NLWJC - Kagan

DPC - Box 045 - Folder 002

Tobacco-Settlement: FDA Jurisdiction Product Regulation [2]

Tob-scr-FDA jurisdic

3-13 Raich meeting

Concerned abt def. of drug - FDA could label anything!

GMPs - non-benign authns.

Concern - range of new powers over non-tobacco products.

FDA Panel - Schultz - Tuesday

(Pub health ips -

don't care if say

can't eliminate tob products)

Kennedy has certain things

That he specifies

Preemptn = labels diff than everything else.

Smokeless Act.) states can't do this

nothing preempted

Targets - used in settlement?

Are these OK with us?

Procedures - used now -

(Circ. where take into acct black mkt)

Sep page - how diff from initial settlement.

Tobacco - settlement - FDA jurisdicti-

HIMA

ALAN H. MAGAZINE
PRESIDENT

March 11, 1998

Mr. William Schultz
Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 1481, HF-22
Rockville, MD 20857

Dear Mr. Schultz:

I want to let you know our concerns about the position of the Food and Drug Administration (FDA) on tobacco legislation that is currently being considered on Capitol Hill. I understand that this position also reflects that of the Administration, including Vice President Gore. As we understand it, the agency supports using existing regulatory authorities for drugs and devices as the basis for regulating tobacco products. We understand that the Administration favors Senator Kent Conrad's legislation (S.1638) that would add "a delivery component of a tobacco product" to the legal definition of devices (Sec. 203) and would clearly authorize the Secretary to regulate "any tobacco product as a drug, device, or both . . . ."

FDA's testimony before the Senate Committee on Labor and Human Resources expresses the belief that the current Act's drug and device authorities "provide[s] a comprehensive set of tools which allows the Agency to craft appropriate restrictions on access to and the advertising of tobacco products." The agency has already applied its authority to regulate drugs and devices to tobacco products--on the grounds that such products are "drug delivery devices."

While FDA's position may be tenable as a matter of legal interpretation (although that issue has not yet been finally decided), we maintain that defining any part of a tobacco product as a medical device is antithetical to the inherent nature of medical devices as articles intended to be used "in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man...." (Federal Food, Drug, and Cosmetic Act, Section 201(h)). Moreover, one of the overarching purpose of the Federal Food, Drug and Cosmetic Act is to authorize a regulatory scheme to primarily ensure that drugs and devices are safe and effective for human use--a standard that is not appropriate for tobacco products.

We understand your interpretation may have been necessary as a basis to assert jurisdiction over tobacco initially. However, we strongly urge you to use the opportunity presented by the current legislative initiatives to seek specific authority to regulate tobacco products *qua* tobacco products--not as drugs, devices, or a combination thereof. There is no reason to attempt to force fit longstanding device principles and laws to accommodate tobacco products. Language in S. 1638 that changes the application of such core standards as safety and effectiveness to a standard where, vis a vis tobacco products, the "best public health result is achieved" is an unnecessary attempt to fit a round peg into a square hole. Congress has ample authority to identify which standards should apply to tobacco and tailor them specifically to the intended purpose.

In addition to our basic philosophical contention that a group of products designed to diagnose and cure disease should not include products that may be deleterious to human health, we are also concerned that there may be unintended consequences of defining tobacco products as drugs, devices, or a combination thereof. For instance, applying device provisions to tobacco products could create administrative or judicial precedents that would be entirely inappropriate for medical devices. The mere existence of such precedents has the potential to cause confusion, legal uncertainty, and additional burdens for an industry committed to patient health.

We are also concerned about the financial impact of FDA's regulation of tobacco products as devices, especially on the budget level of the Center for Devices and Radiological Health (CDRH). Conceivably, the agency could reallocate sizeable portions of the CDRH budget to tobacco regulation on the grounds that tobacco products now fall within the device regulatory authority. This result would be disastrous, not only because base funding for CDRH has already been reduced in FY 98 vs. FY 97, but also because the Administration is proposing further significant reductions to the CDRH budget for FY 99. Given the recent enactment of the "Food and Drug Modernization Act of 1997" --spurred by the need to create efficiencies to help patients gain access to medical devices--the potential harm to the CDRH budget--and the certain consequence of increased review times--would be counterproductive to all the good work done by many parties, including the agency itself, to see this legislation through to completion.

In conclusion, we reiterate our request that you and the Administration work with key members of Congress to enact tobacco legislation that gives FDA appropriate authority to regulate tobacco products as tobacco products, and not as medical devices or drugs.

Thank you for your consideration of this request.

Sincerely,

Alan H. Magazine

AHM/jc

3-19 FDA Jurisdiction - 1/c group - Sen staff

Q: black market? how to take into acct?

Q: action that makes ~~[illegible]~~ product unpalatable to many folks?

4-inch filter, e.g.

> black mkt as consideration in public health inquiry
> ~~[illegible]~~ ~~[illegible]~~ - room to work w/ Hatch

Q: Creation of new chapter?

Effect on new drugs? Dietary supplements?

bring over case law / regs? -- exact same authorities?

> language to wall off all these questions - make clear that this has no effect on other products, etc.

What case law?

What reg?

Bill: As much agency practice as anything else.

	FOOD, DRUG & COSMETIC ACT PROCEDURES	SETTLEMENT PROCEDURES
Classification	•Section 513 establishes the requirements for classifying devices into one of three Classes. (Class I is general controls, Class II is special controls, Class III is premarket approval). •FDA is required to establish a panel of scientific experts to make a recommendation and findings as to the classification of the device. •Interested persons—including the public, the scientific community, and the industry—may submit data and views to the panel regarding classification of the device. •FDA must issue a proposed regulation to classify the device. This proposed regulation must include the panel's recommendation as well as FDA's full statement of reasons for the proposed classification. •Interested persons may comment on the proposed classification. •The final classification regulation is subject to judicial review.	•Automatically classifies all tobacco products into a new subcategory of Class II medical devices.

Tobacco - sec - FDA jurisdiction

	FOOD, DRUG & COSMETIC ACT PROCEDURES	SETTLEMENT PROCEDURES
Performance Standards	•Section 514 establishes requirements for the issuance of performance standards for particular Class II devices. These requirements provide several opportunities for public participation in the development and revision of performance standards. •FDA is required to issue a notice of proposed rulemaking for the establishment of a standard. This notice must include a series of findings to justify that the standard is appropriate and necessary. The notice must also invite interested persons to comment on the proposal generally or to propose alternative standards. •Upon request of an interested party and good cause shown, FDA is required to refer any matter which requires the exercise of scientific judgment to an advisory committee. The advisory committee must issue a report and recommendation on the proposed regulation. The report and recommendation must be made available to the public. •After all processes are complete, FDA then issues a final performance standard regulation.	•The settlement authorizes the issuance of certain performance standards pursuant to section 514 for tobacco products if specific additional requirements are met. •FDA must make a number of findings beyond those in section 514 before a standard can be issued. •FDA must use formal rule-making procedures. Formal rulemaking is enormously resource-intensive and lengthy because it requires an ALJ hearing at which witnesses are presented, factual determinations by the ALJ, and review of the ALJ decision by the Commissioner.

	FOOD, DRUG & COSMETIC ACT PROCEDURES	SETTLEMENT PROCEDURES
Performance Standards (con't)	•Implementation stayed for 60 legislative days under the Congressional review provisions of the Regulatory Reform Act of 1996. In addition, under section 514, a performance standard may not take effect before 1 year after its final publication.	
	•Performance standards can be challenged in federal court. Under the APA, the burden is on the party challenging a standard to show that it is arbitrary and capricious based on the administrative record.	•If the standard is challenged in court, FDA must show that the standard is supported by "substantial evidence" in the administrative record.
	•Section 514 and FDA regulations explicitly provide for citizen's petitions if new concerns with the performance standard later arise.	•Parties may immediately petition FDA to seek review of whether a modification has resulted in the creation of a significant demand for contraband, and seek judicial review if the petition is denied, irrespective of whether judicial review of the standard itself is complete.
	•All of the extensive procedures listed above would apply to performance standards relating to the reduction or elimination of nicotine.	•After a 12 year period, FDA may issue performance standards that include the elimination of nicotine, or have an effect comparable to nicotine elimination. Additional procedures are required. Any such standard must be based on a preponderance of the evidence pursuant to—at manufacturer's election— a Part 12 hearing (which requires sworn witness and cross examination), or notice and comment rulemaking. Findings in addition to those referenced above are required. Implementation stayed for 2 years in order to allow for Congressional review.

	FOOD, DRUG & COSMETIC ACT PROCEDURES	SETTLEMENT PROCEDURES
Ingredient Regulation	•Under FDCA, FDA could regulate ingredients in tobacco products pursuant to the performance standard provision and procedures discussed above.	•Sets up a new system in which manufacturers have 5 years to provide information to FDA that each non-tobacco ingredient is safe within intended conditions of use. FDA has 90 days to review the data, or the ingredient is deemed approved.
	•Section 301(j) of the FDCA and FDA's extensive regulations and procedures ensure that appropriate protection is accorded information that is a trade secret.	•Requires FDA to establish new procedures and requirements for the handing of trade secret information from tobacco companies.
	•Section 502(r) authorizes FDA to issue regulations that require appropriate ingredient disclosure. Before regulations are issued, FDA must provide notice and an opportunity for comment and an opportunity for a hearing.	•Public disclosure requirements are linked to disclosure requirements for food products under the FDCA. This standard may not be adequate for tobacco products, and may not provide the public with information relevant to health.

Tobacco - ser - FDA jurisdiction

Thomas L. Freedman
02/23/98 10:05:22 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Cynthia A. Rice/OPD/EOP, Mary L. Smith/OPD/EOP

cc:
Subject: Re: HHS A-19 on Ingredient Disclosure in Tobacco Products

Do you agree with OMB on this? I do. The proposal might appear to take the place of our asking for a more comprehensive bill.

