NLWJC - Kagan

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Tobacco-Settlement: FDA Jurisdiction Product Regulation [1]

Withdrawal/Redaction Sheet
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Phone No., Address (Partial) (1 page)	11/20/1998	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elena Kagan
OA/Box Number: 14367

FOLDER TITLE:
Tobacco - Settlement: FDA Jurisdiction Product Regulation [1]

2009-1006-F
ke675

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Tob - ret - FDA jurisdiction

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release April 26, 1999

STATEMENT BY THE PRESIDENT

I am very pleased that the Supreme Court has agreed to take up the case regarding the Food and Drug Administration's regulation of tobacco products. Almost three years ago, the FDA put in place a regulation to protect our children from tobacco, which the tobacco companies challenged in court. Every day, 3,000 young people become regular smokers and 1,000 will have their lives cut short as a result. I remain firmly committed to the FDA rule, which will help stop young people from smoking before they start by eliminating advertising aimed at children and curbing minors' access to tobacco products.

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Tob - set - FDA jurisdiction

Scott D. Ballin JD
Tobacco and Health Policy Consultant
P6/(b)(6)
e-mail: s.ballin@ix.netcom.com

[001]

~~*CONFIDENTIAL*~~

DETERMINED TO BE AN ADMINISTRATIVE MARKING Per E.O. 12958 as amended, Sec. 3.3 (c)
Initials: KDE Date: 05/31/2010
2009-1006-F

November 16,1998

TO: Public Health Advocates Interested in FDA Regulation of Tobacco Products

FROM: Scott D. Ballin
Consultant for the ALA

SUBJECT: Legislation and Strategies to Ensure Full FDA Authorities Over Tobacco Products---A Proposal

Over the last several months, on behalf of the American Lung Association but in the interests of the entire public health community, I have spent time talking with a number of people about what FDA tobacco legislation should look like as well as strategies that might be employed to accomplish implementation of this goal. These individuals were approached, not on the basis of the organizations they represent but rather based on their expertise and past experiences on the issue. Their involvement has been invaluable in attempting to develop a piece of legislation that ensures that all of the 'I's' have been dotted and all of the 'T's' have been crossed; and to sort out and devise some suggested strategies. What came across loud and clear is that a legislative proposal needs to be comprehensive and at the same time simple; that the FDA should be given the authorities it needs to get the job accomplished and that Congress should not "micromanage" the agency. (i.e. medical and scientific decisions should be left to experts and not politicians). What also came across loud and clear was the view that we should not give up on the notion that tobacco products are and should be treated as the drugs and devices they are.....recognizing however, that we may have to consider a 'separate chapter' approach. Their advice was also invaluable in trying to focus on how the public health community might be united and coordinated more effectively, not just in Washington but across the country and at the grassroots level.

FDA REGULATION OVER TOBACCO PRODUCTS AS DRUGS AND DEVICES

"A proposal"

LEGISLATION AND STRATEGIES FOR THE 106TH CONGRESS

Prepared by Scott D. Ballin for the American Lung Association and in the interests of the entire public health community

Table of Contents

PART I

THE LEGISLATION

OBJECTIVES:

- To develop legislation that will give the Food and Drug Administration full authority over the regulation of the manufacture, sale, distribution, labeling, advertising and marketing of all tobacco products as drugs and devices under the FD & C Act.

- To ensure that such legislation contains a funding source that allows the FDA to carry out its responsibilities to ensure full regulation of tobacco products

- To ensure that the regulation of tobacco products are part of a comprehensive regulatory framework of drugs and devices and in particular the regulation of therapeutic nicotine delivery devices and other treatments and management for nicotine dependence.

- To ensure that the public health community is committed to a specific legislative proposal for FDA regulation prior to the beginning of the 106th Congress so that such a bill cannot be or should not be amended or watered down.

- To draft the legislation in such a way that it can either be a 'free standing' proposal or can easily be included in a broader legislative package.

- To begin the process to gain House and Senate bipartisan support for such legislation.

- To educate and mobilize grassroots activities designed to work towards passage of legislation as well as putting members of Congress on notice that they will be held accountable in the next election cycle for their failure to support this effort.

- To ensure that this issue is conveyed to the public as one that should be and is supported by both republicans as well as democrats.

- To send a strong message to the FDA, HHS and the White House that full and complete FDA regulatory authorities over tobacco products is essential.

The Fairness in Tobacco and Consistency in Nicotine Regulation Act

WHAT THIS PROPOSED LEGISLATION DOES

1. It provides the Food and Drug Administration authority to regulate all products, which are sold in interstate commerce and contain tobacco as "drugs" and "devices" under the Federal Food Drug and Cosmetic Act.
2. It does this by defining tobacco products as any article or a component of any article, which contains tobacco leaf, homogenized leaf or a tobacco by-product.
3. It amends the act to include tobacco products under the definition of both "drugs" and "devices" under the Act (Section 201)
4. It allows the FDA to establish regulations in order to protect the public health to the maximum extent feasible but does not allow the FDA to ban tobacco products on the sole basis that they are addictive and cause disease.
5. It requires that the regulation of tobacco products be part of a broader, comprehensive, and more consistent regulatory scheme related to the use, abuse and cessation of tobacco products including products designed for treating nicotine dependence.
6. It establishes a Tobacco and Drug Advisory Committee to the Commissioner to assist the agency in working through the many complex, scientific, medical and legal issues related to the regulation of tobacco products.
7. It establishes a tobacco product user fee in order to support the FDA's regulatory and educational programs related to tobacco.
8. It repeals the Federal Cigarette Labeling and Advertising Act as well as the Comprehensive Smokeless Tobacco Health Education Act.
9. It provides the FDA and the Tobacco and Drugs Advisory Committee with temporary subpoena powers to call witnesses and obtain documents etc., that will assist the Committee in carrying out its activities.
10. It clarifies that while FDA jurisdiction pertains to manufactured tobacco products, nothing would prevent the FDA from taking action to remove a product from the market if the manufactured product presented public health problems caused by or during the agricultural production.

WHAT THIS PROPOSED LEGISLATION *DOES NOT DO*

1. It does not allow the FDA to ban tobacco products on the sole basis that such products cause disease and/or are addictive.

2. It does not limit any of the FTC's existing authorities to regulate unfair and deceptive trade practices under the Federal Trade Commission Act.

Note:-This is a **draft** and is intended to represent the primary outline of legislation.

H.R.

In the House of Representatives

A BILL

To amend the Federal Food Drug and Cosmetic Act to establish fair standards for the manufacture, labeling, sale, distribution, advertising and promotion of tobacco products as drugs and or devices, to implement a comprehensive regulatory policy for all consumer products containing nicotine, and for other purposes.

Be it enacted by the Senate and the House of Representatives of the United States in Congress Assembled,

Sec. 1. **SHORT TITLE**

(a) Short title – this Act may be cited as the "Fairness in Tobacco and Consistency in Nicotine Regulation Act of 1999."

Sec. 2 **FINDINGS**

The Congress finds that --

(1) Tobacco product use accounts for approximately 450,000 deaths each year in the United States. Tobacco products cause more disease, addiction, disability and death than are caused by all of the other drugs, medical devices, foods, cosmetics, and dietary supplements regulated by the Food and Drug Administration combined.
(2) Tobacco products and the nicotine contained in them are as addictive as cocaine and heroin.
(3) There is overwhelming evidence that cigarettes and smokeless tobacco products are manufactured and marketed with the intended purposes of "affecting function and structure of the body" and thereby, are subject to regulation under the Food Drug and Cosmetic Act.
(4) There is overwhelming evidence that many tobacco products are marketed with implied or direct health and safety claims and are therefore intended to mitigate or prevent disease" and are thereby, subject to regulation under the food Drug and Cosmetic Act.

(5) While the Food and Drug Administration has the authority to regulate tobacco products which are deemed to be "drugs" and or "devices" under the Food Drug and Cosmetic Act, this authority does not extend to all tobacco products.

(6) Because tobacco products are inherently dangerous as well as used to satisfy an addiction to nicotine, they should be subjected to regulation by the Food and Drug Administration in order to ensure adequate protection of the public health.

(7) The American public is in need of a comprehensive and rational regulatory policy for the regulation of all tobacco products comparable to other drugs and devices. This is particularly important with respect to the regulation of therapeutic nicotine delivery devices and other treatments for nicotine dependence.

(8) A national policy for the regulation of tobacco should be based on and guided by public health concerns. The goals and objectives of this Act are to reduce disease, disability and death caused by tobacco products.

(9) Tobacco advertising and marketing which uses such lifestyle themes of sexual attraction, sophistication, success, good looks and good health, success, and athletic abilities is inherently misleading and should be restricted or prohibited. For more than three decades the tobacco companies have failed to adhere to their own voluntary advertising restrictions which prohibit the use of such images and themes.

(10) Tobacco advertising that uses statements or messages that imply that the product is safer, less addictive or has other positive attributes affecting health is inherently misleading unless such claims can be substantiated based upon sound scientific evidence. For more that three decades the tobacco companies have failed to adhere to their own voluntary advertising restrictions which prohibit the use of direct or implied health and safety claims.

(11) Consumers should be provided with complete and scientifically accurate information about tobacco products so that they can be fully informed about these products. This should include messages related to health, contraindications, disclosure of chemical additives and constituents in tobacco, and any other information deemed important to educate the public and the medical profession.

(12) Tobacco product labeling and advertising which omits important health and safety information necessary for consumers to understand the nature of tobacco products is inherently misleading.

(13) Tobacco companies have, manufactured, sold and marketed their products knowing that such products caused disease death and addiction and there is substantial evidence that they intentionally withheld that information from the public in order to continue to make profits at the expense of their customer's health.

(14) Internal tobacco industry documents have clearly shown that the tobacco industry has long viewed itself as being in the business of selling drugs and in competition with the pharmaceutical industry.

(15) The tobacco industries past behaviors constitute violations of fundamental fairness, corporate ethics, integrity, and responsibility, inconsistent with the ideals and values in a free market system.

Sec. 3-- REGULATION OF TOBACCO PRODUCTS

(a) DEFINITIONS-- Section 201 of the Food Drug and Cosmetic Act is amended by adding at the end the following:

"(gg) The term 'tobacco product' means any article or component of any article used by man which contains tobacco leaf, homogenized tobacco leaf, and or tobacco by-product.

(b) TOBACCO PRODUCTS AS DRUGS AND DEVICES -- SECTION 201(g) and (h) related to the definition of "drugs" under the Food Drug and Cosmetic Act is amended by,

(1) Adding in section 201(g), after subparagraph "(C) articles (other than food) intended to affect function of the body or other animals", a new subparagraph (D) as follows: "(D) tobacco products;".

(2) and redesignating "(D)" as "(E)"

(3) adding in section 201(h) after (3), a new paragraph (4) as follows: "(4) used as a means of delivering nicotine or any other constituents contained in a tobacco product that affects function and structure of the body, and"

(c) HEALTH AND SAFETY STANDARDS FOR TOBACCO PRODUCTS – Section 503 of the Food Drug and Cosmetic Act, "Exemptions and Consideration for Certain Drugs, Devices and Biological Products", is amended by adding at the end thereof a new section (h) as follows: "(h) The Secretary shall promulgate the necessary regulations and performance standards to protect the public health from the dangers of tobacco products and use, except that the Secretary may not ban such products from interstate commerce on the sole basis that they cause disease and or are addictive".

(d) TOBACCO AND DRUGS ADVISORY COMMITTEE -- Section 903 of the Food Drug and Cosmetic Act concerning "Scientific Review Groups" is amended by adding a new section as follows:

"903(d)(I)(1) Not later than sixty days after enactment of this section, the Secretary shall establish at the Food and Drug Administration a "Tobacco and Drugs Advisory Committee".

(2) Members: The Secretary in consultation with the Commissioner of the Food and Drug Administration shall appoint to the Tobacco and Drugs Advisory Committee fifteen (15) experts representing but not limited to the following areas: pharmacology, addiction medicine, advertising and marketing, family medicine, pediatric medicine, behavioral science, biomedical science (including toxicology, chemistry, and engineering), food and drug law, social psychology, public health, public health education, and ethics. The Chairman of the Committee shall be designated by the Secretary.
(3) Ex Officio Members: Qualified representatives from the following agencies shall serve on the committee as ex officio members: the Centers for Disease Control, the National Institute on Drug Abuse, the National Institutes of Health, the Federal Trade Commission, AHCPR, the Health Care Financing Administration, the Office of the Surgeon General, the Environmental Protection Agency, the Department of Defense, the Occupational Safety and Health Administration, the Department of Veteran Affairs, and the United States Department of Agriculture.

(4) Duties: The Tobacco and Drugs Advisory Committee shall advise the Commissioner of the Food and Drug Administration in the development of regulations and other programs related to the manufacture, distribution, sale, labeling, advertising and marketing of tobacco products. In conducting its duties the Advisory Committee shall review and make recommendations to the Commissioner with respect to but not limited to the following:

(i) The labeling of all tobacco products including package inserts and other educational efforts consistent with warnings and other information required for other drugs and devices;
(ii) The methodologies for testing, labeling and information disclosure of constituents and ingredients in tobacco products and constituents in tobacco smoke;
(iii) Restrictions on the advertising and marketing of tobacco products consistent with the requirements for other drugs and devices;
(iv) The most effective measures for reducing use of tobacco products by children and adolescents;
(v) The feasibility of establishing performance standards for tobacco products;
(vi) The technical and commercial feasibility of reducing or eliminating nicotine and addicting harmful or toxic substances in tobacco products and the public health consequences of such actions;
(vii) The establishment of a regulatory review process for all ingredients used in the manufacture of tobacco products;
(viii) The establishment of good manufacturing practices for manufacturers of tobacco products;
(ix) Identifying new areas of research to improve the effectiveness of the regulation of tobacco products as well as effective strategies for reducing nicotine dependence.
(x) The Committee may conduct hearings and establish subcommittees as may be necessary for carrying out its responsibilities.

(5) The Committee shall terminate five years after the day of the appointment of members, except that the Commissioner may extend such date for up to two years in order for the Committee to complete its work.

(6) The Tobacco and Drugs Advisory Committee shall during the period of its existence have subpoena power to obtain documents and hear witnesses that relate to the functions and duties of the committee in carrying out its work.

