

June 30, 1997

To: Elena Kagan

From: Bill Schultz

Attached are four papers in anticipation of the two meetings later today: (1) a discussion of FDA regulation of the product (8 pages); (2) an analysis of the advertising, label, access and education provisions of the proposed agreement (11 pages); (3) a short paper on how the proposed agreement could affect FDA's residual authority to regulate advertising, etc. (2 pages); and (4) a list of additional ideas to include in the proposed agreement (2 pages).

If you have any problems receiving this fax, please call Sara Kay Addis at (202) 205-4102. Thank you.

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FDA REGULATION OF THE PRODUCT

NICOTINE

Existing Authority

Under current law, pursuant to the Agency's jurisdictional determination last August, FDA has broad regulatory authority over nicotine-containing cigarettes and smokeless tobacco products. This authority includes the power to control product components, such as nicotine, and to require modifications to the product.

The Agency has no current plans to lower nicotine levels in cigarettes and smokeless tobacco products. Nevertheless, in the future FDA might determine that nicotine levels should be reduced. There are a variety of regulatory mechanisms that could be used under current law to accomplish that goal. These mechanisms include regulations promulgated under the adulteration and misbranding provisions, restricted device provisions, performance standards, and device classification. These actions, with the exception of performance standards, would be judged under the arbitrary and capricious standard of judicial review. This level of judicial scrutiny gives great deference to the Agency, including any review of how FDA framed the policy questions under consideration.

Furthermore, the existing mechanisms would all be employed using informal, notice and comment rule making procedures similar to those used by FDA to promulgate the final tobacco regulation.

How the Proposed Settlement Expands FDA's Authority to Reduce or Eliminate Nicotine

There are no provisions in the proposed settlement that expand FDA's authority to either reduce or eliminate nicotine.

★ How the Proposed Settlement Limits FDA's Authority to Reduce or Eliminate Nicotine

The proposed settlement limits FDA's authority over nicotine by creating new substantive and procedural obstacles that the Agency would have to address in order to either reduce or eliminate nicotine. The proposed settlement presumably eliminates all regulatory mechanisms other than performance standards to reduce or eliminate nicotine. Some of these other mechanisms, such as the adulteration, misbranding, and restricted device provisions, could be employed more quickly and simply than the process created in the proposed settlement.

In addition, the proposal creates three criteria FDA would have to satisfy to either reduce or eliminate nicotine. These three criteria do not exist in current law. Under the proposed settlement, FDA must find that the modified product:

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(a) will result in a significant reduction of the health risks associated with such products, { Nicotine vs. tar ? }

(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.

*** Reducing Nicotine**

It would be quite difficult to prove, prior to any regulation reducing nicotine goes into effect, that a significant demand for contraband would not be created. While the other criteria -- significant reduction in health risks and technological feasibility -- may not be as difficult to establish, tobacco companies would be able to mount court challenges to contest all three of the Agency's findings.

The degree of deference the Agency would receive by a reviewing court would be altered by virtue of the criteria's existence. The criteria frame and possibly limit the issues FDA could consider. ✓
This reduces the Agency's role to simply gathering the evidence needed to satisfy pre-determined criteria. By contrast, the broader authority FDA currently has over nicotine would give the Agency considerably more flexibility in defining the policy issues and criteria within its jurisdiction.

There are also procedural obstacles created by the proposed settlement. First, nicotine reduction could only be pursued by FDA under formal rulemaking procedures. ✓
Formal rulemaking is cumbersome and time-consuming, and could delay Agency action for years compared to informal, notice and comment rulemaking. Formal rulemaking typically includes a hearing before an administrative law judge, cross examination of witnesses, factual determinations by the judge, and then a review of the judge's decision by the Commissioner.

Second, the proposed settlement creates a new process whereby the industry could petition FDA to contest the Agency's finding that nicotine reduction would not result in a significant demand for contraband. This petition process is vague and could slow the Agency down considerably because a party would be entitled to judicial review if its petition were denied. The petition provision also seems to be an unnecessary step once FDA has conducted a rulemaking where all interested parties already would have had a chance to submit comments and participate in the Agency's decision-making process.

*** Eliminating Nicotine**

Additional substantive and procedural obstacles are included in the proposed settlement that would alter FDA's ability to eliminate nicotine. For instance, the Agency is required to consider

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the "demonstrated market acceptance of alternate products then on the market." What exactly does "demonstrated market acceptance" mean if a cigarette with just one percent of the market is considered commercially viable? In addition, this part of the proposed settlement applies not only to the elimination of nicotine, but also to "such other action that would have an effect comparable to the elimination of nicotine." Could that phrase be construed to include an FDA action that lowers nicotine to a non-addictive level but does not technically eliminate it altogether?

The proposed settlement also requires the Agency to conduct a "Part 12" hearing before it eliminates nicotine. This type of hearing can include sworn witnesses and cross examination and can be a very lengthy proceeding. No such hearing would be required under FDA's current authority were the Agency to act on nicotine. The Agency has the burden of proof (p. 7) whereas in most comparable Agency proceedings the industry has the burden of proof.

The congressional review provision following a decision by FDA to eliminate nicotine would constitute a broadening of that review power if it means that Congress has two years to produce a joint resolution of disapproval under the Regulatory Reform Act of 1996, as opposed to the typical length of time of 60 legislative days.

The judicial review standard is "substantial evidence" (p. 18), rather than the arbitrary and capricious standard that applies to the review of regulations. Moreover, the degree of deference to be paid to the Agency "shall depend upon the extent...the matter is then within the Agency's field of expertise." It is unclear what this provision really means, but it is likely to lower the deference paid to FDA by a reviewing court (p. 18).

INGREDIENTS OTHER THAN NICOTINE

Current Authority

Under the Agency's current authority, it would have the ability to ensure that both the tobacco and non-tobacco ingredients are safe, regardless of whether tobacco products are placed in Class I, II, or III. As Class I devices, FDA would have the authority to insist, as a matter of good manufacturing practice, that only safe ingredients be used in the device. Similarly, if these products are placed in Class II, the performance standard that FDA adopts would require the use of safe ingredients. Finally, if tobacco products were placed in Class III, the use of unsafe ingredients would provide the basis for denial of premarket approval.

How the Proposed Settlement Expands FDA's Authority

The proposal shifts the focus from the product to an evaluation of each ingredient. The establishment of a list of ingredients that are not harmful when used in tobacco products would presumably facilitate FDA's review under whatever regime is applicable and would facilitate the

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use of safe ingredients by the industry. In addition, the listing criterion (reasonable certainty that the ingredient is not harmful) is arguably better suited to tobacco products than the definition of safety that FDA uses for devices. Devices usually involve a balancing of risks and benefits. For tobacco products, for which there presumably are no benefits, the standard, like the safety standard for food additives, focuses only on risk.

How the Proposed Settlement Limits FDA's Authority

A fundamental problem under the proposal is the scope of coverage. Ingredient safety requirements would apply only to non-tobacco ingredients. This would represent a significant contraction of FDA's authority.

Under the proposed settlement, FDA could not require a showing of safety for five years. Manufacturers are given five years from enactment of any legislation to submit a safety assessment, based on the best available evidence, that there is a reasonable certainty in the minds of competent scientists that the ingredient is not harmful under the intended conditions of use.

It is important to recognize also the limitations inherent in this formulation. The firm would only have to rely on the available evidence. There may well not be available the type of testing necessary to determine whether the ingredient is safe, and FDA could not insist on such testing. On the other hand, the language of the standard tracks the language of the definition of "safe" in FDA's food additive regulations (21 CFR 170.3(i)). The difference is that FDA can compel testing under the food additive provisions; it apparently would not be able to do so under the proposal.

The final major problem with the proposed settlement is another problem with timing. Manufacturers would have 5 years to make their submission, but once they do, FDA only has 90 days to approve or disapprove. Significantly, if FDA takes no action within 90 days, the ingredient is deemed to be approved. If all firms were to wait 5 years and then make their submissions, FDA would be overwhelmed, and it is likely that virtually every ingredient would be deemed approved.

INGREDIENT DISCLOSURE

Current Authority

Under section 502(r) of the Food, Drug, and Cosmetic Act, which is applicable to restricted devices like cigarettes and smokeless tobacco, if FDA finds that it is necessary to protect the public health, it can require by regulation the full disclosure of the formula of these products, showing quantitatively each ingredient of the device. The finding that disclosure is necessary is to be based on notice and comment rulemaking, and the regulations implementing that determination are to be issued after an opportunity for a hearing. FDA has yet to exercise this authority with respect to tobacco products.

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The proposal would require tobacco manufacturers to submit a complete list of non-tobacco ingredients to FDA. It also provides for ingredient declaration to the public based on regulations that would be modeled generally after what current federal law requires for foods. However, the manufacturer would be able to claim that at least some of the tobacco product's ingredients are exempt from disclosure, and the burden would be on FDA to challenge that claim with respect to specific ingredients.

How Proposed Settlement Expands FDA Authority

The immediate imposition, without the need to follow the procedural requirements in section 502(r), of a system in which there is disclosure of the non-tobacco ingredients, and the amounts of those ingredients, in each specific tobacco product to FDA and the immediate creation of a system in which there is some type of ingredient labeling on tobacco product labels.

How Proposed Settlement Limits FDA Authority

FDA would be deprived of the ability, assuming that it could make the requisite findings, of structuring an ingredient labeling system that it considered necessary to protect the public health. The legislation envisioned by the statute would impose the following limitations:

1. There would not be complete ingredient labeling.
 - a. Tobacco, water, and reconstituted tobacco sheet made wholly from tobacco would not need to be included in the ingredient list.
 - b. Flavors and colors (other than certified colors) would only have to be declared by those terms ("flavorings" and "color added").
 - c. To the extent that complete ingredient labeling is impractical or results in deception or unfair competition, the Secretary of HHS can establish exemptions by regulation (e.g. "and/or" labeling for fats and oils).
 - d. The ingredient list would have to include the name of each ingredient and, for ingredients that are themselves made up of more than one ingredient, the ingredients of ingredients. However, there would not need to be disclosure of naturally occurring components of ingredients that may have an effect on the public health (e.g., nicotine in tobacco) or ingredients used earlier in the process than the level that FDA has covered (e.g., ammonia added to an

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ingredient of an ingredient).

- e. The proposal would also permit firms to assert that ingredients are exempt from public disclosure under regulations that FDA is to promulgate within 12 months (an incredibly fast time frame) of the enactment of any legislation. It is not clear what standards FDA would use, other than those already listed from the food provisions, in drafting these regulations.
2. There would not be any quantitative information provided. In fact, food ingredients are listed in order of predominance by weight. FDA established this requirement under the Fair Packaging and Labeling Act which, by its terms, does not apply to tobacco products. Thus, there is a question as to whether FDA could require that ingredients be listed in any particular order.

The proposed settlement agreement raises a number of other questions that could have a significant bearing on what has been gained and lost:

1. The list of ingredients submitted to FDA is supposed to include all "ingredients, substances, and compounds." What did the authors think that "substances" and "compounds" added to "ingredients?"
2. The list is supposed to include those things added to the tobacco, paper, or filter. Is there a distinction between the ingredients used to make the filter and the ingredients added to it? This may seem like an odd distinction, but there is FDA case law that suggests it (see, e.g., U.S. v. 29 Cartons of ... An Article of Food, 987 F.2d 33 (1st Cir. 1993)).
3. The proposal would not require disclosure that the tobacco used in a product has been genetically engineered to contain a large amount of nicotine. FDA has never said that genetic engineering needs to be reflected in the common or usual name of a food. (The Cal-gene tomato is still a tomato.) Complaining about the lack of notice of the difference between regular tobacco and genetically engineered tobacco may create problems for FDA's food labeling policy.

OTHER ASPECTS OF TOBACCO PRODUCTS

FDA regulation expressly applies to and defines cigarettes, smokeless tobacco, and loose cigarette tobacco.

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How the Proposed Settlement Expands FDA's Authority to Regulate Tobacco Products

The proposal does not expand FDA's Authority. The proposal goes beyond FDA's rule by covering little cigars.

How the Proposed Settlement Limits FDA's Authority to Regulate Tobacco Products

1. CLASSIFICATION OF EXISTING AND REDUCED RISK TOBACCO PRODUCTS

a. Existing Authority

Under current law, the Agency has the flexibility to regulate products, including new reduced risk tobacco products, in the manner it determines is most appropriate given each product's characteristics, including its safety profile and possible health benefits. For example, the Agency could determine that some new reduced-risk products should be regulated only under the provisions of the Agency's tobacco regulation and determine that others present scientific, health, or safety issues significant enough to require premarket approval.

b. Authority Under the Proposed Settlement

The proposal places these products in a new subcategory of Class II, removing the authority of the Agency to require premarket approval for these products. This means that FDA could not require premarket approval for reduced-risk tobacco products, or Eclipse-like, or other unconventional tobacco/nicotine products. The proposal also creates a vague and unscientific definition of reduced risk products, which would prove extremely difficult for the Agency to apply.

The proposal provides for health claims on tobacco products. However, it would be somewhat counterintuitive to put health claims on tobacco products given their inherent risks. FDA has resisted the notion of health claims on wine for much the same reason.

The proposed settlement would also permit exceptions from the advertising restrictions for reduced risk products. Does this mean that the firms will be able to advertise reduced risk products to minors?

In addition, by requiring the Agency to establish a performance standard for these Class II products, the proposed settlement appears to remove the Agency's authority to determine whether additional special controls (such as postmarket surveillance) may be applied, or whether the Agency is limited to establishing a performance standard. The proposal also establishes new procedural hurdles for the Agency when establishing a standard and requires that the standard be established pursuant to formal rule making, rather than notice and comment rule making as currently required. The black market finding has all of the problems discussed in the previous

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section. The proposed settlement terms delay effective date of standard, grant right to petition black market findings with judicial review, and change the standard on judicial review by reducing the deference to be accorded the Agency's findings. The proposal also appears to remove the Agency's authority to take certain remedial actions (e.g., recall) against the products because of health dangers.

While the proposed settlement gives the Agency the authority to establish performance standards and thus modify tobacco products, the proposal expressly authorizes manufacturers to sell unmodified, conventional tobacco products. This appears to create two groups of tobacco products, those that meet Agency established performance standards and those that meet traditional industry standards regarding nicotine, tar, and other characteristics.

2. GOOD MANUFACTURING PRACTICE (GMP)

a. Existing Authority

Manufacturers of finished devices are required to comply with regulations prescribing current good manufacturing practice for devices, to prevent production of defective devices. For example, they describe requirements for building maintenance, personnel training, record keeping, process controls, equipment design and maintenance, and packaging and labeling controls. The device GMP regulations embody the much broader term "quality systems" under which a manufacturer has more responsibility for the design and manufacture of its products. The regulations contain requirements relating to controls over a product's design which are regarded as very important to the Agency.

b. Authority Under the Proposed Settlement

The proposed settlement narrows considerably the responsibility that tobacco manufacturers, especially management, would have under current device GMP regulations, and limits the authority of the Agency over the design and manufacturing processes used to produce these products. Much of the language of this provision is vague, and it is unclear what is meant, for example, by record keeping and reporting and whether it has the same meaning it does in the device GMP regulations. In the GMP regulations, record keeping and reporting includes such things as complaint files, validation records, and design records. The effective date of requiring GMPs specific to tobacco products is hampered by imposing time restrictions of 24 months or the completion of rule making, whichever is later.

