Modify as follows—

- "(A) a list of all ingredients, ***constituents,*** substances, and compounds (other than tobacco; ***or*** water ~~or reconstituted tobacco sheet made wholly from tobacco~~) that are added to the tobacco (and the paper, ~~or~~ filter, ***or packaging*** of the product if applicable) in the manufacture of the tobacco product, for each brand of tobacco product so manufactured; and

- "(B) a description of the quantity of the ingredients, ***constituents,*** substances, and compounds that are listed under subparagraph (A) with respect to each brand of tobacco product."

Other information appropriate for disclosure to the agency—

"(C) the nicotine content of the product, measured in milligrams of nicotine;

"(D) for each brand or variety of cigarettes— (i) the filter ventilation percentage (the level of air dilution in the cigarette as provided by the ventilation holes in the filter, described as a percentage); (ii) the pH level of the smoke of the cigarette; and (iii) the tar, nicotine, and carbon monoxide delivery level under Federal Trade Commission parameters and any other smoking conditions established by the Secretary, reported in milligrams of tar, nicotine, and carbon monoxide per cigarette;

"(E) for each brand or variety of smokeless tobacco products— (i) the pH level of the tobacco; (ii) the moisture content of the tobacco expressed as a percentage of the weight of the tobacco; and (iii) the nicotine content— (I) for each gram of the product, measured in milligrams of nicotine; (II) expressed as a percentage of the dry weight of the tobacco; and (III) with respect to unionized (free) nicotine, expressed as a percentage per gram of

the tobacco and expressed in milligrams per gram of the tobacco; and

"(F) any other information determined appropriate by the Secretary."

The Secretary should have authority to promulgate regulations on this issue (consistent with existing authority under the FDCA—

- "METHODS.--The Secretary shall have the authority to promulgate regulations to establish the methods to be used by manufacturers in making the determinations required under paragraph (1)."

Section 910(b) [p. 79]: Manufacturers have 5 years to submit their assessments of ingredients, etc.. This would allow them to flood FDA with information shortly before the 5 year period ends. FDA has to act within 90 days or else the ingredient is deemed approved. FDA should be able to require information earlier, on a staggered basis. Appropriate language would be—

- "The Secretary shall develop a procedure for the submission of safety assessments of such ingredients, constituents, substances, or compounds that staggers such safety assessments within the 5-year period."

Section 910(b)(2), basis of assessment: the "the minds of competent scientists" concept in the second element, (B), is not currently in the FDCA, and would be hard to measure (particularly). Should delete (B) (p. 79, line 22, - p. 80, line 2). Replace with—

"(B) demonstrate that there is a reasonable certainty among experts qualified by scientific training and experience who are consulted, that the ingredient, constituents, substance, or compound will not present any risk to consumers or the public in the quantities used under the intended conditions of use."

Section 910(c)(2) [p.80]: 90 days is a short period of time to complete review, particularly given that the ingredient is deemed approved if this deadline is not met, section 910(c)(2)(C). Some other bills allow 180 days and allow the Secretary to later disapprove an ingredient if the deadline is not met. The following edits would address these concerns—

- "(A) GENERAL REVIEW- Not later than 90 days after the receipt of a safety assessment under subsection (b), the Secretary shall review the findings contained in such assessment.

"(B) APPROVAL OR DISAPPROVAL- Not later than ~~90~~ ***180*** days after the completion of a review under subparagraph (A), the Secretary shall approve or disapprove of the safety of the ingredient, ***constituent,*** substance, or compound that was the subject of the assessment and provide notice to the manufacturer of such action. ***The Secretary may,***

for good cause, extend the period for such review.

"(C) INACTION BY SECRETARY- If the Secretary fails to act with respect to an assessment during the ~~90~~ ***180***-day period referred to in subparagraph (B), ~~the safety of the ingredient, substance, or compound involved shall be deemed to be approved.~~ ***the manufacturer of the tobacco product involved may continue to use the ingredient, constituents, substance, or compound involved until such time as the Secretary makes a determination with respect to the assessment.***

Section 910(d) [p.81], disclosure: it is not clear how the public health would be served by having tobacco products meet only the food standards for public disclosure of ingredients (rather than regulations pursuant to device law). A way to address this would to include a provision that provided—

- "a package of a tobacco product shall disclose all ingredients, constituents, substances, or compounds contained in the product in accordance with regulations promulgated under section 701(a) by the Secretary."

Section 910(d)(2) [pp. 81-82]: the food labeling standard is not appropriate.

Section 910(d)(3) [p.82]: Section 301(j) of the FDCA would prohibit FDA from disclosing this information. Need to add a clause after "Notwithstanding paragraph (1)"--

- "or section 301(j),"

Section 910(e), confidentiality [p. 82]: this is unnecessary. FDA already has statutory provisions, regulations, and procedures to protect trade secret information. In addition, the prohibition on using this information to establish a performance standard would significantly reduces its use and would detract from the agency's ability to reduce the risks of these products. FDA has experience in using procedures in rulemaking to ensure trade secrets are protected.