Sec. 4. **TOBACCO PRODUCT MANUFACTURER FEES**

Section 736 of the Food Drug and Cosmetic Act is amended by adding at the end thereof the following new PART 3- FEES RELATED TO TOBACCO PRODUCTS:

"PART 3 –FEES RELATED TO TOBACCO PRODUCTS

(a) FEE PURPOSE – For the purpose of paying the costs associated with the implementation of this Act, each tobacco product manufacturer shall pay an annual fee established pursuant to paragraph (2). Such fee shall be payable on or before January 31 of each year.

(b) ESTABLISHMENT BY THE SECRETARY – Subject to the amount established in Appropriations Acts, each tobacco product manufacturer fee shall be determined by the Secretary based upon the total market share for each brand of tobacco product.

(c) CREDITING AND AVAILABILITY OF FEES –

(1) Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expense of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal limitation.
(2) The fees authorized for collection in subsection (a) —

(A) shall be collected in each fiscal year in an amount equal to specified in appropriations Acts for such fiscal year, and
(B) shall only be collected and available to implement the provisions and regulations pursuant to this Act.

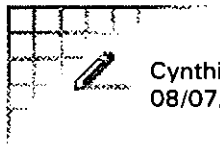
Sec. 5. -- **CONFORMING AMENDMENTS**

(a) Two years after passage of this Act the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act shall be repealed.
(b) Nothing in this Act shall prohibit or prevent the Federal Trade Commission from taking action against tobacco manufacturers and tobacco products under its existing authorities pursuant to the Federal Trade Commission Act.

Sec. 6 – **FDA AUTHORITY OVER ON-FARM PRODUCTION OF TOBACCO**

(a) Should the Food and Drug Administration suspect or determine that a tobacco product contains any deleterious substance or that the tobacco product is adulterated in any way as part of the agricultural production of the tobacco, the FDA shall notify the Environmental Protection Agency and the Secretary of Agriculture of the public health and safety concerns posed by such tobacco. Within sixty days the Secretary of Agriculture and the Environmental Protection Agency shall report back to the Commissioner of the FDA on actions that will be taken in order to ensure proper protection of the public health and safety.
(b) Nothing in this section shall prohibit or prevent the Food and Drug Administration from removing any manufactured tobacco product from interstate commerce if the agency determines that such removal is warranted in order to protect the health and safety of the public.

Tob-nT - FDA jurisdiction



Cynthia Dailard
08/07/98 09:54:54 AM

Record Type: Record

To: Laura Emmett/WHO/EOP

cc: Cynthia A. Rice/OPD/EOP
Subject: For Elena re American Lung Association Petition

ALA_0803.W This is for Elena is response to questions she had regarding the American Lung Association's petition to the FDA re tobacco regulation. I will fax you a page with Elena's questions to us -- would you please attach it to this (for her reference)? Thanks.

To: Elena
From: Cynthia Dailard
CC: Cynthia Rice
Date: August 6, 1998
Re: American Lung Association Petition of the FDA

This memo and the attached chart responds to your question regarding whether the President could take any executive action based on the claims contained in the American Lung Association's petition of the FDA. This citizen petition, filed by the ALA and several other public health and tobacco control organizations on January 15, 1998, urges the FDA to exercise its full authority over tobacco products. The petitioners take issue with the fact that while FDA has asserted its authority over tobacco products as drugs and devices and has established the regulatory framework to regulate the sale of tobacco products to children, it has failed to regulate tobacco products in a manner that is consistent with the regulation of other drugs and devices. The petition urges the FDA to establish regulatory standards for tobacco products that are comparable to those applied to other drugs and devices in areas such as labeling, ingredient disclosure, deceptive claims, and good manufacturing practices. It also identifies the legal and regulatory basis for such regulation, and urges the FDA to establish advisory panels that could provide the agency with guidance in moving toward consistent regulation of tobacco products.

You specifically asked if we could take any of these actions without violating the injunction. It appears that none of these recommended actions would technically violate the injunction. The injunction targets only the 1996 Rule's provisions on underage smoking, while these proposed actions are aimed at FDA regulation of tobacco products generally. However, we must keep in mind that Judge Osteen was clearly seeking to prevent the imposition of new financial burdens on the industry pending the resolution of jurisdiction upon appeal, and he might very well decide to broaden the scope of the injunction should we take any action that appears to create such a financial burden. (For example, the industry would challenge in court any new labeling requirements, saying that they should not have to spend millions of dollars to comply with the requirements while FDA's jurisdiction is being challenged. Judge Osteen is likely to be receptive to this argument.)

The FDA responded to the petition with a boiler plate response indicating that the agency is considering the issues raised by the petition. Based on conversations with Mitch Zeller and Patti Kaeding, I prepared the attached chart summarizing the agency's position regarding the various claims in the petition. Generally, Mitch does not favor taking any of the regulatory action proposed in the petition at this time. He indicated that while setting performance standards and reviewing additives and ingredients would have public health benefits, both would be lengthy and time consuming projects. We could obviously direct them to do so, but we would want to weigh whether such a directive would disrupt the pending court appear, and whether it would help or hurt our chances at reaffirming FDA authority via legislation.

FDA's Response to the American Lung Association Petition regarding Tobacco Regulation
August 6, 1998

	Proposal	Agency Response
Labeling and Advertising	All tobacco products presently on the market should be held to drug and device regulatory standards for labeling, advertising and marketing. This would include full disclosure of chemical additives in tobacco, information on addiction, warnings on contraindications and adverse effects for people with preexisting conditions, and elimination of promotion practices which are misleading (ie,"low tar" claims) .	Good idea but agency is not ready to do this at this time. Agency would need to do a very thoughtful analysis and rulemaking in order to regulate labeling, and currently does not have the scientific evidence necessary to undertake such an effort. Also, companies would likely challenge agency in court, arguing that they should not have to expend the millions of dollars they argue is required to make changes in printing plates, etc., to comply with new labeling and other requirements while FDA's jurisdiction is being challenged. Given the current injunction against the 1996 rule and statements by the judge in conferences, it seems likely the district court would be receptive to such arguments.
Premarket Approval	Any tobacco company making any new products should be required to submit a new drug/device application and provide all health and safety data about the product, a list of all components, a description of manufacturing process and controls, sample labeling, and advertising information. No new product could be marketed until the FDA reviewed and approved the product.	This is extremely controversial. FDA would be attacked from all sides and accused of thwarting the development of "safer" products. In addition, there would need to be a classification proceeding before premarket approval could be required. Classification is a lengthy process that requires, among other things, convening a classification panel of experts and notice and comment rulemaking.
Performance Standards	Performance standards should be required for all tobacco products.	Before the FDA could issue performance standards, it is required by device law to do a classification, which would take up to 5 years. Many scientific questions would need answering before FDA could issue performance standards (ie, is there a threshold level of nicotine which is non-addictive; at what level do the ingredients pose no risk, etc.).

	Proposal	Agency Response
Additives and Ingredients	All additives used in tobacco products (including reconstituted tobacco) should be reviewed, certified and generally recognized as safe when used as intended or removed from the market. All new additives should be approved by FDA before allowed on the market. Tobacco companies should be required to disclose all ingredients.	This is a good idea, but there would need to be a lot of thought and consulting before the agency could proceed down this road. For example, the ingredient review process for over the counter drugs has been a disaster and has taken decades because there is no comprehensive framework or standards for evaluating them. In contrast, the process for evaluating food additives worked well (armed with a list of 500 food additives, it took the FDA 10 years and hundreds of rulemakings to complete the task). It is estimated that there are almost 600 ingredients in tobacco products. Full disclosure of all ingredients may be preempted by the Cigarette and Labeling Act. (The Act requires manufacturers to provide a list to the CDC of tobacco ingredients in the aggregate for all their products. The CDC is required to keep this information confidential.)
Pesticides	The FDA should investigate pesticides and chemical applications to tobacco, particularly those used on foreign tobacco leaf which is imported into this country.	Because the agency has never conducted such analyses on tobacco products, it is currently unable to quantify this. This may also fall under EPA's jurisdiction. (EPA and FDA currently share jurisdiction regarding pesticides in food).
Good Manufacturing Practices	All tobacco companies should be held to all of the good manufacturing practices required by the FDA for other drugs and device manufacturers.	This would require an enormous diversion of FDA resources. It is also not a priority for the agency, given that most tobacco manufacturing practices are generally known to be good (clean facilities, etc). It is also unclear whether existing manufacturing practices for devices would apply to tobacco products, or whether standards for tobacco manufacturing practices would need to be established. (This process if very labor intensive -- it took the agency 5 years to develop the general device standards).
Drug User Fees	Tobacco product manufacturers should be required to pay "drug user" fees similar to requirements for other drug manufacturers.	Requires statutory language.
Registration Requirements	All tobacco manufacturers should be required to register with HHS.	This would provide the agency with the names and addresses of all tobacco manufacturers and a list of their products. The agency has much of this already.

	Proposal	Agency Response
Advisory Panels	1) Agency should establish a Tobacco and Health Advisory Committee to the Commissioner to provide expertise, guidance and assistance in developing, mapping out and implementing a process and a plan that will result in comprehensive and consistent regulations for tobacco products. 2) Agency should establish a permanent Tobacco and Health/Drugs and Devices Advisory Panel charge with reviewing and considering ongoing issues and products related to the manufacture, sale, distribution, labeling, advertising and marketing of tobacco products.	Mitch supports the creation of an advisory panel of experts which could help the agency develop the scientific findings it needs to further regulate tobacco products. It would take approximately one year to convene the panel, although it might take less time if the agency supplements existing panels instead. (The distinction between the two panels proposed by the ALA, however, is unclear.)

LEON G. BILLINGS, INC.

1625 K STREET, N.W.
SUITE 790
WASHINGTON, DC 20006
(202) 293-7800
FAX: (202) 293-7808

Bruce — Could you get hold of this petition and figure out whether we can do anything in it without violating the injunction? Thanks. Elena

Bruce
I think he's onto something here.

June 26, 1998

MEMORANDUM

TO : Rahm Emanuel

FROM : Leon G. Billings

SUBJECT : Regaining the Tobacco Initiative

With the recent demise of the McCain tobacco bill and the announcement of the House Republicans that they intend to limit FDA's authorities for regulation of tobacco advertising and promotion, there is a great opportunity to initiate expansion of the essential elements of FDA authority. In January, 1998, the American Lung Association and other organizations filed a petition with FDA delineating the numerous essential areas of authorities and responsibilities that the FDA should have over tobacco products. ALA's January petition followed a number of other petitions seeking FDA action to regulate the manufacture, sale, distribution, labeling, advertising and marketing of tobacco products as drugs under the Food, Drug and Cosmetic Act. Their supplemental filing lays out the legal and regulatory basis for this request and describes actions that can be taken to demonstrate misleading and deceptive advertising.

The White House should take a more visible role in making public what they believe are the essential elements of "full FDA authority" to keep the real debate center stage and the President in control. The President can publicly instruct the FDA to begin the process of moving forward with the development and implementation of regulations. This could be accomplished simply by having the Secretary of HHS instruct FDA to act on the request in the January ALA petition for the establishment of Advisory Panels on the essential elements including advertising, marketing and new product development.

The House Republicans intend to play the game that they support FDA regulation and that they support enhanced authorities for FTC and challenge anyone to demonstrate that more is necessary. The President has the opportunity to get ahead of the Republican proposal and set the "bottom line" for what is acceptable.

And the initiative sets up a Presidential veto of phony tobacco legislation on public health grounds. Let me know what you think.

Tob - rer - new legis - Hatch - Feinstein
(and)
Tob - rer - FDA jurisdiction

8-20 Hatch - FDA

Bruce - Diffs btw this + Man Amend.

1. std - "maximize net benefits to pub health" (derived from Katzen EO)

our old one: "best _ for public health"

std now in is from Frist.

2. No premkt approval - v. performance stds

theory - perf. std. operates prospectively.

they couldn't mkt new product unless petitioned to change perf std.

can amend perf stds - even after 24 mos. 163, ll 16-19

BS: new product may meet perf std -

still, we would want to do premkt approval.

so we can ensure, e.g., that labeling is approp.

BS: agency never really able to op thru perf stds

OH: This gives you abil to say what products are permiss or new -

BS: we can't anticipate in this way.

also: prospective or retroactive?

who has burden of proof?

BS: talking abt product that only comes on mkt once every five or so yrs.

3. Regs - codified all regs that were on access

but not advert regs.

also: FDA can regulate as to advert. from day of this bill -

What is std for reg auth on advert?? "signif contribute to youth smkg" -

→ meant to mimic court std

On access — codify reg.

then, FDA has continuing reg auth. - 701a - for whatever reason.

BS - says has to be same with Lane

But intent: broad auth to modify access.

4. Pos. act of Cong — IRY

banning a class / eliminating nicotine (totally)

5. Considerations — 182-83

A, B, C - from rule

tech feasibility

accepted by + affordable to adult consumers.

6. Filters, etc.. too?

Seems so.

Bill S.

7. Record inspection -

8. Civil $ penalties

9. Deh of tobacco products (OK)

10. Imports?

Tob - mr - FDA juris. fi~

The Honorable James M. Jeffords
Chairman, Committee on Labor
and Human Resources
United States Senate
Washington, D.C. 20510-6300

Dear Mr. Chairman:

This is in response to your letter of April 27, 1998, to Lead Deputy Commissioner Michael A. Friedman, M.D. regarding the Food and Drug Administration's interpretation of its authority to regulate tobacco products under S. 1415 as reported by the Commerce Committee. A similar letter is being sent to Senator Dan Coats.

We have numbered our responses to correspond to the questions in your letter. For ease of reference, we are enclosing a copy of the Federal Register document containing FDA's Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents published in 61 Fed. Reg. 44396 (August 28, 1996).

(text of questions will be removed from final)

1. Does FDA believe that proposed rule 60 FR 41314 et seq, jurisdictional analysis 60 FR 41453 et seq, final rule 61 FR 44396 et seq, and jurisdictional determination 61 FR 44619 et seq constitute official agency advisory opinions? Is not FDA bound by these documents unless FDA or a court repudiates them? Does FDA view the requirements of the S. 1415 as reported by the Commerce Committee to be consistent with the requirements of the 61 FR 44396 et seq? Would the Greensboro decision made by Judge Osteen continue to be the law in that jurisdiction following enactment of S. 1415 as reported by the Commerce Committee? If there are inconsistencies between the tobacco regulation, Judge Osteen's decision, and S. 1415 as reported by the Commerce Committee, then which statement of law will FDA follow in regulating products under the Act?

