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Tobacco-Settlement: General [2]

Tobacco - settlement

[redacted]

CONFIDENTIAL

MEMORANDUM FOR THE PRESIDENT

FROM: BRUCE R. LINDSEY

SUBJECT: TOBACCO NEGOTIATIONS

DATE: JUNE 9, 1997

Substantial progress has been made in the tobacco settlement negotiations. While there remains at least one outstanding issue - punitive damages, the following is a summary of the negotiations to date:

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 contract 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. 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.

4. 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.

5. PUBLIC DISCLOSURE/PUBLIC POSITION - There has been agreement to disclose all internal health research related documents. There has been discussion about disclosing internal memoranda which contain any reference to health, toxicity, addiction, drug dependence, and marketing to kids, but no final resolution. The industry has said it does not intend to make a public admission as Liggett did in its settlement, but has also said that it will no longer challenge the scientific conclusions about the causal link between tobacco use and disease and nicotine and addiction. The enforcement mechanism and form of this new posture is still unclear and needs to be worked out. At a minimum, no tobacco company person speaking on behalf of, with the authorization of, or using funds from a tobacco company should publicly challenge or seek to call into doubt the scientific conclusions reflected in the Reports of the Surgeon General issued prior to the date of enactment. Protection from liability for "commonly know" hazards of tobacco use could be conditioned on the tobacco companies not challenging the scientific merit of these so-called "commonly known" hazards.

6. PUBLIC HEALTH FUNDS - An annual grant to the Secretary of HHS in the sum of $_____, adjusted for inflation from the effective date, would be made for the following purposes.

A) $_____ annually to accomplish the following purposes:

- the reduction of tobacco product usage, both by seeking to discourage the initiation of tobacco use by persons under the age of 18 and by encouraging current tobacco users to quit through media-based and non-media education, prevention and cessation campaigns. Of the sums allocated to the Secretary for the purpose, no less than $500,000,000 shall be spent in such multi-media campaigns designed to discourage and de-glamorize the use to tobacco products. As one mechanism for implementing this provision, the Secretary is authorized to contract or make grants to non-profit public or private entities who are unaffiliated with tobacco manufacturers or tobacco importers and who have a demonstrated

record of working effectively to reduce tobacco product use and expertise in multi-media communications campaigns.

- research into and development and public dissemination of technologies and methods to reduce the rise of dependence and injury from tobacco product usage and exposure;

- identification, testing and evaluation of the health effects of both tobacco and non-tobacco constituents of tobacco products; and

- the promulgation of such other rules and regulations as are necessary and proper to carry our the provisions of this Act.

B) $_____ annually to the Food and Drug Administration to carry out its obligation under and to enforce the terms of this Act;

C) $_____ annually to fund state and local tobacco control community based efforts modeled on the ASSIST program, designed to encourage community involvement in reducing tobacco use and the enactment and implementation of policies designed to reduce the use of tobacco products;

D) $_____ annually to fund research and the development of methods for how to discourage individuals from starting to use tobacco and how to help individuals to quit using tobacco;

E) $_____ annually for a period of ten(10) years to compensate events, teams, or entries in such events, who lose sponsorship by the tobacco industry as a result of this Act, or who currently receive tobacco industry funding to sponsor events and elect to replace that funding, provided that the event, team or entry is otherwise unable to replace its tobacco industry sponsorship during those given years. Funds use for this purpose shall promote a Quit Tobacco Use theme. After a ten year period, no additional funds shall be used for this purpose and the funds previously allocated to this purpose shall be used as follows: %0% to supplement funding of the multi-media campaigns in paragraph (1) of this subsection; 25% to supplement the funding of the enforcement provisions of paragraph (2) of this subsection; and 25% to supplement the funding of community action programs in paragraph (3) of this subsection.

F) $_____ annually to the Secretary of Agriculture to provide grants to tobacco growing states to formulate and implement economic development plans for tobacco growing counties in their states and to compensate tobacco growers who elect to forego growing tobacco and agree to retire their tobacco allotment in order to assist them in making a transition to an alternate livelihood. For tobacco growers aged 50 or over, as of the effective dates if this statute, the grant shall be in annual payments based upon fifteen (15) years of profit lost from the sale of

tobacco under a formula to be promulgated by the Secretary of Agriculture. For tobacco growers under the age of 50, as of the effective dates of this statues, five annual payments based upon their expected lost income over a 10 year period beginning with their decision to stop growing tobacco. After a 15 year transition period, no additional funds shall be used for this purpose and campaign in paragraph (1) of this subsection, 25% to supplement the funding of the enforcement provisions of paragraph (2) of this subsection; and 25% to supplement the funding of the community action programs in paragraph (2) of this subsection.

(H) $_____ to fund international organizations, like WHO, to develop and implement tobacco control and reduction policies internationally and worldwide.

7. TOBACCO CESSATION FUNDS - Out of the funds to be provided by the industry, $_____ 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. MEDICAID REIMBURSEMENT FUNDS - Out of the funds to be provided by the industry, $_____ would be used to reimburse the states for tobacco-related Medicaid costs. An outstanding issue is what to do with the "federal" portion of these funds. One option is to allow the states to keep the federal portion if they use the money to fund the President's children's health initiative.

9. "LOOK BACK" PROVISION - 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.

10. FDA JURISDICTION -

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 recordkeeping, 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 products[1] 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 mislead 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

[1] An exemption will be grand fathered 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.

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 twelve (12) 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 available that are 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 twelve (12) 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.

11. CIVIL LIABILITY - (to be added later)

Tobacco - settlement

Summary of Tobacco Settlement Proposal
-- DRAFT --

Industry Financial Commitment

Total commitment of about $370 billion over ~~10~~ 25 years, including up-front commitment of $10 billion in ~~"punitive damages"~~ to HHS and annual payments as outlined below. 2 years one through 4, annual payments of 6, 8, 10 and 12 billion.

Annual Payment ~~for 25 Years~~ 25 plus	Funds Transferred To	Use of Funds
$8 billion	All States and HHS (Fed gov't share is 57%)	Reimburse Medicaid costs. Specifically provides $20 billion over 5 years to fund children's health coverage at level of Hatch-Kennedy
$4 billion	Individual plaintiffs (any annual excess will go to HHS)	Liability awards
~~$1.0~~-1.5 billion	HHS, USDA	Counter advertising; smoking research; farmer transition program
~~$1.0~~-1.5 billion	HHS	Smoking cessation and state and local tobacco control programs (ASSIST expansion)

Public Health Provisions

FDA Authority. This is a critical issue still under discussion. While preserving FDA regulation of tobacco as a "drug-delivery device" under the Food, Drug, and Cosmetic Act, the negotiators have considered placing some limits on FDA's ability to regulate nicotine and other cigarette ingredients in the next 12 years, and modifying the regulatory criteria and process somewhat.

Youth Access Restrictions. Codifies FDA rule. In addition, among other things: bans all vending machines, requires tobacco products to be behind the counter; and establishes a nationwide licensing system for tobacco retailers with graduated penalties and supervision. FDA and state attorneys general would have joint enforcement authority over FDA provisions, and industry would fund enforcement effort. May prohibit FDA from modifying agreed-to provisions for up to 7 years.

Marketing and Advertising Codifies FDA rule. In addition, among other things: eliminates all billboards and outdoor signs; eliminates all human images and cartoon characters from all advertising and from all cigarette packages; places further restrictions on store placement of ads; prohibits product placement in movies and on TV. FDA and state

attorneys general would have joint enforcement authority over these provisions, and industry would fund enforcement effort. May prohibit FDA from modifying agreed-to provisions for up to 7 years.

Counter advertising Funds a national, sustained counter-advertising campaign, similar to previous campaigns in California and Massachusetts.

Health Warnings. Revises the warning label system. Requires new black and white Canadian-style warnings occupying at least 25 percent of the front of the package. New possible warnings include: "WARNING: Cigarettes are Addictive;" and "WARNING: Smoking Can Kill you."

Smoking Cessation. Industry would provide funds to the Federal government to subsidize smoking cessation programs for those who want to quit.

State and Local Tobacco Control. Industry would fund state and local tobacco control activity modeled on HHS's ASSIST program. The grant program currently covers a limited number of states, and would be expanded to all states.

Environmental Tobacco Smoke. Embraces Congressman Waxman's proposal to restrict tobacco use in public places and most workplaces to locations separately ventilated to the outside that non-smokers don't pass through. Exempts bars and certain restaurants.

Industry Accountability and Disclosure

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 is $80 million per percentage point under target.

Document Disclosure. All documents ~~which~~ would ~~have been revealed through the litigation process would~~ be made public and the industry would make public its health-related research in the future.

Monitoring of Corporate Behavior. To ensure industry complies with the law, manufacturers would be required to develop detailed compliance plans; corporations would be required to set up incentive plans to encourage compliance; and industry would be required to use auditors and report on behavior to shareholders.

Liability

Right to Sue/ Limitation on Damage Awards. Does not abridge rights of individuals to sue, but limits individual damage awards to no more than $1 million in one year. Prohibits class action suits. Sets up $4 billion annual fund for liability payments. Prohibits punitive damages for past actions. ~~Industry would make one-time $10 billion "punitive" payment to the Federal government for past behavior.~~

Tobacco - settlement

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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.

Tobacco – settlement

THE WHITE HOUSE
WASHINGTON

June 18, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: BRUCE REED
ELENA KAGAN

SUBJECT: TOBACCO STATEMENT

Attached is a new draft of a statement on tobacco, reflecting our meeting this afternoon.

EK/BR I still think that this is unnecessary – esp. given recent developments – but this is a good iteration. POTUS's intent. We should vet this w/ someone who knows about Cong'l legislation – HHS??

We understand that the Attorneys General are considering whether to provide the tobacco industry with protection from punitive damage awards in exchange for further concessions on the part of the industry to protect the public health. If the Attorneys General conclude that they have gotten sufficient extra concessions from the industry to merit giving up on punitives, then we will respect their judgment and not oppose the settlement on this basis. For us, the key question has never been whether a settlement will allow smokers and their lawyers to receive damages above actual losses; the key question is whether the settlement will advance the public health and, in particular, keep children safe from the harm of tobacco products.

We are not now in any position to determine whether the entire settlement advances the public health, because we have not yet had a chance to review the actual terms of any settlement agreement. We will subject any settlement to rigorous evaluation and review, including consultations with outside experts, to decide whether the terms, taken as a whole, are in the interest of the public health. We will be particularly attentive to the piece of the settlement agreement dealing with FDA jurisdiction. The actions the FDA has taken under this Administration forced the industry to the bargaining table, and we will insist that the FDA has all necessary authority to regulate nicotine and tobacco products.

We must recognize that implementation of any agreement will need Congressional approval and that Congress may attempt to modify the agreement's terms. Even if we determine that the agreement as drafted by the parties fully protects the public health -- and we have not now made this determination -- we also must be satisfied that the implementing legislation advances this interest. Accordingly, we will oppose any part of the agreement going into effect until Congress has sent us the implementing legislation in a form that meets our requirements.

George Phillips - 6/18/97 Tobacco - settlement

Phenomenal deal - give us much beyond what we'd ever get - then administrative.

e.g. funding to do anti-smoking campaign.
(late 60s - ads had enormous impact)
FDA had such proposal - OLC said indefensible.