If these provisions are enacted, would also need to add misbranding and prohibited act provisions to provide enforcement mechanisms.

Section 911 [p. 83]:

As discussed above, these provisions should apply. Should delete this section.

Subtitle F--Compliance Plans and Corporate Culture

Sec. 151. Compliance plans.

Sec. 152. Compliance programs.

[pp. 83-99]

Sec. 151. Compliance plans
Sec. 152. Compliance programs

Issue: could these provisions be used as defenses in enforcement FDCA actions?

Under section 152(b)(8) [p. 86], manufacturers of tobacco products would be required to "promulgat[e] corporate policy statements that express and explain the commitment of" the manufacturer to, inter alia, "(A) compliance with applicable Federal, State, and local laws"; and "(B) reducing the use of tobacco products by individuals who are under 18 years of age." We think that the provision, as currently drafted, could be construed merely to require companies to promulgate a commitment not to engage in certain proscribed conduct. Insofar as it were construed in this manner, it would not appear to raise constitutional problems. If, however, the provision were construed to require manufacturers not only to state what they are doing and will do as required by law, but also to state that they are doing so because of their commitment to the principles underlying those "polic[ies]," that would raise problems of compelled speech. See, e.g., Wooley v. Maynard, 430 U.S. 705 (1977); West Virginia State Board of Educ. v. Barnette, 319 U.S. 624 (1943). Cf. Pacific Gas & Elec. Co. v. Public Util. Comm'n of California, 475 U.S. 1 (1986). The provision should be construed to avoid the constitutional concerns that would be presented by the latter construction.

The provision regarding retail establishments (d) may raise anti-trust/anti-competitive concerns [p. 87]

Sec. 153. Whistleblower protections.

Sec. 154. Provisions relating to lobbying.

Section 154(b) [p. 89] provides that "[a] manufacturer, distributor, or retailer of a tobacco product shall require that any lobbyist or lobbying firm employed or retained by the manufacturer, distributor, or retailer, or any other individual who performs lobbying activities on behalf of the manufacturer, distributor, or retailer, as part of the employment or retainer agreement refrain from supporting or opposing any Federal or State legislation, or otherwise supporting or opposing any governmental action on any matter without the express consent of the manufacturer, distributor, or retailer." The Supreme Court has stated that "the First Amendment protects the right of corporations to petition legislative and administrative bodies." First Nat. Bank of Boston v. Bellotti, 435 U.S. 765, 792 n.31 (1978) (citing California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510-511 (1972)); Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 137-38 (1961). Section 154(b) would impose a lobbying restriction on tobacco companies that is not imposed on any other persons or entities -- namely, the requirement that the lobbyists for such companies obtain "express consent" of their principal before "supporting or opposing" any governmental action. In other words, tobacco companies --

unlike all other persons and entities -- would be uniquely disadvantaged by being prohibited from giving their lobbyists a general warrant to lobby on their behalf. Assuming that the traditional First Amendment analysis would apply, discrimination against the lobbying activity of a single type of corporate entity, such as that proposed in section 154(b), likely would be subject to strict scrutiny. Such speaker-based distinctions are presumptively impermissible if "based on the content or messages of [the] groups' speech," Rosenberger v. Rector & Visitors of Univ. of Va., 515 U.S. 819, 834 (1995), or on "the identity of the interests that spokesmen [for the disfavored entities] may represent in public debate over controversial issues," Bellotti, 435 U.S. at 784. Accord Pacific Gas & Elec. Co., 475 U.S. at 15 (plurality opinion); Austin v. Michigan Chamber of Commerce, 494 U.S. 652, 657 (1990). In order to survive strict scrutiny, such a speaker-based restriction must be narrowly tailored to serve a compelling state interest. Id. at 657. Thus, even assuming that the contemplated restrictions on lobbying would survive constitutional review if applied more generally, we have serious doubts whether the more limited restriction imposed by section 154(b) would survive the strict constitutional scrutiny to which it would likely be subject.

Section 154(c)(4) [p. 90] would require lobbyists for tobacco-product manufacturers, retailers and distributors to enter into a signed agreement providing that such a lobbyist will "fully comply with the business conduct policies . . . and commitments (including those relating to the prevention of underage tobacco use) of the manufacturer, distributor, or retailer involved." If section 154(c)(4) were construed to prohibit manufacturers and/or their lobbyists from lobbying to achieve certain ends that might be inconsistent with "prevention of underage tobacco use," it would appear to violate such manufacturers' First Amendment rights. See, e.g., City of Columbia v. Omni Outdoor Adver., Inc., 499 U.S. 365, 379 (1991).