1. The preamble to the tobacco regulations and the jurisdictional determination reflect FDA's application of the Federal Food, Drug, and Cosmetic Act (FDCA or Act) as it currently exists to cigarettes and smokeless tobacco products. The enactment of a separate chapter for tobacco products does not alter any of the underlying factual findings that FDA relied on in support of its actions. However, S. 1415 and the new chapter IX of the FDCA, if enacted, would control the regulation of tobacco products.

The requirements of part 897 of title 21, Code of Federal Regulations (the tobacco regulations), are consistent with the authority provided in the new FDCA provisions in S. 1415 as reported by the Commerce Committee. S. 1415 would amend the Act to include section 901(c), which provides that "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." This provision ensures that these regulations will remain in effect if S. 1415 is enacted, and will not need to be repromulgated pursuant to the separate chapter for tobacco products adopted in S. 1415.

Section 10.85(d), of Title 21, C.F.R., provides that "a statement of policy or interpretation made in . . . the following documents, unless subsequently repudiated by the agency or overruled by a court, will constitute an advisory opinion: (1) Any portion of a Federal Register notice other than a text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation." Thus, the legal interpretations in the preamble to the final rule of certain provisions of chapter V of the Act and the jurisdictional determination represent FDA's current thinking on the interpretation of these provisions, based on the facts relevant to cigarettes and smokeless tobacco products. Because S. 1415 creates a separate chapter for tobacco products, these interpretations of chapter V would no longer be applied to cigarettes and smokeless tobacco products if S. 1415 is enacted.

2. If S. 1415 as reported by the Commerce Committee were law, could FDA assert that it gives the agency additional authority over non-tobacco products? If so, identify the specific provisions that would do so.

2. We believe that S. 1415 only affects the regulation of products that are tobacco products or components, parts, or accessories of tobacco products. Raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product would not be subject to the new FDCA chapter IX in S. 1415. *See* FDCA section 201(kk) in S. 1415 (definition of tobacco products). In addition, S. 1415 includes in section 901(d)(1) of the new FDCA chapter IX the following provision: "Nothing in this chapter shall be construed to affect the regulation of drugs and devices under chapter V that are not tobacco products by the Secretary under the Federal Food, Drug and Cosmetic Act." S. 1415 does not give FDA additional authority over non-tobacco products.

3. If S. 1415 as reported by the Commerce Committee reported bill were law, would FDA continue to assert that it could for any non-tobacco product:

-specify the media in which advertising for that product will be permissible?

- prohibit the use of color or otherwise specify the format of advertising for that product?

- restrict the use of trade or brand names for that product?

- restrict the marketing of that product with respect to product samples, coupon redemption, promotion of sporting, cultural, or other events?

If the answer to any of the above is yes, on which specific authority in the Act and for which products?

3. We believe that S. 1415 only affects the regulation of products that are tobacco products or components, parts, or accessories of tobacco products. S. 1415 includes in section 901(d)(1) of the new FDCA chapter IX the following provision: "Nothing in this chapter shall

be construed to affect the regulation of drugs and devices under chapter V that are not tobacco products by the Secretary under the Federal Food, Drug and Cosmetic Act." The authority for requiring such conditions that FDA has relied on for devices is found principally in sections 515 (premarket approval orders) and 520(e) (restricted devices). Specific products to which FDA's existing authority under chapter V might be applied cannot be identified as we cannot predict how the statute will be interpreted and applied in the future.

4. Does FDA believe that it has the authority under existing law or law as amended by S. 1415 as reported by the Commerce Committee to require a manufacturer of products regulated under the Act to spend money on national public education programs either outright or as a condition of being lawfully marketed? Please answer separately for tobacco and non-tobacco products. If yes, on what specific authority in the Act or proposed amendments?

Does FDA have general authority, other than prescription drug user fees and civil money penalties for violations of device and generic drug law, to require a manufacturer of products regulated under the Act to spend its own funds for any purpose outright or as a condition of being lawfully marketed? Please answer separately for tobacco and non-tobacco products. If yes, on what specific authority in the Act or proposed amendments?

Does FDA have authority under existing law or law as amended by S. 1415 as reported by the Commerce Committee to compel manufacturers of products regulated under the Act to disseminate corrective messages to counteract positive imagery and discourage the use of legal products by adults or by children which are deemed by FDA to be overused or lacking in social utility? To reduce the appeal of a product that is legally marketed for adults but found to be appealing to children?

Please answer separately for tobacco and non-tobacco products. If yes to either question, on what specific authority in the Act or proposed amendments?

4. The authority for corrective or educational messages that FDA has relied on for devices is found principally in sections 518(a) and 520(e) of the Act. For tobacco products under S. 1415, the authority would be in FDCA sections 908(a) and 906(d). The specific drug authorities that FDA might consider relying on would depend on the factual circumstances presented. In addition, courts can require these types of activities pursuant to its remedial authorities.

One example of FDA's use of its authority under section 518(a) of the Act involved the Bjork-Shiley Convexo-Concave (C-C) heart valves, which had been taken off the market because of increased fracture risk, but remained implanted in some 23,000 Americans. Certain patients were at increased risk for fracture, and only about one in three patients survive fracture. In 1990, FDA sent a section 518(a) consultation letter to Shiley regarding

the valve. After meeting with FDA, the Shiley voluntarily instituted a notification program pursuant to which doctors would contact their patients to inform them of their risks of valve fracture, the symptoms possible fracture, and steps to take if symptoms appear. Independent audits showed that patients received notification and found it helpful, but did not understand the information regarding increased risk. Many patients did not find their doctors to be helpful. The audits also showed that some doctors were reluctant to convey information to their patients that might implicate their own medical judgment and liability. As a result, FDA attempted to identify ways to encourage doctors to be more communicative with their patients. In 1992, FDA again sent a 518(a) consultation letter to the Shiley because certain of its heart valves presented an even higher risk to certain patients than had previously been known. After consultation with Shiley, FDA issued a notification order requiring Shiley to notify physicians and patients who had the valves at issue. The order also required Shiley to notify all other patients with Shiley heart valves to inform them that a particular medical journal article about the higher risk did not apply to their device. The 518(a) order specified the contents of these letters in some detail and provided for FDA approval of them before they were sent.

As a general matter, compliance with the requirements of the Act will necessitate the expenditure of funds by manufacturers. For example, in the absence of the Act, some manufacturers would not keep the records necessary to ensure that a product's manufacture is consistent with good manufacturing practice requirements. In other circumstances, an inspection might show that a manufacturer must put into place certain sanitary measures in order to continue to legally market a product.

5. FDA defined "intended use" in the tobacco products rule based on "foreseeable effects" and "consumer use". Can the FDA identify any other product category that could be subject to the "foreseeable effects" and "consumer use" theories of the terms "drug" and "device" as described in the FDA tobacco regulation, under the Act or the amendments to the Act by the Commerce bill?

In particular, would FDA's definition of "intended use" as including foreseeable effects and consumer use encompass caffeine-containing soft drinks? Coffee or tea? Butter? Exercise equipment? Cosmetics? If the answer in any case is "no", please explain why each would not be encompassed in the "drug" or "device" definition.

5. We believe that S. 1415 only affects the regulation of products that are tobacco products or components, parts, or accessories of tobacco products. S. 1415 includes in section 901(d)(1) of the new FDCA chapter IX the following provision: "Nothing in this chapter shall be construed to affect the regulation of drugs and devices under chapter V that are not tobacco products by the Secretary under the Federal Food, Drug and Cosmetic Act."

The jurisdictional determination discussed FDA's legal authority to consider evidence of foreseeable pharmacological effects and uses and actual consumer use in determining the "intended use" of a product for purposes of the Act's "drug" and "device" definitions, 61

Fed. Reg. 45151-191; *see generally* 61 Fed. Reg. 44690-5150, and provides examples of products which FDA found to be "drugs" or "devices" based on these types of evidence. 61 Fed. Reg. 45166-168, 45185-191. The jurisdictional determination also provides examples of cases in which courts relied on these types of evidence. 61 Fed. Reg. 45162-64.

Both the jurisdictional determination and the preamble to the final rule responded to comments that argued that FDA's determination that cigarettes and smokeless tobacco are "drugs" and "devices" would obligate the Agency to regulate caffeine-containing beverages, various food products, exercise equipment, and cosmetics as drugs or drug delivery devices. 61 Fed Reg. 44420-421, 44682-685. Section 201(g)(1)(C) of the Act, the provision of the "drug" definition relied on by the Agency specifically excludes from its coverage products that are "foods" under the Act. 61 Fed. Reg. 44684. For example, with respect to caffeine-containing beverages, FDA stated: "When caffeine is used in soft drink products in accordance with section 402 . . . and when it naturally occurs in other products that are foods, such as coffee, the product is a 'food' under section 201(f)(1) . . . and is explicitly excepted from the definition of drug in section 201(g)(1)(C) . . . ('articles, other than food, intended to affect the structure or any function of the body')." 61 Fed. Reg. 44683; *see* 61 Fed Reg. 44420-421, 44682-683. Under sections 201(g)(1)(C) and 201(h)(3) of the Act, "drugs" and "devices" must be "intended to affect the structure or any function of the body." Although products such as exercise equipment might fall within the literal language of the statute because they have some physical effect on the structure or any function of the body, FDA may, in its discretion, decline to regulate them and in fact has done so.

Finally, although as a general matter, cosmetics are not regulated as drugs in the absence of drug claims, the agency has relied on the foreseeable drug effects of products such as hormone-containing skin creams and fluoride-containing dentifrice products to regulate such products as drugs. 61 Fed. Reg. 45167-168, 45186-187. In 1993, for example, FDA took the position that the inclusion of pharmacologically active levels of hormones in skin creams was a sufficient basis for regulating the products as drugs. 61 Fed. Reg. 44187 (citing 58 Fed. Reg. 47611, 47613 (Sep. 9, 1993)). S. 1415 does not affect FDA's authority on this issue.

6. Under the Act or the Act as amended by S. 1415 as reported by the Commerce Committee were law, please explain why a can or bottle would not be considered to be a drug-delivery device if it contained a caffeinated product. Why would a coffee bean not be a drug-delivery device just as a tobacco leaf is a drug-delivery device in the case of smokeless tobacco? How is this different for a time-release capsule for an over-the-counter cold remedy, a metered-dose inhaler for asthma treatment, a drug-containing lollipop or gum, or a marijuana cigarette?

6. We believe that S. 1415 only affects the regulation of products that are tobacco products or components, parts, or accessories of tobacco products. S. 1415 includes in section 901(d)(1) of the new FDCA chapter IX the following provision: "Nothing in this chapter shall be construed to affect the regulation of drugs and devices under chapter V that are not tobacco

products by the Secretary under the Federal Food, Drug and Cosmetic Act."

FDA's finding that cigarettes and smokeless tobacco are drug delivery devices, and the Act's combination product provisions, are discussed extensively in the jurisdictional determination, 61 Fed. Reg. 45216-218, and in the preamble to the final rule, 61 Fed. Reg. 44420-421. FDA found that, in addition to containing the drug nicotine, cigarettes and smokeless tobacco products contain device components, *i.e.*, the tobacco blend, filter, and ventilation system used in cigarettes, and the processed tobacco and porous pouch (where present) used in smokeless products. With respect to cigarettes, the tobacco blend, filter, and cigarette ventilation system "release a nicotine-containing aerosol, *i.e.*, the tobacco smoke, that, upon combustion outside the body, is inhaled by the smoker and serves as a vehicle for nicotine delivery." 61 Fed. Reg. 45209. The processed tobacco in a smokeless tobacco product "deliver[s] the nicotine to the cheek and gum tissue for absorption," 61 Fed. Reg. 45213, and the porous pouch (if used) in those products "hold[s] the processed tobacco in position in the mouth, controlling the absorption of nicotine into the buccal mucosa." 61 Fed. Reg. 45214. Consistent with the statutory definition of a device, none of these functions relies on "chemical actions within or on the body." See 61 Fed. Reg 45210, 45214-15. Because each of these components is an "instrument, . . . implement, . . . contrivance . . . or other similar or related article," section 201(h), that is intended to "affect[] the structure and function of the body by delivering a controlled amount of nicotine to the body," 61 Fed. Reg. 45209, 45213-15, each is a device in its own right. Thus, the components of cigarettes and smokeless tobacco products fully satisfy the Act's device definition, even though nicotine, the drug component in those combination products, "achieves its primary intended purpose through a series of chemical actions inside the body." 61 Fed. Reg. 45210; *see also* 61 Fed. Reg. 45215. Cigarettes and smokeless tobacco, therefore, are "combination products" within the meaning of section 503(g). 61 Fed. Reg. 45205; 21 C.F.R. § 3.2(e)(1).

As noted above, when caffeine naturally occurs in products that are foods, such as coffee, or when caffeine is used in soft drink products in accordance with section 402 of the Act, the product is a "food" under section 201(f)(1) of the Act and thus explicitly excepted from the definition of "drug" in section 201(g)(1)(C).

7. On what basis can a product that achieves its primary mode of action through chemical action within or on the body or otherwise meets the criteria for a drug in Section 201 be regulated as a device?

Could a product which meets the definition of a drug under Section 201, and for which an NDA is submitted ever be regulated as a device and therefore not be eligible for the market exclusivity provisions of section 505? What provision of the Act or the Act as amended by S. 1415 as reported by the Commerce Committee would prevent FDA from regulating a new transdermal patch pharmaceutical as a device instead of a drug? Is there any limit on FDA's discretion on how to regulate a combination product?

7. We believe that S. 1415 only affects the regulation of products that are tobacco products or components, parts, or accessories of tobacco products. S. 1415 includes in section 901(d)(1) of the new FDCA chapter IX the following provision: "Nothing in this chapter shall be construed to affect the regulation of drugs and devices under chapter V that are not tobacco products by the Secretary under the Federal Food, Drug and Cosmetic Act."

