NLWJC - Kagan

DPC - Box 044 - Folder 008

Tobacco – Settlement: FDA Appropriations

Tob-sct-new Legis-Harkin amendment

(and)

SUPPORT HARKIN AMENDMENT TO FUND FDA'S ON-GOING TEEN SMOKING INITIATIVE

DRAFT

Tob-sct-FDA jurisdiction

Last fall, Congress overwhelmingly approved the Harkin-Chafee-Reed amendment to fund the on-going teen smoking initiative at FDA. The program is currently contracting with 45 states for fiscal year 1998 to ensure that children's access to tobacco products is restricted. However, at the current level of funding, states will only be able to check 20% of tobacco retailers for compliance with the law. The Committee bill only provides the FY 98 amount, $34 million, for the FDA's on-going teen smoking initiative. This is clearly not sufficient.

The amendment that I am offering to the Agriculture Appropriations bill builds upon and strengthens the FDA's on-going teen smoking initiative. It authorizes the FDA's efforts to combat youth smoking, it fully funds the initiative, and it provides for an annual national survey of youth tobacco use.

Authorizes FDA's Youth Anti-tobacco Initiative

This amendment simply reaffirms the FDA's jurisdiction over the product and authorizes the FDA's on-going teen smoking initiative, including restricting children's access to tobacco, regulating tobacco advertising and labeling, setting manufacturing and performance standards, and allowing the development of reduced risk products.

Fully Funds the Program

The amendment fully funds the FDA's youth anti-tobacco efforts by imposing a tobacco industry assessment of $20 per child who uses their products. This assessment would be based on an annual survey of 12-17 year olds to determine exactly which brands of tobacco children are using.

The assessment would raise approximately $100 million for FY 99, bringing the total in the bill to $134 million, the amount requested in the President's budget and the amount provided in S. 1415, the National Tobacco Policy and Youth Smoking Reduction Act. These funds would allow the FDA to provide increased resources for states to conduct compliance checks of tobacco retailers, increasing coverage from 20% to 60% of retailers. In addition, it would allow increased funding for education and outreach to retailers to ensure that they are aware of and comply with the ID check. Currently, FDA is only able to fund a four-week print media campaign in one media market in each state. With this amendment, they will be able to broaden the campaign to reach retailers throughout the state for a longer period of time. In addition, the amendment would provide funds for product regulation and enforcement of the advertising and marketing restrictions.

Authorizes Annual Youth Tobacco Survey

The amendment authorizes the Department of Health and Human Services to conduct a comprehensive, annual survey to provide more detailed accurate information on teen tobacco use, including information on teen tobacco use by brand. The survey will increase the number of young people surveyed and introduce computer assisted survey methods in order to improve the precision of the survey. The collection of precise data on youth tobacco use by brand will give parents new information and provide public health officials with new tools to address youth tobacco use. President Clinton has asked HHS to conduct such a survey.

O:\BAI\BAI98.G46 S.L.C.

DRAFT

AMENDMENT NO. ____ Calendar No. ____

Purpose: To provide authority to the Food and Drug Administration with respect to tobacco.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2159

Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 1999, and for other purposes.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. HARKIN

Viz:

At the end of the bill, add the following:

TITLE ____—FOOD AND DRUG ADMINISTRATION AUTHORITY OVER TOBACCO

SEC. ____01. ASSESSMENT ON MANUFACTURERS.

(a) IN GENERAL.—Not later than June 1 of each fiscal year, the Secretary of Health and Human Services (referred to in this title as the "Secretary") shall assess each manufacturer of tobacco products an amount equal to $20 multiplied by the number of individuals under 18 years

of age who used any tobacco product of such manufacturer in the preceding fiscal year, as determined using data gathered in the child tobacco use surveys under section ____02.

(b) DEPOSITS.—Amount collected under subsection (a) shall be deposited into the general fund of the Treasury.

(c) APPROPRIATION.—There are authorized to be appropriated in each fiscal year, and there are appropriated, an amount equal to the amount deposited into the Treasury under subsection (b) for that fiscal year, to be used by the Food and Drug Administration to carry out activities relating to tobacco under the Federal Food, Drug and Cosmetic Act.

SEC. ___02. CHILD TOBACCO USE SURVEYS.