Sec. 155. Termination of certain entities. (see Insert D - Antitrust Division comments)

Section 155(a) [p. 90] provides that "[n]ot later than 90 days after the date of enactment of this Act, manufacturers, distributors, or retailers of tobacco products shall provide for the termination of the activities of the Tobacco Institute and the Council for Tobacco Research, U.S.A. and the Institute and Council shall be dissolved." The provisions expressly naming certain institutions and prohibiting them from conducting business would be subject to substantial constitutional challenge as a Bill of Attainder. See Nixon v. Administrator of General Services, 433 U.S. 425 (1977); Cummings v. Missouri, 71 U.S. 277, 320 (1866) ("Disqualification from the pursuits of a lawful avocation . . . may also, and often has been, imposed as punishment); SBC Communications, Inc. v. FCC, 981 F.Supp. 996 (N.D. Tex. 1997). In addition, to the extent that such trade organizations are organized "for the purpose of engaging in those activities protected by the First Amendment," see Roberts v. United States Jaycees, 468 U.S. 609, 618 (1984), their compelled dissolution would impermissibly infringe upon First Amendment rights of expression and expressive association, unless such dissolution served compelling state interests, "unrelated to the suppression of ideas that cannot be achieved through means significantly less restrictive of associational freedoms." See id., at 623; Sanitation and Recycling Indus., Inc. v. City of New York, 107 F.3d 985, 998-1000 (2d Cir. 1997). We have serious doubts that the provisions requiring the dissolution of these organizations could be justified under this test.

Section 155(b) [p. 90] restricts the manner in which "[m]anufacturers, distributors, or retailers of tobacco products may form or participate in any trade organization or other industry association." The provision limits the persons who may serve on the board of directors of any industry association. Section 155(b)(2). It also limits the persons with which the association may consult for legal advice. Section 155(b)(2)(C). In addition, it limits the companies with whom the association may meet and prescribes how internal meetings must proceed. Section 155(b)(3). Finally, it provides the Attorney General and, as appropriate, state antitrust authorities, with "access to all books, records, meeting agenda and minutes, and other documents maintained by the association or organization." Section 155(c)(2). To the extent that this provision would apply to industry associations organized "for the purpose of engaging in those activities protected by the First Amendment," see Roberts v. United States Jaycees, 468 U.S. 609, 618 (1984), this provision raises significant constitutional concerns because of the manner in which it would interfere with the internal operations of such associations. See Cousins v. Wigoda, 419 U.S. 477, 487-88 (1975) (striking down law "interfer[ing] with the internal affairs of organization" of a political party); N.A.A.C.P. v. Alabama ex rel. Patterson, 357 U.S. 449, 460 (1958) (striking down compulsory disclosure of member ship lists); Sanitation and Recycling Indus., Inc., 107 F.3d at 998-1000.

Sec. 156. Enforcement. [pp. 94-99]

These provisions will be difficult to police. Also, there may be First Amendment concerns.

Not clear what part of HHS is enforcing this, section 156(b) [p.95]. Depending on the component responsible, it may already have regulations for hearings. Separate procedures should not be required.

Also, there is an item "(f) Scarlet Letter Advertising" that has no text.

TITLE II--REDUCTION IN UNDERAGE TOBACCO USE [pp. 99-112] (see Insert E - Treasury comments; Insert F - HHS comment; Insert G - Treasury/HHS proposal)

Sec. 201. Purpose.

Sec. 202. Determination of underage use base percentages.

Sec. 203. Annual daily incidence of underage use of tobacco products.

[pp. 101-104]

Daily use may not provide the most accurate/useful measure. Other studies based their numbers on usage over the past 30 days.

Sec. 204. Required reduction in underage tobacco use.

Sec. 205. Application of surcharges.

Sec. 206. Abatement procedures.

[pp. 110-112]

The provision allowing any attorney general to be heard at an abatement hearing might significantly prolong the process. Also, this provision might be inconsistent with the way the funding provisions of this legislation is drafted. There may be legal concerns with essentially giving the AGs such an express interest in the money coming in from the companies (i.e., to the extent we wish to condition recipient of the money on particular state actions).

TITLE III--STANDARDS TO REDUCE INVOLUNTARY EXPOSURE TO TOBACCO SMOKE [pp. 113-118] (see Insert H - OSHA edits; Insert I - HHS edits)

Sec. 301. Definitions.

Sec. 302. Smoke-free environment policy.

Section 302 [pp. 114-116] provides that the "responsible entity for each public facility shall adopt and implement at such facility a smoke-free environment policy which meets [certain requirements]." Section 301(2) defines a "public facility" as "any building regularly entered by 10 or more individuals at least 1 day per week, including any such building owned by or leased to a federal, State, or local government entity." The definition does not include buildings or portions of buildings "regularly used for residential purposes," nor does it include buildings that are used as restaurants (other than a fast food restaurant), bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants, or prisons. Notwithstanding the finding regarding the substantial effect on interstate commerce of tobacco use that is set forth in section 3 of S.1415, we recommend that the provision be limited to apply to entities that are either "in or affecting" interstate commerce or whose activities are "in or affecting" interstate commerce in order to minimize the risk that the provision would be challenged as exceeding the scope of Congress's power under the Commerce Clause. See United States v. Lopez, 514 U.S. 549 (1995)

Sec. 303. Citizen actions.