- bans all billboards
- what it takes away: FDA ding levels of nicotine. e.g. of what findings are necessary. Prob OK.
- 10-12 yr gap to eliminate. OK, really.
- pun damn - They've never lost. They're paying enorm. sum - equiv. of p.d. payments item. the "p d" - goes to pub - not windfall to TIs.

this is punishment. (no double-count)

- Why so nervous? (Committee)
  Once they've said: yes, it causes harm.
  Then max. chances will ↑ because
  of whole settlement.

$ - June thru agreement.
  Leg would authorize
  HHS to accept.

All sp. restrictions also in consent decree.

Keep leg stuff to basics.

W/out settlement - won't get these things.

Views generally shared w/in DOJ

Advert arg - really tough. We've about
~~50-50 probably going to lose~~ (depends on
"distrib, sale + use"
panel); then contr arg - some
restrictions prob will be modified,
but many OK.

Chance to move ball really forward on kids -
doesn't preclude other stuff but that's major change of goals

People have gotten optimistic - but there's been so much success.

But we really can't get a lot of those things w/out a settlement

And in timing - long time even if we win before ruling will go into effect. Might be as much as 5 yrs (as little as 18 months)

Walter Dellinger 4/18/97 Tobacco – settlement

Feel very sharply – pure taxes don't serve any pub health functi– in this context.

– deterrent functi– pure taxes – but not here. Resolving this prob. we need to rely on p.d.
– this ~~same~~ as not true we know – completely diff context. This is very particular. No precedent.
– to take any of this $ + use it as lottery windfall for its doesn't serve pub health goal.

This should not be dealbreaker.

They're at the table – we're trying to resolve this by making them pay – this payment should be used for public purposes, not as windfall to particular FTs

Tobacco – settlement

Elizabeth Drye
06/18/97 10:55:28 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:
Subject: Hand out for 12:00, for your review

Outline of Working Group Analyses

I. Brief description of issue area(s)

II. Public health/public interest goals (e.g., effect on children's smoking, adult smokers, addictiveness/safety of product, recovery of Medicaid costs, etc.)

III. Long-term analysis without a settlement

A. Current and planned activities (expected benefits; timing; litigation risk)

B. Additional possible actions (expected benefits; pros and cons)

IV. Long-term analysis with a settlement

Tobacco-settlement

Q&A on Tobacco Settlement
June 20, 1997

Q. Did the Administration help close the deal?

A. No. My staff monitored the talks closely so that we would be in a position to evaluate and respond to any possible settlement. We consistently told the parties that they would have to close an agreement on their own, and they were able to do so without any help from the Administration.

Q. How will you proceed?

A. I have asked my Domestic Policy Advisor, along with the Secretary of Health and Human Services, to undertake a thorough public health review of this agreement. They will consult with all interested agencies, members of Congress, and the public health community.

Q. How long will the review take?

A. The review will take as long as necessary to conduct a careful analysis, but we will seek to work promptly and expeditiously. We expect this to be a matter of weeks, not months.

Q. Dr. Kessler and Dr. Koop have asked in a letter to you that you give them 30 days to complete their own review before signing off on anything. Are you going to wait?

A. I intend to consider closely the views of the public health community, including Drs. Koop and Kessler, before rendering any judgment on the settlement. But it is premature to commit to any firm timetable for reaching my conclusion.

Q. What will you look at in evaluating this agreement?

A. We will evaluate whether this agreement protects the public health -- and particularly the health of our children. We will pay special attention to the part of the agreement dealing with FDA jurisdiction. The actions the FDA has taken under this Administration forced the industry to the bargaining table, and we will insist that the FDA has all necessary authority to regulate nicotine and tobacco products. We also will carefully review the financial terms of the settlement, including whether the money will go toward protecting the health of our children and the general public.

Q. The final deal limits punitive damages -- a key concession to the tobacco

industry. Won't you oppose that given your previous opposition to caps on punitive awards?

A. The limitation on punitive damages for past misconduct is not a deal-breaker for us. We understand that the attorneys general extracted substantial concessions from the tobacco companies for this limitation, and we will evaluate whether the agreement as a whole advances the nation's public health interests.

Q. Are you taking a political risk in considering approval of this settlement?

A. This isn't about politics; it's about protecting the public health. We didn't think about politics when we took on the tobacco companies last year with our announcement of the FDA rule. And we won't look to politics now in evaluating this agreement.

Tobacco - settlement

SUMMARY OF THE PROPOSED RESOLUTION

The proposed resolution, which would be implemented through legislation and a binding contractual protocol to be entered into by participating members of the tobacco industry, mandates a total reformation and restructuring of how tobacco products are manufactured, marketed and distributed in the United States:

(1) by seeking to prevent underage access to, and dramatically reduce underage use of, tobacco products;

(2) by confirming the Food & Drug Administration's authority to regulate tobacco products under the Food, Drug and Cosmetic Act, with certain provisions applicable to tobacco products;

(3) by mandating changes in the corporate culture of tobacco companies;

(4) by setting national requirements limiting smoking in public places (with State and local governments remaining free to set more stringent requirements);

(5) by requiring that the participating members of the tobacco industry pay hundreds of billions of dollars to fund medical research; public education; cessation programs; health-care costs incurred by federal, state and local governments; and federal and state enforcement of the restrictions imposed by the proposed resolution;

(6) by preserving the rights of individuals to sue the tobacco industry;

(7) by ensuring that members of the tobacco industry who seek to avoid the strictures of the new regime will be held fully accountable for any injuries their products may cause; and

(8) by establishing a comprehensive regime of federal regulation and federal and state enforcement to implement these requirements.

The principal details follow.

1. Prevention of Underage Use of Tobacco Products

The proposed resolution strikes at the core problem of underage consumption of tobacco products. The Food & Drug Administration ("FDA") and other public health authorities have concluded that virtually all new consumers of tobacco products are under legal age. The proposed resolution attempts to cure what the FDA has termed a "pediatric disease" by drastically curtailing advertising and marketing practices that have been criticized as appealing to minors; by imposing strict controls restricting the sale of tobacco products to adult consumers only; and by requiring dramatic reductions in the levels of underage use, with the tobacco

industry to pay substantial economic surcharges if the required reductions are not met. In so doing, the proposed resolution incorporates all of the restrictions in the current FDA rule, and in many instances goes substantially beyond them.

A. Curtailment of Advertising

With the specific consent of the tobacco companies participating in the proposed resolution, virtually all forms of non-text tobacco advertising accessible by adolescents will be banned. The proposed resolution would, among many other things:

1. Prohibit use of human images and cartoon characters -- such as *Joe Camel* and the *Marlboro Man* -- in all tobacco-product advertising.

2. Ban all outdoor tobacco-product advertising, including advertising in enclosed stadia and advertising inside a retail establishment that is directed outside.

3. Except for advertising in adult-only facilities or adult publications, limit tobacco-product advertising to black text on a white background.

4 Ban sponsorships (including concerts and sporting events) in the name, logo or selling message of a tobacco brand.

5. Ban all non-tobacco merchandise (such as caps, jackets and bags) bearing the name, logo or selling message of a tobacco brand.

6. Ban direct or indirect payments for tobacco product placement in movies, television programs and video games.

7. Prohibit direct and indirect payments to "glamorize" tobacco use in media appealing to minors, including live and recorded music performances.

8. Prohibit tobacco-product advertising on the Internet unless it is designed to be inaccessible in or from the United States.

B. Access Restrictions

The proposed resolution will also sharply restrict adolescents' access to tobacco products. Without preventing state and local governments from imposing stricter measures, the proposed resolution would incorporate every access restriction embodied in the current FDA rule, and would add additional significant restrictions. The access restrictions include:

1. Setting a minimum age of 18 to purchase tobacco products.

2. Establishing a requirement of face-to-face transactions for all sales of tobacco products.

3. Requiring retailers to check photo identification of anyone under 27.

4. Banning all sales of tobacco products through vending machines.

5. Banning self-service displays of tobacco products except in adult-only facilities.

6. Banning the distribution of tobacco products through the mail except for sales subject to proof of age (with subsequent FDA review to determine if minors are obtaining tobacco products through the mail).

7. Imposing retailer compliance obligations to ensure that all displays, advertising, labeling, and other items conform with all applicable requirements.

The access restrictions would be coupled with an entirely new system of enforcement to ensure that these provisions are meaningful in practice. The proposed resolution mandates minimum federal standards for a retail licensing program: any entity that sells directly to consumers -- whether a manufacturer, wholesaler, importer, distributor or retailer -- would need to obtain and maintain a license. Sellers would be subjected to stiff penalties and potentially to suspension or loss of their licenses if they do not comply with the access restrictions. The federal government and state and local authorities would enforce these access and licensing provisions through funding provided by annual tobacco industry payments.

The proposed resolution also contains powerful economic incentives for the states to do their part to reduce underage tobacco use and to enforce the access restrictions. States are required to achieve levels of compliance with the access restrictions within their borders of 75% by the fifth year after enactment of the proposed resolution, 85% by the seventh year and 90% by the tenth year and each year thereafter. States that fail to do so would lose a significant portion of the health-care program funds that would otherwise be allocated to them out of the payments to be made by the tobacco industry (which are described below). Funds withheld from states on this basis would, in turn, be reallocated to those states that demonstrated superior "no sales to minors" enforcement records.

C. "Look Back" -- Economic Surcharges on the Tobacco Industry if Underage Use is not Greatly Reduced

The proposed resolution would give the tobacco industry powerful economic incentives to further the goal of dramatically reducing underage tobacco use by imposing surcharges on the industry if required reductions are not achieved. The proposed resolution's "look back" provision establishes steep required reductions in the level of underage tobacco use from estimated levels over the past decade: for underage cigarette use, 30% by year 5 after

enactment of the proposed resolution, 50% by year 7 and 60% by year 10, with incidence remaining at such reduced levels thereafter; for underage smokeless tobacco use, 25% by year 5, 35% by year 7 and 45% by year 10, likewise with incidence remaining at such reduced levels thereafter. (These required reductions amount to even steeper declines from estimated current levels of underage cigarette use.)

For any year in which these required reductions are not met, the FDA must impose a mandatory surcharge on the participating members of the industry in question (cigarette or smokeless tobacco) based upon an approximation of the present value of the profit the companies would earn over the lives of all underage consumers in excess of the required reduction (subject to a $2 billion annual cap for the cigarette industry (as adjusted for inflation) and a comparably derived cap for the smokeless tobacco industry). Tobacco product manufacturers could receive a partial refund of this surcharge (up to 75%) only after paying the assessed amount and only if they could thereafter prove to the FDA that they had fully complied with the resolution, had taken all reasonably available measures to reduce youth tobacco usage and had not acted to undermine the achievement of the reduction goals.

2. Regulation of the Tobacco Industry

The proposed resolution mandates new warning labels, requires the industry to disclose research on the health effects of its products and information about non-tobacco ingredients, makes industry-funded cessation programs available to persons who want to quit, and endows the FDA with extensive regulatory powers over the tobacco industry in this country.

A. Warnings and Labeling

The proposed resolution first requires a new set of rotating warnings to be placed on packages of tobacco products. Their content -- such as "WARNING: Smoking can kill you" -- follow requirements in other countries, such as Canada. Their location is to be more prominent than previous warnings: 25% of the front of cigarette packs (at the top of the pack) and 25% of the principal display panel of smokeless tobacco products.

In addition, the proposed resolution would expand the health warning concept as applied to advertising. For example, without limiting the FDA's normal rulemaking authority, the proposed resolution (1) would require that use of currently employed descriptions such as "low tar" and "light" be accompanied by a mandatory health disclaimer in advertisements; and (2) prohibit the use of any health claims without review by the FDA. The FDA would also have the corresponding power, but not the obligation, to modify advertising restrictions with respect to tobacco products that it concludes present sufficiently reduced health risks.