The first part of this question is partially addressed in the response to question 6. As discussed in the preamble to the final rule, 61 Fed. Reg. 44400-404, if a product constitutes a combination, such as a drug/device combination product, the statute leaves to FDA's discretion the determination of which authorities in the Act's drug and device provisions to apply in regulating the combination product. These decisions are made on a case-by-case basis, and take into account the regulatory and public health concerns presented by each combination product.

S. 1415 does not affect regulation of combination products under the Act. With respect to the hypothetical example of a product for which a NDA is submitted, the answer would depend on whether the product is a combination drug/device or drug/biologic product. If it is a combination product that contains a drug component, the agency would evaluate the situation based on the regulatory issues presented by the product.

8. Does FDA believe that products subject to 520(e) are exempt from classification under the Act? Does FDA believe that classification of a device is not mandatory under the Act?

8. FDA expressly stated in its final tobacco rule that, "[a]s required by section 513, the agency will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with the procedures in section 513 of the [A]ct." 61 Fed. Reg. 44412.

The agency's issuance of the regulations restricting cigarettes and smokeless tobacco pursuant to section 520(e) of the Act prior to classifying these products is consistent with both the statutory framework for device regulation and the agency's regulation of other devices. After a product becomes subject to the device provisions, it must be classified into one of three classes. The purpose of classification is to determine whether that device should be subject to special controls (Class II), or premarket approval (Class III), in addition to the "general controls" (Class I) applicable to all devices. Classification, while an important part of device regulation, is not a prerequisite to such regulation, and does not occur immediately. "General controls" on devices apply regardless of whether classification has occurred. "[C]ertain of the general controls," like the adulteration and misbranding provisions, became applicable to all devices "immediately upon enactment of the [Medical Device Amendments of 1976]." H.R. Rep. No. 94-853, at 17. Other general controls, such as restrictions on sale, distribution, and use pursuant to section 520(e), apply only where FDA concludes that there cannot otherwise be reasonable assurance of the safety and effectiveness of a particular device. *Id.* at 24. The statutory scheme for device regulation does not contemplate, much less require, that a device

be classified before it is subject to the general controls applicable to all devices. Nor must a device be classified before the agency may apply restrictions pursuant to section 520(e) to that device. Indeed, the agency ordinarily does *not* complete the classification process before regulating a device under the general controls of the Act. 61 Fed. Reg. 44404. Rather, each of the thousands of devices that have been classified by rulemaking under section 513 was subject to the general controls of the Act prior to the completion of classification rulemaking proceedings. 61 Fed. Reg. 44404; *see generally Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2247 (1996) (recognizing that devices are not classified immediately); *Contact Lens Mfrs. Ass'n v. FDA*, 766 F.2d 592, 603 (D.C. Cir. 1985), *cert. denied*, 474 U.S. 1062 (1986). The one device other than cigarettes and smokeless tobacco that FDA has restricted by regulation (hearing aids) was restricted in 1977, but not classified until 1986. *See* 42 Fed. Reg. 9286 (1977) (promulgating restrictions); 51 Fed. Reg. 40389 (1986) (classifying).

9. Does FDA believe that labeling and advertising of a product is false or misleading under the Act or the Act as amended by S. 1415 as reported by the Commerce Committee if it:

- omitted "important information" that was not "a material fact"

- lacked fair balance

- lacked substantial evidence to support a claim made in the labeling or advertising

If yes to any of the above, please give the statutory authority.

Both section 502(a) of the Act, which applies to drugs and devices, and section 403(a) of the Act, which applies to foods, provide that a product shall be deemed to be misbranded "if its labeling is false or misleading in any particular." Section 201(n) of the Act provides that "If an article is alleged to be misbranded because the labeling or advertising is *misleading*, then in determining whether the labeling or advertising is misleading *there shall be taken into account* (*among other things*) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary." (Emphasis added).

Both section 403(a) and section 502(a) have been interpreted by the courts. S. 1415 adds a new section 903(a)(1), which provides that a tobacco product shall be deemed to be misbranded "if its labeling is false or misleading in any particular." The application of these provisions depends on the facts of each case.

10. Does FDA for purposes of evaluating whether a label is false or misleading, propose the existence of a standard other than failure to reveal material facts?

10. As explained above, sections 403(a) and 502(a) of the Act, and FDCA section 903(a)(1) in S. 1415, provide that a product shall be deemed to be misbranded "if its labeling

is false or misleading in any particular." Although a failure to reveal material fact is one basis for finding that a product is misbranded, courts have interpreted sections 403(a) and 502(a) more broadly. These provisions have been found, for example, to prohibit labeling which has the capacity or tendency to deceive, irrespective of whether the deception is created by exaggeration, overemphasis, indirection, ambiguity, or by use of half or partial truths. *See United States v. Ninety-five Barrels . . . Apple Cider Vinegar*, 265 U.S. 438, 443 (1924); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 41-42 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957); *United States v. One Device, Intended for Use as a Colonic Irrigator*, 160 F.2d 194, 200 (10th Cir. 1947). Statements can be misleading even if they are not technically false and even if literally true. *Apple Cider Vinegar*, 265 U.S. at 443; *United States v. An Article of Device . . . The Ellis Microdynameter*, 224 F. Supp. 265, 268 (E.D. Pa. 1963).

11. Does FDA believe that the "fair balance" requirement in regulations implementing the "true statements" language in Section 502(n)(3) for drugs can be applied to products other than drugs under the Act or under amendments made to the Act by S. 1415 as reported by the Commerce Committee? If so, what is FDA's legal rationale?

11. Section 502(n)(3) of the Act applies to prescription drug products. The regulations promulgated pursuant to section 502(n)(3) could be applied to certain combination products, such as a drug/device combination product that contains a prescription drug. In addition, section 502(r) of the Act provides authority similar to section 502(n)(3) for devices. S. 1415 does not affect either provision.

12. Does FDA believe the substantial evidence standard in section 505 can be applied to products that are not regulated as drugs? If so, what is FDA's legal rationale? What about products for which no therapeutic claim is made? If so, what is FDA's legal rationale?

12. Section 505 of the Act applies to products that are "drugs" under the Act. Section 505 could be applied to products that are drug/device combinations or drug/biologic combinations. *See generally* 61 Fed. Reg. 44400-03. For the reasons articulated in the jurisdictional determination, evidence other than a therapeutic claim may be the basis for a determination that a product is intended as a drug.

13. Does FDA believe that under S. 1415 as reported by the Commerce Committee, it would have authority to supplement funds for tobacco regulatory activity drawn from the National Tobacco Settlement Trust Fund with other funds appropriated to the agency by Congress?

13. FDA believes that appropriation contemplated in S. 1415 for FDA's tobacco activities will be adequate. Future agency authority with respect to funds will depend on the relevant appropriations provisions.

We hope this information is helpful. If we may be of further assistance, please let us know.

[closing]
[signed ??]

Tob - re-FDA jurisdiction

U.S. FOOD AND DRUG ADMINISTRATION
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FACSIMILE TRANSMISSION RECORD

June 16, 1998

4 NUMBER OF PAGES (including coversheet)

TO: Cynthia Dailard, DPC
(202) 456-7871
fax: (202) 456-5581

FROM: Patricia Kaeding, Associate Chief Counsel

Facsimile No. 301-480-2255 Voice No. 301-827-1153

RE: As discussed. Elena will probably be most interested in the one related to Congressional review. The Rep. staffers want to delete the sentence dealing with the FDA regulation entirely because they thought it unnecessary.

NOTE: If you do not receive a legible document, or do not receive all of the pages, please telephone us immediately at the voice number above.

Amends section 9 to clarify when that Congressional Review is not required for regulations that have already ~~complied~~ complied with the requirements of that statute.

Page 24, line 24-25—

Strike text after ".801" and insert the following:

"This section does not apply to any rule under this Act that has been previously been submitted to Congress and the subject of a report of the Comptroller General pursuant to section 801, including the rule set forth in part 897 of title 21, Code of Federal Regulations."

FDA would prefer this.

NOTE: Frist's staffer indicated that the other staffers did not want to refer to a specific rule. This is an alternative amendment.

Page 24, line 24-25—

Strike text after ".801" and insert the following:

"This section does not apply to any rule under this Act that has been previously been submitted to Congress and the subject of a report of the Comptroller General pursuant to section 801."

Amends section 907 (section 101 of S. 1415) to make clear that the Secretary shall consider the possible effects on behavior of the performance standard being promulgated, such as possible increases in thefts related to tobacco products.

Page 56, line 25—

After "demand," insert:

"and the effects of such standard on the behavior of tobacco product users and others,"

Amends section 901 (section 101 of S. 1415) to make clear the considerations relevant to the standard of "appropriate for the protection of the public health" in Food, Drug, and Cosmetic Act chapter IX, as added by S. 1415.

Page 28, insert after line 2:

"(d) For purposes of the provisions of this chapter which employ the standard of appropriate for the protection of the public health, the finding as to whether a regulation would be appropriate for the protection of the public health 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: (1) the increased or decreased likelihood that existing users of tobacco products will stop using such products or reduce their use of such products, and (2) the increased or decreased likelihood that those who do not use tobacco products will start using such products. The Secretary shall consider the countervailing effects of the proposed regulation on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand, and the effects of such standard on the behavior or tobacco product users and others."

Amends new FDCA section 906(d) (section 101 of S. 1415) to delete reference the to "use" so that instead of authority to require that a tobacco product be restricted to sale, distribution, or use upon such conditions as may be prescribed by regulation, FDA is limited to restrictions on sale or distribution.

Page 45, line 17—

Strike "sale, distribution, or use" and insert "sale or distribution".

↑
(this generally refers to doctor use of devices, not consumer use).

Amends new FDCA section 901(b) to clarify the procedures and standard applicable if FDA's jurisdiction is extended to include tobacco products other those tobacco products subject to the 1996 Tobacco Rule.

Page 26, line 17—

After the period add the following:

"The decision to apply the requirements of this chapter to tobacco products not subject to the requirements of part 897 of title 21, Code of Federal Regulations shall be based on a finding of compelling public health circumstances. The Secretary shall not delegate the authority under this subparagraph to subject other tobacco products to this chapter. The Secretary shall consult with an advisory committee before issuing a final regulation subjecting any such other tobacco product to this chapter."

Substitute for 2465 (Coats)

Page 27, line 3, renumber "(2)" as "(3)", and after line 2, insert the following—

"(2) The responsibilities under this chapter and the other responsibilities assigned to the Secretary in the National Tobacco Policy and Youth Smoking Reduction Act as part of the mission of the Food and Drug Administration are in no way intended to undermine the activities of the Administration in carrying out the mission as articulated in section 1003(b) of this Act [as redesignated by this Act], particularly its review and approval responsibilities."

Substitute for Amendment 2466 (Coats)

Section 1003 (as redesignated by this Act) is amended by adding at the end the following—

"(h) The Secretary may establish within the Food and Drug Administration a Center for Tobacco Product Regulation to have primary responsibility for the regulation of tobacco products under chapter IX of the Federal, Food, Drug, and Cosmetic Act."

Comment: Frist's staff may want this to be "shall"

Tob - scr - FDA jurisdiction

Date: June 25, 1998

Re: FDA Issues in Title IV of Hatch/Feinstein Substitute

Full and comprehensive FDA authority over tobacco products, and preservation of FDA's 1996 final rule, is essential to help stop young people from using tobacco products, and to reduce the health risks associated with tobacco use by those who are addicted to those products. This authority must be as effective as FDA's authority over other drugs and devices, which is the authority FDA has asserted in its jurisdictional statement. Such authority would give the agency the *flexibility* to adjust to changing circumstances, for example, future advertising of tobacco products on the Internet or aggressive marketing campaigns that appeal to persons barely over the age of 18. In contrast to the carefully negotiated provisions in McCain bill, the Hatch/Feinstein substitute ("substitute"), does not meet these objectives and, if enacted, would severely limit FDA's ability to regulate tobacco products in a manner that is appropriate for the protection of the public health. The substitute has two major problems. First, it deprives FDA of needed elements of regulatory authority. Second, by eliminating certain authorities and significantly modifying others, the substitute unnecessarily impinges on FDA's ability to exercise, in the most effective manner, regulatory authority over tobacco products. A summary of the most significant concerns with the substitute follow. This summary is based on our preliminary review of the substitute.

- No Authority to Modify Access Restrictions & No Effective Enforcement Authority: The substitute declares the 1996 access restrictions in effect, but deprives FDA of the flexibility to modify access requirements if these access restrictions become inadequate or require redirection. In addition, because the substitute provides no civil money penalty authority, FDA would only be able to enforce the access requirements using its injunctive and criminal authorities. FDA believes these authorities are too harsh for general enforcement of access restrictions at the retail level, fail to provide the needed flexibility, and could undermine meaningful enforcement of the access restrictions.

- Repeals 1996 Advertising Restrictions: The substitute deems the 1996 advertising restrictions null and void. These restrictions are a critical component of FDA regulation. The substitute would include the restrictions in the voluntary protocol provisions. Since the protocol applies only to tobacco manufacturers, tobacco distributors, importers, and retailers would exempt from any restrictions on their advertising.

The substitute authorizes FDA to promulgate addition advertising and marketing restrictions (beyond those in the FDA rule that are incorporated into the protocol) if it determines that such marketing and advertising has *significantly contributed* to the use of tobacco products by individuals under 18 years of age (FDCA Section 906). This finding would probably be impossible to meet. As a practical matter, it would probably mean that the agency could never impose advertising restrictions against retailers and others, or against the manufacturers, even if the manufacturers are successful in using a multi-faceted marketing program to maintain the youth demand for tobacco products. The standard that the agency would have to meet in the inevitable litigation that would follow any agency action goes well beyond the requirements of current First Amendment jurisprudence.

- Contains Unnecessary Procedural Requirements and Other Provisions That Would Constrain FDA's Flexibility in Appropriately Regulating Tobacco Products: The substitute imposes numerous procedural and other requirements on FDA before it can issue many regulations. These provisions would drain FDA resources from focusing on preventing kids from using tobacco products, and provide countless grounds for opponents to delay and litigate regulations. The substitute also allows interested persons, after a regulation is issued (and irrespective of whether a court challenge is also underway), to request changes in the regulation, and requires FDA to act on such a request within 60 days. This provisions could be used by the industry and others to flood the agency with an endless series of requests.