(a) ANNUAL PERFORMANCE SURVEY.—Not later than January 1, 1999, and annually thereafter, the Secretary shall conduct a survey to determine—

(1) the percentage of all young individuals who used a type of tobacco product within the 30-day period prior to the conduct of the survey; and

(2) the percentage of young individuals who identify each brand of each type of tobacco product as the usual brand smoked or used within such 30-day period.

(b) YOUNG INDIVIDUALS.—For the purposes of this section, the term "young individuals" means individuals who are under 18 years of age.

(c) USE OF CERTAIN DATA OR METHODOLOGY.—

(1) IN GENERAL.—In carrying out this section, the Secretary may use the data collected through national surveys of young individuals. Such surveys shall—

(A) be based on a nationally representative sample of at least 20,000 completed interviews of young individuals;

(B) be on a household-based in person survey;

(C) measure the use of tobacco product within the past 30 days; and

(D) identify the usual brand of each type of tobacco product used within the past 30 days.

(2) CONCLUSIVE ACCURATENESS.—A survey using the methodology described in paragraph (1) shall be deemed conclusively proper, correct and accurate for purposes of this Act. The Secretary may, by notice and comment rulemaking, subsequently adopt a different survey methodology.

(3) FINAL DETERMINATION.—The determination of the Secretary as to the amount and allocation of an assessment under section ____01 shall be final and the manufacturer shall pay such assessment within 30 days of the date on which the manufacturer is assessed. Such payment shall be retained by the Secretary pending final judicial review of what, if any, change in the assessment is appropriate.

(4) REVIEW.—The amount of any assessment paid under section ____01 shall be subject to judicial review by the United States Court of Appeals for the District of Columbia Circuit, based on the arbitrary and capricious standard of section 706 of title 5, United States Code. Notwithstanding any other provision of law, no court shall have the authority to stay any payment due to the Secretary under section ____01 pending judicial review until the Secretary has made or failed to make a compliance determination, as described under this section, that has adversely affected the person seeking the review.

(5) NONAPPLICABILITY.—Chapter 35 of title 44, United States Code, shall not apply to information required for the purposes of carrying out this subsection.

(b) ADMINISTRATION.—

(1) TECHNICAL ADJUSTMENTS.—The Secretary may make technical changes in the manner in which the surveys are conducted under this section to reflect improved methodology so long as adjustments are made to ensure that the results of the surveys are comparable from year to year.

(2) PARTICIPATION IN SURVEY.—Notwithstanding any other provision of law, the Secretary may conduct a survey under this section involving minors if the results of such survey with respect to such minors are kept confidential and not disclosed.

(c) TOBACCO PRODUCT.—For the purposes of this title, cigarettes, cigars, little cigars, smokeless tobacco, and roll-your-own tobacco shall each be considered as a separate type of tobacco product.

(d) DE MINIMIS RULE.—The Secretary shall not impose an assessment on a manufacturer under section ____01 with respect to a type of tobacco product if the Secretary determines that the percentage of young individuals using such tobacco product (as determined using the annual surveys conducted by the Secretary under this section) is less than 0.5 percent of the total number of young individuals determined to have used tobacco products in the year involved.

(e) ASSESSMENTS NONDEDUCTIBLE.—The payment of assessment under this title shall not be considered to be an ordinary and necessary expense in carrying on a trade or business for purposes of the Internal Revenue Code of 1986 and shall not be deductible.

(f) JUDICIAL REVIEW.—A manufacturer of tobacco products may seek judicial review of any action under this title only after the assessment involved has been paid by the manufacturer to the Department of the Treasury and only in the United States District Court for the District of Columbia.

SEC. ___03. STATEMENT OF GENERAL AUTHORITY.

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

SEC. ___04. NONAPPLICABILITY TO OTHER DRUGS OR DEVICES.

Nothing in this title, or an amendment made by this title, shall be construed to affect the regulation of drugs, devices, or other products that are not tobacco products by the Secretary under the Federal Food, Drug and Cosmetic Act.

SEC. ___05. CONFORMING AMENDMENTS TO CONFIRM JURISDICTION.

(a) DRUG.—Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (g)(1)) is amended by striking "and (D)" and inserting "(D) nicotine in tobacco products, and (E)".

(b) DEVICE.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—

(A) in paragraph (2), by striking "or" at the end;

(B) in paragraph (3), by striking "and" at the end and inserting "or"; and

(C) by inserting after paragraph (3), the following:

"(4) nicotine-containing tobacco products, and".