B. Disclosure of Health Research and Information

To ensure access by the FDA to full information about the health effects of

tobacco products, the proposed resolution imposes a series of comprehensive disclosure obligations on the tobacco industry. First, the industry is required to disclose to the FDA previously confidential internal laboratory research relating to health, toxicity, addiction and drug dependence, and is under a continuing obligation to disclose to the FDA all such research generated in the future (with protection for proprietary information and applicable privileges). Second, industry documents produced (or to be produced) in the pending Attorney General actions and other litigations relating to smoking and health, addiction or nicotine dependency, "safer" or "less hazardous" cigarettes and underage tobacco use and marketing will be made available to the public in a national tobacco document depository. To the extent the industry continues to assert that any such documents are covered by privileges or protections, the proposed resolution provides for a binding, fast-track procedure by which any interested person may challenge such assertion before a specially appointed federal court. Finally, any subpoena authority that the FDA has with respect to manufacturers of other devices would also apply to tobacco manufacturers.

The proposed resolution also institutes new and greatly expanded disclosure obligations with respect to non-tobacco ingredients. The tobacco industry is required to disclose to the FDA the identity and amount of non-tobacco ingredients used in each brand. The industry is also required to disclose ingredient information to the public to the same degree that current federal law requires for food products (roughly, the identity of ingredients -- other than flavorings -- in descending order of quantity).

C. Cessation Programs

The proposed resolution provides funding for people who want to quit using cigarettes or smokeless tobacco. The proposed resolution authorizes the FDA to accredit cessation programs and techniques that it determines to be effective. Those cessation programs and techniques are then to be made available to members of the public, to be paid for by funds provided under the proposed resolution by the tobacco industry.

D. Regulation of Tobacco Products

The proposed resolution would impose a regulatory regime to govern the manufacturing, content and development of tobacco products in this country. This regime would include FDA approval of the ingredients used in tobacco products and the imposition of standards for reducing the level of certain constituents, including nicotine.

First, the proposed resolution subjects the tobacco industry to the "good manufacturing practice" standards comparable to those applicable to other FDA-regulated industries, but tailored specifically to tobacco products. These standards include requirements regarding quality control systems, FDA inspections (including inspections of facilities and certain records), and record-keeping and reporting. At the same time, the proposed resolution makes clear that tobacco farmers face no greater regulatory burden than the producers of other

raw products regulated by the federal government.

Second, the proposed resolution greatly expands federal regulatory authority over the non-tobacco ingredients used in tobacco products. In addition to requiring full disclosure of these ingredients to the FDA, the proposed resolution requires manufacturers to submit within 5 years a safety assessment for ingredients currently used, and to obtain the FDA's preapproval for any new ingredients. The FDA would have authority to disapprove an ingredient's safety. In connection with this process, manufacturers are required to have procedures for the selection, testing, purchase, storage, and use of ingredients; to keep records regarding the foregoing; and to allow FDA access to such records, with protection of proprietary information.

Finally, the proposed resolution gives the FDA substantial authority over product development by imposing a regulatory regime that would, among other things, set standards for the reduction of certain constituents, including nicotine, to encourage the development of "reduced-risk" tobacco products.

3. Changes in Corporate Culture

The proposed resolution requires fundamental change in the way participating members of the tobacco industry do business in order to ensure that they comply with the spirit, as well as the letter, of the proposed resolution.

Participating manufacturers are required to create, and to update each year, plans to ensure compliance; to identify ways to reduce underage use of tobacco products; and to provide internal incentives for reducing underage use and for developing products with reduced risk.

Participating manufacturers must also implement compliance programs setting compliance standards and procedures for employees and agents that are reasonably capable of reducing violations. These programs must assign to specific high-level personnel the overall responsibility for overseeing compliance; forbid delegation of substantial discretionary authority to individuals who have shown a propensity to disregard corporate policies; establish training or equivalent means of educating employees and agents; and institute appropriate disciplinary measures and steps to respond to violations and prevent similar ones from recurring.

Participating manufacturers are further required to take affirmative steps to inculcate the spirit of the new regime. They must promulgate corporate principles that express and explain the company's commitment to compliance, reduction of underage tobacco use, and development of "reduced-risk" tobacco products. They must work with retail organizations on compliance, including retailer compliance checks and financial incentives for compliance. And they must disband industry associations that have been criticized by public health authorities, and may only form new ones subject to strict oversight of their activities.

Companies would be subject to fines and penalties (including "Scarlet Letter" advertising) for breaching any of these obligations. To assist with enforcement, companies must direct their employees to report known or alleged violations to the company compliance officer, who is in turn required to provide reports to the FDA. Finally, "whistleblowers" in the tobacco industry will be provided with the maximum protection available under current federal statutes.

4. Nationwide Standards To Minimize Involuntary Exposure To Environmental Tobacco Smoke

The proposed resolution mandates the first federal minimum standards governing smoking in public places or at work (with states and localities retaining power to impose stricter requirements). It:

- Restricts indoor smoking in "public facilities" to ventilated areas with systems that exhaust the air directly to the outside, maintain the smoking area at "negative pressure" compared with adjoining areas and do not recirculate the air inside the public facility.

- Ensures that no employee may be required to enter a designated smoking area involuntarily while smoking is occurring.

- Exempts restaurants (other than fast food restaurants) and bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants and prisons.

The Occupational Safety and Health Administration would have authority to enforce these restrictions.

5. Payments by the Tobacco Industry

The proposed resolution requires those companies to pay hundreds of billions of dollars to fund federal and state enforcement efforts; to provide funds to federal, state and local governments for health care needs and research; to provide payments that yield public benefits and thereby resolve punitive damages claims that otherwise might be asserted in litigation based on past conduct; and to pay for the expenses related to the administration of the Act.

A particular priority for these expenditures is to fund a variety of public and private, non-profit efforts to discourage minors from beginning to use tobacco products and to assist current tobacco consumers in quitting. Those programs include research, public education campaigns, individual cessation programs, and impact grants to communities and individuals affected by the Act.

The participating companies are required to make an aggregate $10 billion payment on the date of the proposed resolution's enactment. Thereafter, they are to make

specified annual payments tied to volume of domestic sales; these payments will be increased to reflect inflation and are to continue for as long as the companies continue to sell tobacco products in this nation. (If the industry's specified annual payment is to be reduced in a given year as a result of a decline in volume, but the industry's profit for that year is larger than its 1997 profits (as adjusted for inflation), the reduction in the annual payment due to the decline in volume would be offset to the extent of 25% of the increase in profit.) At current levels of sales, the proposed resolution requires total payments of $368.5 billion over the first 25 years and $743.5 billion over the first 50 years (subject to credits described below in connection with potential civil tort liability). These payments are separate from any surcharges required under the "look back" provision discussed above. These payments would be the joint responsibility of the participating companies, would receive priority in any bankruptcy or reorganization proceeding, and would be the obligation only of a company's manufacturing entity selling domestically. All payments under the proposed resolution (including any pursuant to the "look back" provision) are ordinary and necessary business expenses for the year of payment, and no part thereof is either in settlement of an actual or potential liability for a fine or penalty (civil or criminal) or the cost of a tangible or intangible asset.

The payments would be allocated among the programs and entities referred to above. The proposed resolution contemplates that the companies would then pass the annual payments through to consumers in order to promote the maximum reduction in underage use.

6. Preservation of Right to Sue

In addition to mandating the payments described above, the proposed resolution preserves individuals' right to sue the tobacco industry. In return for the enormous public health benefits and monetary payments described above, the proposed resolution instead affords the participating companies with protection from civil liability in the following ways.

First, the proposed resolution settles the present governmental and parens patriae actions, and bars similar actions from being maintained in the future. It also settles the currently pending class actions, to the extent they are not reduced to final judgment prior to enactment of the Act. Addiction claims are likewise settled.

Second, the proposed resolution preserves access to the tort system by individuals. Existing legal doctrine regarding the type of tort claims that can be brought, as reflected in the Supreme Court's Cipollone decision, is also preserved. Claims could not be maintained, however, on a class or other aggregated basis, and could be maintained only against tobacco manufacturing companies (and not their retailers, distributors or affiliated companies). In addition, claimants could seek punitive damages only with respect to claims predicated upon conduct taking place after enactment of the proposed resolution, since, as noted above, part of the aggregate industry payments are in settlement of punitive damages claims. Finally, except with respect to already pending actions, third-party payor (and similar) claims could be maintained only on a subrogated basis.

Judgments and settlements arising from tort actions would be paid as follows: The proposed resolution sets an annual aggregate cap equal to 33% of the industry's annual payment (including any reductions for volume decline or increases for inflation). Any excess judgments or settlements above the cap in a year would roll over until the next year. Moreover, while judgments and settlements would run against the defendant, they would give rise to an 80-cent-on-the-dollar credit against the industry's annual payment. Finally, to ensure that the available funds are not allocated disproportionately, any individual judgments in excess of $1 million would be paid at the rate of $1 million per year unless every other judgment and settlement could first be satisfied within the annual aggregate cap. In all circumstances, however, the companies would remain fully responsible for costs of defense.

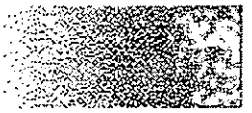
7. Enforcement

Finally, the proposed resolution provides for a comprehensive scheme of enforcement. Violations of the proposed resolution's requirements carry civil and criminal penalties based upon the penalty provisions of the Food, Drug and Cosmetic Act and, where applicable, the provisions of the United States criminal code. Special enhanced civil penalties attach to violations of the obligations to disclose research about health effects and information about the toxicity of non-tobacco ingredients -- up to ten times the penalties applicable to similar violations by pharmaceutical companies.

In addition, terms of the proposed resolution would be embodied in state consent decrees, giving the states concurrent enforcement powers. State enforcement could not impose obligations or requirements beyond those imposed by the proposed resolution (except where the proposed resolution specifically does not preempt additional state-law obligations) and would be limited to the penalties specified in the proposed resolution and by prohibition on duplicative penalties.

The proposed resolution is subject to the approval of the Boards of the companies involved.

Tobacco - settlement



Jerold R. Mande

06/19/97 08:35:38 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Elena Kagan/OPD/EOP, Elizabeth Drye/OPD/EOP
Subject: Write-up on $20B piece

Tobacco use causes a staggering national burden of premature illness and death. Each year, more than 400,000 Americans die from tobacco-related illness. In fact, tobacco alone kills more people in the United States each year than car accidents, alcohol, homicides, AIDS, illegal drugs, suicides, and fires combined

Equally troubling is that most adult smokers don't smoke because they choose to, but because they are addicted to a powerful drug -- nicotine. Mark Twain probably said it best: "It is easy to quit smoking, I've done it a hundred times." Almost 70 percent of adult smokers say they would like to quit completely. Unfortunately, for the overwhelming majority of smokers medical science has yet to devise a simple cure that will break their addiction. Today, the only reliable way we know to stop nicotine addiction is to prevent it from occurring.