Sec. 304. Preemption.

Sec. 305. Regulations.

Sec. 306. Effective date.

TITLE IV--PUBLIC HEALTH AND OTHER PROGRAMS [pp. 118-139]

Subtitle A--Public Health Block Grant Program

Sec. 401. Public Health Trust Fund.

[p. 118, line 18]

Having the Commissioner be trustee of the fund (along with the Secretary) may not be entirely consistent with FDA's mission; also, may not serve intended purpose as the Commissioner reports to the Secretary.

Sec. 402. Block grants to States.

Sec. 403. Allotments.

Sec. 404. Use of funds.

Sec. 405. Withholding of funds.

Subtitle B--Other Programs

Sec. 411. National Smoking Cessation Program.

Sec. 412. National Reduction in Tobacco Usage Program.

Sec. 413. National Tobacco-Free Public Education Program.

Section 413 [pp. 129-133] provides that the Secretary of Health and Human Services shall establish "an independent board to be known as the Tobacco Free Education Board (referred to in this section as the 'Board') to enter into contracts with or award grants to eligible public and nonprofit private entities to carry out public informational and educational activities designed to reduce the use of tobacco products." Section 413 further provides that the Board shall be comprised of nine members, three "of whom shall be individuals who are heads of a major public health organization."

Because the board members would be responsible for awarding federal grants, they would exercise "significant authority" for purposes of the Appointments Clause. See Buckley v. Valeo, 424 U.S. 1, 138-139 (1976) (per curiam). As a result, they would have to be appointed in accordance with the requirements of that Clause. The requirement that three members of the Board must be "heads of a major public health organization" would unduly restrict the constitutionally vested appointment discretion of the Secretary. Accordingly, that limitation should be deleted.

Sec. 414. National Event Sponsorship Program. [pp. 133-136]

Does HHS have an interest in doling money out to groups that lose sponsorship after the ban on brand name sponsorship goes into effect?

Section (c) refers to a section 401(d)(5) with respect to the amounts of money available for this section. There is no section 401(d) in this legislation

Sec. 415. National Community Action Program.

Sec. 416. National Cessation Research Program. [pp. 137-138] (see Insert J - HHS proposal)

Sec. 417. Use of surcharge payments.

TITLE V--CONSENT DECREES, NON-PARTICIPATING MANUFACTURERS, AND STATE ENFORCEMENT [pp. 140-155]

Sec. 501. Purposes.

Subtitle A--Consent Decrees and Non-Participating Manufacturers

Sec. 511. Consent decrees.

Section 511(a) [p. 140] provides that States, in order to receive certain federal payments, and tobacco manufacturers or distributors, in order to receive certain protection from liability, shall enter into consent decrees. The provision does not, however, describe what, if any, litigation the contemplated decrees would resolve. In the absence of a lawsuit, state courts would likely not possess, and federal courts certainly would not possess, the jurisdiction to enter a consent decree. See Local No. 93, Firefighters v. City of Cleveland, 478 U.S. 501, 525-26 (1986). In addition, although section 511 is presumably intended to condition the receipt of federal benefits on the resolution of only certain types of lawsuits between states and tobacco manufacturers or distributors, section 511(a) does not specify the class of lawsuits that must be resolved by decree. The provision should therefore be amended to specify the kind of litigation that, if outstanding on a certain date, must be resolved in order for the parties to qualify for federal benefits. For example, the provision could state that the federal benefits are conditioned upon States and tobacco manufacturers or distributors entering into consent decrees to resolve any outstanding litigation regarding claims by the States that the tobacco manufacturers or distributors are liable for costs related to the health consequences of smoking.

Section 511(b) [pp. 140-143] provides that the consent decrees referred to in section 511(a) "shall contain provisions to clarify the application and requirements of this Act (and the amendments made by this Act), including provisions relating to" a variety of the substantive

provisions set forth in S.1415. The subsection further provides that these provisions clarifying the application and requirements of S.1415 shall include provisions relating to "restrictions on tobacco product advertising and marketing an youth access to such products," 511(b)(1)(B); "the termination, establishment, and operation of trade associations," 511(b)(1)(C); and "restrictions on tobacco lobbying," 511(b)(1)(D).