The required procedures for risk reduction standards appear designed to preclude appropriate and effective standards. Standards must be issued within 24 months of enactment. After two years, the agency would have no authority to issue standards to reduce the risk of tobacco products, even if new scientific evidence would support a standard, for example, that would require the elimination of a dangerous additive using it processing the tobacco. Prior to taking any action based on current science, FDA would have to issue a proposal, seek and obtain recommendations from the advisory committee, have a comment period of at least 120 days, and issue a final standard. The procedures are so cumbersome that the agency might not be able to issue standards based on current scientific evidence.

The substitute also requires that both Houses of Congress act affirmatively — by enacting a joint resolution of approval — to eliminate nicotine or to eliminate cigarettes or smokeless tobacco products. This would be so even if, in the distant future, a safer alternative to nicotine or the product is developed. Requiring an

affirmative Congressional vote on such an action could effectively preclude FDA from using this authority in a reasonable manner. In contrast, the McCain bill would have required Presidential approval of any FDA decision to use this authority and would have required the agency to delay the effective date for a minimum of two years in order to give Congress the opportunity to override FDA's decision.

- Constrains FDA's Ability to Take Actions That Will Result in Safer Products: The substitute's risk reduction standard section deprives FDA of the authority to require safer products by requiring modifications to the filter, paper, or construction of a tobacco product. Under the substitute, FDA's authority is limited to nicotine and ingredients. The substitute also limits FDA's ability to obtain additional information from manufacturers as part of rulemakings. For example, in reviewing ingredients, FDA is to review assessments submitted by the manufacturer. It lacks authority to require additional testing or information before making a decision on the ingredient's safety.

  The substitute eliminates FDA's ability to require premarket approval and testing for new tobacco products. The substitute would require FDA to treat new products — even those that significantly differ from existing products — under the same provisions as conventional products. Future flexibility would be lost. Separate authority for unconventional products is needed because there is a growing trend toward new cigarette-like products that imply that they present less health risks than conventional cigarettes. For example, one tobacco manufacturer is test marketing a tobacco product called Eclipse that heats rather than burns tobacco. Eclipse has been promoted as producing less second hand smoke. Reports indicate that the product may produce as much tar and nicotine as conventional cigarettes, but more carbon monoxide. The manufacturers of such products may not wish to take advantage of the "reduced risk tobacco product" provision. Without a premarket review authority for new and unconventional products, manufacturers could market new, potentially less safe tobacco products without any FDA review. There would be no clear means to obtain data from tobacco manufacturers who are marketing products with important technological modifications. This has the potential to mislead consumers and to use them as guinea pigs in a long-term study of the effects of novel products.

The substitute raises numerous other concerns. A few examples follow. The prohibited act provisions, which FDA would use to seek injunctive relief or criminal penalties, are much more limited than for other FDA-regulated products. For example, FDA could pursue action only against a person who introduces a violative tobacco product into interstate commerce, and not against persons who actually do the adulteration or misbranding. As a result, there would be far fewer circumstances in which FDA could take enforcement actions, and the deterrent effect of the requirements applicable to tobacco products would be reduced. The substitute lacks authority for FDA to examine imports of tobacco products for compliance with FDA requirements, such as the warning label statement requirements, before they enter the United States. The provisions that would replace the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health and Education Act need improvement if the effectiveness of the warnings is to be enhanced. For example, under the substitute, a manufacturer could avoid using warning statements regarding the effects of tobacco use during pregnancy in those publications that are likely to be read by young women.

Tob - sct - FDA jurisdiction

S. 1415 PROVIDES AMPLE OPPORTUNITY FOR CONGRESS TO REVIEW FDA STANDARDS REGARDING THE REGULATION OF TOBACCO PRODUCTS

Hatch Amendment #2535 requires FDA health risk reduction standards to be subject to Congressional review, and requires an affirmative vote of Congress for a standard that would reduce nicotine levels of a tobacco product to zero or result in a general prohibition of cigarettes or smokeless tobacco products.

- Section 10 of S. 1415 makes clear that, consistent with current law, standards subject to 5 U.S.C. 801 will be subject to Congressional Review. In contrast, the amendment would subject all standards to this review, and would needlessly require the expenditure of valuable congressional time on the review of reports for minor regulations.

- Because of the importance of any decision by FDA to eliminate all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or to require the reduction of nicotine yields of a tobacco product to zero, S. 1415 recognizes that it is appropriate for Congress to have the opportunity to review such a decision and enact legislation to override it.

- S. 1415 recognizes this by requiring that FDA may not begin implementing any such standard until at least ***two years*** after the President notifies Congress that a final regulation imposing the restriction has been issued.

- S. 1415's provision ensures that Congress will have sufficient time and opportunity to review the standard and, if desired, vote on whether the standard should be rejected.

- FDA has no plans to use this authority, but scientific developments in the future may make its use appropriate.

- FDA has demonstrated that it would administer its authority to eliminate nicotine reasonably.

    - Although FDA had the authority to reduce or eliminate nicotine at the time it issued its tobacco regulations, the agency did not do so, because, among other reasons, there was not a sufficient scientific basis to conclude that reducing or eliminating nicotine from tobacco products would reduce tobacco use.

    - FDA's refusal to ban cigarettes or smokeless tobacco products was based in part on the significant weight the agency accorded to the risks that a black market would be created and that addicted tobacco users would suffer as a result of sudden withdrawal from nicotine-containing products.

    - FDA is required under S.1415 to take these same factors into account in promulgating any standard eliminating nicotine from tobacco products.

- S. 1415 imposes many procedural requirements on FDA before the agency can issue a performance standard eliminating nicotine from tobacco products.
  - FDA must issue a notice of proposed rulemaking, containing a finding with supporting justification that the performance standard is appropriate for protection of the public health.
  - The notice must contain proposed findings with respect to the risk of illness or injury that the standard is intended to address.
  - FDA must invite interested persons to submit an existing or draft performance standard.
  - FDA must invite participation from informed persons, including industry representatives.
  - FDA must consider the risks to the health of tobacco users and non-users from elimination of nicotine, including the risk that a black market will be created.
  - FDA must, at the request of an interested party, refer the proposed standard to an advisory committee.
- A performance standard eliminating nicotine could not be issued in the absence of scientific evidence that such elimination would significantly reduce the risks of illness or injury from tobacco products.
  - Development of such evidence would require reliable information showing that elimination of nicotine would reduce the risks of tobacco use, and that the benefits of this reduction in use were not outweighed by the risks of a black market or of precipitous withdrawal by addicted tobacco users.

THE FDA ADVERTISING RESTRICTIONS AFFIRMED IN S. 1415 ARE CONSTITUTIONAL RESTRICTIONS ON COMMERCIAL SPEECH AND ARE CRITICAL TO FDA REGULATION OF TOBACCO PRODUCTS

Hatch Amendment #2536 would nullify the advertising restrictions in the 1996 FDA Rule.

- FDA's advertising restrictions are based on a strong factual record and are narrowly tailored to restrict advertising that contributes to young people's use of tobacco.
  - These restrictions were reviewed by First Amendment experts at the Department of Justice before issuance, and are consistent with Constitutional requirements.
- The 1996 Rule's advertising restrictions affirmed by S. 1415 ban outdoor advertising within 1000 feet of schools and public playgrounds; restrict advertising to black-and-white text only (publications, outdoor, point of purchase, direct mail, etc.), except in publications with a predominant adult readership or at adult only facilities; prohibit manufacturers from selling or giving away like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos; and prohibit brand-name sponsorship of sporting or entertainment events, but permits it in the corporate name.
- These advertising restrictions limit the imagery and color that make tobacco advertising so appealing to young people, while freely permitting information to be communicated to adult consumers.
- FDA's advertising restrictions apply not only to actions by tobacco manufacturers, but also to tobacco distributors, importers, and retailers. To stop tobacco product advertising that is appealing to kids, FDA's comprehensive program is needed.
  - A system of advertising restrictions that relies only on agreement by the manufacturers would not stop advertising from these other sources. Moreover, using tobacco manufacturers to police distributors and retailers, as the settlement does, would sanction anti-competitive, collusive, and possibly predatory behavior by the manufacturers.
- Advertising restrictions are a critical component of FDA regulation of tobacco products.
  - Two recent, comprehensive analyzes by the National Academy of Science's Institute of Medicine and the Surgeon General found that tobacco advertising plays a significant role in the decisions of young people to use cigarettes and smokeless tobacco
    - The two reports are the Institute of Medicine's Report, *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youth* (1994); and the Department of Health and Human Services' Centers for Disease Control and Prevention's Report, *Preventing Tobacco Use*

Among Young People, A Report of the Surgeon General (1994). The Institute of Medicine's 1998 Report, *Taking Action to Reduce Tobacco Use* (1998) reaffirms the 1994 IOM Report.

- In addition, the nation's largest psychological association, the American Psychological Association, concluded that tobacco advertising "plays directly to the factors" that are most appealing to youth.

- During its rulemaking, FDA found, based on the evidence and comments received, that comprehensive advertising restrictions are necessary to ensure that the access restrictions on access are not undermined by the product appeal that advertising for these products creates for young people.

    - Otherwise, tobacco companies will continue to use advertising to appeal to kids, associating tobacco with fun, sex, glamour, and sports. As long as the tobacco companies are allowed to advertise to kids and create a demand for tobacco products, it will be impossible to effectively address the problem of youth tobacco use.

- FDA also concluded that ***both*** access ***and*** advertising restrictions are necessary to meet public health goals because they are complementary —

    - The effectiveness of access restrictions on youth access would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions.

FDA REVIEW OF NEW AND UNCONVENTIONAL TOBACCO PRODUCTS IS NECESSARY TO PROTECTING THE PUBLIC HEALTH

Hatch Amendments #2537 and 2538: 2537 would delete the provision authorizing FDA premarket review of certain new tobacco products. 2538 would delete a related provision which requires reports for certain new products; these reports help FDA determine whether premarket review is required for a new tobacco product.

- There is a growing trend toward new cigarette-like products that imply that they present less health risks than conventional cigarettes.
  - For example, one tobacco manufacturer is test marketing a tobacco product called Eclipse that heats rather than burns tobacco. Eclipse has been promoted as producing less second hand smoke. Reports indicate that the product may produce as much tar and nicotine as conventional cigarettes, but more carbon monoxide.
  - The manufacturers of such products may not wish to take advantage of the "reduced risk tobacco product" provisions in § 907 for various reasons, such as a lack of interest in conducting the required studies. The manufacturers of Eclipse, for example, have argued that their product should be regulated as a conventional cigarette.
- The reporting provisions in S. 1415 that would be deleted by Amendment 2538 will allow FDA to decide whether new and modified products should be regulated like conventional tobacco products or whether they require the submission of data on relative health risks, or the imposition of additional or different regulatory controls.
  - In the absence of a premarket notification requirement such as this, there would be no means available to FDA to find out, before marketing, about tobacco products with implied health claims, or with other changes in product technology, and no administrative mechanism to determine whether additional information about the relative health risks of these products is needed to protect consumers.
  - FDA's only option would be to bring an enforcement action against one of these products after it has been marketed. Enforcement actions do not protect consumers from products that remain on the market as the matter is litigated, and the manufacturers seek to delay actions that would protect consumers, as they have done with the FDA tobacco rule.
- Amendment 2537 would delete S. 1415's provisions for pre-market approval authority for new and unconventional tobacco products.
  - This authority is an important means of obtaining reliable data on whether novel tobacco products are more appropriate for the protection of the public health than

conventional tobacco products or introduce new risks.

- Products with implied health claims or new technology, may, for example, convince would-be quitters to continue tobacco product use, or non-users to begin use, on the potentially false assumption that use of the new product has fewer health risks.

    - This was arguably the case with "low-tar" products, which have now been shown to be as, or more, dangerous than the high-tar products they replaced. (The data now show that low-tar products actually increased the incidence of a major form of lung cancer.).

- Without premarket approval authority, there would be no clear means to obtain data from tobacco manufacturers who are marketing products that they imply they have fewer health risks than conventional cigarettes, or products with important technological modifications. This has the potential to mislead consumers and to use them as guinea pigs in a long-term study of the effects of novel products.

S.1415's TOBACCO PRODUCT PERFORMANCE STANDARDS ARE NECESSARY TO PROTECT THE PUBLIC HEALTH

Hatch Amendment #2539: modifies the performance standard section of S. 1415 in several significant respects.

- Amendment 2539 would require performance standards to be promulgated within 24 months of enactment of S. 1415. This would unduly limit FDA's ability to issue appropriate performance standards.
  - Particular performance standards will become appropriate as FDA obtains and reviews information and research related to tobacco products (both that which is in existing industry files and that which will be done in the future). It would be contrary to the protection of the public health to limit the agency to standards which can be initiated, developed, and issued within 24 months.
  - For example, research that begins today might establish three or four years from now that a particular additive in cigarettes is very dangerous to health. A performance standard would be the regulatory mechanism for restricting the use of such an additive. Such regulation, however, would be precluded under the amendment.
  - In addition, the extensive procedural requirements in S. 1415 for the issuance of performance standards (which track current device law) are such that it may be difficult to issue appropriate final standards within 24 months.
- Amendment 2539 would define the regulatory standard of "appropriate for the protection of the public health" that appears throughout the new Federal Food, Drug, Cosmetic Act chapter IX in S. 1415 to mean "maximize the net benefit to the public health" for purposes of certain sections of that chapter.
  - The standard of "appropriate for the protection of the public health" was used in the Senate-drafted provision applicable to distribution of journal articles in FDA legislation passed in 1997 and, under S. 1415, will be relied on when FDA makes a range of decisions for tobacco products under the chapter IX.
    - This standard allows FDA to take into account the fact that over 40 million Americans are addicted to tobacco in making decisions about how to regulate tobacco products
    - S. 1415 directs FDA, in applying this standard, to consider the risks and benefits to the population as a whole, including users and nonusers of the tobacco product. FDA is to take into account the increased or decreased likelihood that: (1) existing users of tobacco products will stop using such products, and (2) those who do not use tobacco products will initiate use.