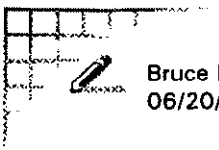
To address these two problems and to begin repayment to the country for knowingly addicting tens of millions of American children to its deadly product the industry will immediately pay $20 billion to the federal government to be spent over the next 5 years for the following public health measures:

- $2 billion a year for cancer research to double our effort to eradicate this disease once and for all;

- $1.2 billion a year for other biomedical research to help the millions of Americans suffering from a host of other chronic, debilitating, and fatal illnesses; and

- $800 million a year to better understand the addictive properties of nicotine and the best approaches for preventing addiction and helping people quit smoking. Research in this area would speed development of non-addicting, less-hazardous tobacco products and alternative nicotine delivery products. Tobacco use should be an adult choice, not an adult addiction. Adult smokers should be able to quit when they choose to.

For the last 30 years the tobacco industry has spent billions of dollars marketing a product it knew was the leading cause of preventable death and disability in the country. We have had to spend billions of dollars learning how to repair the lives they have broken. The tobacco industry must now make a sustained contribution to improving the nation's health through biomedical research.



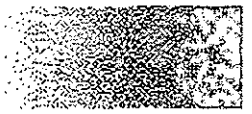
Bruce N. Reed
06/20/97 09:11:02 AM

Record Type: Record

To: Jerold R. Mande/OSTP/EOP

cc: Elena Kagan/OPD/EOP, Elizabeth Drye/OPD/EOP
Subject: Re: Write-up on $20B piece

That looks good. Would you settle for $25B over 8 years?



Jerold R. Mande

06/20/97 09:29:55 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

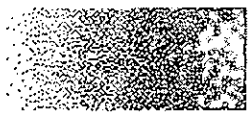
cc: Elizabeth Drye/OPD/EOP, Elena Kagan/OPD/EOP

Subject: Re: Write-up on $20B piece

That would leave 3.1/yr. Probably wouldn't be able to double cancer's budget . I'd say 26 over 7, but I know we aren't negotiating.

P.S. I need to double check the Twain quote.

Tobacco - settlement



Jerold R. Mande

06/20/97 05:13:59 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Elizabeth Drye/OPD/EOP

cc:

Subject: Here's a summary of the settlement from the Campaign's WWW page

Friday, June 20, 1997

1:30 p.m.

Summary of provisions that have been agreed to as part of the settlement agreement 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 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 agreement:

Each company will make specific changes in its position regarding the harm caused by its products.
At least as many, and very likely many more documents will be made public through the settlement process than would have been revealed through the litigation process. Also, the industry has agreed to make public its past, present and future health-related research.

6. Youth Smoking Targets

The industry would be subject to penalties if youth tobacco use fails to drop by 30percent in 5 years, 50 percent in 7 years and 60 percent in 10 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 each and every year in which the target is not met, up to a maximum of $2 billion per year. The baseline for measurement of youth smoking will be an average of youth prevalence rates for the past ten years. This will require a much more substantial reduction in youth smoking than would be required if only the most recent data were used to establish the baseline.

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 the 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 the 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 the 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 the 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 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's authority to regulate nicotine, carcinogens and all other tobacco constituents will be recognized. The agency will create a Science Advisory Board immediately to begin to study and advise how best to regulate nicotine and the other components of tobacco products. FDA will be authorized to remove harmful ingredients and to reduce nicotine levels immediately if it finds that to do so will reduce harm, is technologically feasible, and will not lead to a significant black market in unregulated tobacco products. Administrative procedures consistent with the Food, Drug and Cosmetic Act would apply. After 12 years, the Agency will be authorized to eliminate nicotine entirely, but to do so in a manner that gives Congress time to review it, if it so desires.
For the first time, all non-tobacco ingredients in tobacco products would be required to meet safety standards established by the FDA, with the burden placed on the industry to demonstrate that they are not harmful when used as intended. The safety standard will apply to new ingredients immediately, and to existing ingredients after a five year grace period.
Tobacco companies would be required to provide the FDA with complete information regarding tobacco additives, and would be required to disclose all additives publicly in a manner analogous to the disclosure of food ingredients. However, companies would be protected from disclosure of confidential and proprietary information to the public during the five year grace period.
Provisions are included to require tobacco companies to use the best available technology to produce and market "reduced risk" products.
Implicit health claims for tobacco products, including "low tar" and "low nicotine" products, will be strictly regulated by the FDA. Words such as "light" and that are part of currently established brand names would be allowed to continue, but with the addition of statements to prevent them from being misinterpreted as health claims.

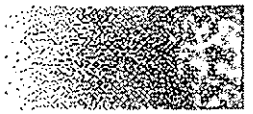
FDA would exercise its normal authority to inspect, enter manufacturing plants, demand certain records and record keeping, and would have its normal enforcement authority.
The tobacco industry would be required to provide FDA with all current and future research and all non-public information it receives that relates to health, toxicity, addiction and drug dependence.
The FDA would be required to create a Scientific Advisory Committee to study issues relating to the regulation of nicotine and other health and safety issues.

12. Tobacco Industry Liability and Other Legal Issues

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. Under the agreement:

The rights of individuals to sue for compensatory damages will not be abridged.
There will be no limits on individual judgments.
The tobacco industry would pay approximately $368.5 billion over 25 years, including approximately $60 billion in lieu of punitive damages for past conduct.
Funding includes approximately $1.5 billion for tobacco control purposes per year and a $25 billion trust fund, to be created over 8 years, to fund additional public health-related matters.
The tobacco industry would be fully liable for punitive damages for any future behavior.
Tobacco companies would be required to reserve $4 billion per year to pay for compensatory damages arising from individual lawsuits. The total amount the industry would be required to pay through litigation in any one year would be capped at $5 billion per year. It is highly unlikely that this fund would be exhausted in any one year. However, if this were to occur, 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.
The Attorneys Generals' lawsuits would be legislatively settled in return for these public health concessions, with the payment of a substantial sum of money to the states to reimburse them for the tobacco-related costs they have incurred. Funding provided to the states would be sufficient to extend health insurance to uninsured children consistent with proposals recently debated in Congress by Senators Hatch and Kennedy.
Class action lawsuits also will be legislatively settled in return for these public health concessions, and future class action lawsuits based on past conduct of the tobacco companies will not be allowed.
The tobacco industry will drop all pending lawsuits against the FDA, EPA and FTC.
The Tobacco Institute and the Council for Tobacco Research will be disbanded.

Tobacco - settlement



Jerold R. Mande

06/20/97 11:41:42 AM

Record Type: Record

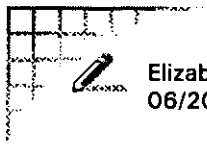
To: Bruce N. Reed/OPD/EOP

cc: Elizabeth Drye/OPD/EOP, Elena Kagan/OPD/EOP
Subject: If you talk to Matt

To add to the "Berlin Wall" list?

A major hurdle for nicotine researchers has been their inability to get research cigarettes. Scientists desperately need them. Tobacco companies have refused to manufacture cigarettes with specified levels of nicotine even though they have the ability to do so. If such cigarettes were available, scientists could probably figure out the right product modification strategy in less than 3 years.

Tobacco - settlement



Elizabeth R. Newman
06/20/97 03:45:41 PM

Record Type: Record

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

cc:
Subject: Statement by the President

THE WHITE HOUSE

Office of the Press Secretary
(Denver, CO)

For Immediate Release June 20, 1997

STATEMENT BY THE PRESIDENT

Less than one year ago, my Administration announced an historic rule to protect children from the harm caused by tobacco products. Two months ago, a court in North Carolina issued a landmark ruling confirming my decision that the Food and Drug Administration has authority to regulate tobacco products to protect our children's health. These victories for the public health drove the tobacco companies to the bargaining table and extracted concessions from them that would have been unimaginable just a short time ago.

I commend the attorneys general and other people working with them, including children's health leaders, for their hard work in negotiating this agreement in a way that seeks to advance our struggle to protect the health of children against the dangers of tobacco. They deserve our thanks for doing so.

We must now carefully consider whether approving this proposed settlement will protect the public health --and particularly our children's health --to the greatest extent possible. Until now, we have not had the opportunity to review the actual terms of the agreement, and we have not concluded whether it is in the best interests of the public health. Over the next several weeks, we will undertake a thorough public health review. I am asking Bruce Reed, my Domestic Policy Advisor --along with Donna Shalala, Secretary of the Department of Health and Human Services -- to engage in extensive consultations with the public health community and others to subject this agreement to the strictest scrutiny. They will

report to me on whether this agreement represents the best means of protecting the nation's public health interests.

In the meantime, we will fight as hard as ever to ensure that the FDA rule stands. Each day, 3,000 young people become regular smokers; 1,000 of them will have their lives cut short as a result. Protecting the health of the public and these children will be our measure of this proposed agreement.

-30-30-30-

Message Sent To: _____

Tobacco - settlement

6-17-97 Tobacco - Bruce/Bruce/TS

Arm twisting on nicotine regulation (BAT)
doc disclosure
whistleblower provision - protection for guys that got us here & others in future
Want WH involvement - help in extracting things - including getting $ up.
today - Press briefing - 3 contentious issues - (by Moore)
- punishment for past misconduct
- remain liable for individ - compens/punis
- nicotine issue - most contentious issue left
(not will fall our way)
Day of announcement - poss for cos. to take billboards down all around country??
Perilously close to going here.

priv TS - Matt going to Kennedy. (not until after this ~~~~~~~~~~~ only)
Is Matt on board? } giving TK chance to be white knight - save these negotiation

MM - Need for you to say something positive abt how we've resolved this issue. / Reas solution of punitive $.
Critical for pub health commun/some AGs

BL - We'd be signing onto underlying deal - at least as to $.
Approval piecemeal.
We still don't know what underlying #s are - add on doesn't mean anything if we don't know baseline.

Chesley - Came to BL w/ $, jurisdiction, tiers on punitives.

Not asking you to like deal

WH has to say - enough $ for kids health will go a long way to make deal OK.

Children's health v. punitive damages

Co - Cos. willing to have Koop on Kessler save on corp. compliance costs

DL - You should look at case this = come as close to Waxman bill as possible.

Add pieces that aren't known - e.g. on doc disclosure

Council Tobacco Institute / Council on Tobacco Research

Co - If we negotiate the $ figures

what happens?

If puns are not resolved on best end,

then puns are hammered out then the 3 who + The Times will back down.

AG - We won't say puns are gone in exchange for kids health until DL/Pres says it.

BL - 6 & 10 12 15 should be ramp up

KH comes on top of that.

Tobacco – settlement

4-24-97 Kessler/Tobacco

Must 1. something agreement

2. Political Pressure to get this done w/ the Cong.

Want a world: if can get bth ag, wine on board.

Substantive changes –

1. Nicotine – need some FDA lawyers / DOJ
   - can change new rules in 3 days
   burdens level of proof (preponderance gov)
   formal rulemaking hearings
   - MT think more abt timeframes
   Ask: how would you manipulate nicotine? want to
   then, give yourselves the authority.

2. How to make sure this will work – smokers ↓
   Performance standards; behavior influencing mechanisms
   If doesn't work – do you do more – e.g. go to plain pkg, ad bans, etc.
   one option is ↑d pens (not cap at 26)
   Ages 15-21 – focus on this.

   Let Waxman play on this.

3. Money
   Lean some of this to Hill – so they can get some input
   Have Pres focus on $ public health entities.

Tobacco - settlement

DRAFT - CLOSE HOLD
Questions and Answers on Review Process of Tobacco Proposed Settlement

Q How long will the Administration's review of the proposed settlement take?

A We're moving expeditiously, but you have to understand that this is a very complex undertaking. We need to have a thorough understanding not only of all the individual parts of this proposal, but also of how those parts interact with one another.