---------- Forwarded by Thomas L. Freedman/OPD/EOP on 02/23/98 09:56 AM ----------

Wm G. White 02/23/98 09:50:14 AM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP

cc: See the distribution list at the bottom of this message
Subject: Re: HHS A-19 on Ingredient Disclosure in Tobacco Products

Josh Gotbaum asked us to seek your views on a legislative proposal that HHS/CDC would like to submit to the Hill this year regarding ingredient disclosure (see attached e-mails for summary.) Although we have no technical objections to the proposal, we recommend not sending this to the Hill this year, since the Administration is not proposing comprehensive tobacco legislation. A very similar proposal as the one HHS/CDC would like to send is also included in the Conrad bill, for which the Administration has expressed support.

Please let us know if you/DPC concur with the OMB recommendation. Thanks. Greg.

---------- Forwarded by Wm G. White/OMB/EOP on 02/23/98 09:39 AM ----------

JOSHUA
GOTBAUM
02/21/98 11:31:19 PM

Record Type: Non-Record

To: Wm G. White/OMB/EOP@EOP
cc: See the distribution list at the bottom of this message
bcc:
Subject: Re: HHS A-19 on Ingredient Disclosure in Tobacco Products

I agree. Touch base with Tom Freedman of DPC to make sure they do as well. thanks.
Wm G. White

Wm G. White 02/19/98 07:14:15 PM

Record Type: Record

To: Joshua Gotbaum/OMB/EOP@EOP, Jill M. Pizzuto/OMB/EOP@EOP

cc: See the distribution list at the bottom of this message
Subject: HHS A-19 on Ingredient Disclosure in Tobacco Products

HHS has sent us an A-19 legislative proposal for CDC that would expand HHS' ability to obtain specific information on the type and quantity of ingredients in tobacco products. We are seeking your guidance on whether you would like HHS to submit this A-19 proposal to Congress.

HD Recommendation: HD staff have no technical objections to the A-19 (see description below). However, given that the Administration is not submitting tobacco legislation to Congress this year, we recommend that HHS not send this A-19 forward. In addition, similar versions of HHS' A-19 are already included in the Jeffords and Conrad tobacco bills,

Summary of the A-19: The A-19 would do the following 3 things:

(1) Authorize HHS to obtain brand-specific information on ingredients in cigarette and smokeless tobacco products, including the quantity of ingredients;

(2) Authorize HHS to report to the public any potential health risks associated with exposure to these ingredients; and

(3) Amend current law to require manufacturers of tobacco products to disclose their products' ingredients in descending order according to weight, measure or numerical count, as part of the packaging.

Current Law requires the tobacco industry to annually provide to HHS a list of ingredients added to tobacco in the manufacturing of tobacco products. However, the industry is neither required to report the quantity and relative proportion of these ingredients nor provide this information by brand or by company. CDC staff advises that the law firm of Covington and Burling provides this list of ingredients to HHS on behalf of the industry. According to CDC staff, HHS is also required to treat this information as confidential to assure that trade secret information is not released or be subject to FOIA requests.

HHS Rationale for A-19: According to CDC staff, HHS is required to analyze and report to Congress the possible adverse health effects of specific ingredients in tobacco products. In order to carry out this authority, HHS believes they must have information on the quantify and brand-specific use of ingredients in these products. They would also like to provide this information to consumers so that they can make fully informed choices regarding the products they choose to purchase.

The AG Settlement includes similar, but not exactly the same, provisions as those included in the HHS A-19. The AG settlement would give FDA the authority to evaluate all additives in tobacco products. (See pages 19-20 of the Settlement.) Under the settlement, no non-tobacco ingredient could be used in manufacturing tobacco products unless the manufacturer could demonstrate within 5 years after the enactment of tobacco legislation that such ingredient is not harmful under the intended conditions of use. It would also require the manufacturers to disclose to FDA the ingredients and the amounts in each brand. Finally, it would require manufacturers to disclose

ingredient information to the public under regulations comparable to what current federal law requires for food products. The HHS A-19 would have the industry report this information to CDC, as opposed to the FDA.

If you concur, we will advise HHS staff that we have no objection to the concept, but that it doesn't make sense to transmit a small piece of tobacco legislation, while not submitting comprehensive language in support of the Budget. Please let us know how you would like to proceed.

Message Copied To:

Barry T. Clendenin/OMB/EOP@EOP
Richard J. Turman/OMB/EOP@EOP
Anne E. Tumlinson/OMB/EOP@EOP
Jim R. Esquea/OMB/EOP@EOP
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mark e. miller/omb/eop@eop

Message Copied To:

Joshua Gotbaum/OMB/EOP
Jill M. Pizzuto/OMB/EOP
Barry T. Clendenin/OMB/EOP
Richard J. Turman/OMB/EOP
Mark E. Miller/OMB/EOP
Jim R. Esquea/OMB/EOP

Tob - ver - FDA jurisdiction

Mar 8 Be Labor Cmte Dems

New bill later tonight

Start markup on Wed

continuation next week

Their attitude - want to work w/ you

2 things that are Their bottom lines (They say)

Dems to move amends

1. To do as drug + device — Amend: substitute Conrad piece
2. Requiring conv vote to reach — Also often amend
   0 level of nicotine

Everything else - supposedly negotiable

Tett has said (to EK) fully exemp power - Just think it should be sup - pg.. pef in round hole

EK reply: strong reasons to do as D/D - over time anyhow, you will doesn't begin to give comp powers.

That's what Tett is doing now, supposedly -

- broaden def of tob. product — any new product
- ingred disclosure - no exemp for recent tob sheet
- new ingreds can't be added w/out FDA approval
- product design/construction/filters
- adulteratn + misbranding auth
- FDA auth re health claims
- FDA auth to change both format + words of labels
- full range of penalties

need larger FDA

From their perspective - subst concessions

* - Need FDA justif of $500m — what's it going to be spent on. | Haven't yet moved on $ — they might be more

Another categ - They say not absent comp auth
licensing process, to CDC/not FDA
+ neg auth

PP 21-24 - additional reg. burdens
They say: all comes from existing law.

Compelling info - list of docs in ∇ is deficient —
broaden def of manufacturer
also other categ of docs -

They say: subpoena power is NO GO.
Ek: but need something!
in pre-mkt approval - can have
real club; not here!

Commercial feasibility - coming up w/ something new?

Industry repr on waiver + advisory boards

* Advertising authority - Ek: basic bottom line
ind will circumvent any stat or
q rules
they know it's a deal breaker

Reduced risk products - will give FDA more auth - not just a q
q scientific impact on users - but overall pub health impact
Prob OK

Preempt – as talking heads.

we say – anti docs/advert – preempt is unthinkable.

Also discussed: walkback

- needs to be co-specific/

delete. The rebate

we've given them supporting

also:

non-tax-deductible

paid before they've appealed.

(tax model)

multipliers, penalties

for continued noncompliance.

ETS – They haven't gone back.

EK said has to be done in statute – rulemaking not good enough

EK: maybe middle thing you could do to make

rulemaking easier.

Jeff, EK not going to McC hearing bec of markup.

Haven't yet broached jurisdictional issue – conceding

something.

EK: If we come up w/ bipart approach, there will be lots of

pressure for McC/leadership to take it up.

Ltd party-line, won't be worth much to J.

Tett. Absolutely making a good faith effort.

What are dealbreakers?
Advertising reg auth.
General concept - abridgment of reg. auth.

Statements - (CDC?)

Spending amends - for child care? ed?
imp - only do if have consensus amongst sides.
real mssg amendments
Harkin: not comfortable bec our bill does only health.

What about earmarking NIH funds? Pub health/tob grps why for some sort of earmark
Harkin: no earmarking.

Intemptical amend to be thrown on.

Get ans tonight - do both (have ans)

GK: offer subst of Conrad piece
Then series on: advert
CDC
doc disclos
commercial feasibility

NIH piece - file both
Conrad - no earmark
Tob Free Kids - 25% earmark

? Propose ↑ from 2.5 ⟶ 3.5 per yr.

could offer $1.50 over 3
but further away we get from Teth agenda – less we'll influence.

Child care – Conrad lang plus more $ (205)

– talk later – → call it up?

High priority = 2 is whether you offer it in this context.

2	$1.50 actual fee	sum of senate
1	child care at $206	
2	NIH = Conrad	tob. free kids
1 or 2?	Conrad – FDA	ours??
2	ETS replacement – using EK bill	ETS – just findings
	lookback – substitute E/K lookback	

All there are message ↑ cong vote on nicotine

Specific ones on FDA issues
each of FDA issues
each piece of lookback
3 on preemption
a. none other than labeling.
b. eliminate preemp of advert
c. " " " doc disclos.
elim. of their confidentiality provision –

(CDC → FDA way it is now – CDC has no auth to change)

tobacco - settle –
FDA jurisdiction

"RULE OF CONSTRUCTION.--Nothing in this Act or the amendments made to the Federal Food, Drug, and Cosmetic Act by this Act shall be construed to affect the regulation of drugs and devices that are not tobacco products by the Secretary of Health and Human Services under the Federal, Food, Drug, and Cosmetic Act."

Tobacco - settlement - FDA jurisdiction

STATEMENT BY

WILLIAM B. SCHULTZ

DEPUTY COMMISSIONER FOR POLICY

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE AND TRANSPORTATION

UNITED STATES SENATE

MARCH 17, 1998

INTRODUCTION

Mr. Chairman and Members of the Committee, I am pleased to testify today on behalf of the Food and Drug Administration (FDA) about proposals for comprehensive tobacco legislation. We at FDA and the Department of Health and Human Services (DHHS) appreciate the leadership that you and Senator Hollings have shown on this issue, Mr. Chairman, and we look forward to working closely with you to achieve our mutual commitment to enact comprehensive legislation to reduce teen tobacco use and the tremendous death and disease caused by tobacco products.