Section 511(b) would be subject to substantial challenge under the "unconstitutional conditions" doctrine to the extent that it would condition the protections from liability for tobacco manufacturers and distributors on the requirement that they enter into consent decrees that contain otherwise unconstitutional restrictions on expressive activities. Even though the provisions referencing the consent decrees would not directly impose restrictions on speech, they would be subject to substantial constitutional challenge if they would permit a manufacturer or distributor to qualify for federal benefits only by agreeing in consent decrees with the States to refrain from exercising First Amendment rights. In arguably analogous contexts, the Court has struck down statutes that conditioned the receipt of federal benefits on the requirement that the recipient of the benefit refrain from engaging in protected expressive activities. See, e.g., FCC v. League of Women Voters, 468 U.S. 364 (1984). Although cases such as League of Women Voters did not involve restrictions on commercial speech, the lead opinion in the recent case of 44 Liquormart Inc. v. Rhode Island, 517 U.S. 484 (1996), expressly invoked the unconstitutional conditions doctrine in striking down a restriction on commercial speech. See id. at 1513 (opinion of Stevens, J.).

Section 511(b)(3) [p. 142] provides that the "terms and conditions contained in the consent decrees described in subsection (a) shall include a provision waiving the federal or State constitutional claims of the parties and providing for severability of the provisions of the decree." The requirement that the consent decrees include a waiver of constitutional claims as a condition of the receipt of federal benefits would itself be subject to substantial constitutional challenge under the "unconstitutional conditions" doctrine. Cf. Louisiana Pac. Corp. v. Beazer Materials & Servs., Inc., 842 F. Supp. 1243, 1250-55 (E.D. Cal. 1994) (applying heightened scrutiny in upholding a settlement with the government that included a private party's waiver of a right to bring a constitutional challenge in the future); Clark v. County of Placer, 923 F. Supp. 1278, 1287-1288 (E.D Cal. 1996) (striking down provision in a settlement with the government that precluded a private party from bringing a constitutional challenge in the future). Indeed, the risk would arguably be greater here than it would be in the settlement context generally. The federal government would be conditioning the receipt of federal benefits by the manufacturers on their willingness to include waivers of their rights to bring constitutional challenges to speech restrictions contained in settlements to which the federal government is not even a party. For that reason, the federal government arguably would be unable to rely on the unique settlement context to justify the imposition of a condition that the decrees contain such speech restrictions. Accordingly, the significant constitutional concerns presented by conditioning benefits on the requirement that the decrees contain otherwise unconstitutional speech restrictions would not be alleviated by the further requirement that the decrees also contain provisions waiving the manufacturers' rights to bring future constitutional challenges to those restrictions. Indeed, such a

requirement might serve only to increase the grounds for constitutional challenge.

Sec. 512. National tobacco control protocol.

Sec. 513. Non-participating manufacturers.

Sections 513(b) [pp. 145-146] appears to heighten the risk of constitutional challenge under the "unconstitutional conditions" doctrine with respect to the provisions concerning the consent decrees. The provision would impose additional fees on manufacturers that do not enter into either a consent decree of the type contemplated by section 511 or the National Tobacco Control Protocol described in section 512. The provisions would therefore arguably serve to "penalize" manufacturers that chose not to accept any otherwise unconstitutional speech restrictions that S.1415 would require to be included as a term of their consent decrees with the States in order for the parties to them to receive the federal benefits.

As to manufacturers that do not enter into the consent decrees described in section 511, section 512 provides that "each tobacco manufacturer to which this Act applies shall enter into a National Tobacco Control Protocol that shall be "developed by the Secretary as a binding and enforceable contract that embodies the terms of this Act[.]" It appears that, notwithstanding the mandatory language of section 512, manufacturers would have the option of electing not to enter into the protocol, and thus that the protocol is intended to serve as a mechanism by which manufacturers may qualify for liability protections without entering into consent decrees with the States.[1] In addition to the protections that would be conferred on participating manufacturers by Title VI, sections 513 provides additional incentives for manufacturers to enter into the protocol by subjecting non-participating manufacturers to "an annual fee" of an unspecified amount to be determined by the Secretary, 513(b), and by requiring them to make higher payments into a Settlement Reserve Fund, 513(c).

To the extent that the protocol would contain terms and conditions that would place restrictions on expressive activity that would violate the First Amendment if imposed directly by statute, it, too, would be subject to substantial constitutional challenge under the "unconstitutional conditions" doctrine. Manufacturers would be required to comply with certain speech restrictions in order to be exempt from the increased payments to the federal government that they otherwise would be required to pay under sections 513 and 514 and to qualify for the liability protections described in Title VI. Accordingly, both the manufacturers who entered into the contracts and later wished to break them, and the manufacturers who did not wish to agree to the terms of the protocol in return for the federal benefits, would be positioned to challenge the terms of these provisions.

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[1] We note that S.1415 is somewhat confusing on this point both because section 512 contains mandatory language and because it does not identify the federal benefits that manufacturers would receive upon entering into the protocol. The benefits are instead set forth in Title VI, which confers liability protections only on manufacturers that have entered into the protocol.

Subtitle B--State Enforcement

Sec. 521. Requirement of no sale to minors law.

Sec. 522. State reporting.

Sec. 523. Reduction in State payments.