(c) RESTRICTED DEVICES.—Section 520(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by striking "or use—" and inserting "or use, including restrictions on the access to and the advertising and promotion of, tobacco products—".

Tob-ser- FDA jurisdiction

March 24, 1998
tob.sep

SPECS FOR FDA AUTHORITIES

Definition: "Tobacco products defined to include any product made from tobacco intended for human consumption; must give FDA authority to expand jurisdiction to cigars, etc.

Validation of FDA Rule: Provisions in rule deemed to have been lawfully promulgated; language similar to Conrad; establish effective date.

General Authority Over Distribution of the Product and Advertising: Secretary may by regulation require that a tobacco product be restricted to sale, distribution, or use upon such conditions (including conditions relating to advertising and promotion) as the Secretary may prescribe.

Authority Over the Product –

a) Existing Products: FDA may, using notice and comment rulemaking, issue standards regarding products, ingredients and components; authority to require premarket review of existing products, for example if safer alternative becomes available.

b) New products: FDA may issue standards or where the product is substantially different from products on the national market; may require premarket review.

c) Standard for a) and b) would be one that requires the Secretary to reach best public health result; prior to making any decision to reduce nicotine or to eliminate product, FDA would take into account number of factors, including black market.

d) Miscellaneous

1) Authority to require reporting of deaths and illnesses and record keeping

2) Good manufacturing practices

3) Postmarket surveillance

***Enforcement* and Related Authorities:**

a) Violation of requirement under the Act relating to tobacco would constitute specified prohibited Acts under section 301, subjecting violator to criminal and injunctive penalties.

OPTIONAL FORM 99 (7-90)
FAX TRANSMITTAL # of pages ▶ 2

To Rich Tarplin	From Bill Schultz
Dept./Agency	Phone #
Fax #	Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

b) Civil money penalties as in section 303(f) -- could probably add tobacco products, as pesticides was added in 1995.

c) Seizure without any interstate commerce requirement as in section 304(a)(2).

d) Prohibition on products that are adulterated or misbranded; specified adulteration and misbranding standards to be included..

e) Recall -- modeled after 519(e) but discretionary; standard probably should relate to a defect in the product; require notification of defective product.

f) Plant and record inspection drafted into section 704, as in Jeffords bill.

g) Interstate commerce -- presumption as in section 709 (or define to limits of Constitution**); add tobacco to sections 703, 705.

h) Authority to require premarket approval of all health-related claims.**

i) Authority to administer oaths and to require production of documents.**

j) Publicity -- add tobacco to section 705.

Warning Label -- Settlement as drafted in Conrad bill.

Other issues:

Preemption

Licensing

Import--Export

** Not in current device law.

II. Elements Necessary to Regulate Tobacco Products Through a New Chapter

A. *Essential Elements for a New Chapter (or Subchapter)*

Section 501, 21 USC § 351, Adulteration: Need a subsection similar to the device provisions of (a), which addresses poisonous, insanitary, ingredients, and adequate controls in manufacture. Need a subsection similar to (e), which addresses devices not in conformity with performance standards. Need a subsection similar to (f), which addresses premarket review. Need a subsection similar to (h), which addresses products not in conformity with good manufacturing practice requirements. Need a subsection similar to (i), which addresses products not in compliance with applicable investigational use requirements.

Section 502, USC § 352, Misbranding: Need a subsection similar to (a), which addresses false and misleading labeling. Need a subsection similar to (b), which addresses packaging and labeling requirements. Need a subsection similar to (c), which addresses prominence requirements for labeling information. Need a subsection similar to (e)(2), (e)(4), which addresses established names. Need a subsection similar to (o), which addresses products from nonregistered establishments. Need a subsection similar to (q), which addresses compliance with restrictions on devices. Need a subsection similar to (r), which addresses statements required of restricted devices and other disclosure requirements. Need a subsection similar to (s), which addresses labeling requirements applicable to products subject to a performance standard. Need a subsection similar to (t), which addresses notification, record-keeping and reporting, and postmarket surveillance requirements.

Section 510, 21 USC § 360, Registration: Need provisions requiring manufacturers to register so that FDA knows that they are operating are needed, similar to subsections (a), (b), (c), (d), (f), (h), (i).

Section 514, 21 USC § 360d, Performance standards: Need to enact authority for performance standards that incorporates the best public health result standard.