Everyone here is familiar with the statistics. Each year 400,000 persons in this country die from use of tobacco products,[1] and most of these men and women started using tobacco during childhood or adolescence.[2] Every day 3,000 children and adolescents begin smoking regularly,[3] 1,000 of whom will die prematurely from tobacco-related diseases.[4] In summary, the case for taking action to reduce youth tobacco use could not be stronger.

I would like to discuss three issues in my remarks today: (1) the Agency's tobacco program; (2) the Administration's position on tobacco legislation; and

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[1]61 FR 44396 at 44398

[2]61 FR 44396 at 44398

[3]61 FR 44396 at 44422

[4]61 FR 44396 at 44399

(3) some of the issues relevant to FDA's authority raised by the bills that have been introduced.

1. FDA'S TOBACCO PROGRAM

FDA's tobacco regulation was announced in August 1996.[5] The Agency's decision to assert jurisdiction over tobacco products and to issue its rule is grounded in two important facts. First, most tobacco users begin during childhood and adolescence.[6] More than 80 percent of the people who smoke have their first cigarette before they are 18 years old, and by that age, half have become regular smokers. And of the infants, children, and adolescents alive today, 5 million will become regular smokers and die because of their smoking.[7] Unfortunately, the problem is getting worse. Smoking rates among eighth and tenth graders have risen by one-third since 1991.[8]

Second, most tobacco users are addicted. In fact, studies demonstrate that between 77 and 92 percent[9] of the 50 million Americans who smoke and a large percentage of smokeless tobacco users are addicted.

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[5]60 FR 41314

[6]61 FR 44396 at 44398

[7]"Projected Smoking - Related Deaths Among Youth--U.S., 5 million," MMWR, November 8, 1996, Vol. 45, No. 44.

[8]"Results from the 1995 Monitoring the Future Survey," National Institute on Drug Abuse Briefing for Donna E. Shalala, Ph.D., Secretary of Health and Human Services, December 13, 1995.

[9]61 FR 44396 at 44398

In response to these facts, FDA, with the support of the President and Secretary Shalala, established the Nation's first ever comprehensive program to protect children from the dangers of tobacco and a lifetime of nicotine addiction. The aim of the program is to reduce tobacco use by children and adolescents by 50 percent in seven years, and it follows many of the recommendations made by the American Medical Association and the National Academy of Sciences' Institute of Medicine. Our program will limit the availability of tobacco products to young people, as well as the appeal that these products have to young people, an appeal that is bolstered in large measure by the billions of dollars in advertising and marketing spent by the tobacco industry.

Each year, young people spend an estimated $1.26 billion[10] on tobacco products despite laws in all 50 states that prohibit sales to minors. Numerous studies have confirmed what we all have seen for ourselves, that adolescents have little difficulty in purchasing tobacco products.[11] In fact, studies of over-the-counter sales have determined that nearly 70 percent of the time children or adolescents attempt to buy cigarettes from retailers, they succeed.[12] And if these youngsters have any problem at the counter, they simply go to a vending machine where

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[10]Difranza JR, Tye, "Who profits from tobacco sales to children?," JAMA, 1990, Vol. 263, pp. 2784-7.

[11]Department of Health and Human Services; "Preventing Tobacco Use Among Young People: A Report of the Surgeon General," Washington, DC: Government Printing Office, 1994, p. 249 (S/N-0017-001-00491-0).

[12]Id.

studies show that they can successfully purchase cigarettes almost 90 percent of the time.[13]

The FDA rule is intended to change all that. The rule sets a Federal minimum age of 18 to purchase tobacco products and requires age verification. It eliminates free samples, sale of single cigarettes and packages with fewer than 20 cigarettes. It bans vending machines and self-service displays except in those places where only adults are permitted, such as certain nightclubs that are inaccessible to people under 18.

The second part of the rule is designed to reduce the appeal of tobacco to children. Tobacco is among the most heavily advertised and promoted products in the United States, with the industry spending $5 billion annually.[14] And this advertising is very effective with kids. The three most heavily advertised brands are smoked by nearly 90 percent of all kids who smoke.[15]

The rule bans outdoor advertising within 1,000 feet of schools and publicly-owned playgrounds. Outdoor advertising beyond these areas is restricted to black-and-white text only. Advertising in publications with a significant readership of people under 18 is also limited to black-and-white text. The rule prohibits the sale or free distribution of products, such as caps or gym bags, that

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[13] Id.

[14] FTC Report to Congress, 1994

[15] 61 FR 44396 at 44482

exhibit cigarette or smokeless tobacco products' brand names or logos. Studies show that nearly half of all young people who smoke own at least one of these items.[16]

Finally, the rule prohibits brand name sponsorship of sporting or entertainment events, such as the use of the Virginia Slims tournaments to attract healthy young women to a product that is deadly and addictive. The rule, however, permits sponsorship in the corporate name, as distinguished from brand name.

The first phase of the rule went into effect on February 28, 1997. Since that date, retailers have not been allowed to sell cigarettes or smokeless tobacco to anyone under the age of 18. And since that same date, retailers have been required to check photo ID for anyone under the age of 27.

The remainder of the regulations were scheduled to go into effect on August 28, 1997, except the sponsorship provision, which was scheduled to go into effect August 28, 1998.

In April 1997, the United States District Court for the Middle District of North Carolina ruled that FDA has jurisdiction to regulate nicotine-containing cigarettes and smokeless tobacco and upheld all of the rule's access and labeling provisions. The Court also delayed implementation of the August 28, 1997 access provisions, pending further court action. Finally, the Court

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[16]61 FR 44396 at 44525

invalidated, on statutory grounds, FDA's advertising restrictions. The government is appealing the advertising portion of the ruling at the same time that it is moving forward to enforce the age and ID provisions. The case currently is before the U.S. Court of Appeals for the Fourth Circuit.

FDA currently is enforcing the access provisions of the rule cooperatively with State and local officials. Half a million retailers sell tobacco, and FDA cannot possibly be in every store. Traditionally, when our regulations need to be enforced at the community level, we have adopted a cooperative model. This is how FDA regulations are enforced for dairy farm and retail food inspections in communities across the country -- by commissioning for the services of State and local officials. We think this is a particularly appropriate way to enforce our tobacco regulations.

Under our plan, a commissioned State or local official will accompany an adolescent under the age of 18 into a retail establishment on an unannounced visit. The adolescent will attempt to purchase cigarettes or smokeless tobacco. Records will be kept documenting each visit. Retailers who refuse to sell to the minor will get a letter from FDA telling them that they are in compliance. Retailers who do sell to the minor will receive a warning letter from FDA informing them that they have violated the rule, and that another unannounced visit will be scheduled. If they sell to the minor during the second unannounced visit, they will receive a letter stating that FDA will seek a penalty of $250. The fines escalate for subsequent violations.

Last year, we signed contracts with 10 states for enforcement of the age and photo ID requirements. The unannounced visits began last August. This year we expect to sign contracts with every single State and territory that is willing to join us in enforcing the rule. Under this program, we eventually will be conducting tens of thousands of unannounced visits across the country each month. In addition, we plan to educate retailers and others about the FDA rule through a multi-media advertising campaign.

2. THE ADMINISTRATION'S POSITION ON TOBACCO LEGISLATION

As you know, on June 20, 1997, 40 State Attorneys General and the major tobacco companies reached a tentative settlement, contingent on enactment of Federal legislation. The Administration spent the summer reviewing and analyzing the proposed settlement. On September 19, 1997, the President called for comprehensive tobacco legislation with a goal of reducing the smoking rate among young people by 50 percent within seven years.

The President stressed that the following five key elements must be at the heart of any national tobacco legislation:

1. A comprehensive plan to reduce teen smoking, including a combination of penalties and price increases that raise cigarette prices up to $1.50 per pack over the next 10 years as necessary to meet youth smoking targets;

2. Express reaffirmation that FDA has full authority to regulate tobacco products;

3. Changes in the way the tobacco industry does business;

4. Progress toward other critical public health goals, such as the expansion of smoking cessation and prevention programs and the reduction of secondhand smoke; and,

5. Protection for tobacco farmers and their communities.

During his State of the Union address and in his recent budget for fiscal year 1999, the President again forcefully emphasized that his top priority is the reduction of underage tobacco use. Reducing teen tobacco use is the most important step that Congress and the Administration can take now to protect the Nation's health in the next century and to minimize future health care costs.

3. ISSUES RAISED BY THE LEGISLATIVE PROPOSALS

As the Committee is well aware, FDA's authority to adopt the provisions of the regulation that I described earlier is grounded in the agency's conclusion that tobacco products are combination drug/device products under the Federal Food, Drug, and Cosmetic Act. That Act provides a comprehensive set of tools which allows the agency to craft appropriate restrictions on access to and the advertising of tobacco products.

Mr. Chairman, in evaluating any legislative proposals, and in deciding on what regulatory authority is appropriate for tobacco products, it is useful to consider what authorities the agency currently exercises for device products. It is our view that the authorities provided in the provisions of the Food, Drug and Cosmetic Act applicable to medical devices are a good fit for regulating tobacco. In fact, we believe they are necessary in order to achieve the President's goal of reducing youth smoking by 50 percent over the next seven years. They provide the foundation for the regulation that the agency issued in August 1996, and they assure the agency that it has the flexibility to adopt additional or different requirements in the future if adjustments in its regulatory approach are appropriate. I will now describe those authorities and how they relate to tobacco products.

First, current law enables the agency to regulate any device, including a combination drug/device, as a restricted device when it finds there is a potentially harmful effect. This means that it may impose, by regulation, restrictions on the access to the product. In the case of devices that the agency has historically regulated, it has restricted the use of the device to certain medical specialities or certain hospitals. In the case of tobacco, FDA has used this authority to restrict the sale of the product to adults, and to ban vending machines and self-service displays in places that are accessible to children.