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**COMPARISON OF THE ADVERTISING, LABEL, ACCESS
AND EDUCATION PROVISIONS**

ADVERTISING PROVISIONS

Codified Language

FDA's rule contains sweeping changes to the manner in which tobacco products can be marketed. It is based on section 520(e) of the Act, which permits additional unspecified restrictions on the sale, distribution or use of a restricted device if the Agency determines that, because of the device's potentiality for harmful effects, there cannot otherwise be a reasonable assurance of its safety. Section 897.30 details a list of permissible forms of labeling and advertising and provides a mechanism for manufacturers, distributors and retailers to notify the Agency of an intention to use media, other than those listed, to advertise tobacco products. The major exception is for outdoor advertising, which is banned within 1000 feet of schools and public playgrounds.

The inventory of permissible media provides a listing of those media affected by the regulation. It does not preclude other forms of advertising. Thus, the restrictions apply only to the listed advertising and labeling media. For example, section 897.32 requires that the listed advertising and labeling shall only appear in black text on a white background, except that unrestricted advertising may appear in adult publications and at adult facilities. In addition, all listed advertising must contain the product's established name and intended use statement. Finally, permitted audio and video advertising at point of sale shall be limited to words only (no music or sound) and static black text on a white background.

The final set of provisions, 897.34(a)-(c) ban the marketing, distribution, etc. of any item (other than tobacco) or service, which bears the brand name (alone or in conjunction with any other word) logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Moreover, it prohibits the provision of gifts or items in consideration of the purchase or proof of purchase of a tobacco product. Finally, the rule prohibits the sponsorship of any athletic, musical, artistic, or other social or cultural event, or any team or entry in any event, in the brand name, etc., as defined above. Sponsorship is permitted in the corporate name, with some limitations.

Statutory Authority

In addition to the requirements spelled out in the rule, section 502(q) of the Act provides that the Agency can find a device misbranded if its advertising is false or misleading. In addition, section 502(r) provides that the Agency can, after appropriate notice and comment, require a full

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disclosure in advertising of the ingredients of a device, if it is necessary to protect the public health.

How the Proposed Settlement Expands FDA's Role

The proposed settlement purports to include all of FDA regulations of advertising and labeling and require additional restrictions. In most cases this is correct. Perhaps of greatest importance, the proposal would incorporate the advertising and marketing provisions in consent orders with various states to be signed by the participating companies, so that, theoretically, those companies would be bound by the restrictions regardless of legal challenges and court decisions. (pp. 27-28)

The proposal incorporates FDA's definition of permissible advertising but also expands it to "restrict tobacco product advertising to [only those] FDA specified media." This is broader than FDA's coverage, which merely provides the list of media covered by the regulation and provides a procedure for companies who wish to use new media prior to its first use. As an example of the breadth of this provision, the proposed settlement also includes a ban on the advertising of tobacco products on the Internet unless designed to be inaccessible in or from the U.S. These expansions of the rule are significant and make the advertising restrictions more inclusive and powerful. (p. 9)

The proposal would require that all permissible advertising be in black text on a white background except for advertising in adult publications and adult facilities. In addition, the proposed settlement language is broader, providing that even in the "unrestricted" media, advertising would not be able to use human images or cartoon characters (the Marlboro Man and Joe Camel). The ban on outdoor tobacco product advertising, would be expanded to include all outdoor advertising (not just that within 1000 feet of schools and playgrounds) including in an enclosed stadia as well as brand advertising directed outside from a retail establishment. (pp. 8-9)

1. Point of Sale Advertising

Advertising at point of purchase¹, permissible under FDA's regulation, and in the proposed settlement, in a black and white format, would be further restricted. Each manufacturer would be permitted to have no more than 2 separate point of sale advertisements at any one location (except manufacturers with 25% or more of the market could have one additional ad). Retailers could display signs of their own. The display area of each sign could not exceed 576 square inches, either individually or in the aggregate and can use letters and recognized typographical markets. Further, no ad could be attached to nor located within two feet of any fixture selling candy.

¹ Appendix VII appears to state that unrestricted point of sale advertising can appear in adult-only stores and in tobacco outlets. The inclusion of "tobacco outlets" is disturbing, if it is intended to expand the coverage of venues permitting unrestricted advertising. If, on the other hand, the term is used to define a sub-set of adult-only venues, that is tobacco stores that sell only tobacco and are adult-only, the inclusion of this additional term is not substantive.

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Finally, display fixtures may contain signs consisting of brand name and price, not larger than 2 inches in height. (p. 63)²

The proposed settlement forbids any arrangement between a supplier and a retailer, which would prohibit the display of another company's advertising. The final provision bans ads in an audio and video format at point of sale, but would permit these to be distributed to adult customers at point of sale. If this is taken literally, it would appear to authorize music videos, ads with people and animals, etc. for home consumption. (p. 63)

2. Bans on Merchandise, Sponsored Events and Gifts

The proposed settlement bans all non-tobacco merchandise (a word that is narrower than FDA's items and services), bans all offers of non-tobacco items or gifts for proofs of purchase, and bans brand sponsorship of events (but does not appear to ban entries or teams) (p. 8).

3. Disclosures

The proposed settlement requires that all advertising carry an FDA-type mandated statement of intended use (the shortened "Nicotine Delivery Device" without an age proscription), but does not require that the established name be included. In addition, advertising would be required to rotate the same health warnings that packaging would be required to display. Appendix 1 describes the format for warning statements, to wit, 20% of advertising space in press and poster advertisements would be dedicated to the health warnings and where relevant to the tar, nicotine disclosure. The type size is also provided. (pp. 10, 43)

4. Low Tar and Light Advertising

The proposed settlement requires the FDA to "require" that all advertising of brands denoted as "light" or "low tar" be accompanied by a mandatory disclaimer, such as, "Brand X not shown to be less hazardous than other cigarettes." In addition, it requires that exemplars of all new advertising and product labeling shall be submitted to FDA for review concurrently with market introduction. The text notes that this requirement is not in limitation of FDA's normal rulemaking authority in this area. (p. 9) This provision should be read in context with two other requirements: (1) that FDA be vested with responsibility to oversee the tar and nicotine testing currently exercised by FTC and to mandate disclosure of tar, nicotine and other constituent disclosures in advertising and

² Point of sale advertising is defined as all printed or graphical materials, which, when used for its intended purpose, can reasonably be anticipated to be seen by customers at a location at which tobacco products are offered for sale. This provision is narrower than FDA's rule, which bans all non-tobacco items, a category that could include clocks with advertising messages and other items at point of sale. (p. 63)

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on packages if it determines this would protect the public health (p. 11) and (2) that three years from enactment of this Act, no cigarette shall be sold in the U.S. with tar which exceeds 12 mg. (as measured by the current FTC method) (p. 16). This latter provision also is prefaced with an assurance that this requirement should not detract from the Agency's authority under the requirements of section 514 of the Performance Standard to ensure minimum hazardous cigarettes.

5. Novel Provisions

The proposed settlement would ban direct and indirect payment for tobacco product placements in movies, television programs and video games. Moreover, it would prohibit payments which "glamorize" tobacco use in media "appealing to minors," including recorded and live performances of music. The first provision is similar to an informal requirement of the FTC that tobacco companies not provide direct payments for product display in media. The FTC receives, via compulsory process each year, a statement from each tobacco company indicating if and how much consideration it has paid for product placement. (p. 9)

How the Proposed Settlement Limits FDA's Role

Several overall questions are raised by the proposal's short descriptions of restrictions. Several of the provisions are described as restricting or banning "tobacco product advertising" in a given media, which is probably more limited than FDA's restrictions on a company's "advertising" in any manner in that media. In addition, the proposed settlement does not appear to accept FDA's denotation of advertising as encompassing "brand name (alone or in conjunction with any other word) logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco." When these descriptions are provided in the settlement (especially concerning merchandise and sponsorship) the description does not include several of the elements of FDA's definition.³ This may be drafter's shorthand, but if it is intentional, it would severely limit the proposal's coverage. (p.8)

Moreover, the scope of FDA's authority to regulate the content of advertising is unclear. Without specifying precisely what FDA's range of authority would be, the proposed settlement provides that the FTC is to retain its existing authority (except for constituent testing), which presumably would include its authority over deceptive and unfair advertising and marketing practices. (P. 32) As a

³ For example, the proposal's language does not include "recognizable pattern of color." The black, white, and red chevron on Marlboro's package can be displayed alone on a sign and be readily recognized without words or symbols and related to Marlboro cigarettes. Under FDA's rule, this would be a prohibited ad. Under the proposed settlement, it might not be. Similarly, FDA's regulation includes the prohibition on the use of brand names "alone or in conjunction with any other word", the proposed settlement does not. The industry has argued, in the past, that the Skoal Racing Team was not an advertisement for its Skoal products because the additional words, "racing team," made the Skoal reference to its cars and not its product. FDA's definition would prohibit this type of advertising.

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result, it is not clear whether this would be concurrent with FDA jurisdiction or instead of FDA jurisdiction.

Analysis

As with the label provisions, generally the proposed settlement provides greater protection. The most important additional provision is the banning of all advertising not on the list of permissible forms, including a ban on product advertising on the Internet. Although we had constitutional concerns about the breadth of such a proposal, the companies are free to agree to accept those restrictions in consent agreements.

The proposal to grant greater protection at point of purchase closes an important avenue of appeal for young people and should be commended. Our only concern is that the proposal incorporates an advantage to companies with more than 25% of the market (Philip Morris and R.J. Reynolds). The restrictions that the rule or the proposed settlement will require, already will advantage a market leader by providing barriers to new entrants in the market.

Problem areas include the proposals apparent more limited definition of advertising (e.g. color and pattern or color) which would constrict the restrictions coverage. Similarly, the proposal's limitation on the ban on brand identified items and services to a requirement that only affects merchandise⁴ and the limiting the ban on sponsorship to just events (not including teams and entries) provides a short term solution that will require additional rulemaking in the future. The Agency is already aware of industry advertising on items (clocks and other items at point of purchase) and in services (Philip Morris's music contest and CD offer "It's a women's thing" and travel agencies in Europe with tobacco brand names). And the industry's use of racing cars is no less problematic than its sponsorship of the race itself. Both associate smoking with sports, heroes, danger, excitement and fun.

The proposed settlement requires the Agency to develop a disclosure for advertising for low tar and light products. This provision in conjunction with other provisions concerning tar and nicotine content, appear to freeze Agency ability to address the problems associated with the current tar and nicotine rating system. For example, if the Agency were to determine that there is no non-deceptive way to advertise a "low tar" product, because it provides little or no benefit, would the Agency be prevented from doing so? It would appear that the proposed settlements mandate to phase out cigarettes with more than 12 mg. tar has staked out a position that lower tar is better. The evidence may not justify this conclusion and the Agency should not be prevented from taking whatever path is appropriate.

⁴ The industry has shown by its practices in Europe and Canada that it can move its imagery and franchise to any number of possible venues. This should be precluded in any final settlement in order to carry the protections forward to new yet undisclosed activities.

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LABEL PROVISIONS

Codified Language

Subpart C, §§ 897.24 and 897.25 require that each package of cigarettes, cigarette tobacco or smokeless tobacco bear the product's established name and a statement of intended use- "nicotine-delivery device for persons 18 or older." These provisions are based on the requirements of section 502(e) and (r) of the Act that mandate the inclusion of this and other information on all package labels. Section 801.61 of FDA rules requires that these statements appear on the principle display panel of the package. The Agency currently lacks the authority to require additional warnings or to change existing health warnings on cigarette and smokeless tobacco packages, 15 U.S.C.1334, Federal Cigarette Labeling and Advertising Act and 15 U.S.C. 4406, Comprehensive Smokeless Tobacco Health Education Act.

How the Proposed Settlement Expands FDA's Role

In contrast to FDA's modest requirements for the package label, the proposed settlement would amend the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, to mandate numerous new health warnings that would be rotated quarterly. Unlike the current Surgeon General's warnings, the messages would not be attributed to the Surgeon General but would all be prefaced with the word "WARNING" and would be short, understandable, declarative sentences. Moreover, the warnings would be required to occupy 25 % of the upper front panel of the package of cigarettes (except for flip top boxes). Twenty-five percent of the principle display panel of smokeless tobacco packages would similarly carry the warning (side panel of the hockey puck can of snuff). Warnings would be in black on white and white on black format alternately, would be printed in 17 point type (Canadian style), and would follow the requirements set forth in the existing United Kingdom standard. (Pp. 9-11)

The proposed settlement also provides that FDA be given express authority to require changes in the warnings (thereby overturning the preemption provisions of the Cigarette and Smokeless acts) with the caveat that it provide public notice and hearing opportunity prior to making changes.

One additional package restriction is found in the advertising provisions of the proposal. The proposed settlement would prohibit the use of human images and cartoon characters (e.g. the Marlboro Man and Joe Camel) from all tobacco product packaging.(p. 9) Reynolds has, in the past, displayed various poses of its Joe Camel character on collector packages of cigarettes. This practice would be outlawed but it appears that Reynolds' original Joe Camel- a drawing of a dromedary in front of a pyramid- would be permitted.

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How the Proposed Settlement Limits FDA's Role

There are no significant provisions that would reduce FDA's regulation of labels. However, the proposed settlement does not require that package labels indicate the established name of the product but does require that packages contain an FDA-type statement of intended use on the side of the package. However, it appears that the statement would be "Nicotine Delivery Device" and would not include the age proscription. (p. 11)

Analysis

In general, the label provisions of the proposed settlement are broader and create greater protection than the FDA rule. For example, the proposed settlement creates a whole new set of short, specific and clear health warnings that would rotate quarterly on all packaging (9 for cigarettes and 4 for smokeless). Although not attributed to the Surgeon General they meet or exceed the recommendations of consumer marketing professionals for effective health warnings. The size, location and format of the warnings on cigarette packaging is optimum, but the location on snuff cans (on the side as opposed to on the lid) insures that it will not be as prominent. The proposal would be improved if the warnings were to appear on both the front and the back principal display panel simultaneously (black on white, and white on black) as is done in Canada.

Under current legislation, cigarette and smokeless tobacco health warnings can only be changed by act of Congress and federal and state agencies are precluded from requiring any different or additional warnings. The proposed settlement improves on this scheme by permitting FDA to change the warnings after it has provided for notice and *hearing* opportunity. This latter requirement exceeds the usual notice and *comment* rulemaking requirement under the Administrative Procedure Act and should be changed to the more expeditious APA procedure.

