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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.

DRAFT
6/30/97

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 propoed 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:

(a) will result in a significant reduction of the health risks associated with such products,

(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

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

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.

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

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.

DRAFT
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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

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.

DRAFT
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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

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 purchase[1], 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.

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[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.

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

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[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 included clocks with advertising messages and other items at point of sale. (p. 63)

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.

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 merchandise [4] 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.

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[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

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. Responsibilites 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.

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.

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 $500,000,000a;|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

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 th 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 subpeonas 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

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.