Q But didn't President Clinton ask for a report within 30 days?

A Well, we certainly expect to meet with the President within approximately 30 days to lay out for him the major issues our review has identified. But again, this is a very complex undertaking, and while we'll be moving forward with vigor, we're going to take as long as we need to get the job done right.

Q Why will the review take so long?

A This is an extremely complicated issue that has critical legal and public health ramifications for our children and our nation. Don't forget it took it took the parties involved in the negotiations four months to reach this proposed settlement. And it took the Department of Health and Human Services 12 months to draft and finalize the historic FDA final rule to protect children from the dangers of tobacco.

We must take apart the proposed settlement and carefully review every angle, and we must also determine whether the proposed deal as a whole advances the nation's public health interests and the progress we've already made to keep tobacco out of the hands of children. We intend to work expeditiously, but will not leave any stone unturned to ensure a good deal, not just on its own terms, but most importantly for the American people.

Q Why is it so complicated?

A There are a number of complex legal and public health issues related to the proposed settlement. For example, the Food and Drug Administration's jurisdiction over tobacco involves very complicated and important legal issues. With the President's leadership and the concrete steps the Food and Drug Administration already has taken, we are making progress in keeping tobacco out of the hands of children. But we want to continue with our lawsuit to make sure that the FDA rule stands. We do not want to do anything to jeopardize our court case. As the President has said, it is critical to protect our children by standing firm in our determination to ban the advertising and marketing of cigarettes that endanger their lives. That is why we must carefully review the part of the agreement that relates to the jurisdiction of the FDA.

This is also a critical public health issue. As the President has said, protecting the public health – and particularly our children's health – is and has always been our primary concern. We know that nearly 3,000 young people become regular smokers each day, and nearly 1,000 of these children and adolescents will die early from their use of tobacco products. We must do everything in our power to dramatically reduce smoking by young people because they deserve a life free from the disease that comes with using tobacco. We cannot support any agreement unless it meets this high standard set by the President – because no less than our children's futures are at stake.

Q But some people are already criticizing the proposed agreement, saying that it is deeply flawed and will need to be changed significantly. How do you respond?

A This massive agreement was only reached last week so we have not yet had enough time to carefully review all of the complex legal and public health issues that the proposed settlement raises. Over the next several weeks we will take the agreement apart and examine every angle, and we also must determine whether the proposed deal as a whole advances the nation's public health interests and the progress we already have made in keeping tobacco out of the hands of our children.

We will consider closely the views of the public health community, all interested agencies, members of Congress and others before rendering any judgment on the proposed settlement. We will work expeditiously, but will not leave any stone unturned to ensure a good deal, not just on its own terms, but most importantly for the American people.

Q Today the public health community attacked the proposed agreement saying that the future restrictions on the government to regulate nicotine are unacceptable. Do you agree?

A Again, this massive agreement was only reached on Friday so we have not yet had enough time to carefully review all of the complex legal and public health issues that the proposed settlement raises. We will conduct a rigorous review of each piece of the agreement, but in then end we must also determine whether the agreement as a whole represents the best means of protecting the nation's public health interests. We will consider closely the views of the public health community, all interested agencies, members of Congress and others before rendering any judgment on the proposed settlement.

But remember that this agreement was built in large measure on the President's bold leadership and the concrete steps the FDA already has taken to keep tobacco out of the hands of children. Last year's historic FDA rule to protect children from the harm caused by tobacco products and the recent landmark ruling upholding that rule in a North Carolina court, drove the tobacco companies to the bargaining table and extracted concessions from them that would have been unimaginable just a short time ago. We are keeping an open mind as we carefully review all of the complex legal and public health issues raised in the proposed settlement – including the issues relating to the jurisdiction of the FDA -- but we will not back away from our commitment to protecting children and the public health. We will not support any agreement unless it meets the high standard set by the President.

Q But what do you think of Koop/Kessler group's conclusion that the deal is "unacceptable?" Aren't their views the ones that will guide the President's decision?

A As we begin our own rigorous public health review, we appreciate the contribution of Doctors Koop and Kessler and the Advisory Committee on Tobacco Policy and Public Health. We look forward to working with the public health community and others to determine whether the proposed settlement upholds the President's highest objectives of protecting our children and the public health.

The proposed settlement raises numerous complex legal and public health issues that we will work conscientiously and expeditiously to review over the next several weeks. We will look closely at every angle to evaluate whether the proposed agreement as a whole advances the nation's public health interests, especially our children's health.

Q: How exactly is this process going to work?

A: We have decided to do our preliminary analysis by setting up four interdepartmental review panels. Each will include a member of the DPC and at least one representative of HHS. All panels will also have representatives of other departments, such as Treasury, Justice and Labor, as the subject matter suggests.

The four areas the panels will explore are regulatory issues, program and budget issues, legal issues, and industry issues.

The regulatory panel will primarily be sorting through the elements in the proposed settlement affecting FDA jurisdiction. It will also look at issues surrounding environmental tobacco smoke. In addition to HHS and the DPC, the Departments of Justice, Labor, Treasury, the General Services Administration and the EPA will be represented on this panel.

The program and budget panel will be looking at proposed uses of settlement funds, including the anti-smoking advertising campaign, grassroots programs, smoking cessation, and any issues that involve research on nicotine, tobacco and health and smoking cessation. In addition to HHS and the DPC, the Department of Treasury and the EPA will be represented on this panel.

The legal panel will be examining issues around liability, enforcement, compliance, and the disposition of tobacco industry documents. In addition to DPC and HHS staff, it will include representatives from a number of units within the Department of Justice, as well as the Departments of Treasury and Interior.

The industry issues panel will be examining the settlement's proposed targets, penalties and incentives; looking at any international impacts of the settlement; and doing an economic analysis. In addition to representatives of the DPC and HHS, the Treasury Department and the Council of Economic Advisors will be represented on this panel.

Q: Will this be the structure for the entire review period? Will each of these panels produce a report?

A: This process is our first cut at a framework for what is a very complicated legal and policy review. Over time, as we move from analysis of the individual issues to a process of synthesizing the issues and looking at the proposed settlement as a whole, the process may shift slightly.

It is unlikely that the panels will produce written reports. We will, however, try to lay out the issues for the President near the end of the process.

Q: What do you mean by an economic analysis? Do you mean trying to find out if the tobacco industry is being "punished" enough, as some have suggested?

A: It is our intention to see how the settlement would differ from the President's own proposal in this respect. We want to understand the effects on the U.S. economy of what the proposed agreement calls, "restructuring the tobacco industry."

Q: Will Bruce Lindsey play a role?

A: [Needed from White House]

Q: Have any of these panels met?

A: All of them have met at least once.

Q: Are the HHS representatives all from FDA?

A: No. Because of the complexity of the proposed settlement, the HHS team includes representatives from all of the agencies of the Public Health Service.

Q: What are some of the issues to be examined by the legal panel?

A: The plan proposed a retail licensing scheme that will, if enacted, cover tens of thousands of large and small sellers of tobacco.

The states are expected, according to the proposal, to enact corresponding licensing laws and to work with federal authorities to implement the various licensing laws.

So that panel will examine issues such as how the laws would work. What if a state failed to enact a state retail licensing law? How could enforcement be handled? Etc.

Q: Why is Treasury on the industry issues panel? What kinds of things will that panel do?

A: To give you just one example, the proposal establishes a number of pools of funds to be used for a variety of purposes. This panel will be making an inventory of those fund pools, learning where the money would come from to support the pools, identifying the purposes for which the different funds would be spent and understanding the mechanisms for dispensing money from the funds (in the proposed agreement, that function is sometimes to be done by a governmental agency, sometimes by an independent commission, sometimes by a group whose membership is specified in the proposal, etc.)

Treasury is involved in part because of those issues, and because the proposal treats the proposed tobacco company payments into these funds as ordinary business expenses, subject to tax treatment consistent with that designation. One important issue is the effects on United States' revenue collections of that structure for treating the tobacco company outlays.

Q: What exactly is the regulatory panel going to look at? Any specific issues there? The Koop/Kessler panel highlighted provisions requiring FDA regulators to prove that its future regulations would lead to measurable health benefits, and would not create a black market for cigarettes. Aren't those provisions clearly unacceptable?

In the proposed settlement, FDA is given many new authorities that may be opportunities for improving public health or may be burdensome obligations with insufficient public health benefit. The regulatory panel will at first be inventorying those new authorities to understand their net public health impact.

Overall, we will also be assessing the proposal's impact on FDA's regulatory powers. That is a very important issue for us. But we want to look at all of the issues before singling any one out for particular concern.

Q: What are some other issues? It still doesn't seem like the review should take so long.

A: Other issues include:

1) The proposal provides that some new laws will be enacted, some regulations created, 40 consent decrees signed by the parties in the Attorneys General state suits and that a national protocol will be drafted to fill in the gaps.

We are looking at the interface of all these legal instruments to understand the ways in which they are interdependent and whether they have stand alone enforceability.

2) The proposal places burdens on states, localities and tribes in many different contexts. We are combing the document to inventory all those burdens so we can assess their impact.

tobacco: settlement

Talking Points on Tobacco Settlement Talks

- The Administration is closely monitoring the settlement talks among the tobacco industry, state attorneys general, public health groups, and private lawyers. Any agreement would have to be passed by the Congress and signed by the President.

- We will carefully review any settlement that emerges from the discussions, and we will seek the advice of the public health community. As the President has said, in reviewing any settlement proposal, our focus will stay squarely on protecting kids and the public health.

Q. Is the Administration trying to help close the deal?

A. Absolutely not. The Administration is monitoring the talks closely, so that the President will be in a position to evaluate and respond to any possible settlement. But the Administration has not yet reached a judgment on the kind of settlement the parties appear to be discussing and is not trying to encourage or close the deal.

Q. Have you started to review the deal?

A. We have begun a thorough review of the provisions that may be in a final deal. We expect to spend the next couple of weeks analyzing the details as they emerge, and consulting with the public health community and others.

Q. How will the review work and how long will it take?

A. A number of the Federal agencies have a role in tobacco, so we will coordinate the review out of the White House. We will take as long as we need to take, but we will seek to work promptly and expeditiously.

Q. Dr. Kessler and Dr. Koop have asked in a letter to the President that you give them 30 days to complete their own review before the President signs off on anything. Are you going to wait?

A. The President has made clear that we would very closely consider the views of the public health community prior to rendering any judgment on a settlement, but we've been in contact with members of the community during the whole course of these discussions. We are not going to act before we know the views of the public health community, including Dr. Koop and Dr. Kessler, but we have not decided on any particular timetable.

Tobacco - settlement

Bruce R/Bruce L — From HHS - Humphrey meeting this morning. Elena

Remarks of Hubert H. Humphrey, III
Attorney General of Minnesota
The Advisory Committee on Tobacco Policy and Public Health
June 18, 1997

Thank you for permitting me to address you this morning. Just as importantly, I want to thank each of you for taking on the tremendous challenge and responsibility of serving on this historic committee. It would be hard to overstate the importance of your role.

We stand today at the most decisive moment in America's 300-year love-hate relationship with tobacco. For the first time in that entire history, and undoubtedly for the last time in our generation, we are on the brink of achieving enduring solutions to the most pervasive, most pernicious health problem of our time. In large measure, your work will determine whether America seizes that opportunity, or whether we instead squander the chance of a lifetime on well-meaning, *but inadequate, answers.*

It is not an exaggeration to say that *today* you are the guardians of the health of our children and grandchildren - - and of our parents, *as well*, because, this struggle must be about the children and the fifty million addicted adults in this country. That is a heavy responsibility, but one which I know you take very seriously, and which you are well-prepared to meet.