ACCESS PROVISIONS

1. Responsibilities of Manufacturers

FDA Rule

The FDA rule directs manufacturers to ensure that all cigarettes and smokeless tobacco products that it manufactures, labels, advertises, packages or sells comply with all applicable regulatory requirements. Manufacturers must also remove from each point of sale all self-service displays, advertising, labeling, and manufacturer-supplied or manufacturer-owned items which violate the rule, unless they are located in an establishment where no person under 18 may enter. Manufacturers must also visually inspect and ensure that products are labeled, advertised, and distributed in accordance with the rule. A manufacturer may not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except

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those in use before January 1, 1995. No manufacturer can sell any cigarette package containing fewer than 20 cigarettes, or distribute any free samples of tobacco products.

Proposed Settlement

In addition to most provisions mentioned in the FDA rule, the proposed settlement states that manufacturers would create plans, with an annual review and update, to "ensure compliance with all applicable laws and regulations" (p.21). Manufacturers would also be required to have compliance programs where their employees would report known or alleged violations by retailers or distributors to FDA (p. 23).

Advantages to the Proposed Settlement

As mentioned above, the proposed settlement requires manufacturers to create a compliance plan and take various actions to reduce the sale of tobacco to minors. The proposal includes fines for failure to fulfill these obligations.

Disadvantages to the Proposed Settlement

There is no express language declaring that manufacturers are responsible for complying with all applicable regulatory requirements and in particular for removing advertisements and other violative articles.

2. Responsibilities of Retailers

FDA Rule

The FDA rule directs retailers to ensure that all cigarettes and smokeless tobacco products that it sells comply with all applicable regulatory requirements. Retailers may not sell tobacco to anyone under 18. They must verify that persons buying tobacco are at least 18 through use of photo ID. Retailers may sell tobacco only through a direct, face-to-face exchange without the help of any electronic or mechanical device, unless the sale is through a vending machine or self-service display in a facility where no one under the age of 18 is allowed to enter. Mail order sales are currently permitted. However, in two years FDA will reconsider this provision if mail order becomes a mechanism by which minors purchase tobacco products. Retailers may not break open a cigarette or smokeless tobacco package. The minimum package size is 20 cigarettes. Retailers must also remove or bring into compliance any violative items, such as self-service displays and advertising, that are in the retail establishment, including both products that the retailer owns and those that it does not. Additionally, retailers may not distribute free samples of tobacco products.

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Proposed Settlement

Many retailer access provisions are identical to the FDA rule. However, in the proposed settlement, all vending machine and mail order sales would be prohibited. In facilities where persons under 18 may enter, all tobacco products must be placed out-of-reach of consumers, or, if on the counter, not visible or accessible to consumers (p. 12). The proposed settlement would also establish a retailer licensing system and impose penalties on licensed and unlicensed retailers (pp. 12-13, 44-45).

Compared to the FDA rule, the proposed settlement is silent on whether they can break open tobacco product packages and whether retailers are obligated to remove all violative items in the retail establishment regardless of ownership. As stated above, the FDA rule prohibits these practices.

Advantages to the Proposed Settlement:

The proposed settlement would create a retailer licensing system with penalties for noncompliance (pp. 12-13, 44-45). It also does not create an exemption for vending machines or for mail order sales, so the face-to-face transaction requirement would apply to all tobacco product sales (except for self-service displays in adult-only facilities). Furthermore, the requirement that on-the-counter tobacco products not be visible to the consumer goes beyond the existing FDA requirement.

Disadvantages to the Proposed Settlement:

The penalties under the retailer licensing system are comparatively weak compared to the sanctions available under the Federal Food, Drug, and Cosmetic Act.

Additionally, the retailer licensing system may be difficult to administer, particularly with respect to Indian lands where FDA may be obligated to administer a tribe's licensing system or to delegate responsibility to a State.

3. Responsibilities of Retailers

FDA Rule

The FDA rule directs distributors to ensure that all cigarettes and smokeless tobacco products that it distributes comply with all applicable regulatory requirements. No distributor may distribute any free samples of tobacco products.

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Proposed Settlement

The proposed settlement is silent on a distributor's responsibilities, and there is no express language stating that distributors are responsible for complying with all applicable regulatory requirements.

Advantages to the Proposed Settlement

There do not appear to be any advantages to the proposed settlement with respect to the responsibilities of distributors.

Disadvantages to the Proposed Settlement

As stated above, the proposed settlement is silent on a distributor's responsibilities, and there is no express language stating that distributors are responsible for complying with all applicable regulatory requirements. However, it was not contemplated in the FDA rule that distributors would have a large role in reducing access of tobacco products to minors.

EDUCATION PROGRAM

Existing Authority

The Food, Drug, and Cosmetic Act (section 518(a)) provides a mechanism for FDA to require manufacturers to notify users and potential users of an unreasonable risk posed by a product. In the preamble to the final rule, FDA indicated that this notification process might be an appropriate means to require tobacco manufacturers to fund multi-media campaigns to educate children and adolescents about the risks associated with tobacco products. The process for requiring companies to undertake this effort would consist of the Agency notifying companies of its intent to require such action, providing an opportunity for a hearing, and, if necessary, imposing a "notification order."

How the Proposed Settlement Expands the Agency's Authority to Require an Education Program

The proposed settlement provides for the establishment of a public education program which the industry would fund for \$500,000,000 annually for 8 years. The benefits of such a program are that it makes available a significant amount of money in a timely manner. Further, it does not appear to place restrictions on the type of educational messages that could be developed. Since the proposed settlement contains no specific provision authorizing FDA to require companies to fund an education program, it appears that the Agency would not be permitted to require such an effort for five years.

How the Proposed Settlement Limits the Agency's Authority to Undertake an Education Program

While \$500,000,000 annually is a significant amount of money, the proposal seems to discontinue all funding after eight years. It is unclear whether FDA could use its existing authority under 518 after the

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eight year period.

Further, the proposed settlement appears to greatly reduce the role of the Government in developing and overseeing a multi-media campaign. Specifically, the proposed settlement authorizes the Secretary of Health and Human Services to establish a public education program to "discourage and de-glamorize the use of tobacco products," and to make grants to state health departments to assist in carrying out these programs. However, it seems to provide primary authority to an independent non-profit organization, which would need to be formed, and it also authorizes the independent body to contract with state health departments. It is unclear whether the Secretary has the authority to select the members of the board. Further, it is unclear whether the proposal intends to have both the Secretary and the independent board contract with state health departments for the same purpose. Finally, since the Office on Smoking and Health within the Department of Health and Human Services has the experience and the expertise to oversee such a program and coordinate it with the state programs, it is uncertain why a new non-profit organization would need to be created.

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**FUTURE REGULATION OF TOBACCO OTHER THAN MODIFICATION
OF THE PRODUCT**

The FDA regulation establishes a goal of reducing tobacco use by children by 50% in 7 years. If this goal is not met, the Agency contemplated imposing additional measures. In addition, it may be appropriate for the Agency to attempt to reduce adult use of tobacco products in the future.

Existing Authority

In addition to the provisions contained in the final tobacco rule, FDA has the ability through informal rulemaking and other mechanisms specified in the statute to impose additional requirements on these products should the Agency find that they are necessary.

Among the measures that the Agency could require through informal rule making are raising the minimum age of sale, limiting the types of retailers that could sell tobacco, making tobacco products available only by prescription, requiring that specific warnings be added to the packaging or labeling of tobacco products, plain packaging further restricting tobacco advertising, or requiring tobacco advertisements and/or products to list ingredients. In addition, informal rule making could be employed quickly and efficiently to correct or clarify any provisions in the final tobacco rule.

Further, as the Agency indicated in the preamble to the final tobacco rule, FDA believes that it could use its authority under 518(a) of the statute to require tobacco companies to notify tobacco users and potential tobacco users of the unreasonable risks posed by their products. For example, the Agency could require companies to fund a multi-media education campaign intended to alert young people about the risks of tobacco use. Under the 518 process, the Agency would notify companies of its intent to require such action, provide an opportunity for a hearing, and, if necessary, impose a "notification order."

Finally, in the event that FDA found that other tobacco products such as cigars and little cigars meet the definition of a drug or a device under the Food, Drug, and Cosmetic Act, the Agency could assert jurisdiction over these products and subject them to the same regulations as cigarettes and smokeless tobacco.

How the Proposed Settlement Enhances FDA's Ability to Implement Future Regulations and Actions

The proposal eliminates any risk that the Agency would not prevail in court on its assertion of jurisdiction or authority to regulate promotion and advertising. The proposed settlement contains measures that go beyond the current FDA rule. They are listed on pages 9, 10, and 12 of the proposal.

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How the Proposed Settlement Impedes or Curtails Future Regulations and Actions

Under current authority, the measures discussed above could be initiated, in accordance with the procedures specified in the statute, if the Agency determined that such measures were necessary. By contrast, under the proposed settlement, any additional Agency action is frozen for five years except in "extraordinary circumstances." Moreover, since cigars or little cigars are not included in the proposed settlement, and FDA were to obtain sufficient evidence to assert jurisdiction over these products, it is unclear whether FDA would be able to assert jurisdiction and regulate cigars during the five-year freeze on regulations.

After five years, the extent to which the Agency could adopt additional measures is unclear. For example, could the Agency raise the minimum age to 19 or 20 (an authority that it clearly would have under the North Carolina district court's decision)? Could it require plain packaging on all tobacco products?

DRAFT**6/30/97****ADDITIONAL IDEAS TO INCLUDE IN THE TOBACCO AGREEMENT****I. General Provisions**

Access--No exemption for adult only facilities

Labeling and Advertising--No exemption for adult facilities or adult publications

II. New Provisions or Authority

Enforcement Authority:

Compulsory Process--Power to issue subpoenas requiring the production of evidence and the attendance and testimony of witnesses

Penalties--New civil money penalties procedure--a quicker version for a small retailer fine (fine, traffic ticket, licensure)

FDA regulations will not preempt more stringent state requirements

III. Other Agencies or Legislative Changes

Repeal state preemption provision of Cigarette Act (Smokeles Act is okay) and any other federal preemption of stricter state provisions

Consider all the tax implications of the settlement, including the possible removal of the tax-deductibility of advertising and promotional expenditures

Department of Agriculture--use tobacco support program to transfer farmers from tobacco to other crops

Department of Commerce--Export policy--develop trade policy that emphasizes the Administration's concern about the health consequences of tobacco use. This goes further than just making trade policy neutral to tobacco export. Proactively export health policy.

Import restrictions on imported tobacco--pesticides etc.

Department of Education--Fund in-school education and media literacy programs

Department of Health and Human Services

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Fund programs at NIDA, etc. to research teenage addiction.

Require reimbursement for smoking cessation treatments by insurance carriers.

Studies (funded) to determine who smokes, why, how much, which brands, and how to intervene.

Department of Labor--OSHA regulations to go into effect--for all workplaces including restaurants.

Department of Transportation--mandate all federally supported carriers to be smoke free. Require all airline terminals, railroad terminals and bus stations to be smoke free.

Independent Regulatory Agencies:

Consumer Product Safety Commission--delete tobacco's exemption from CPSC's jurisdiction.

Fire Safe Cigarettes--create within CPSC authority to implement recommendations on testing and requiring more smoulder resistant cigarettes.

General Services Administration--mandate smoke free workplaces for all Federal establishments.

United States Information Agency--disseminate public health information about tobacco use.

CAMPAIGN for TOBACCO-FREE Kids

TO: S. Buckingham, E. Chapnick, L. Crampton, B. Crain, D. Crane, S. Dickinson, J. Epstein, S. Hicks, A. Hyman, F. Karel, C. Kelley, R. Landry, D. Maier, D. Maple, J. Marx, T. Moreis, B. McHugh-Sanner, J. McKenna, J. O'Hara, M. Schoenfeld, D. Spitz, M. Tharp, B. Wooley, C. Yarborough, P. Yoxall

FROM: Kay Kahler Vose

DATE: June 13, 1997

SUBJECT: Negotiations with Tobacco Industry

Attached is a document produced by the Center that summarizes many of the points of agreement to date on public health issues in the ongoing negotiations between the tobacco industry and the attorneys general. The document contrasts the agreed-upon points with the provisions, or lack thereof, of the FDA Rule.

I hope you find this document helpful.

Please note that this document is not a final version. These are the agreed-upon provisions and they could change when an agreement is finalized. We will update you on any modifications.

Please call me with any questions.

CAMPAIGN for TOBACCO-FREE Kids

Summary of public-health provisions that have been tentatively agreed to as part of the ongoing settlement talks with the Attorneys General, the tobacco industry and public health advocates.

1. Youth Access

The full substance of the August 28, 1996 FDA youth access provisions have been agreed upon.

The FDA rule:

- Bans sales to kids under 18;
- Requires proof of age;
- Limits, but does not ban vending machines;
- Limits self-service displays, but permits tobacco to be displayed on the counter;
- Establishes the minimum pack size at 20 and prohibits the sale of single cigarettes;
- Bans free sampling; and
- Uses FDA's normal enforcement tools with enforcement funding subject to annual Congressional appropriations.

In addition the tobacco industry has agreed to:

- A ban on all vending machines;
- The placement of tobacco products behind the counter and out of reach of consumers;
- Further restrictions of mail order sales, subject to conditions that demonstrate that an effective mechanism exists to restrict sales only to adults;
- A nationwide licensing system for all sellers of tobacco products with graduated penalties and license suspensions for violations of the youth access and marketing provisions to be established. The licensing system shall apply to all sellers of nicotine - containing tobacco products, including manufacturers, distributors, wholesalers, retailers and importers;
- Full funding from money paid by the tobacco industry for enforcement by FDA and state and local authorities;
- States and local governments would not be preempted from enacting stronger laws;

- Dual enforcement authority with both the FDA and state attorneys general, each being able to enforce these provisions. In addition, the FDA will have the power to contract with other state and local authorities to assist it to enforce the rules; and
- Enforcement to require unannounced, random stings.

2. Marketing and Advertising

The industry has agreed to the full substance of the August 28, 1996 FDA youth advertising and marketing provisions (which were struck down in Federal District court but which have been appealed):

The FDA rule before the court ruling:

- Text-only ads in youth oriented magazines and newspapers;
- Ban brand name event sponsorship;
- Limit billboards near schools and limit billboards to text only with no color;
- Ban use of non-tobacco brand names on tobacco products;
- Ban advertising on non-tobacco products, like clothing and gear;
- Ban offers of non-tobacco items or gifts based on proof of purchase; and
- Require ads to carry FDA-mandated statement of intended use.