Section 515, 21 USC § 360e, Premarket approval: Need to develop a provision that authorizes FDA to require premarket review under certain circumstances.

Section 517, 21 USC § 360g, Judicial review: May need a similar provision that establishes requirements and procedures for review of performance standards, and other actions under the device provisions.

Section 518, 21 USC § 360h, Notification and other remedies: Need a provision for recall authority that is a modification of (e). May also need notification provisions similar to (a) and (d).

Section 519, 21 USC § 360i, Records and Reports: Need provisions that are similar to subsections (a) and (d), and are consistent with the FDA tobacco rule application of this section. Under the rule, reports are required from tobacco manufacturers only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process, and from distributors only for adverse events related to contamination. Also need a provision similar to (f), which provides for reports of removals and corrections.

Section 520, 21 USC § 360j, General provisions respecting control of devices intended for human use: Need provisions similar to (c), which deals with trade secret information; (d), which deals with notice and findings for certain agency actions. Need a provision similar to the relevant portions of (e), the restricted device authority. Need a provision similar to (f), the good manufacturing practice requirement authority. Need provisions similar to (g), which deals with investigational activities; (i), which addresses the proceedings of advisory committees and panels.

Section 522, 21 USC § 360l, Postmarket surveillance: Need a provision that allows postmarket surveillance under certain circumstances.

B. *Conforming Amendments to General Provisions of the FDCA*

1. Prohibited Acts and Penalties.

Section 301, prohibited acts: The words "tobacco product," or "or tobacco product", as appropriate, need to be inserted after "device" in the following subsections: (a), which addresses the introduction of adulterated or misbranded products into interstate commerce; (b), which addresses the adulteration or misbranding of a product; (c), which addresses the receipt in interstate commerce of an adulterated or misbranded product; (g), which addresses the manufacture of a misbranded or adulterated product; (h), which addresses the giving of a false guarantee for purposes of section 303(c); (k), which addresses the alteration or labeling that results in the product being adulterated or misbranded. Several new provisions are necessary. Need a provision similar to (l), which deals with premarket review requirements. Need a provision similar to (q), which deals with or notification, record-keeping and reporting, and postmarket surveillance requirements. Need a provision similar to (p), which deals with manufacturer registration requirements. If have detention authority under 304, need to have a provision similar to (r).

Section 303, 21 USC 333, Penalties: Need to amend (f)(1)(A) to include "or tobacco products" after "devices" so as to allow FDA to continue its civil money penalty authority. Also, should amend (B) to exclude tobacco provisions that correspond to the device violations exempted under this provision.

Section 304, 21 USC 334, Seizure: Need to add a new section (E) to (a)(2): "Any adulterated or

misbranded tobacco product" so as to provide seizure authority. Need to amend (d)(1) to add "tobacco product," after "device," so as to provide for disposition of the goods after condemnation. There may need to be other modifications depending on the export provision adopted for tobacco products. If want administrative detention authority for devices to be available for tobacco products, need to amend (g).

A new provision for compulsory process for tobacco products would be appropriately located in a new section 308.

2. General Authority.

Section 703, 21 USC 373, Records of Interstate Shipment: Need to add "tobacco products," after "devices" each time that it appears, so as to provide authority to obtain records of interstate shipment.

Section 704, 21 USC 374, Inspection: To provide FDA with full inspectional authority need to: add "tobacco products," after "devices" each time that it appears in (a)(1)(A); add "or tobacco products that are restricted under section ___" after "restricted devices" in (a)(1)(B); and add "tobacco product," after "devices," in (b).

Section 705, 21 USC 375, Publicity: To authorize FDA to disseminate information in the event of situations involving imminent danger to health, need to add "tobacco product," after "device" in (b).

Section 709, 21 USC § 379a, Presumption of existence of jurisdiction: Need to add "or tobacco product" after "device".

3. Imports and Exports.

Section 801, 21 USC § 801, Imports: Need to add "tobacco products," after "devices," in subsection (a) to allow FDA authority over tobacco product imports.

Sections 801(e) and 802, Exports: Need a provision allowing export of tobacco products that do not meet the requirements of the FDCA.

4. Miscellaneous.

Section 903, FDA: Need to add "tobacco products" after devices in (a)(2)(C) to expressly authorize FDA to conduct research relating to these products.

III. Language to maintain existing regulations, precedent, and authorities

With respect to the 1996 regulations, the following may be sufficient—

> 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 lawfully and properly promulgated under sections ___ of the Food, Drug and Cosmetic Act as amended by this title.