- Codifying the standard of "maximize net benefits to public health" into the Federal Food, Drug, and Cosmetic Act would introduce a new standard that has not been previously used for public health statutes.
    - This standard would create costly litigation over the meaning of "maximize net benefits" in the context of public health regulation.
    - The standard could result in less public health protection because it could prevent the agency from choosing among regulatory options when the evidence shows that each of the options would result in significant public health benefits and be appropriate for the protection of the public health, but does not establish that any one particular option is the approach that would maximize net benefits.
    - Modifying the standard in certain provisions of chapter IX, as amendment 2539 proposed, would weaken the regulatory program by setting different standards for various regulatory actions under chapter IX.

- S. 1415 expressly requires FDA, in issuing a performance standard, to conduct a notice-and-comment rulemaking and, if appropriate, seek input from an advisory committee as part of that rulemaking. In issuing a performance standard, S. 1415 requires FDA weigh a variety of consequences that could result from possible new regulations on tobacco products, including the use of contraband products and the development of black markets, and the effects of the regulation on both users and nonusers of the products.
    - The amendment would add expressly require FDA to consider certain additional factors, such as whether the standard would result in a significant increase in the numbers of individuals seeking cessation treatment and consumer acceptable of the standard, that could be very difficult to assess, and would provide the tobacco manufacturers ample grounds to delay the standard in endless litigation.

S. 1415 PROVIDES AMPLE OPPORTUNITY FOR CONGRESS TO REVIEW ANY FDA DECISION TO ELIMINATE NICOTINE OR A CLASS OF TOBACCO PRODUCTS

Hollings Amendment #2473 would require an act of Congress before FDA could issue a performance standard banning a class of tobacco products or eliminating nicotine content in a tobacco product

- Because of the importance of any decision by FDA to eliminate all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or to require the reduction of nicotine yields of a tobacco product to zero, S. 1415 recognizes that it is appropriate for Congress to have the opportunity to review such a decision and enact legislation to override it.

- S. 1415 recognizes this by requiring that FDA may not begin implementing any such standard until at least ***two years*** after the President notifies Congress that a final regulation imposing the restriction has been issued.

- S. 1415's provision ensures that Congress will have sufficient time and opportunity to review the standard and, if desired, vote on whether the standard should be rejected.

- FDA has no plans to use this authority, but scientific developments in the future may make its use appropriate.

- FDA has demonstrated that it would administer its authority to eliminate nicotine reasonably.

    - Although FDA had the authority to reduce or eliminate nicotine at the time it issued its tobacco regulations, the agency did not do so, because, among other reasons, there was not a sufficient scientific basis to conclude that reducing or eliminating nicotine from tobacco products would reduce tobacco use.

    - FDA's refusal to ban cigarettes or smokeless tobacco products was based in part on the significant weight the agency accorded to the risks that a black market would be created and that addicted tobacco users would suffer as a result of sudden withdrawal from nicotine-containing products.

    - FDA is required under S.1415 to take these same factors into account in promulgating any standard eliminating nicotine from tobacco products.

- S. 1415 imposes many procedural requirements on FDA before the agency can issue a performance standard eliminating nicotine from tobacco products.

- FDA must issue a notice of proposed rulemaking, containing a finding with supporting justification that the performance standard is appropriate for protection of the public health.

- The notice must contain proposed findings with respect to the risk of illness or injury that the standard is intended to address.

- FDA must invite interested persons to submit an existing or draft performance standard.

  - FDA must invite participation from informed persons, including industry representatives.

  - FDA must consider the risks to the health of tobacco users and non-users from elimination of nicotine, including the risk that a black market will be created.

  - FDA must, at the request of an interested party, refer the proposed standard to an advisory committee.

- A performance standard eliminating nicotine could not be issued in the absence of scientific evidence that such elimination would significantly reduce the risks of illness or injury from tobacco products.

  - Development of such evidence would require reliable information showing that elimination of nicotine would reduce the risks of tobacco use, and that the benefits of this reduction in use were not outweighed by the risks of a black market or of precipitous withdrawal by addicted tobacco users.

Tob – ser – FDA jurisdiction

S/S Convenience stores

1. FDA provision re category of retail outlet people normally request with that they intend to use
2. Establishes diff classes of retail outlets re promotion rules:
   adult-only / tobacco stores/everyone else
   same rules should apply to all – ok to ↑ on them.
   By protocol: agreement -- should be able to do this (CIA not involved)
   If by govt action – one term is ~~we can~~ you will win on all or lose on all.
3. Point-of-sale advert –
   "Packs of cigarettes" – exclusion not in McC bill
   2> that is in FDA bill

Amendments – (2)

?

Adult-only facilities – admit lots of children.
No material diff. in prob. of success if add tob. stores + adult-only

Tob-ser-FDA jurisdiction –

May 1, 1998

AMENDMENT TO PREVENT ARBITRARY RESTRICTIONS ON TOBACCO SALES BY CATEGORIES OF RETAIL OUTLETS

Proposed change in bill language:

Replace current section 906(d)(3) with the following:

"(3) No regulation promulgated pursuant to paragraph (1) shall restrict the sale of any tobacco product by a specified category of retail outlets."

Proposed report language:

As originally adopted by the Committee, section 906(d)(3) recognized the importance of any restriction on the sale of tobacco products by categories of retail outlets and provided a two-year congressional review period for any such restriction. Restrictions on categories of retail outlets could arbitrarily injure the business of responsible retailers with no record of unlawful sales to minors. A more targeted and equitable remedy for unlawful sales is provided in the mandatory state licensing program contained in section 235, which provides for the suspension or revocation of licenses in the event of unlawful sales.

May 1, 1998

AMENDMENT TO PROVIDE FOR EQUAL TREATMENT OF RETAILERS

Proposed change in bill language:

Amend section 123(a) to read as follows:

"SEC. 123. POINT-OF-SALE RESTRICTIONS

(a) Except as provided in subsection (b), the protocol shall provide that no manufacturer, distributor, or retailer shall engage in point-of-sale advertising of any tobacco product in any retail establishment."

Proposed report language:

As originally adopted by the Committee, section 123(a) contained an exemption for tobacco shops and adult-only stores. These exemptions would favor specific classes of trade and could prejudice the competitive position of other retailers which engage only in lawful sales to adults. The exemptions would also create an artificial incentive for specialized tobacco outlets, which could become a new vehicle for aggressive promotion of tobacco use. The amendment provides competitive equity among retailers and will result in more comprehensive protection.

Tob - mr - FDA jurisdiction

REGULATORY AUTHORITY OVER TOBACCO PRODUCTS IS APPROPRIATELY PLACED AT FDA

- The Food and Drug Administration (FDA) is the leading public health agency with authority to protect public health and to provide regulatory oversight of products that affect the human body, such as foods, drugs, and medical devices.

  - There are other federal public health agencies and there are other federal regulatory agencies. But FDA is the only agency that has extensive experience in both areas. This experience, combined with its recent development of the tobacco access and advertising regulations, makes it the only federal agency that can hit the ground running to implement the regulatory program to combat youth tobacco use in S. 1415.

- Under S. 1415, tobacco products fit appropriately into the regulatory framework that FDA has had in place for over sixty years.

- The scientific and regulatory expertise that resides within FDA is uniquely suited to provide the oversight that will be needed to protect the public health from the hazards of nicotine products. FDA's medical experts already evaluate and approve nicotine replacement drug and device products. In addition, regulatory offices within the agency are experienced in industry-wide product regulation.

- FDA's enforcement authorities, which S. 1415 expressly extends to tobacco products, are essential in order to protect public health. Enforcement actions are necessary to ensure that manufacturers and retailers comply with requirements such as those in the final rule issued in 1996 to protect young people from the hazards of tobacco products, and to protect the public from future violations.

- A distinctive feature of FDA's regulatory authority is the flexibility inherent in the Federal Food, Drug, and Cosmetic Act, and in the new provisions added to that Act by S. 1415, that enable FDA to swiftly and effectively address problems linked to the products for which it is responsible. As tobacco companies design new marketing campaigns or develop new products, FDA has a great amount of flexibility to respond to industry actions that could harm public health.

ID'S OF PURCHASERS UNDER THE AGE OF 27 MUST BE CHECKED

- Under the FDA rule, a retailer must not sell cigarettes or smokeless tobacco to anyone under 18. Therefore, purchasers must be 18 or older.

- Under the FDA rule, retailers must require customers under the age of 27 to present a photo ID (any photo ID with a birth date is acceptable).

  - FDA's rule contains this requirement because the evidence compiled by the agency during its rulemaking showed that it is very difficult to judge the age of many teenagers and young adults simply from their appearance, partly because young people mature at different rates. To ensure that older-looking teenagers are asked for ID, it makes sense to set the requirement to check identification somewhere above 18.

  - FDA's requirement is consistent with a report prepared by twenty-six State Attorneys General recommending that the age for photo ID should be significantly higher than the minimum age of sale.

  - In addition, materials developed and distributed to retailers by the tobacco industry and leading retailer organizations specifically recommended that retailers card anyone who appears to be under 26.

- Under the FDA rule, a retailer is not required to check the ID's of regular customers who are known to be at least 18 years old every time they buy tobacco products. Retailers must check a customer's photo ID at least once to ensure that the customer is at least 18 years old.

S. 1415 PROVIDES AMPLE OPPORTUNITY FOR CONGRESS TO REVIEW ANY FDA DECISION TO ELIMINATE NICOTINE OR A CLASS OF TOBACCO PRODUCTS

- Because of the importance of any decision by FDA to eliminate all cigarettes, all smokeless tobacco products, or any similar class of tobacco products, or to require the reduction of nicotine yields to of a tobacco product to zero, S. 1415 recognizes that it is appropriate for Congress to have the opportunity to review such a decision and enact legislation to override it.

- S. 1415 recognizes this by requiring that FDA may not begin implementing any such standard until at least ***two years*** after the President notifies Congress that a final regulation imposing the restriction has been issued.

- S. 1415's provision ensures that Congress will have sufficient time and opportunity to review the standard and, if desired, vote on whether the standard should be rejected.

- FDA has no plans to use this authority, but scientific developments in the future may make its use appropriate.

- FDA has demonstrated that it would administer its authority to eliminate nicotine reasonably.

    - Although FDA had the authority to reduce or eliminate nicotine at the time it issued its tobacco regulations, the agency did not do so, because, among other reasons, there was not a sufficient scientific basis to conclude that reducing or eliminating nicotine from tobacco products would reduce tobacco use.

    - FDA's refusal to ban cigarettes or smokeless tobacco products was based in part on the significant weight the agency accorded to the risks that a black market would be created and that addicted tobacco users would suffer as a result of sudden withdrawal from nicotine-containing products.

    - FDA is required under S.1415 to take these same factors into account in promulgating any standard eliminating nicotine from tobacco products.

- S. 1415 imposes many procedural requirements on FDA before the agency can issue a performance standard eliminating nicotine from tobacco products.

    - FDA must issue a notice of proposed rulemaking, containing a finding with supporting justification that the performance standard is appropriate for protection of the public health.

    - The notice must contain proposed findings with respect to the risk of illness or injury that the standard is intended to address.

- FDA must invite interested persons to submit an existing or draft performance standard.

- FDA must invite participation from informed persons, including industry representatives.

- FDA must consider the risks to the health of tobacco users and non-users from elimination of nicotine, including the risk that a black market will be created.

- FDA must, at the request of an interested party, refer the proposed standard to an advisory committee.

- A performance standard eliminating nicotine could not be issued in the absence of scientific evidence that such elimination would significantly reduce the risks of illness or injury from tobacco products.

  - Development of such evidence would require reliable information showing that elimination of nicotine would reduce the risks of tobacco use, and that the benefits of this reduction in use were not outweighed by the risks of a black market or of precipitous withdrawal by addicted tobacco users.

S. 1415 APPROPRIATELY MAKES EXPLICIT FDA'S AUTHORITY TO RESTRICT TOBACCO PRODUCT ADVERTISING

- S. 1415 expressly provides that FDA may by regulation require that a tobacco product be restricted to sale, distribution, or use upon such conditions, ***including restrictions on the access to and the advertising and promotion of the tobacco product***, if FDA determines that such regulation would be appropriate for the protection of the public health.
  - This provision has no effect on FDA's regulation of drugs and devices.
- Advertising restrictions are a critical component of FDA regulation of tobacco products.
  - Two recent, comprehensive analyses by the National Academy of Science's Institute of Medicine and the Surgeon General found that tobacco advertising plays a significant role in the decisions of young people to use cigarettes and smokeless tobacco.
    - The two studies are the Institute of Medicine's Report, *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youth* (1994), see especially chapter 4; and the Department of Health and Human Services' Centers for Disease Control and Prevention's Report, *Preventing Tobacco Use Among Young People, A Report of the Surgeon General* (1994), see especially chapter 5.
    - The Institute of Medicine's 1998 Report, *Taking Action to Reduce Tobacco Use* (1998) reaffirms the 1994 IOM Report.
  - In addition, the nation's largest psychological association, the American Psychological Association, concluded that tobacco advertising "plays directly to the factors" that are most appealing to youth.
  - During its rulemaking, FDA found, based on the evidence and comments received, that comprehensive advertising restrictions are necessary to ensure that the access restrictions on access are not undermined by the product appeal that advertising for these products creates for young people.
    - Otherwise, tobacco companies will continue to use advertising to appeal to kids, associating tobacco with fun, sex, glamour, and sports. As long as the tobacco companies are allowed to advertise to kids and create a demand for tobacco products, it will be impossible to effectively address the problem of youth tobacco use.

- FDA also concluded that ***both*** access ***and*** advertising restrictions are necessary to meet public health goals because they are complementary —
  - The effectiveness of access restrictions on youth access would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions.

- Because advertising restrictions are so critical, the agency's authority in this area should not be left ambiguous and open to lengthy court challenges.