In addition to the FDA provisions above, the industry has also agreed to:

- The elimination of all billboards and outdoor signs, including all signs in stadia and arenas and signs that face outwards in enclosed areas, such as stores;
- The elimination of all human images and cartoon characters from all advertising and from all cigarette packages;
- Additional restrictions on point of purchase advertising regarding the placement on point of purchase ads to limit their size and number, remove them from the line of sight of children and remove them from close proximity to candy and other goods likely to attract children;
- The elimination of internet advertising and the agreement on the use of whatever technology is available to make tobacco advertisements that are placed on the internet from foreign countries inaccessible in the US;
- The prohibition on product placement in movies and on TV;
- The prohibition on any payments or fees to celebrities to smoke in movies or on TV or to any other person or entity to glamorize tobacco use in movies or on TV, and the prohibition of any "in-kind" actions to accomplish any of these same purposes;

- Without limiting the FDA's normal authority, limits on the use of words, such as "light", that currently appear in some product names and that could be misinterpreted as health claims;
- Protection against First Amendment challenge: an agreement to consent to the placement of all of the advertising restrictions contained in the August 28, 1996 FDA rule plus the above noted restrictions in consent decrees to insulate the restrictions from First Amendment challenges by parties outside the tobacco industry;
- Dual enforcement authority with both the FDA and state attorneys general, each being able to enforce these provisions. In addition, the FDA will have the power to contract with other state and local authorities to assist it to enforce the rules; and
- Funding from the tobacco industry to pay the cost of enforcement for both FDA and the state authorities with enforcement power.

3. Public Education/Counter Advertising

The tentative agreement with the tobacco industry includes:

- Funds for the largest, most-sustained nationwide public education/counter advertising program ever done for tobacco or for any other public health hazard. The campaign would be similar to those campaigns in Massachusetts and California. The program would operate independent of the tobacco industry, which would have no say over the content or placement of the program. Funding for the program would be guaranteed, and to the extent possible, the program would be insulated from political pressure.

4. Health Warnings

- There would be a dramatic revision of the warning label system. The current system would be replaced with the far more specific, more detailed eight Canadian warnings.

They include warnings, such as:

- ◆ "WARNING: Cigarettes are Addictive";
 - ◆ "WARNING: Cigarettes Cause Cancer";
 - ◆ "WARNING: Smoking Can Kill You"; and
 - ◆ "WARNING: Tobacco Smoke Causes Fatal Lung Disease In Non- Smokers"
- The warnings on packages would be moved to the front of the cigarette package and the most prominent side of the smokeless tobacco product package.
- The warnings would appear in the Canadian format (the top of the front with white lettering on a black background). The warning would occupy at least 25 percent of the top of the front of the package. All warnings would appear simultaneously on tobacco packages and would be rotated quarterly on ads by brand.

5. Full Disclosure

Under the possible agreement:

- Decades of deception would come to an end and the industry would tell the truth about what it knows.
- All documents which would have been revealed through the litigation process would be made public and the industry would agree to make public its health-related research in the future.

6. Youth Smoking Targets

- The industry would be subject to penalties if youth tobacco use fails to drop by 30 percent in 5 years, 50 percent in 7 years and 60 percent in ten years. The penalty would be based on the value of a teen tobacco user to the industry over the lifetime of the individual. It would be worth approximately \$80 million per percentage point by which the target was not met.

7. Funding for State and Local Tobacco Control Activity

Active state and local tobacco control efforts have been proven successful in reducing tobacco use. Current programs are under funded and funding for these programs is in jeopardy.

Under a possible agreement:

- State and local tobacco control activity modeled after the successful ASSIST program would be funded out of tobacco industry funds, permitting the ASSIST program to be funded in every state from these funds.

8. Tobacco Cessation

Under a possible agreement:

- Out of funds to be provided by the industry, funding would be provided for tobacco cessation programs and devices for those who want to quit and for whom cost is an issue. These funds would be available to individuals nationwide.

9. Protection from Environmental Tobacco Smoke

Under a possible agreement:

- Protection from environmental tobacco smoke would come from the enactment of the text of HR 3434 (the bill originally introduced by Congressman Waxman) that restricts tobacco use in public places and most workplaces to locations that are separately ventilated to the outside and through which non-smokers do not pass.

To avoid heavy opposition from the hospitality industry, restaurants (excluding fast food restaurants), casinos, bingo parlors, and bars would be exempted.

- The federal law would not preempt state and local governments from retaining or enacting more restrictive requirements governing ETS.

10. Monitoring Corporate Behavior

The tobacco industry has the most irresponsible corporate record of any industry in the United States. Currently, no mechanism exists to ensure that the industry complies with the letter or the spirit of existing law.

Under a possible agreement:

- Manufacturers would be required to develop detailed compliance plans describing how they intend to comply with the law and monitor their own employees behavior.
- Corporations would be required to set up incentive plans to encourage compliance and internal compliance checks to catch and report violations.
- Corporations would be required to establish a corporate code of behavior with outside monitors, a system of auditing, and reports to shareholders and the FDA.

11. General Authority of the FDA

FDA's authority over tobacco products as "drugs" and "devices" has been upheld by the trial court in North Carolina and is now on appeal. To date, the FDA has only sought to exercise its authority by establishing youth access and marketing rules, but it has far broader authority.

Under the tentative agreement:

- The judicial challenge by the tobacco industry would be dropped and FDA's authority explicitly recognized. Therefore, tobacco will continue to be categorized as a "drug" and a "device" under the Food, Drug and Cosmetic Act and the agency's authority to regulate the products as "restricted medical devices" will be recognized.
- FDA would exercise its normal authority to inspect, enter manufacturing plants, demand certain records and record keeping, and would have its normal enforcement authority.
- The tobacco industry would be required to provide FDA with all research it conducts and all non-public information it receives that relates to health, toxicity, addiction, drug dependence.
- In general, FDA's powers to regulate tobacco, including nicotine, would not be circumscribed. The details of this are still being negotiated.

12. Tobacco Industry Liability

The tobacco industry has lost only one court challenge in its history and only Liggett has actually paid any money in damages. Nonetheless, the tobacco industry faces unprecedented court challenges today. The issues about the tobacco industry's future liability are still being discussed, but several facts are already known if there is an agreement:

- The rights of individuals to sue will not be abridged.
- There will be no limits on individual judgments.
- Whether or not individuals have greater success in the future in court against the tobacco industry than they have had in the past, the tobacco industry will be required to pay billions of dollars to victims and public health causes for the harm done by their products.
- In return for the industry's commitment to pay several billion dollars a year, whether or not there are any judgments against it, it has been proposed to cap the overall damages the industry would pay through litigation in any one year. It is highly unlikely that this fund would be exhausted in any one year. However, if this were to occur, then payments to individuals winning cases against the industry would be extended over more than one year. This would not result in restricting the overall award an individual could receive, but it could lead to a delay in the total payment. Any money from the annual fund not won through litigation would then be transferred to national public health, anti-tobacco programs and would not revert to the tobacco industry.
- While industry requests for broader protection are no longer on the table, there do remain unresolved issues concerning whether tobacco cases could be brought as class actions and whether preemptive damage claims to be paid out of the fund would be permitted.

~~CONFIDENTIAL~~

TO: Kevin Thurm
Deputy Secretary

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: RLB DATE: 12/19/13

FROM: Bruce R. Lindsey
Assistant to the President
And Deputy Counsel

RE: Summary of Discussions on FDA-related Issues

DATE: June 4, 1997

As you know, much of the discussions with the tobacco industry have focused on FDA/public health related issues. While there is no final agreement, the following is a summary of those discussions to date. I would appreciate HHS/FDA's comments and suggestions on these issues.

1. Youth Access - The industry would agree to the full substance of the August 28 FDA youth access provisions. In addition, the industry would agree to the following:
 - A. A ban on all vending machines;
 - B. The placement of tobacco products behind the counter and out of reach of consumers;
 - C. The restriction of mail order sales, subject to conditions that demonstrate that an effective mechanism to restrict sales to adults. FDA would have the authority to review and revise the rules concerning mail order sales within two years, if it determines that these sales are resulting in significant sales to or access to minors;
 - D. While these provisions would be enacted into legislation, FDA would be given the administrative authority to augment and modify these rules after a set period of time, not to exceed 7 years, to further reduce tobacco use among minors;
 - E. States and local governments would have the authority to enact stronger laws.
 - F. A nationwide licensing system for all sellers of tobacco products with a system of graduated penalties and license suspensions for violations of the youth access and marketing provisions would be established. The licensing system would apply to all sellers of nicotine containing tobacco products, including manufacturers, distributors, wholesalers, retailers, importers;
 - G. FDA would have the primary authority over the enactment of regulations concerning these provisions and full enforcement authority over them. However, there would be dual enforcement authority with both the FDA and state attorneys general each, being able to enforce these provisions and, in addition, the FDA would have the power to contract with other state and local authorities to assist it

in enforcing the rules;

- H. Enforcement would include unannounced, random stings;
- I. The tobacco industry would pay the cost of enforcement for both FDA and the state authorities with enforcement power.

2. Marketing and Advertising - The industry would agree to the full substance of the August 28 FDA advertising and marketing provisions. In addition, the industry would agree to the following:

- A. The eliminations of all billboards and outdoor signs, including all signs in stadiums and arenas and signs in enclosed areas, such as stores that face outwards;
- B. The elimination of all human images and cartoon characters from all advertising and from all cigarette packages;
- C. Additional restrictions on point of purchase advertising regarding the placement of point of purchase ads to limit their size and number, remove them from the line of sight of children and remove them from the close proximity to candy and other goods likely to attract children. The exact details of these restrictions have yet to be resolved. There has also been discussion of restricting point of sale advertising in stores within 1000 feet of schools and playgrounds to price lists;
- D. The elimination of internet advertising and the agreement on the use of whatever technology is available to make tobacco advertisements that are placed on the internet from foreign countries inaccessible in the US;
- E. The prohibition on product placement in movies and on TV, the prohibition on any payments or fees to celebrities to smoke in movies or on TV or to any other person or entity to glamorize tobacco use in movies or on TV, and the prohibition of any "in-kind" actions to accomplish any of these same purposes;
- F. While these provisions will be enacted into legislation, FDA would be given the administrative authority to augment and modify these rules after a set period of time, not to exceed 7 years, to further reduce tobacco use among minors;
- G. An agreement to consent to the placement of all of the advertising restrictions contained in the August 28 FDA Rule plus the above noted restrictions in private binding agreements and/or in consent decrees to insulate the restrictions from the First Amendment challenges by parties outside the tobacco industry;
- H. FDA would have the primary authority over the enactment of regulations concerning these provisions and full enforcement authority over them. However, there would be dual enforcement authority with both the FDA and state attorneys general, each being able to enforce these provisions and, in addition, the FDA would have the power to contact with other state and local authorities to assist it to enforce the rules;
- I. The tobacco industry would pay the cost of enforcement for both FDA and the state authorities with enforcement power;
- J. The portion of these advertising and marketing restrictions that relate to purely local advertising would not preempt stronger state and local laws.

3. Public Education Counter Advertising - Funds would be provided for a major nationwide public education/counter advertising program similar to those found in Massachusetts and California. The program would operate independent of the tobacco industry which would have no say over the content or placement of the advertisements. Funding for the program would be guaranteed, and to the extent possible, the program would be insulated from political pressure. The program could be administered by FDA, the CDC, or an independent entity.
4. Health Warnings - While FDA does have authority to require tobacco companies to provide health information to consumers in a variety of ways, FDA does not have authority over the current warnings on the package. The industry would agree to a revision of the warning label system, replacing the current warnings with the more specific, more detailed Canadian warnings including a warning on addictions. The warnings would be moved to the front of the cigarette package (and the most prominent side of the smokeless tobacco product package). The warnings would appear in the Canadian format (the top of the front with white lettering on a black background) and occupy at least 25% of the top of the front of the package.
5. Performance Standards - The concept of performance standards are implied in the FDA Rule, but only with regard to the modification or the supplementation of the youth access and marketing restrictions. Discussion with the industry have also focused on performance standards tied to economic sanctions if youth smoking rate reduction targets are not met. The industry would be subject to penalties if youth tobacco use failed to drop by 30% in 5 years, 50% in 7 years and 60% in ten years. The penalty would be based on the value of a teenaged tobacco user to the industry over the lifetime of the teenager. It would be worth approximately \$80 million per percentage point by which the target was not met.
6. Funding for State and Local Tobacco Control Activity - State and local tobacco control activity modeled after the successful ASSIST program would be funded out of tobacco industry funds. While the exact amount had not been agreed to, we expect the ASSIST program would be funded in every state from these funds.
7. Tobacco Cessation - Out of the funds to be provided by the industry, funding would be provided for tobacco cessation programs and devices for those who want to quit and for whom the cost is an issue. The Secretary of HHS would be authorized to set standards and procedures for the approval of cessation programs and devices.
8. Protection from Environmental Tobacco Smoke - Protection from environmental tobacco smoke would come from the enactment of the text of HR 3434 (originally introduced by Congressman Waxman) that restricts tobacco use in public places and most workplaces to locations that are separately ventilated to the outside and through which non smokers do not pass. Restaurants (excluding fast food restaurants) and bars would be exempted but

state and local governments would be permitted to enact more restrictive requirements governing ETS. This would replace the need for OSHA to complete its rulemaking. Enforcement has not been discussed. It could be OSHA or FDA, but enforcement authority needs to be shared with State Attorneys General and local authorities.

9. General Authority of the FDA

- A. Tobacco products would have the same definition as contained in the FDA Rule. Jurisdiction would also cover Roll Your Own, Little Cigars, Fine Cut, etc.
- B. Tobacco would continue to be categorized as a "drug" and a "device" under the Food, Drug and Cosmetic Act. The agency's authority to regulate the products as "restricted medical devices" would be explicitly recognized and tobacco products would be classified as a subcategory of a Class II device pursuant to Sec 513 of the Act. The Food, Drug and Cosmetic Act would apply to these products as provided by the Act and the amendments to the Act contained herein.
- C. The Class II Classification would permit the FDA to require product modification of tobacco products, including the regulation of nicotine content, and would provide that the sale of tobacco products to adults in the form that conforms to Performance Standards established for tobacco products pursuant to Sec 514 shall be permitted notwithstanding Secs. 516, 502j and 518e. Until the establishment of the Performance Standards under Sec 514, the FDA would not prohibit the sale and manufacture of traditional tobacco products now on the market to adults solely because they are inherently dangerous or because they have not previously been approved as new drugs.
- D. FDA would exercise its normal authority to inspect, enter manufacturing plants, demand certain records and record keeping, and would have its normal enforcement authority. Industry information would be given the same proprietary protection as information from other industries.
- E. The tobacco industry would be required to provide FDA with all research it conducts and all non-public information it receives that relates to health, toxicity, addiction, drug dependence, etcetera, and the FDA would have the power to subpoena such information.
- F. FDA would have the authority to require a new system for testing and disclosure of nicotine, tar, and other product and smoke constituents that FDA determines the public should know to protect the public health. This authority would be transferred from the FTC and would include the authority to require additional package and advertising disclosures established after an APA rule making. The FDA would have the authority to require tar and nicotine disclosures on both the

package and ads. The FDA's other disclosure authorities would not be circumscribed.