Exploring whether general device regulations and precedent could made to apply under a new sub/chapter.

IV. Other factors to consider when reducing nicotine or eliminating products besides black market:

- impact on health of adolescent tobacco users
- impact on health of adult tobacco users
- impact on health of non-tobacco users

Prescription
Prohibition on tob. products

Tobacco - re - FDA jurisdiction

DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE GENERAL COUNSEL
PHONE: 202/690-7741
FAX: 202/690-7998

I told Harriet to give this to you through Rich

TO: Elena Kagan

DATE:

DEPARTMENT/OFFICE:

PHONE:

FAX: 456-2878

FROM: HARRIET S. RABB
GENERAL COUNSEL

COMMENTS: Tobacco Legislation

Please deliver ASAP

PAGES INCLUDING COVER: 4

Amendment No._____ **Calendar No._____**

Amendment to Committee Amendment to S. 1415

Purpose: ensure that Congress has the ability to review all regulations promulgated under this Act pursuant to its authority under the Congressional Review Act.

In the Committee on Commerce, Science, and Transportation

Amendment to be proposed by Mrs. Hutchison

Viz:

On page 2, ~~line 17, strike the following:~~

(c) FDA Rule in Effect. --- The provisions of part 897 of title 21, Code of Federal Regulations, shall be deemed to be lawful and to have been lawfully promulgated under the authority of this chapter. The provisions of such part that are not in effect on the date of enactment of this chapter shall take effect ~~as if such part of~~ upon such later date as determined by the Secretary by order.

(d) Regulations required to be issued. --- In lieu of issuing any regulations required to be issued under this chapter, the Secretary may by order make any regulations issued under this Act for parallel provisions elsewhere in the Act applicable to tobacco products covered by this Chapter.

and insert the following:

(c) Congressional Review. ---- In accordance with section 801 of title 5, United States Code, Congress shall review, and may disapprove, any rule ~~of the Secretary proposed~~ under this Act.

bill that is subject to section 801.

establish an effective date for

Nothing in this ~~Act~~ bill shall ~~delay~~ ~~effective~~ provisions of such part that are in litigation,

~~[Any Board take for purposes that litigation.]~~

~~Upon Completion of litigation~~ ^ those provisions that are not in effect on the date of enactment of this chapter shall take effect ~~[illegible]~~ upon such later date as determined by the Secretary by order.

47570 Larry Dirita
42060 Lisa Jaeger

The provisions of part 897 of title 21, Code of Federal Regulations issued on August 28, 1996, shall be deemed to be lawful and to have been lawfully promulgated under the authority of this chapter. Nothing in this bill shall be deemed to establish an effective date for provisions of such part that are in litigation. Consistent with the litigation, those provisions that are not in effect on the date of enactment of this chapter shall take effect upon such later date as determined by the Secretary by order.

Tob - cr - FDA jurisdiction

MM - Need new preemption division?
Non-tobacco ingredients

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Section 502, USC § 352, Misbranding: Need a subsection similar to (a), which addresses false and misleading labeling. Need a subsection similar to (b), which addresses packaging and labeling requirements. Need a subsection similar to (c), which addresses prominence requirements for labeling information. Need a subsection similar to (e)(2), (e)(4), which addresses established names. Need a subsection similar to (f), which relates to adequate directions and warnings against certain uses on the labeling. Need a subsection similar to (o), which addresses products from nonregistered establishments. Need a subsection similar to (q), which addresses compliance with restrictions on devices. Need a subsection similar to (r), which addresses statements required of restricted devices and other disclosure requirements. Need a subsection similar to (s), which addresses labeling requirements applicable to products subject to a performance standard. Need a subsection similar to (t), which addresses notification, record-keeping and reporting, and postmarket surveillance requirements.

Section 510, 21 USC § 360, Registration: Need provisions requiring manufacturers to register and provide FDA with certain information, similar to subsections (a), (b), (c), (d), (f), (h), (I), (k).

Section 514, 21 USC § 360d, Performance standards: Need to enact authority for performance standards that would be based on the best public health result.

Section 515, 21 USC § 360e, Premarket approval: Need to develop a provision that authorizes FDA to require premarket review under certain circumstances.

Section 517, 21 USC § 360g, Judicial review: May need a similar provision that establishes requirements and procedures for review of performance standards, and other actions under the device provisions.