TITLE VI--PROVISIONS RELATING TO TOBACCO-RELATED CIVIL ACTIONS [pp. 156-162]

By virtue of section 511(a), manufacturers who enter into the consent decrees referenced in Title V would receive the liability protections set forth in Title VI (which erroneously cross-referenced to as Title VII), including, for example, a ban on class actions for certain claims. In addition, Title VI would provide manufacturers that had entered into the National Tobacco Control Protocol with the same protections against liability from claims that arise from the use of a tobacco product. Insofar as these protections would preempt state rules of procedure for state law causes of action in state court, they may be subject to substantial federalism-based constitutional challenges.

Sec. 601. General immunity. [pp. 156-158]

As an initial matter, section 601(a)(1) extinguishes pending "[c]ivil actions that have been commenced by a State or local governmental entity, or on behalf of such an entity against a manufacturer, distributor, or retailer that is a signatory to the National Tobacco Control Protocol.'" The provision should be amended to define with greater specificity the types of pending "civil actions" that would be extinguished. This might be accomplished by incorporating the language used in section 601(a)(2): "all claims arising from the use of a tobacco product."

Section 601(b) then extinguishes all pending "[c]lass actions for claims arising from the use of a tobacco product" against a manufacturer, and grants manufacturers that sign the protocol immunity from all such future actions. Section 602(c) further provides that "[n]o class action suits, joinder of parties, aggregation of claims, consolidation of actions, extrapolations, or other devices to resolve cases other than on the basis of individual actions shall be permitted without the consent of the defendant." These provisions would bar the use of class actions and other state court procedures for consolidating actions in connection with state law claims brought in state court.

' We note that the provision makes an erroneous cross-reference to section 612. The cross-reference should be amended to refer to section 512 in order to conform with the provision in S. 1415 that establishes the protocol.

Although there is no Supreme Court precedent directly on point concerning the constitutionality of federally imposed prohibitions on state court procedures for state law causes of action in state court, we believe that such prohibitions would be constitutional under the principles set forth in FERC v. Mississippi, 456 U.S. 742 (1982). The Court has repeatedly noted, however, that "[t]he general rule, bottomed deeply in belief in the importance of state control of state judicial procedure, is that federal law takes the state courts as it finds them." Johnson v. Fankell, 117 S. Ct. 1800, 1805 (1997) (internal quotations omitted). There are therefore risks that the provisions would be challenged on federalism grounds.

The substantial risks of federalism-based challenges that are raised by these provisions could be reduced if a state's compliance with them were made a condition on the State's receipt of federal funds, see South Dakota v. Dole, 483 U.S. 203 (1987), New York v. United States, 505 U.S. 144 (1992), or as a more limited alternative to the federal government's restriction on the sale of cigarettes within states, see FERC, supra. For example, the provision could state that the sale of cigarettes at other than adults-only locations is prohibited unless a State bars the availability of class actions, as well as the other procedures and remedies that are identified in Title VI, against participating manufacturers.

Alternatively, the risk of challenge could be minimized if the federal statute were to establish a federal mechanism for permitting recovery on claims against participating manufacturers that were related to the use of tobacco products. The federal statute could preempt all such claims unless they sought recovery from the monies that the manufacturers would be required to pay into a federal liability fund -- or otherwise to set aside -- as a condition on their qualifying for federal liability protections. The federal statute could provide that recovery of these reserved funds would be subject to the annual liability caps set forth in Title VI, as well as other recovery rules designed to ensure allocational equity within the substantive caps. These rules could include those that would preclude recovery of damages for claims that were brought as part of a class action or that were ordered pursuant to a finding of punitive damages.

This approach would accord with the constitutional principles that permit Congress to require state courts to adopt certain federal procedures as incidents of the federal causes of action that they entertain. Felder v. Casey, 487 U.S. 131 (1988); Dice v. Akron, C. & Y.R.Co., 342 U.S. 359 (1952). We believe that these same principles should also permit Congress to require state courts to adhere to certain federal procedures when entertaining state law claims that are subject to federally imposed substantive limitations on the damages that may be recovered upon a finding of liability. Cf. Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984) (state law punitive damages may be preempted). Thus, here, Congress could prohibit consolidated state law causes of actions in state courts as a permissible procedural incident of the substantive defenses against damages actions that federal law would provide to those tobacco manufacturers that had placed funds in reserve in order to provide payments for liability judgments.

The risk of a federalism-based challenge could also be reduced if the federal statute were to establish a federal cause of action for claims by smokers against manufacturers of tobacco

products that would supplant analogous state law causes of action but incorporate the existing state law standards of liability. See In re TMI, 940 F.2d 832 (3d. Cir. 1991), cert. denied, 503 U.S. 906 (1992) (discussing Price-Anderson Act). State courts entertaining these federal causes of action could then be required to adhere to the procedural limitations on consolidated actions when entertaining such suits. See Felder, supra; Dice, supra.