Second, using this same restricted device authority, the agency may impose certain requirements on marketing and advertising. In the case of hearing aids, for example, the agency has required that consumers be given certain

information prior to purchasing the product. In the case of tobacco, FDA has used this authority to restrict tobacco advertising so that it is not appealing to children. The tobacco industry has challenged the agency's authority to restrict advertising of its products, and that authority should be expressly affirmed in any legislation.

Third, the Act gives FDA broad authority over the product. It may classify a device in Class I, providing for minimal regulation through general controls; Class II, providing for regulation over the product through special controls, which can include performance standards; or Class III, providing for premarket review. While the agency has made no final decisions on how to classify existing tobacco products it could use Class II to prohibit the use of any additives found to be harmful. On the other hand, under the existing law, it could use Class III to require that new and novel products be tested and evaluated prior to marketing. Under the Act, the agency is required to provide a public process before taking any of these actions, and every final agency decision is subject to judicial review.

Fourth, current law provides the agency with an array of enforcement tools for regulating device products, all of which would be available for tobacco products. These authorities include: criminal and civil money penalties; recall authority; authority to detain products without a court order; authority to seize products with a court order; authority to inspect records and facilities; and misbranding and adulteration authority.

Finally, I would like to mention one additional advantage of using the Act's existing device authority to regulate tobacco products. The device law dates back to 1976, and during the past 20 years it has been interpreted in case law, regulation and agency practice. Over that time, the agency has established a complete regulatory scheme for device products, and the 1996 regulation imposing access and advertising restrictions on tobacco products builds on that scheme. On the other hand, legislation establishing an entire new law for regulating tobacco would be implemented through new regulations, new case law and new agency practice. This could make it more difficult for the agency to implement its tobacco program and could result in significant delay in reaching the goals that we all share -- dramatically reducing youth tobacco use.

With regard to legislation, there is another critical point which is sometimes overlooked. The President's second principle of reaffirming FDA's full authority to regulate tobacco products cannot be satisfied simply by codifying the agency's current regulations, without also affirming the agency's general authority over tobacco products. While the agency believes that these regulations are the most effective regulatory approach at this time, no one can predict whether additional restrictions will be appropriate in the future, and if so what they will be. Any legislation should anticipate that the tobacco companies will adjust their marketing practices to the new requirements and therefore legislation must retain FDA's current authority to make necessary adjustments in its regulatory approach in order to maintain an effective program for reducing youth use of tobacco products.

Equally important, legislation should not impose novel procedural requirements on the regulation of tobacco products as medical devices, such as those contained in the proposed settlement. These new requirements are unnecessary because normal FDA procedures already provide significant opportunities for input from the public, the scientific community, and the industry. At the same time, these new procedures would significantly hinder the agency's ability to regulate in a manner that best serves the public health.

For example, in issuing performance standards, FDA must currently issue a notice of proposed rulemaking. This notice must include a series of findings about the public health benefits of the standard, and an invitation to interested persons to propose alternative standards. Also, upon request of an interested party and good cause shown, FDA is required to refer a proposed regulation for a performance standard to an advisory committee. After all relevant processes are complete, FDA then issues a final performance standard regulation, which is subject to judicial review pursuant to the arbitrary and capricious standard. If new concerns with the standard later arise, FDA regulations explicitly provide for citizen's petitions that would allow interested parties to seek redress from the agency. Clearly, current law provides considerable opportunity for public participation in the development and revision of performance standards.

The proposed settlement would impose additional procedural requirements -- such as formal rule-making procedures -- that are unnecessary and would severely impede the agency's administrative process. Formal rulemaking is enormously resource-intensive and lengthy because it requires an ALJ hearing

at which witnesses are presented, factual determinations by the ALJ, and review of the ALJ decision by the Commissioner. The final decision and standard is reviewable based on a susbtantial evidence standard in which FDA would have the burden of proof. In addition, if a standard is ever issued, parties may immediately petition FDA to seek judicial review of whether a particular modification has resulted in the creation of significant demand for contraband and seek judicial review. These provisions would have the effect of consuming the agency in endless administrative and judicial processes and would thereby interfere with its ability to protect the public health.

New legislation can and should be quite simple. As everyone in this room is well aware, the tobacco industry has challenged FDA's regulation, and the case is pending in the Fourth Circuit for the United States Court of Appeals. While we are convinced that the courts will ultimately sustain FDA's full regulatory authority over tobacco products, any legislation should eliminate the questions about that authority. This can be done by adding the words "nicotine" and "tobacco products" to the definitions of drug and device, respectively. Legislation should also add the words "tobacco advertising" to the restricted device authority to eliminate any argument about whether the agency has authority under that provision over tobacco advertising.

Lastly, it has also been argued that the requirement that FDA find devices to have a "reasonable assurance of safety and efficacy" could lead to a ban of tobacco products. FDA found in its tobacco rule that such an action would not be appropriate. Instead, the agency found that because more than 40 million

Americans are addicted to tobacco products the best public health result is to leave tobacco products on the market. Nevertheless, for tobacco products, the safety and efficacy standard could be changed to one that more generally emphasizes the public health, perhaps with criteria spelled out for the agency to consider.

Mr. Chairman, I want to emphasize that these changes would do no more than ratify and clarify FDA's existing authority over tobacco products. They would have no impact on the agency's authority over other device and drug products. Instead they would eliminate the current litigation over the agency's regulation, and would allow the agency to implement its program to reduce youth smoking using authorities com parable to those that it has for other products.

CONCLUSION

In closing, FDA and the Administration strongly support comprehensive tobacco legislation to significantly reduce young people's tobacco use and meet the other goals announced by the President. We look forward to working closely with you, Mr. Chairman, and other members of the Committee to meet the challenge of enacting the kind of comprehensive legislation that enables us to meet our public health objectives. We stand ready to work with you to address the concerns we have raised today.

Thank you for giving me this opportunity to share the view of the Food and Drug Administration on this important legislative initiative. I would be pleased to answer any questions you may have.

tobacco - set - FDA jurisdiction

Statement

of

Richard M. Cooper

on behalf of

R.J. Reynolds Tobacco Company

before the

Senate Committee on
Labor and Human Resources

Tuesday, February 24, 1998

I am Richard Cooper. I am with the law firm of Williams & Connolly, and I represent R.J. Reynolds Tobacco Company. I am here on behalf of Reynolds to discuss the food and drug law aspects of the Proposed Resolution entered into last June and S. 1648, recently introduced by the Chairman.

MOST OF FDA'S CURRENT TOBACCO REGULATIONS ARE NOT IN EFFECT.

In 1996, FDA asserted that it has the authority to regulate cigarettes and smokeless tobacco products as "drugs" and medical "devices" under the Federal Food, Drug, and Cosmetic Act ("FDCA").[1] FDA's assertion of jurisdiction over cigarettes and smokeless tobacco products and its tobacco regulations, based on current law, are under challenge in the courts. I will not comment on the pending litigation, but I think it fair to say that there is at least a serious question about the validity of the agency's overall position; and the district court has held invalid FDA's regulations on tobacco advertising and promotion.[2]

As of today, the only FDA tobacco regulations that are in effect are the prohibition on sales to persons under age 18 and the requirement of photographic identification. All of FDA's other tobacco regulations have been stayed by the district court.[3] So, as of today, there are no operative FDA restrictions on tobacco product labeling, advertising or promotion.

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1 61 Fed. Reg. 44,396 (Aug. 28, 1996).

2 Coyne Beahm, Inc. v. FDA, 958 F. Supp. 1060, 1083-86 (M.D.N.C. 1997).

3 Id. at 1086-87. The court allowed the regulations FDA had previously implemented to remain in effect, and stayed the effectiveness of the other regulations. The regulations previously implemented were 21 C.F.R. §897.14(a) and (b), relating to minimum age for purchase and photographic identification. See 61 Fed. Reg. at 44,396.

CURRENT FOOD AND DRUG LAW IS NOT SUITED TO THE REGULATION OF TOBACCO PRODUCTS.

In 1980, FDA pointed out that the FDCA does not "provide authority suitable to the regulation of cigarettes."[4] In 1994, FDA Commissioner Kessler essentially agreed with that assessment.[5] The reason for these statements is easily explained. As FDA Deputy Commissioner William Schultz told this Committee in 1996, "A fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold."[6] FDA, in adopting its tobacco regulations, has declared that cigarettes are "unsafe," "dangerous," and a "cause [of] great pain and suffering."[7] FDA has also determined that, for now, a ban on cigarettes would not be in the public interest.[8] Yet, given its findings and given the law as Deputy Commissioner Schultz accurately described it, how can

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4 Letter from Mark Novitch for FDA Commissioner Jere E. Goyan to John F. Banzhaf, III and Peter N. Georgiades 3 (Nov. 25, 1980)(FDA Dkt. Nos. 77P-0185, 78P-0338/CP).

5 The following exchange occurred between Rep. Synar and Commissioner Kessler:

> Rep. Synar: . . . You really have two options if you determine nicotine is a drug. You will have to ban the product unless it can be shown that it can be applied safely and effectively in curing some type of disease, or you will be able to regulate it; is that correct?
>
> Dr. Kessler. The tools are limited. Yes.

Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 103d Cong. 68 (1994) ("1994 House Hearings").

6 Statement by FDA Deputy Commissioner William B. Schultz Before the Senate Comm. on Labor and Human Resources, 104th Cong. 8 (1996).

7 61 Fed. Reg. at 44,412, 44,420 (1996); see also id. at 44,405; 60 Fed. Reg. 41,314, 41,349 (Aug. 11, 1995).

8 60 Fed. Reg. at 41,349.

FDA allow the continued marketing of cigarettes as "drugs" and "devices"? Under current law, the agency has no good answer to that question.