Section 518, 21 USC § 360h, Notification and other remedies: Need a provision for recall authority that is a modification of (e). Also need notification provisions similar to (a) and (d).

Section 519, 21 USC § 360i, Records and Reports: Need provisions that are similar to

subsections (a) and (d). Under the rule, reports are required from tobacco manufacturers only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process, and from distributors only for adverse events related to contamination. Also need a provision similar to (f), which provides for reports of removals and corrections.

Section 520, 21 USC § 360j, General provisions respecting control of devices intended for human use: Need provisions similar to (d), which deals with notice and findings for certain agency actions. Need a provision similar to (f), the good manufacturing practice requirement authority. Need provisions similar to (g), which deals with investigational activities; (i), which addresses the proceedings of advisory committees and panels; and (k), which addresses contracting for research and testing activities.

Need a provision similar to the relevant portions of (e), the restricted device authority, that expressly authorizes allows the Secretary by regulation to require that a tobacco product be restricted to sale, distribution, or use upon such conditions (including conditions relating to advertising and promotion) as the Secretary may prescribe.

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A new provision for compulsory process for tobacco products would be appropriately located in a new section 308.

2. General Authority.

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IV. Additional authorities

Authority to require premarket approval of all health-related claims.

Tobacco - int — FDA jurisdictic

FDA legal issues -

① Ban on mail orders - They are consist. w/ where we are

② Behind-the-counter - can't do - change of our rule.

③ Farms/warehouses - Can we reach?

??? X the IT to suspicion of illegalities affecting public health

conds, practices, or circumstances on farms

Harder to do - usually associated w/ tobacco use.

will not inspect on farms unless it has partic

reason to believe that conds, circs, & practices pose

a public health risk to public health not typically associated

with tobacco use.

④ Black markets -- McCain desire -- In making any decision -

of issuing a standard to change the product, have to take

into acct all comments, including enforcement.

⑤ Prescription - give up. ⑥ Limitation on outlets - NO

⑦ Ban the class of products or decision to eliminate nicotine

definition - section

sit in Congress for 2 yrs.

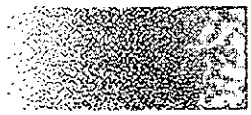
language - Cong has op to review

⑧ GMP - ok - not subject to FDA control ⑨ Acetate - not for live use -

Then waiver

Give up on subpoenas

Tobacco- settlement- FDA jurisdiction



Jerold R. Mande

02/02/98 07:10:46 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Hot Tobacco Items

1. DoJ is scheduled to testify this Thursday before a House Judiciary oversight hearing regarding the civil liability portions of the proposed tobacco settlement. DoJ has alerted OMB that we probably won't see the testimony until Wed. I have alerted OMB that this is a sensitive subject, and it would be helpful to know who is testifying and the lead in their testimony by tomorrow.

2. Sen. Jeffords in planning to introduce his tobacco bill on Thursday with an FDA section that contains many of the problems the 6/20 deal had plus a lot of new problems that someone clever has thought up. Jeffords is also on record saying he wants to move tobacco legislation that can be reported out of his committee 18-0. We should consider whether we want to send a message directly to Jeffords (not his staff) about the problems with his bill. I believe it is important we do this before he introduces the bill. It will be a significant setback to comprehensive tobacco legislation if Jeffords goes on record supporting the approach to tobacco regulation outlined in his bill. Jeff Teitz on Kennedy's staff has urged us to contact Jeffords.

Message Sent To:

Bruce N. Reed/OPD/EOP
Elena Kagan/OPD/EOP
Christopher C. Jennings/OPD/EOP
Donald H. Gips/OVP @ OVP
Thomas L. Freedman/OPD/EOP
Toby Donenfeld/OVP @ OVP
Sarah A. Bianchi/OPD/EOP
Virginia N. Rustique/WHO/EOP

tobacco settlement - FDA jurisdicti

DRAFT 9/5/97; FOR DISCUSSION PURPOSES ONLY

PROPOSED RESOLUTION/NON-TOBACCO INGREDIENTS

SCOPE - Legislation would apply to all ingredients, substances and compounds (other than tobacco, water and reconstituted tobacco sheet made wholly from tobacco) added by the manufacturer to the tobacco, paper or filter of the tobacco product.