Many of you have spent long years in the trenches of the tobacco wars. Some are relatively new to the subject. But I trust all of you are aware of the painful history of America's well-intentioned but *naive* and *fruitless efforts* to bring this industry to bay. Time and time again over the decades we have thought the victory was ours; we have toasted their defeat, only to learn - - sometimes years later - - that we were bamboozled once more, and that the tobacco industry had cried all the way to the bank.

Thirty years ago, we celebrated when we "forced" these companies to put the Surgeon General's warning on the packs, only to learn now that they *desperately wanted* those warnings to protect them in the courtroom. We celebrated when we "forced" them to take their ads off of television, only to learn later that, by eliminating all the counter-advertising, we had actually helped them. Every time we think we're *dancing on this industry's grave*, they have instead found a way to keep dancing on those of our loved ones, by the hundreds of thousands.

Ladies and gentlemen, in my office we enforce the consumer protection laws of our state. Every day, 500 consumers call us about questionable deals they encounter in the marketplace, whether it might be a shady real estate deal, a high-pressure used car sale, or a crooked telemarketing come-on. We tell them four things I hope you will keep in mind when you review any so-called "megadeal."

First, we tell them: "get it in writing". Golden promises count for nothing. Second, we tell them: "read the fine-print." The sales pitch may sound great, but does the fine print give

away what the headlines promise? Third, we tell them to be suspicious of salesmen who say that you have to sign the deal today, and you can't take the time to think about it. And finally, we tell them: "***when it sounds too good to be true, it probably is***." In fact, that's often the best warning signal that it's time to get out your magnifying glass and a fine-tooth comb to find the hidden dangers.

If caution is appropriate when a consumer buys a car or takes out a mortgage, how much greater caution is in order when we deal with the greatest public health problem of our time?

We're counting on you to help us think this through. Not just to analyze and critique the sketchy proposal that's being brought forward. We're looking to you to help us think through, in the broadest sense, what this industry should look like when we win the tobacco wars. Make no mistake about it. We are winning. We're winning the legal skirmishes. We're winning the public debate. And more importantly, we're winning the hearts and minds of the American people. The only thing that can hold back the power of public sentiment is a "deal" that declares another false victory. The industry can only achieve that victory if we are lulled into complacency or if we fail to ask the tough questions.

So we're counting on you to ask all the hard questions and to take the time to get all the answers.

Let me suggest some of the questions I hope you'll consider:

First, "what's the rush?" Every day a new development [redacted] strengthens the public's position. In the next seven months, four states will go to trial. If anyone is worried about the strength of those cases, or about who should be first up to bat, I can tell you we'll be happy to go first in Minnesota, where our trial is set for January 19, if others would prefer to delay their cases to see how we do. We can't wait to tell a jury about the things we've found among the industry's secret documents. As our attorney likes to say, "they're not smoking guns. They're smoking howitzers."

Some people think all the important information is already out. I'm here to tell you: it isn't all out. The depth, the pervasiveness of this conspiracy and fraud is overwhelming. There has never been anything like it. I believe we owe a fundamental duty to future generations to see this through - - to make sure we don't settle until ALL the information is before the public.

Because of our court's orders, I can't talk about some of the things we're doing. But I can tell you that I read a newspaper report yesterday that says our attorneys deposed the former research director of Philip Morris on Monday and that he took the Fifth Amendment. Without my commenting on the accuracy of that report, I want you to think what will happen to public opinion, just a few months from now, if senior tobacco executives start parading before juries, and showing up on the evening news, invoking the Fifth Amendment whenever they're asked about whether they buried the technology to make cigarettes safer, or how they manipulated nicotine. At that point, this industry will be ready to sign a real settlement, on the public's terms, and not on the industry's terms.

Now, please understand. I do realize that time is of the essence because more kids start smoking each day. I'm not arguing that America should sit back for years until all the appeals are exhausted. But I hope you will also remember, that if we take just a little longer to see that the American people have all the facts, we won't need the tobacco industry's permission to hold it to the same rules that govern everyone else.

If we take just enough time to get it right, America can make the rules, and we won't have to trade away the rights of victims or the powers of the federal government to fashion a real solution. And that will save a lot more kids than locking ourselves in for 10 or 25 years or more to a horse-trade that guarantees this industry a profitable future well beyond our lifetimes.

Second, I hope you will insist that all the facts come out. I saw some bullet points of a deal last week that described what has supposedly been agreed to. I was distressed to see that my colleagues were seriously proposing to let the industry off the hook by *only* disclosing their internal scientific research documents. This is a perfect example of why you need to be suspicious of the short-hand or bullet-point summaries you will be getting. What this proposal would do in reality is let the industry keep secret the documents that count - - the ones where they've hidden the most important evidence about their products - - the documents they've hidden all these years behind claims of "attorney-client privilege." That's where the truth lies, including the truth about their scientific and medical knowledge.

Those are the key documents. They've never seen the light of day. We're on the verge of getting them in our Minnesota case. Our judge has ruled that the court's Special Master will be reviewing 500,000 pages of these documents to see which ones hold evidence of fraud and which ones are attempts to bury critical medical and scientific evidence that has been hidden for decades behind a shield of phony privilege claims.

Is this something you should care about, or is it just an issue for the lawyers? Let me give you an example. When Liggett and Myers settled with the states last spring, it agreed to drop the claim of privilege on its documents. That will give us a peek behind the privilege veil. Our Minnesota court is still sorting that out, but last week, Congressman Waxman released a Liggett document, which had been hidden for thirty years, that revealed that they spent $13 million dollars to develop a cigarette technology that virtually eliminated tumors in mouse-painting experiments, but that they buried the research.

If Liggett was finding things like that, what has Philip Morris got? Should we really consider a settlement that says they don't have to tell us, that they can shred those documents instead?

Third, I hope you'll ask tough questions about the money.

As far as I'm concerned, any settlement that sends tobacco stocks soaring can't be a good deal for America.

The leading Wall Street expert says Philip Morris stock will go up forty percent if we accept the deal under discussion. What's wrong with this picture, folks?

The experts tell us this industry can afford hundreds of billions more than any figure currently on the table. Experts say they can easily pay two dollars a pack, compared to the figures being discussed, which would work out to perhaps fifty or sixty cents per pack. The leading expert, Professor Jeff Harris at MIT, tells us the first two dollars a pack is essentially "free" to the industry, because they'll just pass it along in higher prices and won't even feel any pain *unless* the price is more than two dollars. So I hope you'll ask how much they can afford and how much they ought to pay. And of course, keep in mind that a higher per pack price for cigarettes can lead to significant reductions in smoking, especially among young people.

I also hope you'll ask whether any settlement places all the burden on addicted smokers, or whether the companies themselves ought to bear some of the burden, in the form of interrupted dividends, or sale of assets, or secondary stock offerings, rather than just shifting it to their customers.

I hope you'll ask whether the proposal does justice for the victims who have lost their health or their lives to this deadly product. I hear the proposal would bar class action settlements, which would isolate and impoverish any individual claimants foolish enough to challenge the world's most ferocious litigation opponent. This would virtually guarantee there will be no future impact litigation. Is that appropriate? Or necessary?

The proposal would guarantee the industry it will never have to pay more than $4 billion a year to its victims, even though the CDC tells us those victims suffer about $100 billion each year in medical costs and economic losses. Over time, with inflation, those losses will be $200 and $300 billion a year, but the proposed settlement would apparently shelter the industry behind a guarantee that its losses would be limited to $4 billion.

The $4 billion being proposed for victims would barely pay for a decent funeral for the 500,000 victims of tobacco and secondhand smoke we bury every year. I hope you'll ask whether that's enough.

I could go on, but you get the point. This is not the time for false urgency. *We need to slow down and get this right.* We need your Committee *to take all the time it needs to think carefully and thoughtfully.* Anything we set in place now will not be revisited in our lifetimes.

As public health leaders and advocates, I hope you will consider some key areas when looking at any deal, which I raised with my colleagues in a letter dated May 2:

- Does a settlement preserve full FDA jurisdiction over tobacco products and content, including nicotine?
- What will a settlement do for the nation's 50 million addicted tobacco users and do about rising smoking rates, especially among teens?
- Is the deal enforceable through the courts?
- Will the Tobacco Institute and the Council for Tobacco Research be allowed to continue their activities?
- Does a settlement incent the companies to develop less dangerous products?

Should we dawdle? Of course not. But we've squandered every opportunity that has come along in the past. We've lost thirty years and allowed this industry to bury millions of Americans because we didn't take the time to get it right. Let's not repeat that mistake, because we won't have another chance to get it right. Help America decide, objectively and with a clear eye, whether any settlement proposal is truly worth buying today, or whether we should do what it takes to get all the information, create real reforms and set a fair price for all the harm that's been done.

4-19-97 Skip Humphreys Mtg

Pub law of in print today

Trial date - Jan 1998

Done w/ discovery process except for priv q's.

Don't move so fast that you interfere w/ ability to get docs.

Best time for reports - when both sides know what other side has for.

Lot more $ + lot more info. → Haven't seen any agr. long

Each case diff. in this issue.

Minn's - stat fraud + antitrust statutes (state)

compare Miss - equitable doctrines

Also - need full FDA authority.

No special arrangements for tobacco industry.

Youth lookback $ - 80¢ per point.

Just a cost of doing business - not severe enough.

Nicotine control plus effective econ penalty - then, might get benefits

Advert doesn't make much diff -

Key is real econ penalty - to me real corporate penalty.

We'll go on. Perhaps combo of settlement and some suits will work to benefit of all of us - in developing coherent public policy.

Ind. can absorb significants of additional costs before cutting into profits.

The Advisory Committee on Tobacco Policy and Public Health

Co-Chairs: Dr. C. Everett Koop and Dr. David A. Kessler

1711 N St. NW
Washington, DC 20036
(202) 833-9500

June 10, 1997

Bill Clinton
President of the United States
The White House

Dear Mr. President,

As you may be aware, we have been asked by a bipartisan group of members of Congress to convene an advisory committee on national tobacco policy. This group, which is composed of the major public health and national tobacco control groups, was formed to develop a comprehensive and rational public health policy toward tobacco.

The Advisory Committee on Tobacco Policy and Public Health met for the first time last week. It is our intention to complete our work within the next 30 days and report back to those members of Congress.

On behalf of the advisory panel, we respectfully request that you refrain from taking a position on any proposed new tobacco control legislation that might emerge from the settlement talks until the public health community has had sufficient time and opportunity to examine and consider the implications of any such proposal.

For instance, at our meeting last week, members of our advisory panel were quite concerned about reported provisions that might ultimately limit the authority of the FDA in regulating the manufacture and marketing of tobacco products.

To assist you in your deliberations, the advisory committee has embarked on an intensive, collaborative effort to establish a comprehensive blueprint for a realistic national tobacco control policy that would be acceptable to the American public.

We believe the proposals that will be made by this panel will reflect the best advice and views of the public health community. Whether or not a settlement is reached among the lawyers, the nation needs a public health blueprint against which all policy decisions should be made. We fully expect to have this blueprint ready by early July.

We thank you for your consideration of this request and look forward to working with you on this important matter.

Sincerely yours,

C. Everett Koop, M.D.

David A. Kessler, M.D.