The provisions that would permit participating manufacturers to remove consolidated state law causes of action involving non-diverse parties to federal court would raise concerns regarding whether federal courts would possess "federal question" jurisdiction under Article III to hear them. See Verlinden B.V. v. Central Bank of Nigeria, 461 U.S. 480 (1993); In re TMI, supra. The risk would be reduced by establishing a federal cause of action as described above, see In re TMI, supra, or by providing for minimal diversity in such cases rather than for removal in all cases without regard to the diversity of parties.

Sec. 602. Civil liability for past conduct.

Sec. 603. Civil liability for future conduct.

Sec. 604. Non-participating manufacturers.

TITLE VII--PUBLIC DISCLOSURE OF HEALTH RESEARCH [pp. 162-169] (see Insert K - DoJ Documents proposal)

Title VII would establish a uniform federal scheme for compelling disclosure of documents held by tobacco companies. To secure the civil liability protections described in Title VI, tobacco companies would be required to deliver to a central depository documents pertaining to health research, addiction or dependency, safer tobacco products, and the relationship between advertising and youth smoking. Companies could withhold documents from the depository based on claims of attorney-client privilege, work product privilege, or trade secret protection, but these claims could be disputed by federal, state and local government officials and by members of the public. Disputes over tobacco claims of privilege from disclosure, whether raised in conjunction with the establishment of the tobacco document depository or in litigation, would be decided by a three-member dispute resolution panel. The panel would apply uniform federal standards. Attorney-client and work product privileges would be decided under the ABA/ALI Model Rules or "the principles of federal law." Trade secret claims would be decided under the Uniform Trade Secrets Act.

These provisions raise several constitutional concerns:

1. Compulsory disclosure of company documents could create a risk of significant takings liability, since companies could argue that the uniform federal trade secret standard, specified in the bill, failed to shield documents that would have been protected under otherwise applicable state-law standards. See Ruckleshaus v. Monsanto, 467 U.S. 986, 1003 (1984). Section 702(a)

of the bill appears to eliminate this risk by making consent to the federal document disclosure regime part of the price of civil liability protection under Title VI. Compare Ruckleshaus, 467 U.S. at 1007 (voluntary disclosure of trade secrets "in exchange for the economic benefit of [pesticide] registration can hardly be called a taking"). The bill, however, is not entirely clear on this point. Section 702(a) invites tobacco manufacturers to "establish and maintain" the document depository in order "[t]o be eligible to receive the protections provided under title VI." Although a manufacturer's decision to "establish and maintain" the depository presumably encompasses a decision to accept the federal document disclosure regime, other provisions of section 702 suggest that the disclosure rules are mandatory. Section 702(c) states that "manufacturers . . . shall provide" documents to the depository, not that "consenting manufacturers" shall do so. In addition, section 702(d) speaks of "documents required to be provided." If, as we assume to be the case, the drafters of S. 1415 intend to make document submission by manufacturers a condition of receipt of a federal benefit and not a mandatory obligation, sections 702(c) and (d) should be revised to clarify this point.

Title VII could also give rise to takings claims based on the compulsory disclosure of documents belonging to the Tobacco Institute and the Council for Tobacco Research, U.S.A. Although the bill apparently contemplates inviting tobacco manufacturers to submit documents to the depository in exchange for liability protection, the Council and Institute would be required to make such submissions without obtaining any corresponding benefit. The takings risk associated with these compulsory disclosures, however, would appear to be limited. It is likely that many of the documents that the bill would direct the Institute and Council to place in the depository have already been disclosed in litigation. It is also likely that few documents belonging to the Institute and Council would qualify for trade secret protection under state law but under the newly established uniform federal standard. Moreover, it seems likely that relatively few of the documents that the bill would require the Institute and Council to disclose would contain trade secrets of great commercial value. Nevertheless, the possibility exists that section 702 would compel the Institute and Council to disclose trade secrets that would have been protected from disclosure under otherwise applicable state law. In addition, wholesale compulsory disclosure of documents belonging to these entities, compelled by statute rather than by court-supervised discovery processes, might be treated as a compensable infringement on a constitutionally protected property interest.'

Apart from the risk of takings claims by the Institute and Council, we note that the compulsory disclosure provisions implicate the constitutional concerns regarding the First Amendment and Bill of Attainder Clause discussed in connection with the corporate culture provisions contained in Title I, Subtitle F.

' Compare Nixon v. United States, 978 F.2d 1269 (D.C. Cir. 1992) ("history, custom and usage" qualify presidential papers as personal property of the President, and abrogation of former President Nixon's rights to his papers, including most critically the right to exclude others, constitutes a taking).

2. Section 702(d)(3) provides that decisions of the dispute resolution panel will be "final and binding upon all Federal and State courts." This provision would require state courts to admit evidence, based on the federal panel's rejection of certain privilege and trade secret claims, that those state courts would otherwise exclude in cases premised on state-law causes of action. This provision could implicate the federalism concerns described in our discussion of the Title VI provisions that would preempt state procedures concerning consolidation of actions for state-law causes of action in state court.