PROCEDURES - Within 12 months of the effective date of legislation, FDA would be required to promulgate regulations relating to the reporting, testing, evaluation and disclosure of all covered additives.

GENERAL PROVISIONS - The substantive requirements for covered additives would be as follows:

Reporting and Disclosure

- Reports to FDA, on a confidential basis, of all additives by-brand, together with specific amounts used. Reports to be updated as and when additives change.

- Disclosure to public on a by-brand basis by means other than on packages, such as inserts or general publications. Disclosure in descending order by quantity, with same exceptions as under food regime (i.e., flavorings and additives with no effect on finished product). FDA may challenge assertions that an additive is exempt from disclosure.

- FDA may require disclosure of additives otherwise exempt if such additives have already been disclosed for the relevant brand in order to comply with law of another jurisdiction.

Testing and Evaluation

- For each additive in use as of date of enactment, manufacturer must submit safety assessment.

- All safety assessments must be submitted within 5 years of enactment (4 years after latest date regulations may be issued) to allow both manufacturers and the agency time to comply with applicable standard. Manufacturers should submit assessments on a rolling basis as they are completed within reasonable time frame after regulation is finalized (e.g., @ 25% per year by the end of the second through fifth years after enactment).

- FDA may disapprove the use of such additives pursuant to a statutory standard.

- After 5 year period, no additive may be used if a safety assessment has not been submitted.

- Any proposed additives not in use as of enactment date require prior evaluation by FDA; statutory timetable for agency action. Same as to any proposed increase in use level of currently used additive above amount specified in safety assessment.

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Tobacco: FDA appropriations

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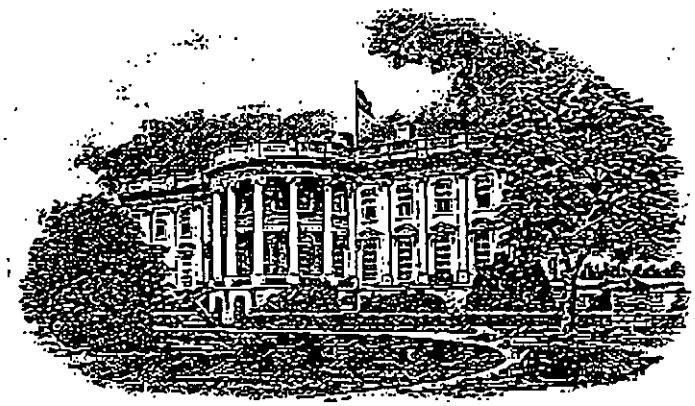

TO: Elena Kagan
Dom. Policy

FROM: Kay Casstevens

DATE: _____

number of pages including cover: 4

COMMENTS: Urgent, per e-mail

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_____

- Breaux
- Bryan
- Cleland (GA)
- Daschle
- Hollings (don't bother)
- Inouye
- Landrieu
- Moynihan
- Reid
- Robb
- Harkin Braun

Talk to D's staff

United States Senate

WASHINGTON, D.C. 20510

July 22, 1997

Dear Colleague:

The Agriculture Appropriations Bill that will soon be on the Senate floor represents a laudable effort under difficult circumstances, but it contains a glaring shortfall. The Food and Drug Administration's budget requested $34 million for enforcement and outreach efforts in all 50 states to carry out rules to prevent kids from purchasing tobacco. The reported bill provides only $4.9 million for this purpose, the same as last year and far too little for an effective nationwide effort to help America's children avoid the deadly trap of tobacco. We are asking your support for a floor amendment we will be offering to provide the full funding needed for FDA's critically important efforts to prevent youth smoking.

Nearly 90 percent of adult smokers began at or before age 18. Today, just like every day of the year, another 3,000 of our young people will become regular smokers, 1,000 of whom will die prematurely because of their smoking. At current rates, more than 5 million children under age 18 who are alive today will be killed by smoking-related disease.

In August of 1996, FDA issued rules implementing a plan to reduce the number of children who begin smoking. The centerpiece of this plan is enforcement of provisions that set a national legal age of 18 for the purchase of tobacco products and require retailers to check photo I.D.s of consumers seeking to purchase tobacco who appear to be younger than 27 years of age. FDA needs the full $34 million to implement the minimum age and photo I.D. rules, which were fully upheld by the federal district court in Greensboro, North Carolina. The FDA initiative is not a big new federal program. The bulk of the money will go directly to support state and local efforts.