Tobacco - FTC proceedings

U.S. Department of Justice
Office of the Assistant Attorney General
Civil Division

George Jordan Phillips
Counselor to the Assistant Attorney General

950 Pennsylvania Ave., N.W., Room 3143
Washington, D.C. 20530
(202) 514-5713 Fax (202) 514-8071

June 18, 1997

HAND DELIVER TO THE FOLLOWING RECIPIENTS:

Mr. Bruce Lindsey
Assistant to the President
and Dep. Counsel
2nd Floor West Wing

Ms. Elana Kagan
Dep. Asst. to the Pres. for
Domestic Policy
Room 218, OEOB

Ms. Elizabeth Drye
Chief of Staff
Office of Policy Development
Room 266, OEOB

Mr. Charles Burson
Counsel to the President
Room 222, OEOB

Re: R.J. Reynolds Tobacco Company v. U.S. Federal Trade Commission, et. al., U.S. District Court, Middle District, North Carolina, 6:97CV00651.

Dear Bruce, Charles, Elana and Elizabeth:

Enclosed is a copy of the complaint filed yesterday at 4:30 p.m. by RJR to enjoin the Commission's Joe Camel proceeding. They did not ask for an immediate injunction and given our experience in the same court in the FDA case where the plaintiffs filed before FDA took final action, we assume that we will simply file a motion to dismiss based on the lack of any final agency action. In the FDA case the Judge never ruled on our motion but the lawsuit did not become active until the FDA issued the final regulation at which time the plaintiffs filed an amended complaint.

I also enclosed the press release that RJR issued yesterday to announce the filing of this lawsuit.

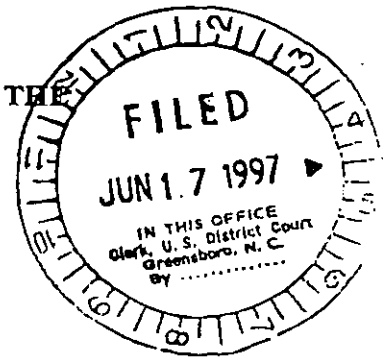
We have informed the FTC about this lawsuit.

Sincerely,

George J. Phillips

cc: Frank W. Hunger
Enclosures

IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF NORTH CAROLINA
WINSTON-SALEM DIVISION



R.J. REYNOLDS TOBACCO COMPANY

Plaintiff,

v.

UNITED STATES FEDERAL TRADE COMMISSION, and

ROBERT PITOFSKY
Chairman,

Defendants.

Civil Action No. _____

6:97CV00651

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

1. Plaintiff R.J. Reynolds Tobacco Company ("Reynolds") brings this action seeking declaratory and injunctive relief. Seven years of harassment, threats, political attacks, and investigation by the Federal Trade Commission ("FTC" or "the Commission"), culminating on May 28, 1997 in the *de facto* reopening of an investigation closed three years earlier and the issuance of an administrative complaint against Reynolds, violates the FTC's procedures, the Administrative Procedure Act, the Government in the Sunshine Act, and the Due Process Clause of the Fifth Amendment of the United States Constitution. Reynolds seeks an order requiring the Commission to abide by the procedures, rules, decisions, and statutes that govern the Commission's administrative actions.

2. Without this Court's intervention, the Commission's harassment and the

political interference will continue and intensify, the notice and opportunity to comment required under the FTC's procedures will be denied to Reynolds, and the disclosures required by the Government in the Sunshine Act and mandated by Congress will be suppressed by the Commission.

THE PARTIES

3. Plaintiff is a New Jersey corporation with its office and principal place of business located at 401 Main Street, P.O. Box 2959, Winston-Salem, North Carolina 27102.

4. Defendant Federal Trade Commission is an executive agency of the United States of America.

5. Defendant Robert Pitofsky is Chairman of the Federal Trade Commission.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 because the claims for relief arise under the laws of the United States and pursuant to 5 U.S.C. § 552b(h) because a claim for relief arises under the Government in the Sunshine Act.

7. This is an actual case and controversy under 28 U.S.C. § 2201 and 5 U.S.C. § 552b, and the Court has authority to grant the declaratory relief requested pursuant to 28 U.S.C. § 2202 and 5 U.S.C. §§ 706(2) and 552b. Finally, this is an administrative action reviewable pursuant to 5 U.S.C. §§ 701 *et seq.* and 552b(h)(1).

8. Venue exists in this district pursuant to 28 U.S.C. § 1391(e).

FACTUAL BACKGROUND

9. In 1988, Reynolds introduced an anthropomorphic illustrated camel named Joe to advertise and promote its Camel brand cigarettes.

10. Since 1990, the Commission has harassed Reynolds with a continuous series of investigations, including numerous demands for access to Reynolds' files and repeated threats of punitive sanctions for the use of Joe Camel. The harassment did not stop even after the Commission formally ordered the proceeding closed in a decision issued over three years ago.

11. On June 6, 1994, after four years of investigation, the Commission took final action, by a 3-2 vote, to close its investigation after determining that there was no "reason to believe" that the Joe Camel advertisements "would lead children to smoke or to smoke more." In so deciding, the Commission declared it had "spent a great deal of time and effort reviewing the difficult factual and legal issues raised in this case, including a comprehensive review of relevant studies and statistics," and it had considered "every possible avenue to a lawsuit."

12. Having determined that it was without reason to believe that Reynolds had violated Section 5 of the FTC Act, the Commission nevertheless renewed its pursuit of Reynolds beginning in April 1995. The Commission took this action in disregard of its June 1994 decision closing the investigation and without reopening such investigation pursuant to established procedures. It has since subjected Reynolds to numerous excessive demands for information.

THE INITIAL PROCEEDINGS

13. The Commission's investigation of the Joe Camel Campaign began on August 1, 1990, with the issuance of comprehensive Civil Investigative Demands ("CIDs") that required Reynolds to furnish, among other things,

a. All documents referring or relating to the Camel brands' target audience; and

b. All documents referring or relating to the Camel brand's advertising and marketing strategies.

14. Over the course of the next four years, Reynolds produced more than 30,000 documents and other items in response to the original and subsequent document requests, made witnesses available, and submitted reports from various experts.

15. Upon information and belief, during this period the Commission staff considered and rejected numerous different theories of liability.

16. On May 10, 1993, the Commission's Bureau of Consumer Protection notified Reynolds that it would recommend a complaint alleging that Reynolds violated Section 5 of the FTC Act by disseminating advertisements that appealed to underage smokers.

17. Upon information and belief, after the submission of additional evidence and analysis by Reynolds the Commission refused to issue the proposed complaint.

18. On March 2, 1994, the Bureau of Consumer Protection again notified Reynolds that it would recommend a complaint that alleged that Reynolds violated Section 5 of the FTC Act.

19. Again, the Commission rejected the staff recommendation. On June 6, 1994, by a vote of 3 to 2, the Commission directed the staff to close the investigation and took the extraordinary step of publishing the reasons for that final action:

> Although it may be intuitive to some that the Joe Camel advertising campaign would lead more children to smoke or lead children to smoke more, the evidence to support that intuition is not there . . . . Because the evidence in the record does not provide a reason to believe that the law has been violated, we cannot issue a complaint.

THE SUBSEQUENT PROCEEDINGS

20. The Commission's decision to close the investigation brought no relief from harassment for Reynolds. Instead, in 1995 the Commission staff once again initiated an investigation targeting the Joe Camel Campaign. This investigation continued for three more years. During this period, Reynolds received four additional document requests asking Reynolds to search millions of documents in its possession. These document requests involve time periods and categories of evidence that the Commission staff had previously determined Reynolds did not have to search. At no time, however, did the Commission staff provide Reynolds with notice and opportunity to be heard on the reopening of the investigative file, and at no time did the Commission follow its procedures and formally reopen the investigation.

21. The Clinton Administration and some members of Congress also expressed implacable opposition to the use of Joe Camel in advertising:

a. On October 16, 1995, the Food and Drug Administration proposed regulations that would ban the use of Joe Camel in virtually all advertising. 60 *Fed. Reg.* 53560 (Oct. 16, 1995).

b. On July 30, 1996, Congressman Tim Roemer sent a letter to the Commission, co-signed by 66 other Members of Congress requesting that the Commission "reopen and complete its investigation started in 1994."

c. On August 26, 1996, President Clinton, in announcing final FDA regulations, 61 *Fed. Reg.* 44396 (Aug. 28, 1996), stated "[w]ith this historic action today, Joe Camel and the Marlboro Man will be out of our children's reach forever."

22. On March 12, 1997, the staff notified Reynolds that it was again requesting the Commission to file a complaint against Reynolds. In so doing, the Commission staff failed to follow long-standing Commission practice by affording Reynolds an opportunity to rebut the

complaint allegations prior to forwarding its complaint to the Commission. This was at least the third proposed complaint by the staff against Reynolds since the initial CIDs issued in 1990.

23. On several occasions, Chairman Pitofsky informed Reynolds that, in accordance with Commission Rules (e.g., 16 C.F.R. §§ 2.31, 3.72), "new evidence" was the sole basis for the proposed complaint and that, if Reynolds wanted to be heard, it should immediately seek appointments with the Commissioners. Reynolds protested that it had not had an opportunity to meet with staff and that it was not offered enough time to produce evidence in response to the proposed new complaint, but nonetheless did so.

24. At meetings with the Commissioners, Reynolds again presented facts that showed that there was no legal or factual basis for the Commission to reverse its 1994 decision to close the investigation. As for the "new" evidence, Reynolds informed the Commission that a nearly completed national survey then being conducted by an independent research organization would show Camel's share of underage smokers to be nearly the same level Complaint Counsel claimed it was before the Joe Camel Campaign was conceived. This evidence directly contradicted a crucial paragraph of the proposed complaint.

25. On May 27, 1997, the office of Chairman Pitofsky requested additional information about the new survey. Reynolds explained that final results of the survey would be available on May 29, 1997.

26. On May 28, 1997, the Secretary of the Commission informed Reynolds that the Commission had met that day and voted 3-2 to issue a complaint alleging that the Joe Camel Campaign violated Section 5 of the FTC Act, 15 U.S.C. § 45. The Commissioners who were on the Commission in 1994 did not change their vote. The two Commissioners appointed by President

Clinton voted in favor of the complaint.

27. Upon information and belief, prior to its notification of Reynolds, the Commission had already notified numerous media outlets, Members of Congress, and Clinton Administration officials of the meeting and of a 2:00 p.m. press conference announcing the complaint.

28. At the press conference, Complaint Counsel described the "underage tracking data," which supported their "reason to believe" a violation of the law has occurred, as having been "available to the Commission at the time it made its original [1994] decision."

29. On May 28, 1997, Donna Shalala, Secretary for Health and Human Services, stated: "[t]he Clinton Administration is committed to kicking Joe Camel and others who glamorize tobacco products out of our children's lives."

30. On May 29, 1997, Reynolds received the expected survey results, which revealed that Camel's market share among underage smokers was 3 percent -- approximately the same level that Complaint Counsel claimed was its share prior to the advent of the Joe Camel Campaign.

31. On June 9th, 1997, Reynolds was served with document requests and interrogatories that would require the review of over four million pages spanning 25 years of Reynolds' operations.

COUNT 1

VIOLATION OF COMMISSION PRACTICE AND THE ADMINISTRATIVE PROCEDURE ACT

32. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1 through 31.

33. Upon information and belief, the Commission did not authorize a reopening of the investigation as required by Commission rules.