Many anomalies are created by FDA's attempt to regulate the continued marketing of cigarettes under the current FDCA. I will briefly note just three.

o Section 502(j) of the statute prohibits the marketing of any drug or device that is "dangerous to health when used in the . . . manner . . . suggested in the labeling thereof."[9] FDA has expressly found that "cigarettes and smokeless tobacco are dangerous . . . ."[10] Indeed, Congress, in the Public Health Cigarette Smoking Act of 1969, while determining that the sale of cigarettes should remain lawful, directed that cigarettes be labeled as "dangerous to your health."[11] There is no explanation as to how it is consistent with § 502(j) for FDA to permit the continued sale of a product it has expressly found to be "dangerous".

o Section 505 of the FDCA provides that, before any "new drug" is marketed, it must have been approved by FDA as safe and effective.[12] Under FDA's current theory that a cigarette combines a drug (nicotine) with a device (the rest of the cigarette), the nicotine is an unapproved new drug. This conclusion is obvious to anyone familiar with food and drug law, even though FDA has not squarely addressed the point. The agency has never explained how it is consistent with § 505 to permit the continued sale of a product that the agency has analyzed as containing an unapproved new drug.

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9 21 U.S.C. § 352(j).

10 61 Fed. Reg. at 44,420; see also id. at 44,412.

11 Pub. L. No. 91-222, § 4, 84 Stat. 88 (1970)(amending 15 U.S.C. § 3333).

12 21 U.S.C. § 355.

o Section 502(f)(2) of the FDCA provides that a drug or device is misbranded if it fails to bear "adequate warnings against use . . . by children."[13] The statute permits no exceptions to this requirement. A warning is adequate, presumably, if it largely prevents the occurrence of the harm against which the warning is needed. FDA asserts that its tobacco regulations are needed to prevent underage smoking, which it calls a "pediatric disease."[14] Nevertheless, it may surprise you to learn that Commissioner Kessler, on behalf of FDA, found that the current congressionally mandated tobacco product labels contain adequate warnings against use by children.[15] Had Commissioner Kessler not made that finding, he would have had to conclude that, if tobacco products are subject to the FDCA, they are misbranded and thus illegal.[16] FDA cannot require additional warnings on cigarette labels because the Federal Cigarette Labeling and Advertising Act precludes it from doing so.[17]

These and other anomalies that arise from the effort to regulate tobacco products under the current food and drug law demonstrate that that law simply is not suited to the regulation of this class of products.

THE PROPOSED RESOLUTION PROVIDES A BETTER APPROACH.

The regulatory provisions of the Proposed Resolution, if enacted into law and embodied in other legally binding documents, are superior to FDA's current tobacco regulatory program in three major respects.

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13 21 U.S.C. § 352(f)(2).

14 61 Fed. Reg. at 45,238.

15 61 Fed. Reg. at 44,465.

16 FDCA § 301(a), 21 U.S.C. § 331(a).

17 15 U.S.C. § 1334(a).

First, there would be a new congressional enactment, and the current challenge to FDA's basic assertion of jurisdiction and its specific regulations would end.

Second, the anomalies I have just referred to would be avoided.

Third, in many respects already described to this Committee by previous witnesses, the Proposed Resolution would preserve and go beyond FDA's program. Many of the regulatory provisions in the Proposed Resolution that duplicate or go beyond FDA's program could not be imposed by FDA because they are not authorized by current law, and some could not be enacted even by the Congress because, as governmental impositions, they would violate the Constitution.

THE PROPOSED RESOLUTION'S REQUIREMENTS FOR FINDINGS AND PROCEDURAL SAFEGUARDS ARE REASONABLE AND APPROPRIATE.

I want to address what I understand to be the two most controversial points in the regulatory provisions of the Proposed Resolution: (1) the findings required for FDA to mandate modifications of tobacco products or to ban nicotine, and (2) the procedural safeguards applicable to such administrative actions.

The Required Findings.

Under the Proposed Resolution, FDA would have plenary authority to require the modification of tobacco products, including the gradual reduction (but not elimination) of nicotine yields, if it found, with respect to any particular modification, that it

(a) will result in a significant reduction of the health risks associated with such products to consumers thereof;

(b) is technologically feasible; and

(c) will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard. In determining the risk of the demand for a market in contraband products,

> the FDA shall take into account the number of dependent tobacco product users and the availability, or lack thereof, of alternative products then on the market and such other factors as the Agency may deem relevant.[18]

Similar types of findings are required with respect to a ban on nicotine.[19] I assume that the first finding is not controversial: plainly, if a proposed product modification does not provide a significant reduction in risk, it is not worth mandating.

The second finding is also self-evidently reasonable and appropriate. If a product modification is not technologically feasible, it cannot be accomplished, however desirable in theory; and, therefore, it should not be required. The purpose of a mandated product modification is not to punish the industry, but to provide a benefit to consumers. For government to mandate the impossible makes no sense as a matter of policy, and probably would violate the Due Process Clause. Moreover, it is entirely reasonable and appropriate to provide that, before requiring a product modification, FDA find that the modification is technologically feasible. An industry providing products for tens of millions of consumers should not be put through a mandatory product modification program unless there is, in fact, good reason to believe that the modification is technologically feasible in commercial manufacturing.

I understand that the third finding is the really controversial one; yet, it, too, is entirely reasonable and appropriate. The required finding reflects good public policy and is within the scope of administrative capability.

We have had unhappy experience in this country with alcohol prohibition. FDA has acknowledged that a black market should be avoided, and that there is a risk that a ban on

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[18] Proposed Resolution 15-16 (June 20, 1997) ("PR").

[19] PR 15-17.

tobacco products would lead to a black market.[20] The same risk could be presented by mandated product modifications that would render the products unacceptable to all or many current users. Therefore, as a matter of sensible public policy, whatever unit of government has the authority to ban nicotine or to require that tobacco products be modified must take into account, in exercising that authority, the risk that its action may lead to a black market.

If Congress were to reserve the authority to ban nicotine or to require tobacco product modifications, Congress surely would take that risk into account before acting. If, as the Proposed Resolution provides, that ultimate authority is to be delegated to FDA (subject to an opportunity for Congressional review), then FDA surely should ensure that a black market would not occur. Under our system of administrative law, the way for FDA to demonstrate that it has adequately taken that issue into account is to make a finding with respect to it. Surely it would

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[20] The agency has stated:

> There are approximately 50 million Americans who currently smoke and another 6 million who use smokeless tobacco. It is particularly relevant that that 77 to 92 percent of all smokers are addicted and that a substantial number of all users of smokeless tobacco are addicted.
>
> The agency believes that these factors must be considered when developing a regulatory scheme that achieves the best public health result for these products. The sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous. First, there could be significant health risks to many of these individuals. Second, it is possible that our health care system would be overwhelmed by the treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users. Third, the agency also believes that, given the strength of the addiction and the resulting difficulty of quitting tobacco use, a black market and smuggling would develop to supply smokers with these products. It also seems likely that any black market products would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.

61 Fed. Reg. at 44,413 (footnotes omitted).

be folly to authorize an administrative agency to create a new Prohibition by banning nicotine or requiring modifications of tobacco products. If an agency is to have the power to ban or require modifications, it should also have the responsibility to determine, on the basis of the available evidence, that a new Prohibition, with all its adverse social consequences, would not occur.

Commissioner Kessler stated in 1994 that "the regulation of cigarettes raises societal issues of great complexity and magnitude"[21]; and, with the risk of a ban and resultant black market plainly in mind, he referred to "the enormous social consequences that could attach to a decision to assert jurisdiction."[22] Sound public policy requires that, before a ban or product modification is imposed, it be determined that those potentially "enormous social consequences" will not occur.

It is within the capability of FDA to make the required finding. Some product modifications may not adversely affect consumer acceptability, and so would not even raise the possibility of a black market; in such a case, the required finding could be made easily. In other cases, relevant evidence could be derived from, inter alia, (i) the medical, scientific, and social scientific literature; (ii) experience in this and other countries; (iii) the opinions of social scientists, experts in law enforcement, and other relevant experts – set forth in consensus statements and in individual assessments of specific regulatory proposals; (iv) records made in legislative and administrative hearings; and (v) studies of public opinion (e.g., of likely public reactions to particular types of product modification). FDA has stated:

> That a black market and smuggling will occur can be predicted by examining the current situation with illegal drugs in the United States and past experience with prohibition of [sic] respect to alcoholic beverages. In both

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21 Letter from David A. Kessler, M.D. to Scott D. Ballin, Esq. 3 (Feb. 25, 1994), reproduced in 1994 House Hearings at 25-27.

22 1994 House Hearings at 69.

> situations, individuals continued using the products. Moreover, in the case of cigarettes, even increased cost due to tax disparities can lead to smuggling and black markets. S. Rept. 95-962, 95th Cong., 2d Sess., (June 28, 1978); Joosens, L. and M. Raw, "Smuggling and Cross Border Shopping of Tobacco in Europe," *British Medical Journal*, vol. 310, May 27, 1995.[23]

Thus, FDA has concluded that this kind of finding can, indeed, be made.

In view of the "enormous social consequences" of creating a new Prohibition, surely no unit of government would want to impose a ban or product modification without having concluded that such action would not lead to a black market. It is thus reasonable and appropriate to require FDA, before imposing a ban or product modification, to make a finding with respect to it.

The Procedural Safeguards.

The Proposed Resolution specifies the following procedural safeguards with respect to a mandated product modification other than a ban on nicotine or other modification that has an effect comparable to a ban on nicotine:

> The authority to require such a product modification can be exercised upon a showing of "substantial evidence," based upon an administrative record developed through a formal rule making subject to the Administrative Procedures [sic] Act, with the right of judicial review, and any such modification shall be subject to the current procedures of the Regulatory Reform Act of 1996 to provide time and a process for Congress to intervene should it so choose. In the event that a party subsequently files a petition seeking an administrative review of whether a modification has, in fact, resulted in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard and FDA denies the petition, the petitioner shall have the right to seek judicial review of the denial of the petition.[24]

These provisions specify the following procedural safeguards: (i) formal rulemaking, (ii) the "substantial-evidence" standard, (iii) judicial review, (iv) application of the "Regulatory Reform

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23 61 Fed. reg. at 44,413, n.27.