Our amendment provides an offset within the Agriculture Appropriations Bill of $34 million obtained through increasing the tobacco marketing assessment from the current one percent of the national price support level to 2.1 percent for the 1998 crop of flue-cured tobacco and the 1997 crop of burley and other tobacco. The full cost of the increase would be borne by purchasers of tobacco. In addition, for tobacco covered by the amendment, the half of the current one-percent assessment now paid by producers would be shifted to purchasers, thus providing assessment relief to tobacco farmers.

FDA's initiative against youth smoking was begun long before the tobacco settlement talks even started. The minimum age and photo I.D. check rules are in place and are working, but there is a pressing need for more funding to allow all 50 states to carry out youth smoking prevention efforts. With the evidence we now have regarding the epidemic of teen smoking and its implications for the future, there is no excuse for delaying full implementation of this critical program. We should not await the uncertain fate of the tobacco settlement before putting the necessary resources into FDA's enforcement and outreach efforts against underage smoking. At the same time, adopting our amendment would in no way prejudice or in any way affect the outcome of any legislation designed to implement the settlement.

Sincerely,

Tom Harkin

John H. Chafee

Frank R. Lautenberg

FUNDING FOR FDA YOUTH TOBACCO INITIATIVE

* The amendment would raise $34 million in fiscal 1998 so that FDA, working with the states, can carry out rules to prevent kids from smoking. It is a drop in the bucket compared to the $50 billion that tobacco drains from our health care system each and every year.

* If we can prevent kids from smoking we can head off a tremendous amount of human disease and suffering, medical costs and loss of life. Even tobacco companies say they are against kids smoking.

  * But look at the facts: 4.5 million kids age 12-17 are smokers today and high school seniors are smoking at the highest rate in 17 years.

  * Nearly 90 percent of adult smokers began at or before age 18. Today, just like every day of the year, another 3,000 young people will become regular smokers. A thousand of them will die prematurely because of their smoking.

  * If current rates continue, more than 5 million children under age 18 who are alive today will be killed by smoking-related disease.

* A root cause of this youth smoking plague is the easy access kids have to tobacco. Studies have shown that children and adolescents were able to buy tobacco products 67 percent of the times they tried. Kids buy $1.26 billion of tobacco products each year.

* FDA has adopted rules to cut illegal sales to minors by setting a national legal age of 18 for purchase of tobacco products and requires retailers to check photo I.D.s of consumers seeking to purchase tobacco who appear to be younger than 27 years of age. The authority of FDA to carry out these rules was fully upheld by the federal district court in Greensboro.

* And the American public overwhelmingly supports putting a stop to illegal sales of tobacco to minors. According to a new poll, 92 percent of Americans agree that young people should be required to show a photo I.D. to buy tobacco products. 87 percent agree with the FDA rule setting a national minimum age of 18 for buying tobacco and mandating I.D. checks of all tobacco purchasers appearing to be under age 27.

* The President's FDA budget request includes $34 million for carrying out the legal age and photo I.D. rules upheld by the Court in Greensboro. Of that amount, $24 million will be used for enforcement, with most of these funds going to state and local officials for carrying out the rule. The remaining $10 million will be used for outreach efforts, including educating retailers about the rule.

* Providing FDA full funding for this initiative is essential. As the

letter from Secretary Shalala makes clear, the full $34 million is needed to carry out the age and photo I.D. rules. "Without these funds, FDA will not have the credible national enforcement program required to reduce significantly young people's access to tobacco."

* A letter from former Surgeon General C. Everett Koop and another from 33 attorneys general urge full funding of the $34 million for FDA's youth smoking initiative. Dr. Koop says it best: " A vote against the funding is a vote with the tobacco industry and its campaign to lure kids into the deadly addiction."

* The offset for the amendment is simple and well-focused. It provides a small increase for FY 98 in the current marketing assessment on tobacco to raise the full $34 million for funding the FDA youth tobacco enforcement and outreach effort.

* The increase will be paid for entirely by the tobacco companies that purchase domestic tobacco and import foreign tobacco. The cost of this initiative will be placed squarely on those who profited by selling tobacco to young people, not on the tobacco farmer and not on taxpayers.

* The amendment is also crafted to relieve tobacco farmers of their current obligation to pay half of the marketing assessment on the tobacco covered by the amendment. This amendment says the tobacco companies will pay the whole assessment, including the increase.