G. With regard to non tobacco ingredients:

- No such ingredient would be permitted unless the industry demonstrates that it is not hazardous under the proposed conditions of use as it would be used in the tobacco product. The burden would be on the industry to provide FDA with such data pursuant to a rule promulgated by the agency. As the agency does for other products, it would set up a standard of the type of testing of each ingredient based upon the "best available evidence" and information provided. Once the industry provides such information and data, the FDA would be required to review it and make a determination in a time certain as to whether it meets the agency's safety standards. The safety standard would apply to new ingredients immediately, but there would be a five year grace period for ingredients already in tobacco products on the date of enactment. However, nothing would be done to undermine the Massachusetts disclosure law and its requirements in the interim period.
- The industry would be required to provide FDA with a list of ingredients (including those in paper and filter as well as other product components) by brand and by quantity in each brand, subject to the same confidentiality protections given to other industries for similar information.
- FDA would be permitted to require the public disclosure of ingredients information as it does for foods in a manner that does not disclose trade secrets, (i.e., a flavoring that had been tested and approved as safe for use in a burning tobacco product could be identified in the same manner as flavorings are disclosed in foods.) This is the same standard for public disclosure provided in the Massachusetts disclosure law. During the five year grace period, the industry would not be required to publicly disclose confidential, proprietary information concerning these flavorings and spices.

H. FDA would have its typical authority over the manufacturing of the product, including the establishment of Good Manufacturing Practice Standards, product quality criteria, pesticide residue standards, etc. Tobacco farmers would face no greater regulatory burden than the producers of other raw products regulated by the federal government.

I. Products sold that an objective, reasonable consumer would believe pose less of a health risk:

- tobacco product manufacturers would be barred from making claims that could reasonably be interpreted to state or imply a reduced health risk unless the

manufacturer had demonstrated to FDA that the product scientifically did in fact “significantly reduce the risk to health” from ordinary tobacco products¹ and in that case,

- FDA would have to approve all claims (direct or implied), as well as the content and placement of any such advertisements, to prevent the public from being misled and to prevent the contraction of, the marketplace.
 - For less hazardous products, FDA would be authorized to permit scientifically based specific health claims and to permit exceptions to the advertising restrictions that apply to other products if FDA determines that such advertising would reduce harm and promote the public health. The FDA would promulgate a rule to govern how these determinations would be made.
 - The industry would be required to notify FDA of any technology that reduces the risk from tobacco products and, for a commercially reasonable fee, to cross license all such technology, but only to those companies also covered by the same obligations. Procedural protections would be built in to resolve license fee disputes, if the private parties can’t agree among themselves first. If the technology reported to the FDA is in the early development stages, the manufacturer would be provided confidentiality protection during the development process.
- J. To further the public health, to promote the production of “reduced risk” tobacco products, and to minimize the harm to the public by insuring that the best available, feasible safety technology becomes the industry standard, the FDA would have the authority to promulgate Performance Standards to govern product modification pursuant to Sec 514 of the Act:
- For a period of no less than ten years following the effective date of the Act, the Product Performance Standard would be governed by the following principles: The agency would be permitted to adopt performance standards that require the modification of existing tobacco products, including the gradual reduction, but not the elimination of other constituents or other harmful components of the product, based upon the demonstration that the modification: a) would result in a significant reduction of the health risks associated with such products to the consumer, b) is technologically feasible, and c) given the number of dependent tobacco product users and the lack of alternatives that are

¹ An exemption will be grandfathered in for products who, for example, currently have the word “light” or other similar words in their established product name. These brands will be able to continue to use that name, however, provided that all advertisements for the product state that the name does not imply that the product is safer than other tobacco products on the market.

currently acceptable to the mass market of tobacco users, the products as modified meets with sufficient consumer acceptance so that it would not result in the creation of a significant market in contraband products that do not meet the safety standard. In determining the risk of the creation of a market in contraband products, the FDA could take into account the availability of alternative products then on the market.

The authority to require such product modification could be exercised upon a showing of "substantial evidence", based upon the administrative record developed through a formal rule making subject to the Administrative Procedures 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.

- Separate from the requirements of the Sec 514 Performance Standard noted above, the agency would also have the authority to promulgate ceilings on tar and nicotine yields in tobacco products that gradually reduce but do not eliminate the presence of these constituents over the 10 year time period pursuant to agreed upon levels, unless the agency finds that the reduction would not reduce mortality and morbidity.
- The agency would also have the authority to mandate the introduction of "less hazardous tobacco products" that are technologically feasible, after a formal rule making subject to the Administrative Procedures Act with the right of judicial review. The goal of any rule mandating the introduction into the marketplace of "less hazardous tobacco products" for which the technology exists is to guarantee that a mechanism exists to insure that products which appear to hold out the hope of reducing risk are actually tested and made available in the marketplace and not held back.
- After the initial ten year period, the agency would be permitted to set product safety standards that go beyond the standards it is authorized to set pursuant to the above noted principles and procedures and, if it does so, it shall be guided by the following expanded principles: The agency would be permitted to require the alteration of tobacco products then being marketed, including the elimination of nicotine and any other demonstrated harmful component of the product, provided: a) the safety standard would result in a significant overall reduction of the health risks to the nation associated with tobacco products, b) the modification is technologically feasible, and c) given the number of dependent tobacco users then in existence and the availability and demonstrated market acceptance of alternated products then on the market, the modification would not result in the creation of a significant market in contraband products that do not meet the safety standard. In determining the overall health benefit of a change, the agency may

take into consideration factors, such as the effectiveness of smoking cessation techniques and devices then on the market.

Given the significance of such an action, the agency would be permitted to require the elimination of nicotine or take such other action that would have an effect comparable to the elimination of nicotine based upon "substantial evidence" pursuant to a Part 12 hearing, or notice and comment rule making with a right to judicial review. Any such action shall be phased in, and no such phase shall begin in less than two years, to permit time for a meaningful Congressional review pursuant to the current procedures of the Regulatory Reform Act of 1996.

- K. Enforcement - FDA would have its normal enforcement authority. Such authority would be supplemented by concurrent, parallel enforcement by state attorneys general and enforcement authorities related to the licensing system noted above. In addition, competitors within the industry would be able to bring actions against others in the industry who they believe had violated their obligations under the Act or other relevant laws.

cc: Elena Kagan

	F D C A	S E T T L E M E N T	
Regulatory Mechanism	1. adulteration or misbranding provisions 2. restricted device provisions 3. performance standards 4. device classification 5. other (?)	Nicotine Reduction products classified as class II devices; FDA sets performance standards	Nic. Elimination or Equivalent Action Products classified as class II devices; FDA sets performance standards
Required Agency Findings	Sets general controls to provide adequate assurance of safety and effectiveness (class II devices)	FDA must show <u>reduction</u> : 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 <u>elimination</u> : 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)
Time Frame	No constraints	for at least 12 years	1. FDA can require nicotine <u>elimination</u> 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)



U.S. Department of Justice

DRAFT

Washington, D.C. 20530

June 30, 1997

Memorandum

To: Stephen Preston, George Phillips

Fr: Michael Raab

Re: Preemption Issues Raised By Proposed Tobacco Settlement

This memorandum considers preemption issues presented by the Proposed Resolution dated June 20, 1997, which provides for the settlement of numerous lawsuits relating to tobacco products. Part I of the memorandum briefly summarizes current law governing the preemption of state and local requirements regarding medical devices. Part II provides a preliminary analysis of relevant provisions of the Proposed Resolution.

I. Current Law.

Section 521(a) of the Federal Food, Drug and Cosmetic Act of 1938, as amended ("Act"), preempts any state-law "requirement" with respect to a medical device that is "different from, or in addition to," federal requirements imposed under the Act. 21 U.S.C. 360k(a). The Supreme Court has held that Section 521(a) does not preempt state common-law claims that are premised on the failure of a medical device to satisfy federal requirements. *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2255 (1996); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). However, state-law requirements that are more stringent than specific counterpart requirements imposed under federal law are subject to preemption under Section 521(a). See *id.* at 2257-2258; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment); 21 C.F.R. 808.1(d).

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Section 521(b) of the Act permits States and their political subdivisions to apply to the FDA for an exemption from Section 521(a). 21 U.S.C. 360k(b). The FDA can exempt a state-law requirement if (1) the requirement "is more stringent than" its federal counterpart or (2) the requirement "is required by compelling and local conditions" and "compliance with the

requirement would not cause the device to be in violation of" any federal requirement applicable under the Act. 21 U.S.C. 360k(b).

The existence of an express preemption provision such as Section 521 does not foreclose the possibility of implied "conflict" preemption. See *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1487-1488 (1995). Such preemption can occur when compliance with both the state and federal requirements is impossible, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963), or where the state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

II. Proposed Resolution.

The Proposed Resolution (p. 13) would subject tobacco products to regulation under the Act as Class II medical devices. Absent a specific legislative exemption, state and local requirements with respect to such devices therefore would be subject to preemption under the terms of Section 521. As explained below, the Proposed Resolution appears to envision that Section 521 would apply to requirements governing the design and manufacture of tobacco products, but not with respect to other requirements applicable to such products.

a. In apparent reference to Section 521, the Proposed Resolution provides (p. 33) that "the provisions of [the Act] designed to provide uniformity in product manufacturing and design requirements relating to medical devices will apply to tobacco products * * *." Thus, the Proposed Resolution appears to anticipate that state and local requirements relating to the manufacture and design of tobacco products would be subject to preemption under Section 521(a).

The Proposed Resolution (p. 33) would permit the FDA to grant exemptions from preemption (presumably under Section 521(b) of the Act) for state and local requirements "relating to performance standards or good manufacturing practices." But the Proposed Resolution would alter the scope of the agency's authority under Section 521(b) in two respects. First, the Proposed Resolution provides (p. 33) that States and localities could "adopt additional or different requirements relating to performance standards or good manufacturing practices * * * only * * * if the requirement[s] would not unduly burden interstate commerce." Under current law, an exemption may not be granted if "the [FDA] Commissioner determines that the granting of an exemption would not be in the best interest of public health, taking into account the potential burden on interstate commerce." 21 C.F.R. 808.25(g)(3). By requiring only that the Commissioner "tak[e] into account" the possible burden on interstate commerce in deciding whether an exemption is warranted, rather than expressly prohibiting

exemptions where a state-law requirement "unduly burden[s]" interstate commerce (p. 33), the current regulation appears to vest the FDA with broader discretion than the statute contemplated by the Proposed Resolution.¹

Second, the Proposed Resolution (p. 33) would prohibit States and localities from applying for exemptions for requirements relating to the "non-tobacco ingredients" included in tobacco products until five years after the effective date of implementing legislation. That limitation appears to be related to the requirement (p. 19) that manufacturers submit a safety assessment for each non-tobacco ingredient in their tobacco products within five years after enactment of implementing legislation.

b. As explained above, the Proposed Resolution (p. 33) provides for the preemption of state and local requirements relating to the design and manufacture of tobacco products under terms that are generally consistent with Section 521. However, outside the design and manufacture context, the Proposed Resolution envisions a significantly broader role for States and localities. The Proposed Resolution is intended to "[e]nsure that * * * the States [will] have the regulatory flexibility to address issues of particular concern to public health officials, such as youth tobacco usage and tobacco dependence" (p. 2),² and (p. 3) that state and local governments will have authority to regulate exposure to tobacco smoke in public places.³ But the Proposed

¹ Moreover, the FDA can alter its regulation; the agency obviously could not amend the proposed statutory restriction.

² See also Proposed Resolution, p. 11 ("*Without preventing state and local governments from imposing stricter measures, the [contemplated federal] legislation would incorporate every access restriction of the FDA Rule, and more.*" (emphasis added)); *id.* at 12 ("*The [contemplated federal] legislation would mandate minimum federal standards for a retail licensing program that the federal government and state and local authorities would enforce through funding provided by the Industry payments.*"); *id.* at 32 ("*While setting a federal 'floor' for tobacco control measures in many substantive areas, this legislation preserves, to the maximum extent, state and local government authority to take additional tobacco control measures that further restrict or eliminate the product's use by and accessibility to minors.*"); *ibid.* ("*The legal authority of a state or local government to further regulate, restrict or eliminate the sale or distribution of tobacco products, and to impose state or local taxes on such products, also remains unchanged.*").

³ Proposed Resolution, p. 3 (proposing to "[e]stablish a minimum federal standard with tough restrictions on smoking in (continued...)")

Resolution does not propose any specific legislative exemption from Section 521 for state and local requirements relating to such matters. And Section 521(a) by its terms applies to "any requirement" applicable to a medical device, 21 U.S.C. 360k(a); it is not limited to requirements relating to a device's design and manufacture. Thus, unless Congress enacts such an express limitation for tobacco products, it is by no means clear that States could enforce the type of requirements envisioned under the Proposed Resolution, absent an exemption from the FDA under Section 521(b).⁴

c. The Proposed Resolution (p. 33) calls for continued "national uniformity of warning labels, packaging and labeling requirements, and advertising and promotion requirements related to tobacco and health," as required under current law.⁵ The Proposed

³(...continued)
public places with enforcement funding from the Industry Payments, while preserving the authority of state and local governments to enact even more severe standards." (emphasis added)); *id.* at 32 ("This legislation also permits state and local governments to enact measures that further restrict or eliminate employee and general public exposure to smoking in workplaces and in other public and private places and facilities.").

⁴ However, the FDA interprets Section 521(a) to apply only where there is a specific counterpart federal requirement applicable to the device. See 21 C.F.R. 808.1(d); see also *Medtronic, Inc.*, 116 S. Ct. at 2257-2258; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment). Under that interpretation, in order to determine whether a particular state or local requirement is preempted, it would be necessary to determine whether relevant federal directives imposed under the proposed legislation satisfy that threshold requirement.

⁵ We are aware of two federal statutes that preempt state and local regulation of warning labels on tobacco products. The Federal Cigarette Labeling and Advertising Act, as amended, specifies the content and format of the warning labels that must be placed on packages of cigarettes, 15 U.S.C. 1333, and provides that "[n]o statement relating to smoking and health, other than the statement required by [15 U.S.C. 1333], shall be required on any cigarette package." 15 U.S.C. 1334(a). The Act further provides that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." 15 U.S.C. 1334(b). The Comprehensive Smokeless Tobacco Health and Education Act of 1986 specifies the content and format of warning labels that must be placed on packages of smokeless tobacco, 15 U.S.C. 4402, (continued...)