24 PR 16.

Act of 1996"[25]; and (v) judicial review of denial of a petition. There is nothing unreasonable or inappropriate in any of these safeguards; indeed, safeguards (ii), (iii), and (v) merely restate current law with respect to performance standards for devices. In general, increased procedural safeguards are appropriate in proportion to the importance of the matter being decided. Precisely because a ban or required modification of tobacco products could have "enormous social consequences," these procedural safeguards are fully warranted.

Formal rulemaking involves both an opportunity for written comment and an evidentiary (trial-type) administrative hearing. This combination of procedures is appropriate for rulemakings in which it is desirable to have both (i) widespread public participation (through notice-and-comment) and (ii) close attention to facts (through a trial-type administrative hearing). Formal rulemaking for tobacco product modifications or a ban would not be unique under the FDCA. The statute already provides in § 701(e)[26] for formal rulemaking with respect to the issuance, amendment, or repeal of any regulation relating to a host of FDA responsibilities:

- o labeling of foods for special dietary use, under FDCA § 403(j)[27];
- o emergency permit controls for foods, under FDCA §404(a)[28];
- o tolerances for poisonous or deleterious substances in foods, under FDCA § 406[29];

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25 This is a reference to the Small Business Regulatory Enforcement Fairness Act of 1996, which is title II of the Contract with America Advancement Act of 1996, Pub. L. No. 104-121, 110 Stat. 847 (1996), and in particular to subtitle E of title II, entitled "Congressional Review," which added a new chapter 8 to title 5, United States Code. See 110 Stat. at 868-74.

26 21 U.S.C. § 371(e).

27 21 U.S.C. § 343(j).

28 21 U.S.C. § 344(a).

- deficiencies in compendial standards for drugs, under FDCA § 501(b)[30];
- designation of habit-forming drugs, under FDCA § 502(d)[31];
- packaging and labeling of drugs liable to deterioration, under FDCA 502(h)[32]; and
- food standards for dairy products under FDCA § 401.[33]

Formal rulemaking also applies to regulations relating to

- advertising of prescription drugs, under FDCA § 502(n)[34];
- color additives, under FDCA § 721(d)[35]; and
- food additives, under FDCA § 409[36].

In light of this long list of formal rulemaking requirements under the FDCA, it is entirely reasonable and appropriate to provide for formal rulemaking for a ban on nicotine or mandated modification of tobacco products. Such rulemakings warrant both opportunity for widespread public participation through written comments and close attention to facts through a trial-type hearing.

The substantial-evidence standard already applies, under current law, to "the promulgation of a regulation under section 514[37] establishing, amending, or revoking a

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29 21 U.S.C. § 346.

30 21 U.S.C. § 351(b).

31 21 U.S.C. § 352(d).

32 21 U.S.C. § 352(h).

33 21 U.S.C. § 341.

34 21 U.S.C. § 352(n).

35 21 U.S.C. § 379e(d).

performance standard for a device" and to a decision under FDCA § 516[38] to ban a device[39] Thus, under current law if a tobacco products were a device and FDA sought to impose on it a performance standard under current FDCA § 514 or to ban it under § 516, the substantial-evidence standard would apply in judicial review of such a standard.

More generally, the substantial-evidence standard is the one appropriate for judicial review of agency actions based on a trial-type hearing. It already applies very commonly under the FDCA: in the many types of proceedings involving formal rulemaking.[40] In addition, it applies to decisions on approval or withdrawal of approval of new drugs.[41]

In light of the widespread use of the substantial-standard under the FDCA, and in light of the importance of a decision to require a modification of tobacco products, it is reasonable and appropriate to apply that standard here.

I assume that providing an opportunity for judicial review of FDA actions to ban or modify tobacco products or to deny a petition with respect to a prior such action is not controversial. All FDA rules are subject to judicial review, under either or both of the APA and

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36 21 U.S.C. § 348.

37 21 U.S.C. § 360d.

38 21 U.S.C. § 360f.

39 "A regulation described in paragraph (2) or (5) of subsection (a) and an order issued after the review provided by section 515(g) shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole." FDCA § 517(c), 360g(c). Section 517(a)(2) refers to regulations under § 514 relating to performance standards; § 517(a)(5) refers to regulations under § 516 relating to bans; and § 515(g), 21 U.S.C. § 360e(g) refers to orders approving, denying approval, or revoking approval of a device.

40 See FDCA §§ 701(f)(3), 502(n), 721(d), 21 U.S.C. §§ 371(f)(3), 352(n), 379e(d). The standard for review of regulations relating to food additives is "fair evaluation of the entire record at such hearing." FDCA § 409(g)(2), 21 U.S.C. § 348(g)(2).

41 FDCA § 505(h), 21 U.S.C. § 355(h)

special review provisions of the FDCA. FDA denials of citizen petitions filed under the agency's procedural regulations[42] are also judicially reviewable.

The application of the 1996 regulatory reform legislation simply provides an opportunity for Congress to review what FDA has done, and to decide whether it wants to act. In general, that statute delays the effective date of a final agency rule for 60 days following its submission to Congress or its publication in the Federal Register (whichever occurs later), and provides expedited procedures for congressional review and consideration of a joint resolution of disapproval. Current law provides for such review; and, indeed, FDA's final tobacco rule was subject to this very Congressional review process, without undue burden on FDA.[43] The Proposed Resolution seeks merely to assure the continued applicability of this existing Congressional review procedure. In view of the "enormous social consequences" that could result from FDA action in this context, an opportunity for the elected representatives of the people to consider the matter is entirely reasonable and appropriate.

Finally, with respect to a ban on nicotine, or other action that would have an effect comparable to the elimination of nicotine, the Proposed Resolution calls for five additional safeguards: (i) no such action may be taken for twelve years; (ii) any such action shall be phased in; (iii) the phase-in shall not begin for two years, to permit time for Congressional review under the 1996 regulatory reform legislation; (iv) the preponderance-of-the-evidence standard shall apply; and (v) "in any judicial review, the deference accorded to [FDA's] findings shall depend

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42 21 C.F.R. § 10.30.

43 See 61 Fed. Reg. at 44,615.

upon the extent to which the matter at issue is then within the Agency's field of expertise".[44] In this unique context, these safeguards are all reasonable and appropriate.

The 12-year deferral of a ban on nicotine is reasonable and appropriate. FDA has repeatedly said that a ban on tobacco products is not in the public interest,[45] and that it has no plans for a ban. Twelve years is a reasonable time to see how provisions in whatever legislation is enacted to reduce underage use of tobacco products actually work. Since virtually no one now asserts that tobacco sales to adults should be banned, if new statutory programs do succeed in reducing underage use satisfactorily, there will be no justification for a ban. Those who object to the 12-year deferral should state why a ban on nicotine within the next twelve years is sound public policy.

A phase-in of any ban is necessary in view of the potentially enormous adjustment that millions of individuals and hundreds of thousands of farmers and businesses would have to make.

The two-year period for Congressional review is also appropriate. Given the potential momentousness of a ban on nicotine, a time for Congressional review is plainly warranted. A two-year period for such review is reasonable.

The preponderance-of-the-evidence standard is the one used in ordinary civil litigation. It merely requires a finding from the evidence that it is more likely than not that a particular factual proposition is correct. Again, in view of the societal importance of a decision to ban nicotine, it is reasonable to require that the factual premises for the decision be more likely true than false.

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44 PR 17-18.

45 See, e.g., n. 20, supra.

Deference to administrative findings of fact is based principally on the presumed expertise of an agency. Where an agency makes findings with respect to the potentially "enormous social consequences" that may result from its action, it is entirely appropriate to make judicial deference to those findings depend on the extent to which the matter is within the agency's expertise. If the matters to which FDA's findings relate are within its expertise, the findings will be accorded deference; if the matters are not within the agency's expertise, then they will not – and should not – be accorded deference.

THE TOBACCO INDUSTRY IS WILLING TO WORK WITH THIS COMMITTEE ON APPROPRIATE PROVISIONS IN COMPREHENSIVE TOBACCO LEGISLATION.

On June 20, 1997, the tobacco industry committed to support the Proposed Resolution. It continues to support the Proposed Resolution. The industry fully recognizes, however, that only Congress legislates for the American people; and that Members of Congress have a wide range of ideas about appropriate national policy toward tobacco.

The regulatory provisions of S. 1648 follow those of the Proposed Resolution in many respects, and differ from them in some. Thus, the industry can support many aspects of the bill. There are other aspects of the bill the industry cannot support.

For example, very serious constitutional as well as policy questions are raised by the bill's nonconsensual provisions on advertising and promotion, the lookback provision, and the bill's requirements for disclosure of information without assured protection of trade secrets. The industry has serious concerns about the bill's provisions on preemption and environmental tobacco smoke. My testimony should make clear that the industry also has serious concerns about the bill's omission of procedural safeguards and requirements for findings. The industry has other serious concerns as well; I am not being exhaustive.

Nevertheless, the industry very much appreciates that a lot of thought and effort have gone into S. 1648, and that the bill moves the process forward. On behalf of Reynolds and the other companies that signed the Proposed Resolution, I am authorized to say that the industry looks forward to working with the Chairman and the other Members of this Committee and the staff on appropriate provisions in comprehensive tobacco legislation.

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 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"

FDA's regulation of tobacco advertising pursuant to Section 520(e) of the Act was invalidated by the District Court. 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-"

The following clarification is not necessary, but would codify the approach explained in the preamble to the FDA Tobacco Rule, 61 F.R. 44412-12.

> 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

Piece from Judy

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,"

Additional provisions:

1. Findings specifically supporting advertising restrictions to provide the factual support for FDA's restrictions-- First Amendment considerations.