3. The bill calls for the dispute resolution panel to be staffed by "Federal judges," appointed by the Judicial Conference of the United States (§ 702(d)(1)) and empowered to employ special masters (§ 702(d)(6)). If the bill is intended to ensure the broadest possible public participation in the resolution of document disclosure questions, the dispute resolution procedure could be revised to provide for initial determination by an administrative agency or Article I court, where individuals would not have to demonstrate Article III standing, followed by appropriate Article III review of disputes where the requirements of Article III standing could be satisfied.[19]

Sec. 701. Purpose.

Sec. 702. National Tobacco Document Depository.

TITLE VIII--ASSISTANCE TO TOBACCO GROWERS AND COMMUNITIES [pp. 169-219] (see Insert L - USDA comments)

Sec. 801. Short title; table of contents.

Sec. 802. Definitions.

SUBTITLE A--TOBACCO COMMUNITY REVITALIZATION TRUST FUND

Sec. 811. Establishment of Trust Fund.

Sec. 812. Contributions by tobacco product manufacturers and importers.

SUBTITLE B--AGRICULTURAL MARKET TRANSITION ASSISTANCE

Sec. 821. Payments for lost tobacco quota.

Sec. 822. Industry payments for all Department costs associated with tobacco production.

Sec. 823. Tobacco community economic development grants.

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[19] We are continuing to consider constitutional issues that may be raised by the structure and manner of appointment of the dispute resolution panel described in the bill.

Sec. 824. Modifications in Federal tobacco programs.

SUBTITLE C--FARMER AND WORKER TRANSITION ASSISTANCE

Sec. 831. Tobacco worker transition program. [pp. 197-204]

Section 831 of the bill provides for federal transition assistance to farmers and workers whose livelihoods are adversely affected by the bill's reform of the tobacco industry. The mechanism for determining workers' eligibility for this assistance includes a preliminary state-level review of requests for assistance. Section 831(b)(2) provides that upon receipt of a petition for assistance, each "Governor shall" notify the Secretary (of either Labor or Agriculture, the reference is obscure)" of the petition; complete and transmit to the Secretary a preliminary assessment of whether the petition satisfies the bill's eligibility criteria; and provide immediate assistance under other federal assistance statutes to workers who are preliminarily found to qualify for transition assistance. These gubernatorial responsibilities appear to be mandatory rather than elective. The bill does not characterize performance of these tasks as the price of federal benefits to the state government.

The bill might arguably be construed to afford governors the option of declining to perform any of the tasks listed in section 831(b)(2). The consequence of their refusal, on this reading, would be that affected workers in their states would not obtain Title VIII certifications or, as a consequence, transition assistance. If the mandatory reading of the governors' obligations is the correct one, section 831 would appear to effect an unconstitutional commandeering of the state's sovereign powers. See Printz v. United State, 117 S. Ct. 2365, 2383 (1997) ("The Federal Government may not compel the States to enact or administer a federal regulatory program." (quoting New York v. United States, 505 U.S. 144, 188 (1992)). Accordingly, if the governors' assistance in evaluating claims for transition assistance is deemed necessary, we recommend that the provision of this assistance be made a precondition to the states' receipt of specified federal funds.

Sec. 832. Farmer opportunity grants.

SUBTITLE D--IMMUNITY

Sec. 841. General immunity for tobacco producers and warehousers.

[p. 219]

" Section 802(5) indicates that within Title VIII the term "Secretary" refers to the Secretary of Labor in some instances and to the Secretary of Agriculture in others. However, because the cross-references in section 802(5) are obviously incorrect, it is unclear to which Secretary the Governors would report under section 831(b).

This provision should be amended to make clear that this "general immunity" does not apply to "an active tobacco producer, tobacco-related growers association, or tobacco warehouse owner or employee" who is **also** a "tobacco product manufacturer, distributor, or retailer."

TITLE IX--EFFECTIVE DATES AND OTHER PROVISIONS [pp. 220-228] (see Insert M - OMB comments; Insert N - OMB legislative language)

Sec. 901. Effective dates.

[pp. 220-222]

These appear to be generally acceptable; need to review more carefully (some of them may be insufficient, but FDA would taken individual circumstances into account in taking enforcement action).

Sec. 902. Native Americans.

Sec. 903. Preemption.

[p. 227]

Suggest modifying 903(a)--

- (a) GENERAL PREEMPTION- Except as otherwise provided for in this section, nothing in this Act shall be construed as prohibiting a State from imposing requirements, prohibitions, penalties or other measures to further the purposes of this Act that are ***equal to or*** in addition to the requirements, prohibitions, or penalties required under this Act. . .

Not clear whether it is the legislation's intent to exempt tobacco products from FDCA section 521, 21 U.S.C. § 360k, which preempts any state or local requirement with respect to a device which is different from, or in addition to, any requirement applicable under the FDCA to that device, or relates to the safety or effectiveness of the device. Under the FDCA, states and localities may apply for exemptions from preemption.