Resolution (p. 33) would also provide the FDA with "express authority to require changes in the language of the warnings" required under federal law, as long as the agency provided public notice and an opportunity for hearing prior to adopting those changes. Accordingly, state and local requirements with respect to those matters would continue to be preempted.

d. The Proposed Resolution (p. 44) provides that the sale of tobacco products to consumers by an unlicensed seller "shall be a criminal violation, and be subject to minimum penalty of \$1,000, or imprisonment, for 6 months, or both, if an individual, or in the case of a corporation, by a maximum penalty of \$50,000." The Proposed Resolution (p. 44) further authorizes States to adopt more stringent penalties. Section 521(a) should not prevent States from enforcing such penalties. That provision addresses the preemption of state and local "requirements," 21 U.S.C. 360k(a); it does not purport to preempt state and local remedies or penalties that encourage compliance with federal requirements. Cf. *Medtronic, Inc.*, 116 S. Ct. at 2255 ("The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law"); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part) ("Section [521] does not preclude States from imposing different or additional remedies, but only different or additional requirements.").

The Proposed Resolution also would subject a tobacco product licensee to civil sanctions for any violation of the provisions of state licensing laws regarding sales to minors. State sanctions could not exceed the penalty schedule set out in the Proposed Resolution. (p. 44.) Assuming that Section 521(a) would not preempt the substantive requirements imposed by the state licensing laws, that provision should not bar the imposition of the specified civil penalties to enforce those requirements. However, the FDA has informed us that the proposed schedule prescribes more lenient penalties than those currently imposed by many States. That schedule (if enacted) would preempt more stringent provisions of state law.

⁵(...continued)

and provides that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by [15 U.S.C. 4402], shall be required by any State or local statute or regulation to be included on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product." 15 U.S.C. 4406(b). However, the Act further provides that "[n]othing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person." 15 U.S.C. 4406(c).

e. The Proposed Resolution provides (p. 26) that "[s]tate enforcement actions — whether brought under the [federal legislation contemplated by the Proposed Resolution] or a State's consumer protection law could not impose obligations or requirements beyond those imposed by the [contemplated federal] legislation (except where the legislation does not specifically preempt additional state-law obligations) * * *." It is not entirely clear how that rather convoluted statement can be reconciled with Section 521, which generally preempts more onerous state-law requirements, but authorizes the FDA to grant exemptions from preemption. It appears that the statement is intended to preempt state requirements that are more stringent than those imposed by the contemplated federal legislation, except where the legislation does not specifically provide for such preemption. To accomplish that objective, an express legislative provision precisely limiting the scope of Section 521 would appear to be necessary.

The Proposed Resolution further provides (p. 26) that state enforcement actions "would be limited to the civil and criminal penalties established by the legislation and by the prohibition on duplicative penalties." The limitation to "penalties established by the [contemplated federal] legislation" appears to be in some tension with the Proposed Resolution's treatment of retailer penalties (p. 44), which, as discussed above, prescribes the maximum civil penalties that States can impose, but permits States to adopt criminal penalties that are more stringent than those imposed under federal law.⁶

⁶ The reference to "the prohibition on duplicative penalties" (p. 26) is unclear. The Double Jeopardy Clause bars the imposition of both civil and criminal penalties in some circumstances. See *United States v. Halper*, 490 U.S. 435 (1989). It is uncertain whether the reference to "the prohibition on duplicative penalties" is intended to encompass any greater restrictions.

June 30, 1997

To: Elena Kagan

From: Bill Schultz

Attached are four papers in anticipation of the two meetings later today: (1) a discussion of FDA regulation of the product (8 pages); (2) an analysis of the advertising, label, access and education provisions of the proposed agreement (11 pages); (3) a short paper on how the proposed agreement could affect FDA's residual authority to regulate advertising, etc. (2 pages); and (4) a list of additional ideas to include in the proposed agreement (2 pages).

If you have any problems receiving this fax, please call Sara Kay Addis at (202) 205-4102. Thank you.

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FDA REGULATION OF THE PRODUCT

NICOTINE

Existing Authority

Under current law, pursuant to the Agency's jurisdictional determination last August, FDA has broad regulatory authority over nicotine-containing cigarettes and smokeless tobacco products. This authority includes the power to control product components, such as nicotine, and to require modifications to the product.

The Agency has no current plans to lower nicotine levels in cigarettes and smokeless tobacco products. Nevertheless, in the future FDA might determine that nicotine levels should be reduced. There are a variety of regulatory mechanisms that could be used under current law to accomplish that goal. These mechanisms include regulations promulgated under the adulteration and misbranding provisions, restricted device provisions, performance standards, and device classification. These actions, with the exception of performance standards, would be judged under the arbitrary and capricious standard of judicial review. This level of judicial scrutiny gives great deference to the Agency, including any review of how FDA framed the policy questions under consideration.

Furthermore, the existing mechanisms would all be employed using informal, notice and comment rule making procedures similar to those used by FDA to promulgate the final tobacco regulation.

How the Proposed Settlement Expands FDA's Authority to Reduce or Eliminate Nicotine

There are no provisions in the proposed settlement that expand FDA's authority to either reduce or eliminate nicotine.

★ How the Proposed Settlement Limits FDA's Authority to Reduce or Eliminate Nicotine

The proposed settlement limits FDA's authority over nicotine by creating new substantive and procedural obstacles that the Agency would have to address in order to either reduce or eliminate nicotine. The proposed settlement presumably eliminates all regulatory mechanisms other than performance standards to reduce or eliminate nicotine. Some of these other mechanisms, such as the adulteration, misbranding, and restricted device provisions, could be employed more quickly and simply than the process created in the proposed settlement.

In addition, the proposal creates three criteria FDA would have to satisfy to either reduce or eliminate nicotine. These three criteria do not exist in current law. Under the proposed settlement, FDA must find that the modified product

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(a) will result in a significant reduction of the health risks associated with such products, *[Nicotine vs. tar ?]*

(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.

* Reducing Nicotine

It would be quite difficult to prove, prior to any regulation reducing nicotine goes into effect, that a significant demand for contraband would not be created. While the other criteria -- significant reduction in health risks and technological feasibility -- may not be as difficult to establish, tobacco companies would be able to mount court challenges to contest all three of the Agency's findings.

The degree of deference the Agency would receive by a reviewing court would be altered by virtue of the criteria's existence. The criteria frame and possibly limit the issues FDA could consider. This reduces the Agency's role to simply gathering the evidence needed to satisfy pre-determined criteria. By contrast, the broader authority FDA currently has over nicotine would give the Agency considerably more flexibility in defining the policy issues and criteria within its jurisdiction.

There are also procedural obstacles created by the proposed settlement. First, nicotine reduction could only be pursued by FDA under formal rulemaking procedures. Formal rulemaking is cumbersome and time-consuming, and could delay Agency action for years compared to informal, notice and comment rulemaking. Formal rulemaking typically includes a hearing before an administrative law judge, cross examination of witnesses, factual determinations by the judge, and then a review of the judge's decision by the Commissioner.

Second, the proposed settlement creates a new process whereby the industry could petition FDA to contest the Agency's finding that nicotine reduction would not result in a significant demand for contraband. This petition process is vague and could slow the Agency down considerably because a party would be entitled to judicial review if its petition were denied. The petition provision also seems to be an unnecessary step once FDA has conducted a rulemaking where all interested parties already would have had a chance to submit comments and participate in the Agency's decision-making process.

* Eliminating Nicotine

Additional substantive and procedural obstacles are included in the proposed settlement that would alter FDA's ability to eliminate nicotine. For instance, the Agency is required to consider

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the "demonstrated market acceptance of alternate products then on the market." What exactly does "demonstrated market acceptance" mean if a cigarette with just one percent of the market is considered commercially viable? In addition, this part of the proposed settlement applies not only to the elimination of nicotine, but also to "such other action that would have an effect comparable to the elimination of nicotine." Could that phrase be construed to include an FDA action that lowers nicotine to a non-addictive level but does not technically eliminate it altogether?

The proposed settlement also requires the Agency to conduct a "Part 12" hearing before it eliminates nicotine. This type of hearing can include sworn witnesses and cross examination and can be a very lengthy proceeding. No such hearing would be required under FDA's current authority were the Agency to act on nicotine. The Agency has the burden of proof (p.7) whereas in most comparable Agency proceedings the industry has the burden of proof.

The congressional review provision following a decision by FDA to eliminate nicotine would constitute a broadening of that review power if it means that Congress has two years to produce a joint resolution of disapproval under the Regulatory Reform Act of 1996, as opposed to the typical length of time of 60 legislative days.

The judicial review standard is "substantial evidence" (p.18), rather than the arbitrary and capricious standard that applies to the review of regulations. Moreover, the degree of deference to be paid to the Agency "shall depend upon the extent...the matter...is then within the Agency's field of expertise." It is unclear what this provision really means, but it is likely to lower the deference paid to FDA by a reviewing court (p.18).

INGREDIENTS OTHER THAN NICOTINE

Current Authority

Under the Agency's current authority, it would have the ability to ensure that both the tobacco and non-tobacco ingredients are safe, regardless of whether tobacco products are placed in Class I, II, or III. As Class I devices, FDA would have the authority to insist, as a matter of good manufacturing practice, that only safe ingredients be used in the device. Similarly, if these products are placed in Class II, the performance standard that FDA adopts would require the use of safe ingredients. Finally, if tobacco products were placed in Class III, the use of unsafe ingredients would provide the basis for denial of premarket approval.

How the Proposed Settlement Expands FDA's Authority

The proposal shifts the focus from the product to an evaluation of each ingredient. The establishment of a list of ingredients that are not harmful when used in tobacco products would presumably facilitate FDA's review under whatever regime is applicable and would facilitate the

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use of safe ingredients by the industry. In addition, the listing criterion (reasonable certainty that the ingredient is not harmful) is arguably better suited to tobacco products than the definition of safety that FDA uses for devices. Devices usually involve a balancing of risks and benefits. For tobacco products, for which there presumably are no benefits, the standard, like the safety standard for food additives, focuses only on risk.

How the Proposed Settlement Limits FDA's Authority

A fundamental problem under the proposal is the scope of coverage. Ingredient safety requirements would apply only to non-tobacco ingredients. This would represent a significant contraction of FDA's authority.

Under the proposed settlement, FDA could not require a showing of safety for five years. Manufacturers are given five years from enactment of any legislation to submit a safety assessment, based on the best available evidence, that there is a reasonable certainty in the minds of competent scientists that the ingredient is not harmful under the intended conditions of use.

It is important to recognize also the limitations inherent in this formulation. The firm would only have to rely on the available evidence. There may well not be available the type of testing necessary to determine whether the ingredient is safe, and FDA could not insist on such testing. On the other hand, the language of the standard tracks the language of the definition of "safe" in FDA's food additive regulations (21 CFR 170.3(i)). The difference is that FDA can compel testing under the food additive provisions; it apparently would not be able to do so under the proposal.

The final major problem with the proposed settlement is another problem with timing. Manufacturers would have 5 years to make their submission, but once they do, FDA only has 90 days to approve or disapprove. Significantly, if FDA takes no action within 90 days, the ingredient is deemed to be approved. If all firms were to wait 5 years and then make their submissions, FDA would be overwhelmed, and it is likely that virtually every ingredient would be deemed approved.

INGREDIENT DISCLOSURE

Current Authority

Under section 502(r) of the Food, Drug, and Cosmetic Act, which is applicable to restricted devices like cigarettes and smokeless tobacco, if FDA finds that it is necessary to protect the public health, it can require by regulation the full disclosure of the formula of these products, showing quantitatively each ingredient of the device. The finding that disclosure is necessary is to be based on notice and comment rulemaking, and the regulations implementing that determination are to be issued after an opportunity for a hearing. FDA has yet to exercise this authority with respect to tobacco products.

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The proposal would require tobacco manufacturers to submit a complete list of non-tobacco ingredients to FDA. It also provides for ingredient declaration to the public based on regulations that would be modeled generally after what current federal law requires for foods. However, the manufacturer would be able to claim that at least some of the tobacco product's ingredients are exempt from disclosure, and the burden would be on FDA to challenge that claim with respect to specific ingredients.

How Proposed Settlement Expands FDA Authority

The immediate imposition, without the need to follow the procedural requirements in section 502(r), of a system in which there is disclosure of the non-tobacco ingredients, and the amounts of those ingredients, in each specific tobacco product to FDA and the immediate creation of a system in which there is some type of ingredient labeling on tobacco product labels.

How Proposed Settlement Limits FDA Authority

FDA would be deprived of the ability, assuming that it could make the requisite findings, of structuring an ingredient labeling system that it considered necessary to protect the public health. The legislation envisioned by the statute would impose the following limitations:

1. There would not be complete ingredient labeling.
 - a. Tobacco, water, and reconstituted tobacco sheet made wholly from tobacco would not need to be included in the ingredient list.
 - b. Flavors and colors (other than certified colors) would only have to be declared by those terms ("flavorings" and "color added").
 - c. To the extent that complete ingredient labeling is impractical or results in deception or unfair competition, the Secretary of HHS can establish exemptions by regulation (e.g. "and/or" labeling for fats and oils).
 - d. The ingredient list would have to include the name of each ingredient and, for ingredients that are themselves made up of more than one ingredient, the ingredients of ingredients. However, there would not need to be disclosure of naturally occurring components of ingredients that may have an effect on the public health (e.g., nicotine in tobacco) or ingredients used earlier in the process than the level that FDA has covered (e.g., ammonia added to an

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ingredient of an ingredient).

- e. The proposal would also permit firms to assert that ingredients are exempt from public disclosure under regulations that FDA is to promulgate within 12 months (an incredibly fast time frame) of the enactment of any legislation. It is not clear what standards FDA would use, other than those already listed from the food provisions, in drafting these regulations.
2. There would not be any quantitative information provided. In fact, food ingredients are listed in order of predominance by weight. FDA established this requirement under the Fair Packaging and Labeling Act which, by its terms, does not apply to tobacco products. Thus, there is a question as to whether FDA could require that ingredients be listed in any particular order.

The proposed settlement agreement raises a number of other questions that could have a significant bearing on what has been gained and lost:

1. The list of ingredients submitted to FDA is supposed to include all "ingredients, substances, and compounds." What did the authors think that "substances" and "compounds" added to "ingredients?"
2. The list is supposed to include those things added to the tobacco, paper, or filter. Is there a distinction between the ingredients used to make the filter and the ingredients added to it? This may seem like an odd distinction, but there is FDA case law that suggests it (see, e.g., U.S. v. 29 Cartons of ... An Article of Food, 987 F.2d 33 (1st Cir. 1993)).
3. The proposal would not require disclosure that the tobacco used in a product has been genetically engineered to contain a large amount of nicotine. FDA has never said that genetic engineering needs to be reflected in the common or usual name of a food. (The Cal-gene tomato is still a tomato.) Complaining about the lack of notice of the difference between regular tobacco and genetically engineered tobacco may create problems for FDA's food labeling policy.

OTHER ASPECTS OF TOBACCO PRODUCTS

FDA regulation expressly applies to and defines cigarettes, smokeless tobacco, and loose cigarette tobacco.

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How the Proposed Settlement Expands FDA's Authority to Regulate Tobacco Products

The proposal does not expand FDA's Authority. The proposal goes beyond FDA's rule by covering little cigars.

