tobacco - companies

Statement

of

Richard M. Cooper

on behalf of

R.J. Reynolds Tobacco Company

before the

Senate Committee on
Labor and Human Resources

Tuesday, February 24, 1998

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 60 Fed. Reg. at 41,349.

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

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

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

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

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9 21 U.S.C. § 352(j).

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

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

12 21 U.S.C. § 355.

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

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

THE PROPOSED RESOLUTION PROVIDES A BETTER APPROACH.

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

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13 21 U.S.C. § 352(f)(2).

14 61 Fed. Reg. at 45,238.

15 61 Fed. Reg. at 44,465.

16 FDCA § 301(a), 21 U.S.C. § 331(a).

17 15 U.S.C. § 1334(a).

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

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

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

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

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

The Required Findings.

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

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

(b) is technologically feasible; and

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

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

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

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

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

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

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

19 PR 15-17.

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

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

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[20] The agency has stated:

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

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

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

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

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

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

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

22 1994 House Hearings at 69.

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

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

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

The Procedural Safeguards.

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

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

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

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

24 PR 16.

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

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

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

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

26 21 U.S.C. § 371(e).

27 21 U.S.C. § 343(j).

28 21 U.S.C. § 344(a).

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

Formal rulemaking also applies to regulations relating to

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

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

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

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29 21 U.S.C. § 346.

30 21 U.S.C. § 351(b).

31 21 U.S.C. § 352(d).

32 21 U.S.C. § 352(h).

33 21 U.S.C. § 341.

34 21 U.S.C. § 352(n).

35 21 U.S.C. § 379e(d).

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

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

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

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

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36 21 U.S.C. § 348.

37 21 U.S.C. § 360d.

38 21 U.S.C. § 360f.

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

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

41 FDCA § 505(h), 21 U.S.C. § 355(h)

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

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

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

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42 21 C.F.R. § 10.30.

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

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

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

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

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

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

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44 PR 17-18.

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

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

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

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

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

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

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

J. Phil Carlton, Esquire

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Tobacco Companies - EW

COPY

March 25, 1998
VIA HAND-DELIVERY

Mr. Bruce N. Reed
Assistant to the President for Domestic Policy
Executive Office of the President
The White House
2nd Floor, West Wing
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. Reed:

Along with other signatories to the June 20, 1997 proposed tobacco resolution, we have been working closely with members of Congress to explain the resolution's provisions. We know that representatives of the Administration have been meeting with members of Congress as well. We are now hearing reports about Administration proposals that we find alarming. If these proposals are ultimately incorporated in a proposed bill, it will be impossible for the companies to support such legislation or to sign the protocol that contains some of the most important parts of the proposed resolution.

While many aspects of the Administration's recent statements and purported positions are problematic, among the most troublesome are the following:

Industry Payments. As you know, the goal of the resolution was to reduce underage tobacco use by a number of measures, including increasing the retail price of a pack of cigarettes. Since then, the President has indicated that his desired price increases would be $1.10/pack in 5 years and $1.50/pack in 10 years. The industry has not objected to those numbers because it understood them to be consistent with the June 20 resolution, which would bring about price increases very close to the President's numbers.

Recent statements by Administration officials, however, indicate that the contemplated price increases of $1.10/pack in 5 years and $1.50/pack in 10 years must represent a "net" figure — i.e., excluding wholesaler and retailer price markups, state sales tax, and federal excise tax increases, etc. — that will flow into the federal treasury. These statements are a serious departure from the figures contemplated in the proposed resolution. Indeed, rather than a $1.10/pack increase at retail in 5 years, the White House proposal would, according to analysts, result in as

much as a $2.40/pack increase to a retail price of $4.25/pack. One analyst estimates that these per-pack increases would translate into total industry payments of some $644 billion over 25 years without any regard to declines in industry volume. In other words, the Administration would require industry payments of approximately $26 billion per year whether 24 billion packs are sold or 1 billion packs are sold. The White House must know that the industry could never agree to such a system — it would almost certainly result in industry bankruptcies.

As you know, before agreeing to the payments contemplated by the June 20 proposed resolution, each company engaged in a serious analysis of the impact the agreement would have on each company's economic viability. Back in June, the companies finally concluded that $368.5 billion was as far as the industry could go without threatening the economic viability of individual companies. That analysis has not changed.

In his September 17th remarks regarding the tobacco settlement, President Clinton stated that "this is not about money. It is not about how much money we can extract from the tobacco industry. It is about fulfilling our duties as parents and responsible adults to protect our children." In his statement, the President "call[ed] for a combination of industry payments and penalties to increase the price of cigarettes by up to $1.50 a pack over the next decade" as necessary to meet the youth smoking reduction targets. The report of this new proposal emanating from the White House is entirely inconsistent with the President's public statements and will cause the failure of a comprehensive approach to tobacco legislation.

Look-back Surcharges. We understand the Administration to be advancing look-back proposals that are well beyond anything that was ever discussed with the industry. Reduction targets that begin in year two and would go beyond the 60% in the June 20 proposed resolution — not to mention employing methodology and numbers that the industry could never accept — raise questions as to whether the White House is serious about wanting a comprehensive resolution.

Civil Liability. This is another area of the settlement in which the White House was involved in helping the parties to work out the details. In particular, during the course of the negotiations that led to the settlement of past punitive damages claims against the industry in exchange for an additional $60 billion to be used for public purposes, the White House indicated a willingness to issue a public statement that, at least with respect to the punitive damage aspects of the resolution, the proposed resolution was satisfactory.

We are concerned about reports that the White House has been urging members of Congress not to support anything more than a bare cap on liability payments. While we appreciate that the White House does not want to appear to be the advocate for civil liability relief, it has never been our understanding that the White House would lobby against the very provisions that the White House helped to work out.

We do not understand why the White House is taking a radically different position with respect to these issues. It is critical to the companies — and to the settlement itself — that the White House stand behind its earlier statements and positions, upon which we have relied.

The industry remains committed to achieving comprehensive national tobacco legislation as contemplated by the June 20 proposed resolution. While we recognize that Congress and the President ultimately must determine the precise terms of any national tobacco legislation, the industry will not be able to participate in any resolution that is too expensive financially or leaves the industry without the civil liability protections that were an essential part of the proposed resolution.

Sincerely,

J. Phil Carlton

cc: Mr. Erskine Bowles
Mr. Bruce Lindsey
Ms. Elena Kagan
The Honorable John McCain
The Honorable Ted Stevens
The Honorable Conrad R. Burns
The Honorable Slade Gorton
The Honorable Trent Lott
The Honorable Kay Bailey Hutchison
The Honorable Olympia Snowe
The Honorable John Ashcroft
The Honorable Bill Frist
The Honorable Spencer Abraham
The Honorable Sam Brownback
The Honorable Ernest F. Hollings
The Honorable Daniel K. Inouye
The Honorable Wendell H. Ford
The Honorable John D. Rockefeller IV
The Honorable John F. Kerry
The Honorable John B. Breaux
The Honorable Richard H. Bryan
The Honorable Byron L. Dorgan
The Honorable Ron Wyden
The Honorable Tom Daschle
The Honorable Don Nickles