2. Provisions requiring new, shorter, more numerous specific rotating health warnings for cigarette and smokeless tobacco packaging and advertising with residual authority in FDA to change content, format, etc.

3. Specific authority for the use of compulsory process.

4. A provision permitting the Secretary to adopt a performance standard under section 514(a)(2) regardless of whether the product has been classified under section 513.

5. Elimination of the preemption of state action (except as to warning labels on packaging) and of liability at common law.

6. Provisions enabling a state/federal licensing scheme for retailers.

7. Preservation of state and local authority to enact laws and regulations that are in furtherance or in addition to federal requirements.

8. A document disclosure provision to ensure that FDA has access to all relevant trade secret and commercial confidential materials currently in existence.

Tobacco - settlement - FDA jurisdiction

Cynthia A. Rice 02/24/98 04:05:21 PM

Record Type: Record

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

cc:

Subject: Today's Jeffords and McCain hearings

The news from today's hearings is that both chairmen said they will mark up their bills next week -- the dates weren't specific, but both implied next Tuesday.

I think we may need a meeting on the FDA jurisdiction issues Jeffords bill raises -- i.e., do we oppose/support creating a separate title for tobacco and switching jurisdiction from FDA to CDC? HHS seems to oppose both.

Message Sent To:

Bruce N. Reed/OPD/EOP
Elena Kagan/OPD/EOP
Thomas L. Freedman/OPD/EOP
Mary L. Smith/OPD/EOP
Jerold R. Mande/OSTP/EOP

Tobacco - settlement - FDA jurisdiction and notes + memos

FDA Regulation

The first priority of the Administration, in considering any tobacco legislation, shall be to confirm and protect the jurisdiction of the FDA to regulate tobacco products. This authority can be no less strong -- though because of the nature of the product, it may be somewhat different -- than that which the FDA exercises over other drugs and devices. Further, the authority cannot be circumscribed by any special procedural rules or requirements. The FDA must be able to regulate tobacco products, including by ordering the reduction or elimination of nicotine or other constituents, through its normal procedures in the furtherance of public health interests.

The Administration therefore supports legislation specifically empowering the FDA to require the modification of tobacco products based on a finding that this change would reduce the risk of the product to the public and is technologically feasible. **[Pick one of the following two sentences:]** [The FDA shall consider all relevant factors in making this determination, including the number of addicted tobacco users, the availability of alternative products, and the risk of a significant contraband market in tobacco products resulting from the proposed action.] [The FDA need make no further findings in support of this decision, but consistent with its duty to protect the public health, the FDA may not go forward if a party affirmatively demonstrates that the action would create a significant contraband market in tobacco products.] The FDA may order a modification of a tobacco product (including the reduction or elimination of nicotine) at any time, although a decision to eliminate nicotine shall not take effect for two years to allow time for congressional review. In determining whether to require modification of a tobacco product, the FDA shall use its normal procedures.

Internal Notes:

Even as written, the settlement's provision on FDA jurisdiction had significant virtues. First, the provision specifically conferred jurisdiction to regulate tobacco products on the FDA, thereby removing the legal uncertainty now attending the FDA rule. (The Fourth Circuit almost certainly will rule against the FDA; the Supreme Court is a toss-up.) Second, the provision established a "risk reduction" standard to guide the regulation of tobacco products in place of the "safety and efficacy" standard applicable to other drugs and devices. Because the former makes sense when applied to inherently dangerous products whereas the latter does not, the change in standard would facilitate the FDA's regulation of tobacco products.

This provision of the settlement, however, also contained several glaring weaknesses. First, the FDA was required to prove a negative in order to reduce or eliminate nicotine -- i.e., that the action would not create a significant demand for contraband products. Second, the FDA could not eliminate nicotine for a period of 12 years. Third, the FDA could not take any action to modify tobacco products without surmounting a number of procedural hurdles -- e.g., formal rulemakings -- not usually applicable to administrative action.

The above statement eliminates the 12-year prohibition and the special procedural hurdles

contained in the proposed settlement. The statement offers two alternatives on the contraband issue. The first and preferable alternative is to convert the contraband question from a make-or-break finding into a mere "consideration." The second alternative is to flip the burden of proof on the contraband issue, so that the tobacco industry will have to prove that the proposed action will create a contraband market (instead of the FDA having to prove that it will not). This alternative removes the burden of proving a negative from the FDA, but still makes the FDA's action wholly dependent on the question of whether it will create a contraband market.

Tobacco - settlement - FDA jurisdiction/product reg

Alternative Substitute, September 5, 1997

NOTE: This language is intended only as a substitute for Section 5A and 5B (pp. 15-18) of the Proposed Resolution.

Performance Standards

To further the public health, to promote the production of "reduced risk" tobacco products, and to minimize the harm to consumers of tobacco products by insuring that the best available, feasible safety technology becomes the industry standard, FDA will have the authority to promulgate Performance Standards pursuant to Section 514 that require the modification of tobacco products to reduce the harm caused by those products (including the components that produce drug dependence), provided that the standard shall not require the prohibition on the sale to adults of traditional tobacco products in the basic form as described in the August 28, 1996 FDA Rule at 61 Fed. Reg. At 44616 (to be codified at 21 C.F.R. Section 897.3).

The Food and Drug Administration (F.D.A.) shall have the authority to promulgate Performance Standards pursuant to Section 514 that require the modification of tobacco products, including the reduction or elimination of nicotine and the reduction or elimination of other constituents or other harmful components of the tobacco product,[1] based upon findings, on a fair evaluation of the entire record, that (1) the standard will result in a reduction of the health risk associated with such product[2] to tobacco consumers and potential tobacco consumers; (2) the standard is technologically feasible, and (3) the likely benefits of the standard outweigh any likely countervailing social, economic, or other consequences of such standard. In making such a finding, the F.D.A. shall take into account the number of dependent tobacco product users, the availability and demonstrated market acceptance of alternate products then on the market, and such other factors as the F.D.A. may deem relevant.

In the event a party subsequently files a petition seeking an administrative review of whether a modification has, in fact, resulted in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard and FDA denies the petition, the petitioner shall have the right to seek judicial review of the denial of the petition.

Should the F.D.A. require the elimination of all, or substantially all, of the nicotine, any such action shall not take effect for a period two years to allow for Congressional review pursuant to the Regulatory Reform Act of 1996.

---

[1] The elimination of nicotine or other harmful constituent shall not be deemed to violate the provision precluding the prohibition on the sale of traditional tobacco products, to adults, even if it results in a reduction of the number of the consumers who use the tobacco products then remaining on the market.

[2] This includes the reduction in harm which will result from decreased drug dependence from the reduction and/or elimination of nicotine from (a) those who continue to use tobacco products, but less often, and (b) those who stop using tobacco products.

Additionally:

- Within one year of the effective date of this Act, the FDA shall establish a Scientific Advisory Committee to examine and determine the effects of the alteration of nicotine yield levels and to examine and determine whether there is a threshold level below which nicotine yields do not produce drug dependence and, if so, to determine that level, and also review any other safety, dependence or health issue so designated by FDA.

- Separate from and without detracting from the Agency's authority under the requirements of the Section 514 Performance Standard noted above, effective three years from the date of enactment of this Act, no cigarette shall be sold in the United States which exceeds a 12 mg "tar" yield, using the testing methodology now being used by the Federal Trade Commission.

Fax to Bill Schultz

Performance Standards

The Food and Drug Administration (F.D.A.) shall have the authority to promulgate Performance Standards pursuant to Section 514 that require the modification of tobacco products, including the reduction or elimination of nicotine and the elimination of other constituents or other harmful components of the tobacco product,[1] based upon a finding that the standard will result in a reduction of the risk associated with such product to the public[2] and is technologically feasible. In making such a finding, the F.D.A. shall take into account the number of dependent tobacco product users, the availability, or lack thereof, of alternative products then on the market, the risk of a significant demand for a market in contraband products, and such other factors as the F.D.A. may deem relevant.

Should the F.D.A. require the elimination of nicotine, such action shall not take effect for a period of two years to allow for Congressional review pursuant to the Regulatory Reform Act of 1996.

Additionally:

*Within one year of the effective date of this Act, the F.D.A. shall establish a Scientific Advisory Committee to examine and determine the effects of the alteration of nicotine yield levels and to examine and determine whether there is a threshold level below which nicotine yields do not produce drug dependency and, if so, to determine that level, and also review any other safety, dependence or health issue so designated by the F.D.A.

*Separate from and without detracting from the F.D.A.'s authority under Section 514, effective three years from the date of enactment of this Act, no cigarette shall be sold in the United States which exceeds a 12 mg "tar" yield, using the testing methodology now being used by the Federal Trade Commission.

---

[1]The elimination of nicotine or other harmful constituent shall not be deemed to violate the prohibition on the sale of traditional tobacco products to adults, even if it results in a reduction of the number of the consumers who use the tobacco products then remaining on the market.

[2]This includes the reduction in harm which will result from decreased drug dependence from the reduction and/or elimination of nicotine from (a) those who continue to use tobacco products, but less often, and (b) those who stop using tobacco products.

8-8 Bill Schultz

Works pretty well
on Rely Class 2 procs (514)

If want to add:
(1) send to advisory cmte (would do anyway)
give us scientific info
not binding

(2) Part 15 hearing
op for oral arg in Ct of Appeals
More general than notice + comment

Device stat - passed 76
Most → not reg. at all before then.
Cong in 76 - put all devices in one of 3 classes -
If can achieve reas assurance of s+eff, w/ controls in Cl 1 → 1
→ adulteration
misbranding
gd manu stds
so on

Cl 2 - performance std -
detailed reg - there are stds you have to meet to
mkt the product. If still can't assure ...

Cl 3 - premarket review
case by case basis.