How the Proposed Settlement Limits FDA's Authority to Regulate Tobacco Products

1. CLASSIFICATION OF EXISTING AND REDUCED RISK TOBACCO PRODUCTS

a. Existing Authority

Under current law, the Agency has the flexibility to regulate products, including new reduced risk tobacco products, in the manner it determines is most appropriate given each product's characteristics, including its safety profile and possible health benefits. For example, the Agency could determine that some new reduced-risk products should be regulated only under the provisions of the Agency's tobacco regulation and determine that others present scientific, health, or safety issues significant enough to require premarket approval.

b. Authority Under the Proposed Settlement

The proposal places these products in a new subcategory of Class II, removing the authority of the Agency to require premarket approval for these products. This means that FDA could not require premarket approval for reduced-risk tobacco products, or Eclipse-like, or other unconventional tobacco/nicotine products. The proposal also creates a vague and unscientific definition of reduced risk products, which would prove extremely difficult for the Agency to apply.

The proposal provides for health claims on tobacco products. However, it would be somewhat counterintuitive to put health claims on tobacco products given their inherent risks. FDA has resisted the notion of health claims on wine for much the same reason.

The proposed settlement would also permit exceptions from the advertising restrictions for reduced risk products. Does this mean that the firms will be able to advertise reduced risk products to minors?

In addition, by requiring the Agency to establish a performance standard for these Class II products, the proposed settlement appears to remove the Agency's authority to determine whether additional special controls (such as postmarket surveillance) may be applied, or whether the Agency is limited to establishing a performance standard. The proposal also establishes new procedural hurdles for the Agency when establishing a standard and requires that the standard be established pursuant to formal rule making, rather than notice and comment rule making as currently required. The black market finding has all of the problems discussed in the previous

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section. The proposed settlement terms delay effective date of standard, grant right to petition black market findings with judicial review, and change the standard on judicial review by reducing the deference to be accorded the Agency's findings. The proposal also appears to remove the Agency's authority to take certain remedial actions (e.g., recall) against the products because of health dangers.

While the proposed settlement gives the Agency the authority to establish performance standards and thus modify tobacco products, the proposal expressly authorizes manufacturers to sell unmodified, conventional tobacco products. This appears to create two groups of tobacco products, those that meet Agency established performance standards and those that meet traditional industry standards regarding nicotine, tar, and other characteristics.

2. GOOD MANUFACTURING PRACTICE (GMP)

a. Existing Authority

Manufacturers of finished devices are required to comply with regulations prescribing current good manufacturing practice for devices, to prevent production of defective devices. For example, they describe requirements for building maintenance, personnel training, record keeping, process controls, equipment design and maintenance, and packaging and labeling controls. The device GMP regulations embody the much broader term "quality systems" under which a manufacturer has more responsibility for the design and manufacture of its products. The regulations contain requirements relating to controls over a product's design which are regarded as very important to the Agency.

b. Authority Under the Proposed Settlement

The proposed settlement narrows considerably the responsibility that tobacco manufacturers, especially management, would have under current device GMP regulations, and limits the authority of the Agency over the design and manufacturing processes used to produce these products. Much of the language of this provision is vague, and it is unclear what is meant, for example, by record keeping and reporting and whether it has the same meaning it does in the device GMP regulations. In the GMP regulations, record keeping and reporting includes such things as complaint files, validation records, and design records. The effective date of requiring GMPs specific to tobacco products is hampered by imposing time restrictions of 24 months or the completion of rule making, whichever is later.

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**COMPARISON OF THE ADVERTISING, LABEL, ACCESS
AND EDUCATION PROVISIONS**

ADVERTISING PROVISIONS

Codified Language

FDA's rule contains sweeping changes to the manner in which tobacco products can be marketed. It is based on section 520(e) of the Act, which permits additional unspecified restrictions on the sale, distribution or use of a restricted device if the Agency determines that, because of the device's potentiality for harmful effects, there cannot otherwise be a reasonable assurance of its safety. Section 897.30 details a list of permissible forms of labeling and advertising and provides a mechanism for manufacturers, distributors and retailers to notify the Agency of an intention to use media, other than those listed, to advertise tobacco products. The major exception is for outdoor advertising, which is banned within 1000 feet of schools and public playgrounds.

The inventory of permissible media provides a listing of those media affected by the regulation. It does not preclude other forms of advertising. Thus, the restrictions apply only to the listed advertising and labeling media. For example, section 897.32 requires that the listed advertising and labeling shall only appear in black text on a white background, except that unrestricted advertising may appear in adult publications and at adult facilities. In addition, all listed advertising must contain the product's established name and intended use statement. Finally, permitted audio and video advertising at point of sale shall be limited to words only (no music or sound) and static black text on a white background.

The final set of provisions, 897.34(a)-(c) ban the marketing, distribution, etc. of any item (other than tobacco) or service, which bears the brand name (alone or in conjunction with any other word) logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Moreover, it prohibits the provision of gifts or items in consideration of the purchase or proof of purchase of a tobacco product. Finally, the rule prohibits the sponsorship of any athletic, musical, artistic, or other social or cultural event, or any team or entry in any event, in the brand name, etc., as defined above. Sponsorship is permitted in the corporate name, with some limitations.

Statutory Authority

In addition to the requirements spelled out in the rule, section 502(q) of the Act provides that the Agency can find a device misbranded if its advertising is false or misleading. In addition, section 502(r) provides that the Agency can, after appropriate notice and comment, require a full

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disclosure in advertising of the ingredients of a device, if it is necessary to protect the public health.

How the Proposed Settlement Expands FDA's Role

The proposed settlement purports to include all of FDA regulations of advertising and labeling and require additional restrictions. In most cases this is correct. Perhaps of greatest importance, the proposal would incorporate the advertising and marketing provisions in consent orders with various states to be signed by the participating companies, so that, theoretically, those companies would be bound by the restrictions regardless of legal challenges and court decisions. (pp. 27-28)

The proposal incorporates FDA's definition of permissible advertising but also expands it to "restrict tobacco product advertising to [*only those*] FDA specified media." This is broader than FDA's coverage, which merely provides the list of media covered by the regulation and provides a procedure for companies who wish to use new media prior to its first use. As an example of the breadth of this provision, the proposed settlement also includes a ban on the advertising of tobacco products on the Internet unless designed to be inaccessible in or from the U.S. These expansions of the rule are significant and make the advertising restrictions more inclusive and powerful. (p. 9)

The proposal would require that all permissible advertising be in black text on a white background except for advertising in adult publications and adult facilities. In addition, the proposed settlement language is broader, providing that even in the "unrestricted" media, advertising would not be able to use human images or cartoon characters (the Marlboro Man and Joe Camel). The ban on outdoor tobacco product advertising, would be expanded to include all outdoor advertising (not just that within 1000 feet of schools and playgrounds) including in an enclosed stadia as well as brand advertising directed outside from a retail establishment. (pp. 8-9)

1. Point of Sale Advertising

Advertising at point of purchase¹, permissible under FDA's regulation, and in the proposed settlement, in a black and white format, would be further restricted. Each manufacturer would be permitted to have no more than 2 separate point of sale advertisements at any one location (except manufacturers with 25% or more of the market could have one additional ad). Retailers could display signs of their own. The display area of each sign could not exceed 576 square inches, either individually or in the aggregate and can use letters and recognized typographical markets. Further, no ad could be attached to nor located within two feet of any fixture selling candy.

¹ Appendix VII appears to state that unrestricted point of sale advertising can appear in adult-only stores and in tobacco outlets. The inclusion of "tobacco outlets" is disturbing, if it is intended to expand the coverage of venues permitting unrestricted advertising. If, on the other hand, the term is used to define a sub-set of adult-only venues, that is tobacco stores that sell only tobacco and are adult-only, the inclusion of this additional term is not substantive.

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Finally, display fixtures may contain signs consisting of brand name and price, not larger than 2 inches in height. (p. 63)²

The proposed settlement forbids any arrangement between a supplier and a retailer, which would prohibit the display of another company's advertising. The final provision bans ads in an audio and video format at point of sale, but would permit these to be distributed to adult customers at point of sale. If this is taken literally, it would appear to authorize music videos, ads with people and animals, etc. for home consumption. (p. 63)

2. Bans on Merchandise, Sponsored Events and Gifts

The proposed settlement bans all non-tobacco merchandise (a word that is narrower than FDA's items and services), bans all offers of non-tobacco items or gifts for proofs of purchase, and bans brand sponsorship of events (but does not appear to ban entries or teams) (p. 8).

3. Disclosures

The proposed settlement requires that all advertising carry an FDA-type mandated statement of intended use (the shortened "Nicotine Delivery Device" without an age proscription), but does not require that the established name be included. In addition, advertising would be required to rotate the same health warnings that packaging would be required to display. Appendix 1 describes the format for warning statements, to wit, 20% of advertising space in press and poster advertisements would be dedicated to the health warnings and where relevant to the tar, nicotine disclosure. The type size is also provided. (pp. 10, 43)

4. Low Tar and Light Advertising

The proposed settlement requires the FDA to "require" that all advertising of brands denoted as "light" or "low tar" be accompanied by a mandatory disclaimer, such as, "Brand X not shown to be less hazardous than other cigarettes." In addition, it requires that exemplars of all new advertising and product labeling shall be submitted to FDA for review concurrently with market introduction. The text notes that this requirement is not in limitation of FDA's normal rulemaking authority in this area. (p. 9) This provision should be read in context with two other requirements: (1) that FDA be vested with responsibility to oversee the tar and nicotine testing currently exercised by FTC and to mandate disclosure of tar, nicotine and other constituent disclosures in advertising and

² Point of sale advertising is defined as all printed or graphical materials, which, when used for its intended purpose, can reasonably be anticipated to be seen by customers at a location at which tobacco products are offered for sale. This provision is narrower than FDA's rule, which bans all non-tobacco items, a category that could include clocks with advertising messages and other items at point of sale. (p. 63)

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on packages if it determines this would protect the public health (p. 11) and (2) that three years from enactment of this Act, no cigarette shall be sold in the U.S. with tar which exceeds 12 mg. (as measured by the current FTC method) (p. 16). This latter provision also is prefaced with an assurance that this requirement should not detract from the Agency's authority under the requirements of section 514 of the Performance Standard to ensure minimum hazardous cigarettes.

5. Novel Provisions

The proposed settlement would ban direct and indirect payment for tobacco product placements in movies, television programs and video games. Moreover, it would prohibit payments which "glamorize" tobacco use in media "appealing to minors," including recorded and live performances of music. The first provision is similar to an informal requirement of the FTC that tobacco companies not provide direct payments for product display in media. The FTC receives, via compulsory process each year, a statement from each tobacco company indicating if and how much consideration it has paid for product placement. (p. 9)

How the Proposed Settlement Limits FDA's Role

Several overall questions are raised by the proposal's short descriptions of restrictions. Several of the provisions are described as restricting or banning "tobacco product advertising" in a given media, which is probably more limited than FDA's restrictions on a company's "advertising" in any manner in that media. In addition, the proposed settlement does not appear to accept FDA's denotation of advertising as encompassing "brand name (alone or in conjunction with any other word) logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco." When these descriptions are provided in the settlement (especially concerning merchandise and sponsorship) the description does not include several of the elements of FDA's definition.³ This may be drafter's shorthand, but if it is intentional, it would severely limit the proposal's coverage. (p.8)

Moreover, the scope of FDA's authority to regulate the content of advertising is unclear. Without specifying precisely what FDA's range of authority would be, the proposed settlement provides that the FTC is to retain its existing authority (except for constituent testing), which presumably would include its authority over deceptive and unfair advertising and marketing practices. (P. 32) As a

³ For example, the proposal's language does not include "recognizable pattern of color." The black, white, and red chevron on Marlboro's package can be displayed alone on a sign and be readily recognized without words or symbols and related to Marlboro cigarettes. Under FDA's rule, this would be a prohibited ad. Under the proposed settlement, it might not be. Similarly, FDA's regulation includes the prohibition on the use of brand names "alone or in conjunction with any other word", the proposed settlement does not. The industry has argued, in the past, that the Skoal Racing Team was not an advertisement for its Skoal products because the additional words, "racing team," made the Skoal reference to its cars and not its product. FDA's definition would prohibit this type of advertising.

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result, it is not clear whether this would be concurrent with FDA jurisdiction or instead of FDA jurisdiction.

Analysis

As with the label provisions, generally the proposed settlement provides greater protection. The most important additional provision is the banning of all advertising not on the list of permissible forms, including a ban on product advertising on the Internet. Although we had constitutional concerns about the breadth of such a proposal, the companies are free to agree to accept those restrictions in consent agreements.

The proposal to grant greater protection at point of purchase closes an important avenue of appeal for young people and should be commended. Our only concern is that the proposal incorporates an advantage to companies with more than 25% of the market (Philip Morris and R.J. Reynolds). The restrictions that the rule or the proposed settlement will require, already will advantage a market leader by providing barriers to new entrants in the market.

Problem areas include the proposals apparent more limited definition of advertising (e.g. color and pattern or color) which would constrict the restrictions coverage. Similarly, the proposal's limitation on the ban on brand identified items and services to a requirement that only affects merchandise⁴ and the limiting the ban on sponsorship to just events (not including teams and entries) provides a short term solution that will require additional rulemaking in the future. The Agency is already aware of industry advertising on items (clocks and other items at point of purchase) and in services (Philip Morris's music contest and CD offer "It's a women's thing" and travel agencies in Europe with tobacco brand names). And the industry's use of racing cars is no less problematic than its sponsorship of the race itself. Both associate smoking with sports, heroes, danger, excitement and fun.

The proposed settlement requires the Agency to develop a disclosure for advertising for low tar and light products. This provision in conjunction with other provisions concerning tar and nicotine content, appear to freeze Agency ability to address the problems associated with the current tar and nicotine rating system. For example, if the Agency were to determine that there is no non-deceptive way to advertise a "low tar" product, because it provides little or no benefit, would the Agency be prevented from doing so? It would appear that the proposed settlements mandate to phase out cigarettes with more than 12 mg. tar has staked out a position that lower tar is better. The evidence may not justify this conclusion and the Agency should not be prevented from taking whatever path is appropriate.

⁴ The industry has shown by its practices in Europe and Canada that it can move its imagery and franchise to any number of possible venues. This should be precluded in any final settlement in order to carry the protections forward to new yet undisclosed activities.

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LABEL PROVISIONS

Codified Language

Subpart C, §§ 897.24 and 897.25 require that each package of cigarettes, cigarette tobacco or smokeless tobacco bear the product's established name and a statement of intended use- "nicotine-delivery device for persons 18 or older." These provisions are based on the requirements of section 502(e) and (r) of the Act that mandate the inclusion of this and other information on all package labels. Section 801.61 of FDA rules requires that these statements appear on the principle display panel of the package. The Agency currently lacks the authority to require additional warnings or to change existing health warnings on cigarette and smokeless tobacco packages, 15 U.S.C.1334, Federal Cigarette Labeling and Advertising Act and 15 U.S.C. 4406, Comprehensive Smokeless Tobacco Health Education Act.