S. 1415 ENSURES THAT FDA WILL ADEQUATELY CONSIDER WHETHER A PROPOSED REGULATORY ACTION WILL RESULT IN HEIGHTENED DEMAND FOR CONTRABAND

- S. 1415 requires that FDA find that regulations to be imposed on a tobacco product "are appropriate for the protection of the public health."
  - In making this finding, FDA is directed to consider the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and
  - Taking into account the increased or decreased likelihood that: (1) existing users of tobacco products will stop using such products, and (2) those who do not use tobacco products will initiate use.
  - FDA is to weigh a variety of consequences resulting from possible new regulations on tobacco products, ***including the use of contraband products and the development of black markets***, and consider the effects of the regulation on both users and nonusers of the products.
  - This standard is not be applied to any other product regulated under the Federal Food, Drug, and Cosmetic Act.
- Requiring FDA to affirmatively ***find*** that a particular regulatory action will not result in the heightened demand for contraband would severely restrict the Agency's authority as it would be forced to prove an unknown.
  - It could be very difficult to prove a negative—that a black market will not occur.
  - If FDA makes the finding, its decision would be delayed by extended litigation.
- FDA's 1996 tobacco rule reflects the agency's consideration of the contraband issue:
  - Considering the large number of Americans who are currently addicted to nicotine, FDA determined that a ban on cigarettes and smokeless tobacco would unlikely be effective in protecting consumers from the serious risks of these products. FDA found that black markets and smuggling could develop, offering products that likely "would be even more dangerous than those currently marketed."
  - FDA concluded that, to address effectively the death and disease caused by cigarettes and smokeless tobacco, addiction to these products must be eliminated or substantially reduced.
  - FDA found that this goal could be achieved best by preventing minors from beginning use of tobacco products, and not by banning the products.

Tob - or - FDA jurisdict

FDA

Amendment to preserve integrity of existing FDA regulatory programs for drugs and devices.

As reported from the Senate Commerce Committee, S. 1415 creates the possibility of unintentional changes in the scope of existing and future FDA authority over live-saving drugs and devices. ***These problems exist even though S. 1415 establishes the regulation of tobacco in a separate chapter from drugs and devices under the Food Drug and Cosmetic Act because S. 1415 also deems as lawfully issued the FDA regulation which asserts that tobacco products ARE drug-delivery devices***. This amendment preserves the letter and spirit of the recently enacted FDA reform bill (S. 830) as well as S. 1415, has no effect on FDA's ability to regulate tobacco and tobacco products, and does not change FDA's existing authority under the Act.

Problem

In developing the proposed rule to regulate tobacco, FDA developed novel and expansive interpretations of its drug and device authority to assert jurisdiction over tobacco products using notions of intended use, foreseeable use, and combination products. ***The concepts developed by FDA in the tobacco regulation have far reaching implications for drugs and devices and are no longer needed since S. 1415 provides a statutory grant of authority to FDA to regulate tobacco.***

Using the same logic in the FDA tobacco rule, FDA could assert that a can of Coke is a drug-delivery device subject to the same all-encompassing FDA regulatory program envisioned for cigarettes. Further, FDA could deprive a drug manufacturer of the market exclusivity time now allowed to innovator products to make up for time lost off of patent life during FDA review by asserting that a particular product, although a drug, be subject to regulation under the device laws which do not provide for market exclusivity.

Solution

The FDA should not have to repromulgate the final regulations issued August 28, 1996 (62 Fed. Reg. 44615-18). Therefore, the amendment deems the final regulation as promulgated by the Secretary pursuant to the new chapter IX and existing section 701 of the Food Drug and Cosmetic Act and not pursuant to chapter V (the drug and device chapter). The amendment also establishes that the jurisdictional findings and preambles of the proposed and final rules do not constitute advisory opinions of the FDA and are without effect.

Further, the amendment clarifies that Congress is conferring authority on FDA to regulate tobacco. Finally, the amendment clarifies that policies issued or regulations promulgated under the new Chapter IX governing tobacco products shall not affect the regulation of drugs and devices.

AMENDMENT NO. ____ Calendar No. ____

Purpose: To clarify Food and Drug Administration regulations relating to tobacco.

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

S. 1415

To reform and restructure the processes by which tobacco products are manufactured, marketed, and distributed, to prevent the use of tobacco products by minors, to redress the adverse health effects of tobacco use, and for other purposes.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENTS intended to be proposed by _____

Viz:

On page 251, line 6, strike "confirm the authority of" and insert "clarify the authority of".

On page 266, strike lines 17 through 23.

On page 266, line 24, strike "(d)" and insert "(c)".

On page 267, line 1, insert after "chapter" the following: ", or any policy issued or regulation promulgated thereto".

jm 9011(c) The provisions of part 897 that are not in effect on the date of enactment of this chapter shall take effect as in such part or upon such later date as determined by the Secretary by order.

On page 338, between lines 16 and 17, insert the following:

SEC. 103. CONSTRUCTION OF CURRENT REGULATIONS.

(a) IN GENERAL.—The final regulations promulgated by the Secretary in the August 28, 1996 issue of the Federal Register (62 Fed. Reg. 44615-18) and codified at part 897 of title 21, Code of Federal Regulations, ~~are~~ shall be deemed to have been promulgated by the Secretary pursuant to chapter IX and section 701 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, and not pursuant to any provision of chapter V of the Federal Food, Drug, and Cosmetic Act. The Secretary shall amend the designation of authority in such regulations in accordance with this subsection.

(b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products and ~~shall be without effect~~ shall not be cited as precedent in any future regulatory action involving FDA's use of its compliance policy authority.

(1) The preamble to the proposed ~~regulation~~ Rule in the document entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents" (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document entitled "Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act" (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final ~~regulation~~ Rule in the document entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document entitled "Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination" (61 Fed. Reg. 44619–45318 (August 28, 1996)).

Tob - air - FDA jurisdicti—

Re-draft May 11, 1998

AMENDMENT TO PREVENT ARBITRARY RESTRICTIONS ON TOBACCO SALES BY CATEGORIES OF RETAIL OUTLETS

Proposed change in bill language:

Replace current section 906(d)(3) with the following:

"(3) No regulation promulgated pursuant to paragraph (1) shall restrict the sale of any tobacco product by a specified category of retail outlets unless the Secretary finds that fifty percent (50%) of the retail outlets in the specified category in the United States have had their licenses pursuant to section 235 revoked or suspended for illegal sales of tobacco products to minors within a period of five (5) consecutive years, provided that no such restriction shall apply to any retail outlet whose license pursuant to section 235 is in good standing."

Proposed report language:

As originally adopted by the Committee, section 906(d)(3) recognized the importance of any restriction on the sale of tobacco products by categories of retail outlets and provided a two-year congressional review period for any such restriction. Restrictions on categories of retail outlets could arbitrarily injure the business of responsible retailers with no record of unlawful sales to minors. The proposed amendment provides a more targeted and equitable remedy for unlawful sales by incorporating the mandatory state licensing program contained in section 235, which provides for the suspension or revocation of licenses in the event of unlawful sales.

From conv. store operators

Rob-out-FDA jurisdiction

New FDA convenience store language

May 11, 1998

PROPOSED AMENDMENT TO FDA CHAPTER OF McCAIN

Rewrite the second sentence of section 906(d)(3) to read as follows:

Therefore, any such restriction may not take effect --

(A) **unless the Secretary has identified a pattern of violations of restrictions on sale, distribution or use among the category of retail outlets that will be subject to such restriction, and**

(B) before the date that is 2 years after the President notifies the Congress that a final regulation imposing the restricting has been issued.

[new language in bold]

Tobac - ter - FDA jurisdiction

MARCH 2, 1998

CONCERNS REGARDING SENATOR JEFFORDS' TOBACCO LEGISLATION

FDA Authority

- the bill does not regulate nicotine as a "drug" or tobacco products as "drug delivery devices." Instead, it provides an entirely new and substantially weaker set of regulatory provisions for tobacco products.

- the definition of tobacco product needs to be broad enough to clearly include all new tobacco products which the industry may develop

- only cigarettes and smokeless tobacco are subject to regulation, not cigars, pipe tobacco or other tobacco products

- clarify language to make clear that all regulatory authority over tobacco can be exercised by notice and comment rulemaking with no special administrative hurdles; delete extra requirements such as p.21, lines 13-21, p.22 lines 23-35, p.23 lines 18-25

- delete exclusion of "reconstituted tobacco sheet" from ingredient disclosure

- does not give FDA adequate authority to order the production of all information relevant to the regulation of tobacco products. The document disclosure section is too limited. FDA should be given subpoena power for tobacco regulation.

- confidentiality language on p.17, lines 5-14 is much too broad and should be deleted. It would make confidentiality the norm and disclosure the exception.

- the provision on pgs.18-19 allowing the Secretary to disclose "in the interest of public health" should apply to all information from tobacco companies, not just ingredients.

- requires FDA to consider the "commercial feasibility" of a proposed health risk reduction standard. This would make tobacco company profitability an issue in decisions which should be based solely on health considerations. It would allow tobacco companies to use commercial feasibility as a basis for challenging FDA rules in court.

- "technological feasibility" language would impede FDA's ability to force companies to explore new technology by limiting its rulemaking to existing technology

- authority of FDA to modify existing ingredients should begin upon passage, not five years after passage as stated on p.28. Five year period should only apply to submission of health risk assessments by companies on p.29.

- allows new ingredients to be put in cigarettes without prior FDA approval

Youth Access -- Licensing of Retailers

- enforcement given to Center for Disease Control and Prevention, rather than FDA

- CDC has no enforcement capacity or enforcement experience

- CDC not given authority to promulgate additional youth access restrictions, only to implement the statutory restrictions

- standard for state compliance should be 95%, not 90%

- penalties for sale to minors much too low -- should begin at minimum of $500 for first offense, scale up to $1,500 and 7 day suspension for third offense, etc.

- no back up enforcement by federal government if state does not act

Youth Smoking Reduction Targets & Lookback Penalties

- penalties imposed industry-wide by market share. Should be imposed on a company-specific basis to maximize deterrent effect

- allows companies to apply for and receive a rebate of 75% of the penalties if they acted in good faith. Totally destroys deterrent effect of lookback. Can litigate for years.

- does not require the company to pay prior to challenging in court

- percentage reduction targets should be higher and smokeless tobacco should be subject to the same percentage reduction as cigarettes

- penalties should not be tax deductible

- penalties are substantially higher than June20th agreement, but much lower than penalties in Kennedy and Conrad bills

- penalties should double and triple for consecutive year violations

- formula should be based on "monthly use" rather than "daily use" of tobacco products by minors

Environmental Tobacco Reduction

- no statutory provision, merely directs OSHA to set indoor air quality standards within a year

- OSHA says it would take at least five more years to do by regulation, should be statutorally established findings, policy, and scope of coverage

- requires an affirmative vote of Congress before the FDA could implement an order reducing nicotine levels to zero or banning cigarettes or smokeless tobacco

- includes representatives of the tobacco industry on the scientific advisory board

- no authority over tobacco product design, construction, non-ingredient components such as filters

- no protection against adulterated products

- no authority to prohibit misbranded products

- no authority is given to the FDA to regulate tobacco company marketing or advertising. Thus, each change in the advertising rules would have to be made by Congress. There is no enforcement authority provided for the statutory advertising rules.

- no FDA authority to prohibit misleading claims in advertising or to prevent express or implied health claims

- regulatory authority of FDA to change text of warnings should include format as well

- the provisions on FDA authorization of reduced risk tobacco products is too narrow, the process is tilted in favor of allowing such products to be marketed, does not adequately consider overall health risk to public

- FDA should not have to wait five years to revoke designation of reduced risk product

- overly broad pre-emption of state and local authority to regulate areas such as advertising, ingredient disclosure and testing. Sec. 902 is document disclosure which certainly should not pre-empt state and local efforts to compel greater disclosure

- provides funding of only $100 million per year, as opposed to $300 million in June 20th agreement

- penalty provisions not comprehensive

Advertising Restrictions

- statutorally established with no mechanism for monitoring or enforcement

- no regulatory authority to alter or supplement the restrictions based on future industry action

- each change would require an act of Congress

Tobacco - scr - FDA jurisdiction

Admin. Concerns w/ Jeffords

FDA's authority to regulate tobacco products as contemplated in S. 1648

The President has stated that the Administration will support proposed tobacco legislation only if it affirms the FDA's full authority to regulate tobacco products. That means the authority must be as effective as FDA's authority over other drugs and devices, and must be sufficiently flexible to meet changing circumstances. S. 1648, if enacted, does not meet that standard. The bill has two problems. First, the bill deprives the FDA of needed elements of regulatory authority. Second, by creating a separate Chapter for tobacco products, the bill unnecessarily impinges on FDA's ability to exercise, in the most effective and efficient manner, its authority over tobacco products..

I. The separate Chapter created by S. 1648 to regulate tobacco product suffers from the following specific deficiencies:

A. Access. The bill deprives FDA or any other HHS agency of the ability to modify access requirements if the current access restrictions in the FDA rule are inadequate or require redirection (such as limiting the types of stores where tobacco products can be sold). The bill also bifurcates access and advertising regulatory authority, the former going to the Centers for Disease Control; the latter to FDA. That division of responsibility weakens both authorities.

B. Advertising. The bill deprives FDA of the authority to modify advertising restrictions if the ones in the current rule require amendment or supplementation.

C. Flexibility. The bill requires that both Houses of Congress act affirmatively -- by enacting a law --to eliminate nicotine or to eliminate tobacco products (even if, in the distant future, a safer alternative to nicotine or the product is developed).

D. Product Safety. The bill limits FDA's authority to set standards pertaining to nicotine and other ingredients in tobacco products, and deprives FDA of the authority to require safer products through regulation of, for example, the filter, paper or tobacco leaf. In addition, the bill eliminates FDA's ability to require premarket approval and rigorous testing for new tobacco products.

E. Enforcement. The bill does not contain the following enforcement authorities that are in current law: civil money penalties; recall authority; authority to detain illegal products without a court order; and authority to seize products pursuant to a court order. Additionally, the bill eliminates FDA's current adulteration and misbranding authority for tobacco products – which is the authority to bring individual enforcement actions without issuing a regulation.

II. Even if all of the above elements of FDA authority were added to S. 1648, the creation of a separate Chapter for regulation of tobacco products creates unnecessary obstacles to the effective exercise of FDA authority. Three points illustrate this.

A. The inference that would be drawn from enactment of a new Chapter is that Congress intended to create a tobacco jurisdiction in FDA not only separate from but different than that

exercised over all other FDA-regulated products. The current statutory scheme that FDA has used to regulate tobacco has been interpreted in more than 20 years of regulations, guidances and judicial cases. Enactment of a new Chapter would replace all of that with a stand-alone, uninterpreted and unexplicated new jurisdiction, the full scope and extent of which would have to be re-built through agency action and judicial rulings.