1000 in Cl 2 500 in 1 200 in 3

But proc. of Cl. 2 (51X) complicated, so agency never did them at all. (perf standards)

1990 - amendment - Cl 2 doesn't have to have perf stds
Add other kinds of controls -
Then - simplified proc - basically N+C rulemaking.

Most likely way we would have done it - by perf std in Class 2.

1 - 8~~8~~8 - ~~540~~ 847 - 5078 beeper.

Tobacco - settlement - FDA jurisdic

Reduced Risk Product

if done virtually every thing

reg diversion (no need to have even compulsory licensing payment)

FDA can reg exploitation

If done virtually

patent system

middle ground

Melamet:

Should have could in development (as settlement does - gets this right)

shorter patent life on

make them give away stuff they have now.

lower as to future -

go to regular patenting

← Melamet

Reg	Law -
Call Brill - procs	Dr. Disclo Antitrust Class acti-

x FDA comments of our tobacco strategy, saying for, we want to work on that, not remove it.

Tobacco: settlement – regulatory

- Our review of the proposed tobacco settlement so far has revealed numerous areas where the attorneys general have made real progress -- but our review also reveals at least one serious problem that we will have to correct before going forward.

- The problem is that the settlement too greatly limits the ability of the FDA to regulate the manufacture of tobacco products -- and particularly, to ~~control the amount of~~ nicotine ~~that tobacco companies can put into~~ cigarettes. This is a crucial defect because it is nicotine that addicts people to cigarettes, and the best hope of breaking that addiction may be by ~~controlling the level of~~ nicotine in cigarettes.

control

and Smokeless tobacco.

reducing

~~Re-limiting~~

The agreement creates at least three new obstacles that the FDA would have to surmount in order to reduce the amount of nicotine in cigarettes:

-- It would force the FDA to find that ~~the~~ reduction in nicotine would not result in a black market, which ~~given the speculative nature of this inquiry, would be extremely difficult to do~~ would be almost impossible to prove in a legal challenge.

make a ruling -- a

against

rarely used

-- It would force the FDA to use a formal ~~notice and comment~~ rulemaking rather than the less cumbersome and time-consuming procedures that the FDA almost always uses to regulate drugs.

20 yrs.

and medical devices.

-- It would force the FDA to use a higher standard of proof than is used in comparable regulatory proceedings (a "substantial evidence" rather than an "arbitrary and capricious" standard).

- Our review is ongoing, and we have not yet determined precisely how these problems should be addressed. But we believe that we must change (1) what the FDA must find before it can ~~reduce~~ regulate nicotine and (2) what procedural rules and mechanisms the FDA must use to take this action. For example, we might say that the FDA should be able to reduce nicotine as long as the agency shows in an informal proceeding of the kind the agency usually uses that the reduction is technologically feasible and would reduce the health risks associated with smoking.

- We very much want to correct problems of this kind because the agreement would make real progress in a number of areas -- for example, on advertising and second-hand smoke. But we will insist that the FDA has the regulatory authority it needs to protect the public health -- and particularly the health of our children.

Everyone, including public health ~~officials~~ advocates, agrees that

Pros

- Strengthens the FDA's authority in key ways – advertising, access, warnings, licensing, and overall agenda
- ~~Some public health officials argue that~~ it's valuable to enshrine FDA authority into law, so that ~~future~~ higher CT or future Administration can't undercut Greensboro decision ~~of these FDA~~
- No ~~immediate~~ plans to ban or reduce nicotine. Not ruled out some period of time w/no ban – more concerned w/ std FDA must meet to regulate over long haul. (Rule makes clear...)

environment for

Regulatn of Product

Another overarching issue - even additional products (e.g. cigars)

Nic. ↓ - never thought of as part of FDA phase
Impossible to project - 10 or 20 yrs from now.
Any curtailment is a big deal.

2 missing pieces of data
a) level of nic below which product not add.
b) don't know what would happen if tried to wean ppl smoking more than

Take out nicotine OR take out max. other products
↓
harm reduction theory

Push toward reduced risk products - should there be that?
Flexib. usually held by FDA taken away on this.
Buying into sys that encourages dev of reduced risk products.

II. Nicotine - gradual elim
Findings are key - decides what the factual q's are.
burden of proof - on FDA; not usually
new: "injurious to health as labeled"
"product cannot be made safe + effective" } easy
tech feas - no prob.
"signif" reduc of risk - potential issue

Canada - huge b.m. - black mkt - real issue.
~~Liber~~ when tax went up. 2 total speculative - already made a finding the other way.

Formal rulemkg / informal rule mkg

Other proced probs. - another src of findings

prepnd. of ev.

Petitions - when b. m. does occur.

Dietary supps.
Special legislation

11. Reduced risk products

less flexib. to look at charact / safety profile of each product

Low tox cig = we might decide to do as reg cig.

Eclipse = we may put into a wholly diff categ.

→ How much info could we req. of industry:

90-day period - deemed approved!

Need flexib. to ask for lots of data.

2 by classifying it as something other than a normal cig.

	FDCA	SETTLEMENT	
		Nicotine Reduction	Nic. Elimination or Equivalent Action
Regulatory Mechanism	1. adulteration or misbranding provisions 2. restricted device provisions 3. performance standards 4. device classification 5. other (?)	Products classified as class II devices; FDA sets performance standards	Products classified as class II devices; FDA sets performance standards
Required Agency Findings	Sets general controls to provide adequate assurance of safety and effectiveness (~~for class III devices~~)	FDA must show reduction: 1. will result in significant reduction in health risk 2. will be technologically feasible *3. will not create a black market* (agency must consider # of dependent tobacco users, availability + demonstrated market acceptance of alternate products on the market.)	FDA must show elimination: 1. will result in significant reduction in health risk 2. will be technologically feasible *3. will not create a black market*
Time Frame	No constraints	for at least 12 years	1. FDA can require nicotine elimination only after initial 12 year period 2. elimination must be phased in- can't begin sooner than 2 years
Regulatory Process	notice and comment rulemaking	formal rulemaking	formal rulemaking; FDA establishes Scientific Advisory Committee on nicotine reduction within 1 year.
Allowed Industry Appeal	APA judicial review	rt. to judicial review; can petition FDA to review its finding that no black market has been created.	can elect to have a Part 12 hearing or judicial review; can petition FDA to review its finding that no black market has been created.
Standard of Review	arbitrary & capricious	substantial evidence "In any judicial review, the deference accorded to the Agency findings shall depend upon the extent to which the matter at issue is then within the Agency's field of expertise." (p. 18)	preponderance of evidence (burden on FDA)

Tobacco - Settlement - FDA jurisdiction

Tobacco - settlement -
FDA jurisdiction

7/10/97 Product Regulation

FDA has no intent to ban product
Also - DK said couldn't reduce nicotine - bec science isn't there
(could be there / need $ - mkt would make big diff)

Current law - auth to reduce/ban - safety + efficacy
n+c ruling
md rev - arb / cap.

DOT - std - should be geared to this product -
FDA sort of agrees: from legal pt of view - b/c.
just ask: reduce danger/health risk.
Easier to regulate under diff regimen

but thinks: as practical mtr. can do what we need to do.

3 options -
period - no auth to ban or reduce
" reduce, but not elim
"
don't imagine we will do anything
for 5 years - even to reduce
After that: who knows? this is on nicotine - not other harmful
Diff people have diff views? products.
After at # 4 yrs - almost a triggering mechanism.
Gene - may not be next year at SCT - the following yr.
So there's really a time lag anyway.

Addition - before take such an action - go to an
advisory panel - academics, etc.
Usually used to bolster agency decisions.

Procedures

1. Formal rulemaking = big hassle.
   → hearing before ALJ — w/ possibly cross-exam.
   ↓
   "Part 12"

2. Where's the b of proof
   can we take pos that co. has

3. Std of proof —
   → "subst ev" for 1st 12 yrs   "prepond of ev" for next 12.

4. Std of review
   now — arb + cap
   They say — subst ev for first 12 yrs.
   Some cts say — no difference
   Gene — not much diff as practical mtr. Cts looking at partic record.

5. Deference —
   "Things we have expertise about"
   2 for example — any expertise on black market.
   also: goes to both legal / factual

6. Congressional review.
   2 yr. effective date.
   doesn't mtr.

   not just smokers

   (1) Health std / Curtailed Deference
   (2) Yr-long period / Rulemaking, Burden of proof, Standard of proof, Standard of review
   (3) cong review / tech bars.

Findings

1. Simil reduction

Concept makes a lot of sense.

Some concern abt way this is written – can we only look at current smokers?

- or prospective smokers
- and non-smokers

2. Tech feasible –

Not quite sure why they put it in –

doesn't seem much q. whether can be.

If they're trying to fit at "consumer acceptance,"

then that's a problem.

3. Cultural cut.

Probs gone over.

If just something to be considered?

Presumably OK.

Policy process

↓

already are

new – OK –

problem is

JUST THAT it's

pegged to cultural finding

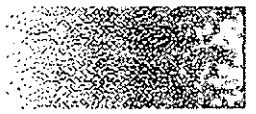
Non-tobacco inpreds – p. 20.

taken from food additive std – qu: does it fit?

bill – yes – it's OK

The problem is ridiculous.

Tobacco - settlement - FDA jurisdictic



Jerold R. Mande

06/20/97 11:59:14 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Elizabeth Drye/OPD/EOP, Elena Kagan/OPD/EOP
Subject: May sound nice - bad idea: Hurdles FDA must clear to regulate nicotine

This morning's rumors include requiring FDA to prove any proposed product modifications are both feasible and wouldn't lead to a black market. Certainly that should be the goal of any required modifications. But forcing FDA as an administrative requirement to clear this hurdle would effectively prevent FDA from acting, and remove an important incentive for industry to develop feasible alternatives.

Another industry argued for years that CFC alternatives weren't feasible, but once Congress passed a law banning them alternatives sprung up at startling speed.