How the Proposed Settlement Expands FDA's Role

In contrast to FDA's modest requirements for the package label, the proposed settlement would amend the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, to mandate numerous new health warnings that would be rotated quarterly. Unlike the current Surgeon General's warnings, the messages would not be attributed to the Surgeon General but would all be prefaced with the word "WARNING" and would be short, understandable, declarative sentences. Moreover, the warnings would be required to occupy 25 % of the upper front panel of the package of cigarettes (except for flip top boxes). Twenty-five percent of the principle display panel of smokeless tobacco packages would similarly carry the warning (side panel of the hockey puck can of snuff). Warnings would be in black on white and white on black format alternately, would be printed in 17 point type (Canadian style), and would follow the requirements set forth in the existing United Kingdom standard. (Pp. 9-11)

The proposed settlement also provides that FDA be given express authority to require changes in the warnings (thereby overturning the preemption provisions of the Cigarette and Smokeless acts) with the caveat that it provide public notice and hearing opportunity prior to making changes.

One additional package restriction is found in the advertising provisions of the proposal. The proposed settlement would prohibit the use of human images and cartoon characters (e.g. the Marlboro Man and Joe Camel) from all tobacco product packaging.(p. 9) Reynolds has, in the past, displayed various poses of its Joe Camel character on collector packages of cigarettes. This practice would be outlawed but it appears that Reynolds' original Joe Camel- a drawing of a dromedary in front of a pyramid- would be permitted.

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How the Proposed Settlement Limits FDA's Role

There are no significant provisions that would reduce FDA's regulation of labels. However, the proposed settlement does not require that package labels indicate the established name of the product but does require that packages contain an FDA-type statement of intended use on the side of the package. However, it appears that the statement would be "Nicotine Delivery Device" and would not include the age proscription. (p. 11)

Analysis

In general, the label provisions of the proposed settlement are broader and create greater protection than the FDA rule. For example, the proposed settlement creates a whole new set of short, specific and clear health warnings that would rotate quarterly on all packaging (9 for cigarettes and 4 for smokeless). Although not attributed to the Surgeon General they meet or exceed the recommendations of consumer marketing professionals for effective health warnings. The size, location and format of the warnings on cigarette packaging is optimum, but the location on snuff cans (on the side as opposed to on the lid) insures that it will not be as prominent. The proposal would be improved if the warnings were to appear on both the front and the back principal display panel simultaneously (black on white, and white on black) as is done in Canada.

Under current legislation, cigarette and smokeless tobacco health warnings can only be changed by act of Congress and federal and state agencies are precluded from requiring any different or additional warnings. The proposed settlement improves on this scheme by permitting FDA to change the warnings after it has provided for notice and *hearing* opportunity. This latter requirement exceeds the usual notice and *comment* rulemaking requirement under the Administrative Procedure Act and should be changed to the more expeditious APA procedure.

ACCESS PROVISIONS

1. Responsibilities of Manufacturers

FDA Rule

The FDA rule directs manufacturers to ensure that all cigarettes and smokeless tobacco products that it manufactures, labels, advertises, packages or sells comply with all applicable regulatory requirements. Manufacturers must also remove from each point of sale all self-service displays, advertising, labeling, and manufacturer-supplied or manufacturer-owned items which violate the rule, unless they are located in an establishment where no person under 18 may enter. Manufacturers must also visually inspect and ensure that products are labeled, advertised, and distributed in accordance with the rule. A manufacturer may not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except

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those in use before January 1, 1995. No manufacturer can sell any cigarette package containing fewer than 20 cigarettes, or distribute any free samples of tobacco products.

Proposed Settlement

In addition to most provisions mentioned in the FDA rule, the proposed settlement states that manufacturers would create plans, with an annual review and update, to "ensure compliance with all applicable laws and regulations" (p.21). Manufacturers would also be required to have compliance programs where their employees would report known or alleged violations by retailers or distributors to FDA (p. 23).

Advantages to the Proposed Settlement

As mentioned above, the proposed settlement requires manufacturers to create a compliance plan and take various actions to reduce the sale of tobacco to minors. The proposal includes fines for failure to fulfill these obligations.

Disadvantages to the Proposed Settlement

There is no express language declaring that manufacturers are responsible for complying with all applicable regulatory requirements and in particular for removing advertisements and other violative articles.

2. Responsibilities of Retailers

FDA Rule

The FDA rule directs retailers to ensure that all cigarettes and smokeless tobacco products that it sells comply with all applicable regulatory requirements. Retailers may not sell tobacco to anyone under 18. They must verify that persons buying tobacco are at least 18 through use of photo ID. Retailers may sell tobacco only through a direct, face-to-face exchange without the help of any electronic or mechanical device, unless the sale is through a vending machine or self-service display in a facility where no one under the age of 18 is allowed to enter. Mail order sales are currently permitted. However, in two years FDA will reconsider this provision if mail order becomes a mechanism by which minors purchase tobacco products. Retailers may not break open a cigarette or smokeless tobacco package. The minimum package size is 20 cigarettes. Retailers must also remove or bring into compliance any violative items, such as self-service displays and advertising, that are in the retail establishment, including both products that the retailer owns and those that it does not. Additionally, retailers may not distribute free samples of tobacco products.

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Proposed Settlement

Many retailer access provisions are identical to the FDA rule. However, in the proposed settlement, all vending machine and mail order sales would be prohibited. In facilities where persons under 18 may enter, all tobacco products must be placed out-of-reach of consumers, or, if on the counter, not visible or accessible to consumers (p. 12). The proposed settlement would also establish a retailer licensing system and impose penalties on licensed and unlicensed retailers (pp. 12-13, 44-45).

Compared to the FDA rule, the proposed settlement is silent on whether they can break open tobacco product packages and whether retailers are obligated to remove all violative items in the retail establishment regardless of ownership. As stated above, the FDA rule prohibits these practices.

Advantages to the Proposed Settlement:

The proposed settlement would create a retailer licensing system with penalties for noncompliance (pp. 12-13, 44-45). It also does not create an exemption for vending machines or for mail order sales, so the face-to-face transaction requirement would apply to all tobacco product sales (except for self-service displays in adult-only facilities). Furthermore, the requirement that on-the-counter tobacco products not be visible to the consumer goes beyond the existing FDA requirement.

Disadvantages to the Proposed Settlement:

The penalties under the retailer licensing system are comparatively weak compared to the sanctions available under the Federal Food, Drug, and Cosmetic Act.

Additionally, the retailer licensing system may be difficult to administer, particularly with respect to Indian lands where FDA may be obligated to administer a tribe's licensing system or to delegate responsibility to a State.

3. Responsibilities of Retailers

FDA Rule

The FDA rule directs distributors to ensure that all cigarettes and smokeless tobacco products that it distributes comply with all applicable regulatory requirements. No distributor may distribute any free samples of tobacco products.

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Proposed Settlement

The proposed settlement is silent on a distributor's responsibilities, and there is no express language stating that distributors are responsible for complying with all applicable regulatory requirements.

Advantages to the Proposed Settlement

There do not appear to be any advantages to the proposed settlement with respect to the responsibilities of distributors.

Disadvantages to the Proposed Settlement

As stated above, the proposed settlement is silent on a distributor's responsibilities, and there is no express language stating that distributors are responsible for complying with all applicable regulatory requirements. However, it was not contemplated in the FDA rule that distributors would have a large role in reducing access of tobacco products to minors.

EDUCATION PROGRAM

Existing Authority

The Food, Drug, and Cosmetic Act (section 518(a)) provides a mechanism for FDA to require manufacturers to notify users and potential users of an unreasonable risk posed by a product. In the preamble to the final rule, FDA indicated that this notification process might be an appropriate means to require tobacco manufacturers to fund multi-media campaigns to educate children and adolescents about the risks associated with tobacco products. The process for requiring companies to undertake this effort would consist of the Agency notifying companies of its intent to require such action, providing an opportunity for a hearing, and, if necessary, imposing a "notification order."

How the Proposed Settlement Expands the Agency's Authority to Require an Education Program

The proposed settlement provides for the establishment of a public education program which the industry would fund for \$500,000,000 annually for 8 years. The benefits of such a program are that it makes available a significant amount of money in a timely manner. Further, it does not appear to place restrictions on the type of educational messages that could be developed. Since the proposed settlement contains no specific provision authorizing FDA to require companies to fund an education program, it appears that the Agency would not be permitted to require such an effort for five years.

How the Proposed Settlement Limits the Agency's Authority to Undertake an Education Program

While \$500,000,000 annually is a significant amount of money, the proposal seems to discontinue all funding after eight years. It is unclear whether FDA could use its existing authority under 518 after the

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eight year period.

Further, the proposed settlement appears to greatly reduce the role of the Government in developing and overseeing a multi-media campaign. Specifically, the proposed settlement authorizes the Secretary of Health and Human Services to establish a public education program to "discourage and de-glamorize the use of tobacco products," and to make grants to state health departments to assist in carrying out these programs. However, it seems to provide primary authority to an independent non-profit organization, which would need to be formed, and it also authorizes the independent body to contract with state health departments. It is unclear whether the Secretary has the authority to select the members of the board. Further, it is unclear whether the proposal intends to have both the Secretary and the independent board contract with state health departments for the same purpose. Finally, since the Office on Smoking and Health within the Department of Health and Human Services has the experience and the expertise to oversee such a program and coordinate it with the state programs, it is uncertain why a new non-profit organization would need to be created.

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**FUTURE REGULATION OF TOBACCO OTHER THAN MODIFICATION
OF THE PRODUCT**

The FDA regulation establishes a goal of reducing tobacco use by children by 50% in 7 years. If this goal is not met, the Agency contemplated imposing additional measures. In addition, it may be appropriate for the Agency to attempt to reduce adult use of tobacco products in the future.

Existing Authority

In addition to the provisions contained in the final tobacco rule, FDA has the ability through informal rulemaking and other mechanisms specified in the statute to impose additional requirements on these products should the Agency find that they are necessary.

Among the measures that the Agency could require through informal rule making are raising the minimum age of sale, limiting the types of retailers that could sell tobacco, making tobacco products available only by prescription, requiring that specific warnings be added to the packaging or labeling of tobacco products, plain packaging further restricting tobacco advertising, or requiring tobacco advertisements and/or products to list ingredients. In addition, informal rule making could be employed quickly and efficiently to correct or clarify any provisions in the final tobacco rule.

Further, as the Agency indicated in the preamble to the final tobacco rule, FDA believes that it could use its authority under 518(a) of the statute to require tobacco companies to notify tobacco users and potential tobacco users of the unreasonable risks posed by their products. For example, the Agency could require companies to fund a multi-media education campaign intended to alert young people about the risks of tobacco use. Under the 518 process, the Agency would notify companies of its intent to require such action, provide an opportunity for a hearing, and, if necessary, impose a "notification order."

Finally, in the event that FDA found that other tobacco products such as cigars and little cigars meet the definition of a drug or a device under the Food, Drug, and Cosmetic Act, the Agency could assert jurisdiction over these products and subject them to the same regulations as cigarettes and smokeless tobacco.

How the Proposed Settlement Enhances FDA's Ability to Implement Future Regulations and Actions

The proposal eliminates any risk that the Agency would not prevail in court on its assertion of jurisdiction or authority to regulate promotion and advertising. The proposed settlement contains measures that go beyond the current FDA rule. They are listed on pages 9, 10, and 12 of the proposal.

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How the Proposed Settlement Impedes or Curtails Future Regulations and Actions

Under current authority, the measures discussed above could be initiated, in accordance with the procedures specified in the statute, if the Agency determined that such measures were necessary. By contrast, under the proposed settlement, any additional Agency action is frozen for five years except in "extraordinary circumstances." Moreover, since cigars or little cigars are not included in the proposed settlement, and FDA were to obtain sufficient evidence to assert jurisdiction over these products, it is unclear whether FDA would be able to assert jurisdiction and regulate cigars during the five-year freeze on regulations.

After five years, the extent to which the Agency could adopt additional measures is unclear. For example, could the Agency raise the minimum age to 19 or 20 (an authority that it clearly would have under the North Carolina district court's decision)? Could it require plain packaging on all tobacco products?

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ADDITIONAL IDEAS TO INCLUDE IN THE TOBACCO AGREEMENT

I. General Provisions

Access--No exemption for adult only facilities

Labeling and Advertising--No exemption for adult facilities or adult publications

II. New Provisions or Authority

Enforcement Authority:

Compulsory Process--Power to issue subpoenas requiring the production of evidence and the attendance and testimony of witnesses

Penalties--New civil money penalties procedure--a quicker version for a small retailer fine (fine, traffic ticket, licensure)

FDA regulations will not preempt more stringent state requirements

III. Other Agencies or Legislative Changes

Repeal state preemption provision of Cigarette Act (Smokeles Act is okay) and any other federal preemption of stricter state provisions

Consider all the tax implications of the settlement, including the possible removal of the tax-deductibility of advertising and promotional expenditures

Department of Agriculture--use tobacco support program to transfer farmers from tobacco to other crops

Department of Commerce--Export policy--develop trade policy that emphasizes the Administration's concern about the health consequences of tobacco use. This goes further than just making trade policy neutral to tobacco export. Proactively export health policy.

Import restrictions on imported tobacco--pesticides etc.

Department of Education--Fund in-school education and media literacy programs

Department of Health and Human Services

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Fund programs at NIDA, etc. to research teenage addiction.

Require reimbursement for smoking cessation treatments by insurance carriers.

Studies (funded) to determine who smokes, why, how much, which brands, and how to intervene.

Department of Labor--OSHA regulations to go into effect--for all workplaces including restaurants.

Department of Transportation--mandate all federally supported carriers to be smoke free. Require all airline terminals, railroad terminals and bus stations to be smoke free.

Independent Regulatory Agencies:

Consumer Product Safety Commission--delete tobacco's exemption from CPSC's jurisdiction.

Fire Safe Cigarettes--create within CPSC authority to implement recommendations on testing and requiring more smoulder resistant cigarettes.

General Services Administration--mandate smoke free workplaces for all Federal establishments.

United States Information Agency--disseminate public health information about tobacco use.

	F D C A	S E T T L E M E N T	
Regulatory Mechanism	1. adulteration or misbranding provisions 2. restricted device provisions 3. performance standards 4. device classification 5. other (?)	Nicotine Reduction Products classified as class II devices; FDA sets performance standards	Nic. Elimination or Equivalent Action Products classified as class II devices; FDA sets performance standards
Required Agency Findings	Sets general controls to provide adequate assurance of safety and effectiveness (class II devices)	FDA must show <u>reduction</u> : 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 of alternate products on the market.)	FDA must show <u>elimination</u> : 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 of alternate products on the market.)
Time Frame	No constraints	for at least 12 years	1. FDA can require nicotine <u>elimination</u> 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)