By contrast, clarification in the Food Drug and Cosmetic Act of the definitions of "drug" and "device" to explicitly include tobacco products -- and clarification of FDA's statutory authority to place restrictions on medical device products to explicitly include tobacco advertising -- leaves in place this entire regulatory context. Should Congress so choose, the standard for safety and efficacy of new products could be amended to one that achieves an enhanced public health outcome.

B. New statutes require years to implement. A new Chapter will almost certainly require new rules, which will take years to implement, especially given the virtual certainty of legal challenges.

C. Finally, a new Chapter will almost certainly generate litigation over whether the FDA must scrap entirely its current regulation and re-start the regulatory process after new legislation is adopted.

3/5
1 p.m.

Changes to Jeffords

References are to o:\bai\bai98.467

Section 2. findings [pp. 2-4]

- Need advertising-specific findings. The following would be appropriate (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.

Title I—Regulation of Tobacco Products and Tobacco Product Development [p. 8]

- Creates a separate section for tobacco products. Does not affirm FDA jurisdiction over nicotine as a drug and tobacco products as devices. Lose residual authority under FDCA's device provisions. (See attached language for provisions necessary to affirm FDA jurisdiction).

- By creating a separate Chapter for tobacco products, the bill unnecessarily impinges on FDA's ability to exercise, in the most effective manner, its authority over tobacco products. Even if all of problems with S. 1648 were addressed in the context of a separate chapter, the creation of a separate Chapter for regulation of tobacco products creates unnecessary obstacles to the effective exercise of FDA authority. Three points illustrate this.

  - The inference that would be drawn from enactment of a new Chapter is that Congress intended to create a tobacco jurisdiction in FDA not only separate from but different than that exercised over all other FDA-regulated products. The current statutory scheme that FDA has used to regulate tobacco has been interpreted in more than 20 years of regulations, guidances and judicial cases. Enactment of a new Chapter would replace all of that with a stand-alone, uninterpreted and unexplicated new jurisdiction, the full scope and extent of which would have to be re-built through agency action and judicial rulings.

    By contrast, clarification in the Food Drug and Cosmetic Act of the definitions of "drug" and "device" to explicitly include tobacco products—and clarification of FDA's statutory authority to place restrictions on medical device products to explicitly include tobacco advertising—leaves in place this entire regulatory contex. Should Congress so choose, the standard for safety and efficacy of new products could be amended to one that achieves an enhanced public health outcome.

  - New statutes require years to implement. A new Chapter will almost certainly require new rules, which will take years to implement, especially given the virtual certainty of legal challenges.

- ▸ Finally, a new Chapter will almost certainly generate litigation over whether the FDA must scrap entirely its current regulation and re-start the regulatory process after new legislation is adopted.

Section 101 [pp. 10-11]

- Lacks necessary conforming amendments, such amending section 703 to allow FDA access to records of interstate commerce of tobacco products (amendment would be unnecessary if tobacco products are drug delivery devices).

- Because bill excludes tobacco products from regulation as drugs and devices, bill does not provide FDA with authority to seize violative (e.g., misbranded or adulterated) tobacco products. Would need to amend section 304, and add misbranding and adulteration provisions applicable to tobacco products (the adulteration and misbranding provisions applicable to drugs and devices are located in FDCA sections 501 and 502; if tobacco products are regulated as devices, these provisions would automatically become available and seizure would be an enforcement option).

- Also, the bill does not contain the following other enforcement authorities that are in current law: civil money penalties; recall authority; and authority to detain illegal products without a court order.

- In addition, would need to amend import provision of the FDCA (section 801) to permit FDA to have import authority over tobacco products (amendment would be unnecessary id the products are regulated as drug delivery devices).

(Section references below are to proposed new FDCA sections)

Section 900, definitions [p. 11-13]

- Adding all of these definitions may limit future FDA flexibility. Also, section 201 defines categories of regulated products rather than specific products within the category (e.g., the FDCA defines "food" but not vegetable, etc.). Under the traditional FDCA approach, it is only necessary to define "tobacco products," e.g.—

  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.

- The definition of cigarettes [p. 9], for example, would not include new products that contain tobacco but contain a nicotine substance (rather than nicotine). But it would require the agency to treat new products--even those that differ significantly in composition--under the same provisions as conventional cigarettes. Future flexibility would be lost.

- It is not entirely clear from the limitation on the definition of tobacco products whether loose, roll-your-own tobacco would be covered as a tobacco product [p. 11].

Section 902. Submission of Health Information to the Secretary [pp. 13-18]

- page 14, lines 1-7: 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.

- These provisions should be additive to other obligations FDA may impose under the FDCA.

  - For example, under the FDCA's device provisions and its regulations (see FDCA section 519), FDA has authority to require device manufacturers to supply certain records to the agency. Under 21 C.F.R. 860.7(g)(2), FDA can require manufacturers to "make reports or provide other information bearing on the classification of a device and indicating whether there is a reasonable assurance of safety and effectiveness of the device and whether it is adulterated or misbranded under the act." This provision could encompass categories of information not included in proposed section 902.

  - In addition, with respect to ingredients, FDA has authority under section 502(r)(2), to issue regulations that require a restricted device's advertising to contain "a full description of the components of such device or the formula showing quantitatively each ingredient of such device." The ingredient information required to be submitted to the Secretary under proposed section 902(a)(1) is more narrow than what FDA might require by regulation for public disclosure.

- page 16, lines 7-16: Except for certain ingredient and compound information, it appears that all of the information submitted under section 902 is to be considered privileged and confidential under FOIA exemption 5 U.S.C. 552(b)(4), and exempt from public disclosure. Much of this information would otherwise be releasable under FOIA. The legislation does not appear to contain any provisions for public disclosure of information, other than ingredient and related information.

- The provisions for the protection of trade secret information are unnecessary [page 17]:

  - FDA already has regulations and extensive procedures in places to protect trade secret information. The unauthorized release of trade secret information obtained under the FDCA is a prohibited act under section 301(j), and is subject to criminal penalties.

- page 18, section 902(d)(5): This provision allows the Secretary to require ingredient, substance, or compound information to be disclosed, irrespective of trade secret status, if the Secretary determines disclosure is in the interest of public health. This provision does not appear to overcome FDCA section 301(j)'s prohibition on disclosure of trade secret information by FDA employees. HHS does not currently have this authority, and the mandated release of this information could expose the government to takings claims in which monetary damages would be assessed the government.

Section 903. Tobacco Product Health Risk Reduction Standards [pp. 18-34]

- Section 903(b)(2), p. 20: the provision requiring the Secretary to act withing 60 days on requests for changes in the standard could be used by industry to flood the agency with endless requests for changes. FDA has regulations in place for petitioning the agency on issues.

- Section 903(b)(3)(B), pp. 21-22: requires Secretary to minimize trade disruption in determining effective dates of standards. Economic concerns should not be emphasized over public health concerns.

- Section 903(c)(1)(A), page 23: This provision limits FDA's authority to set standards pertaining to nicotine and other ingredients in tobacco products, and deprives FDA of the authority to require safer products through regulation of, for example, the filter, paper or tobacco leaf. FDCA Section 514 provides FDA with broad authority to establish performance standards. Section 514 specifically authorizes FDA to promulgate performance standards that include—

  > (i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,
  >
  > (ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

(iii) provisions for the measurement of the performance characteristics of the device,

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title; and

(C) where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

- Section 903(c)(2) makes these types of modifications "considerations" in regulating the composition of tobacco products, pp. 24-26. But the section, unlike section 514, does not authorize the Secretary or FDA to promulgate performance standards in these areas that do not include nicotine or ingredients.

- Page 26-27, Congressional review: The bill requires that both Houses of Congress act affirmatively — by enacting a law — to eliminate nicotine or to eliminate tobacco products (even if, in the distant future, a safer alternative to nicotine or the product is developed). In addition, this authority cannot be delegated by the Secretary to FDA.

Section 903(d) tobacco products risk assessment standards [pp. 27-34]

- Manufacturers have 5 years to submit their assessments of ingredients, etc. [pp. 28-30]. This would allow them to flood FDA with information shortly before the 5 year period ends. FDA has to act withing 180 days of receipt [p. 31]. It would be preferable to allow FDA to require the companies to submit findings on a staggered basis.

- section 903(d)(3)(D), basis of assessment [p. 30]: the standard for the companies' submission(s) is problematic. It could permit them to do submit less than complete reports of investigations and research. Also, "minds of competent scientists" is not a standard in FDCA. A preferable standard would be "reasonable certainty of no harm," etc.

- The limitation, section 903(e)(2) is too broad; it would prevent FDA from taking enforcement against a manufacturer who is in compliance with the risk reduction standard yet violates the advertising restrictions.

Section 904, good manufacturing practices [pp. 34-40]

- This provision is similar to existing GMP authority generally tracks existing authority, section 520(f).

- But the section lacks authority for requiring record-keeping and reporting of adverse events. These are important aspects of existing device authority.

- Section 904(d), agricultural producers: this could be permit tobacco manufacturers to circumvent requirements. A qualification would avoid this problem—

> 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 905, warning statement requirements

- common or usual names, pp. 54-55: requiring only disclosure of the common or usual names of ingredients significant limits the informative available to the public. Under the device provisions, FDA could require fuller disclosure.

Section 906, advertising restrictions [p. 55-66]

- The bill significantly limits FDA's authority to modify advertising restrictions if the ones in the current rule require amendment or supplementation. To ensure future flexibility, would be preferable to simply expressly clarify FDA's authority to promulgate advertising restrictions. It is not necessary to include specific advertising restrictions in the statute.

- There may be Constitutional concerns with the provisions that go beyond the FDA tobacco rule. In addition, some of the specific restrictions are not as comprehensive as FDA provisions. Specific examples include:

  —the bill [p. 56] permits advertising at events "that does not include a significant number of individuals who are under 18." This is a vague standard, and would be difficult enforce.

  —the ban on use of human images and cartoon characters [p. 56] leaves companies with a wide range of images to attract children (e.g., live animals, scenery, inanimate objects, etc.). FDA's analysis of the available research shows that limiting all advertising to black and white text only (with certain exceptions for adult forums) is the most effective approach. If these provision mean that black and white text advertising is the norm, and that human images and cartoon characters are banned even in adult facilities and adult publications, it would be acceptable from a policy perspective.

—section permits audio and video materials to be distributed (but not played) at point of sale [p. 58]. 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 materials may not, however, leave the facility (except in adult-only facilities and they cannot leave the facility).

- Facility exception, section 902(c)(2)(A)(i)(III) [p. 62]: 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).

  Also, the provision bases the definition of adult facility on the locations in which vending machines are permitted. The access restriction provisions are no longer part of the proposed amendments to the FDCA, so we cannot determine whether this definition is appropriate. The FDA tobacco rule limited it to "facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time."

- Section 906(c)(2)(B): Format and content requirements; definition of adult publication [pp. 62-63]: is less comprehensive than FDA rule. Should have to meet both (i) and (ii). Under the bill, a publication could have over 2 million youth readers but have tobacco advertisements because 2 million readers constitute only 5% of the magazine's total readership.

- Standard for promulgating additional restrictions, section 906(e) [p. 65]: "significantly contributing to the use of tobacco products by individuals who are under 18 years of age" would be difficult to establish, and is more than what is Constitutionally required under current First Amendment jurisprudence.

Section 907, reduced risk [pp. 66-72]

- Eliminates FDA's ability to require premarket approval and rigorous testing for new tobacco products.

- Appears to limit FDA's discretion in determining whether a product should be designated as "reduced risk." This determination is to be based, in part on "short-term human testing." It may be appropriate to have longer studies before a determination is made [p. 67, top].

- Products retain the reduced risk designation for 5 years—information could become available before that time that warrants revocation of the designation [p. 68]. Under this provision, FDA could take no action during that time.

- The meaning of section 906(d) "limitation"--which provides that a product that is designated as a reduced risk product and is compliance with the section "shall not be regulated as a drug or device"--is unclear [page 68, bottom].

- Page 69, development of reduced risk tobacco product technology: The Secretary is required to determine within 6 months whether the technology is likely to result in less hazardous products. This may not be sufficient to appropriately evaluate the technology.

- Commercial feasibility should not be accorded the same status as public health considerations in the Secretary's evaluation of the technology [p. 71].

Access restrictions

This section for access restrictions has been dropped from the current draft of the FDCA provisions. The previous draft deprived FDA or any other HHS agency of the ability to modify access requirements if the current access restrictions in the FDA rule are inadequate or require redirection (such as limiting the types of stores where tobacco products can be sold). The bill also bifurcated access and advertising regulatory authority, the former going to the Centers for Disease Control; the latter to FDA. That division of responsibility weakens both authorities. CDC is not a regulatory agency, and does not have the experience to administer a regulatory program. By contrast, FDA is an enforcement agency, has experience in conducting enforcement actions, and an array of enforcement tools available. The FDCA provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a). As discussed in my written statement, FDA currently is enforcing aspects of its restrictions on youth access to tobacco products embodied in the FDA tobacco rule (21 C.F.R. §§ 897.14, 897.16). FDA is enforcing these age and photo ID provisions cooperatively with state and local officials.

Section 908, advisory committee [pp. 72-74]

- FDA currently has this authority under existing section 904. The membership categories may not be appropriate. For example, it is not clear whether a representative of the general public selected from groups representing tobacco product users would have experience relevant to the consideration of technical FDA regulatory issues. In addition, the inclusion of a tobacco manufacturer representative might hinder the group's ability to reach consensus.

- The advisory committee's role is unclear. The provisions appear to give the committee a role in decision-making (as opposed to providing advice and information, which is the usual role of such groups).

Section 910, judicial review [pp. 74-77]

- Not clear why a special process is required; could use established procedures of APA.

- FDA matters are usually reviewed at the district level in the first instance (rather than the courts of appeal) [p. 75].

- The provision allowing for submission of additional information, section 910(b) [p. 76], could significantly delay proceedings and, as a result, unduly delay implementation of FDA/HHS actions.

- Section 910(f) [p. 77], statement of reasons requirement: this may impose extra burdens on agency, beyond what would do as part of notice-and-comment rulemaking.

Provisions necessary to expressly acknowledge FDA's jurisdiction

A statement validating the regulations enacted by FDA--

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

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

> Drug-Section 201(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"

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

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

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

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

(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,"