34. The Commission failed to follow its own Rule 2.31, 16 C.F.R. § 2.31(a), as well as its customary practice, which provide respondents an opportunity to submit relevant information prior to the recommendation of a complaint.

35. The Commission failed to follow its own Rule 3.72, 16 C.F.R § 3.72(b), which requires the Commission to justify the reopening of a Commission proceeding based on changes in fact, changes in law, or the public interest. Instead, without any new evidence that would contradict its prior conclusion, and in conscious disregard of exculpatory evidence, the Commission acted to open its investigation (*de facto*) and, as a consequence, issued an administrative complaint in response to political pressure from the Administration and Members of Congress.

36. The Commission's relentless investigation despite formal closure of its investigation on June 6, 1994, in disregard of its own rules and procedures, and its *de facto* reopening of that investigation in response to political pressure and without new evidence to contradict its prior decision, has so tainted the investigatory and adjudicative processes as to contravene the Administrative Procedure Act. 5 U.S.C. §§ 554, 556, and 706(2)(B),(D).

COUNT II

GOVERNMENT IN THE SUNSHINE ACT VIOLATION

37. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1 through 36.

38. The Commission's May 9, 1997 Notice of its closed May 28 meeting listed one item on the agenda: "Consideration of various courses of action in a nonpublic Part II matter."

According to the Notice, the Commission had voted unanimously on May 8, 1997 to close this meeting to the public.

39. Pursuant to the Government in the Sunshine Act, 5 U.S.C. § 552b, it is the practice of the Commission, when meeting to consider bringing a complaint, to provide notice that it will meet for "consideration of enforcement action in a nonpublic Part II matter."

40. The Commission's May 19, 1997 Notice announced the addition of a nonadjudicative matter to the Commission's meeting agenda for May 28, 1997: "Consideration of enforcement action in a nonpublic Part II [investigatory] matter."

41. On May 23, 1997, the Commission announced the deletion from the May 28, 1997 agenda of the nonadjudicative item that had been noticed on May 19, 1997.

42. The May 9, 19, and 23 Notices were not published in the Federal Register, nor did any of the three Notices designate an official (as well as the official's phone number) who would respond to inquiries about the meeting on May 28, 1997.

43. Upon information and belief, in no week over the past two years other than the week of May 26 has the Commission failed to provide meeting notices on its Website and on the FTC "Weekly Calendar and Notice of 'Sunshine' Meetings." The Weekly Sunshine Calendar for the week of May 26, 1997 was suppressed by the Commission until May 30 -- two days after the Commission vote.

44. Upon information and belief, the Commission did not vote at the beginning of its May 28, 1997 meeting to close that meeting. Even if such a vote were taken, it was never made public.

45. Upon information and belief, the Commission did not promptly make

available to the public the minutes or transcripts, or a portion thereof, of the May 28, 1997 Commission meeting.

46. Upon information and belief, the Commission never made available to the public the minutes or transcripts, or a portion thereof, of the June 6, 1994 Commission meeting. See supra paragraph 11.

47. The failure to announce its closed May 28, 1997 meeting, the failure to make public its vote at the beginning of that meeting to close that meeting, and the failure to make public any part of the transcript of the May 28, 1997 and June 6, 1994 meetings violate the Government in the Sunshine Act. 5 U.S.C. § 552b and 16 CFR § 4.15.

COUNT III

DUE PROCESS CLAUSE VIOLATION

48. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1 through 47.

49. The Commission has continuously investigated Reynolds' Joe Camel Campaign since 1990.

50. The Commission has failed to follow its own Rule 2.31, 16 C.F.R. § 2.31(a), as well as its customary practice, which provide respondents an opportunity to submit relevant information prior to the recommendation of a complaint.

51. The Commission failed to follow its own Rule 3.72, 16 C.F.R § 3.72(b), which requires the Commission to justify the reopening of a Commission proceeding based on changes in fact, changes in law, or the public interest.

52. The Commission has failed to follow its own Rule 4.15, 16 C.F.R. §

4.15(a)(4), which requires public notification of Commission actions.

53. The Commission's filing of a complaint in 1997 with no new relevant evidence was in response to direct political pressure from the President and Members of Congress.

54. The Commission's reopening of its investigation without new evidence, disregard for its own rules and procedures, and the filing of a complaint in response to undue political pressure has so tainted the investigatory and adjudicative processes as to contravene Reynolds' due process rights under the Fifth Amendment of the United States Constitution.

WHEREFORE, Plaintiff R.J. Reynolds Tobacco Company demands judgment against Defendants, Federal Trade Commission and Chairman Robert Pitofsky, as follows:

A. An Order declaring that (1) the decision to reopen the investigation of the Joe Camel Campaign on May 28, 1997, after nearly seven years of investigation, was invalid because of unreasonable delay, unlawful harassment, and undue political pressure, and is void under 5 U.S.C. § 706(2)(B) and (D); and (2) the decision to reopen the investigation of the Joe Camel Campaign on May 28, 1997 is contrary to established FTC practices and its own regulations and is void under 5 U.S.C. § 706(2)(D).

B. An Order requiring the Commission to close its investigation and withdraw its complaint against Reynolds regarding Joe Camel advertising and permanently enjoining the Commission from (1) holding an adjudicative hearing on the lawfulness of such advertising because of harassment and political interference; or (2) holding an adjudicative hearing on the lawfulness of such advertising without first complying with the practices and regulations of the Commission; and (3) granting such further relief as the court finds appropriate.

C. An Order declaring the Commission violated the Government in the Sunshine Act and its own Rules of Practice, enjoining the Commission from future violations of the Government in the Sunshine Act and its own Rules of Practice, requiring the Commission to provide Reynolds a full and complete copy of any minutes or transcript from its meetings on June 6, 1994, and May 28, 1997, as well as all other meetings pertaining to the Joe Camel Campaign, and awarding Plaintiff reasonable attorneys fees and other litigation costs pursuant to 5 U.S.C. § 552b(i).

Respectfully submitted this 17th day of June 1997.

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Martin L. Holton, III
N.C. State Bar No. 12632
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Attorneys For Plaintiff

Tuesday June 17 5:07 PM EDT

Company Press Release

Source: R.J. Reynolds Tobacco Company

R.J. Reynolds Tobacco Company Statement on Complaint Filed Against the Federal Trade Commission

WINSTON-SALEM, N.C., June 17 /PRNewswire/ -- R.J. Reynolds Tobacco Company today released the following:

When the Federal Trade Commission voted on May 28 to issue a complaint against the Joe Camel advertising campaign, we said that action was unprecedented, unfounded and unwarranted. Even to reopen the investigation ended in 1994 because the facts did not support the allegations, the FTC had to show new facts not available then. It has one: a 75% plummet in underage smoker interest in Camel. Instead, the FTC contorted its statute, bringing a rarely used claim of ``unfairness.'' The facts suggest that the only thing unfair about the Joe Camel case is the way the Commission has proceeded. Indeed, our review of the Commission's path to its complaint revealed a relentless pursuit of Joe Camel paved with egregious flaunting of law and procedures.

As the lawsuit we filed in federal court today indicates, the FTC action against Joe Camel violated not only the Commission's own rules and procedures, but also the Administrative Procedure Act, the Government in the Sunshine Act and the Due Process Clause of the Fifth Amendment of the United States Constitution. We have asked the court to review the facts -- which clearly demonstrate an agency engaged in harassment and political interference in a fair process -- and order the Commission to close this investigation, to withdraw its complaint against Joe Camel and to be enjoined against such future violations of law and procedure.

Reynolds Tobacco did not take this action without great consideration. But the facts overwhelmingly led us to conclude that it would be wrong to passively allow our government to ignore its own rules, the law, and the Constitution for the sake of political expediency. Indeed, we believe that we have a responsibility to take a stand on behalf of all advertisers subject to FTC regulation to preserve the integrity of the Commission's proceedings.

SOURCE: R.J. Reynolds Tobacco Company
Contact: Peggy Carter, R.J. Reynolds Tobacco Company, 910-741-7674

More news for related industries: advertising, healthcare, tobacco.

Tobacco – settlement

MEMORANDUM

TO: Bruce and Elena

FROM: Chris

RE: **TOBACCO REVENUE MEETING TODAY AT 1PM**

cc: Elizabeth

DATE: June 12

At 1pm, there will be a meeting to discuss (a) the legalities of how the Federal government can take a share of the tobacco settlement; (b) possible uses of the money. Representatives from HHS, Labor, Treasury, OMB, NEC, DPC and the Vice President's Office will be in attendance.

Preliminary estimates suggest that the annual amount of the settlement related to Medicaid will be about $8 billion. Since the Federal government now pays 57 percent of Medicaid costs, on average, that means about $4.5 billion per year (the money will increase / phase in over time).

I have asked HHS to be primarily responsible for the substance of the discussion. Their lawyer will discuss the legal issues. Then, one of the policy people will suggest some general options for the use of the funds. It is assumed, in these discussions, that we will pass the $16 billion children's health initiative and this money will either supplement it or be used for something different. Examples of ideas include: expanding Medicaid for kids and using the $16 billion for grants for middle-income children; extending Medicaid for low-income seniors; funding public hospitals and clinics; and launching major research initiatives.

The meeting is more idea generating than decision making.

Please call with questions.

If you give this up, can't you condition the whole $ billion?

BR told Phil Carlton

If he gets these #s + this auth,
he should call me in morning

We'd need to know the language
if they're comfortable
Then they can present it —
tentative ag —
will need to w/ bt.

Tobacco - settlement

Tobacco -
settlement

6-11-97 | Tobacco Moore/ Myers

Moore: Tension - HHS ⟷ WH
What's the problem over here?
Close to resolution -
need input from you. Why won't you talk?

Thurm: When there's a deal, secy will review.

Moore: You don't want to participate when we draft language in your area -
e.g., FDA jurisdiction?? Sounds crazy to me.
We have lang. That's acceptable to pub health commun - should be
to you.
→ Asked by WH to do these negots.
We want you on board - if there's a prob, let's fix it now.
If there's X sentence you want to change, do it now.

Myers: Pos that says "only review at end" - misses op. to get the ag bts,
farmer.

BR - What does that doc represent?

Myers - Agreed to unless everything agreed to, in some sense.
But - I share my memos w/ the industry as to what's agreed to.
So there aren't miscommunications.
All these topics - we've moved beyond
Doc disclosure - agreed to but only up to a limit at this point
Wording re pos. on addictive effects of product - specific not yet
agreed to.
FDA area - has continued to be worked. Now all but B&W have
said YES. B&W has agreed to concept - but worried about

product modification part ("death warrant")

Moore – Negotiated as far as we're going to go

fix it; get closure on FDA – we're there

Myers 80% of doc deals w/ health

90-95% completed by Thursday night

Fri morn mtg – CEOs & 5 tobacco cos = all – FDA piece

Not done

– liability provisions not in this piece – not going to settle punis

90% done ← – prompt fix piece (some)

Can share doc after tomorrow's conf call –

fully agreed to.

Moore: We can bring lawyers in here – They'll say they've agreed

But inst is not prepared to make pub statt.

They would not deny it if ag. was w/in newspapers.

Myers: I'll be giving exec doc w/ major health orgs

before doc is made public

Moore: Each of AGs is doing same thing this week

Doc totally framed out –

mid-next week

If we're in trouble, we'll settle stuff – but for overall health gains. Don't want to do that but will

Myers: But want informal input prior to being framed out deal –

if not, I'll blunder along – but that's what I hear

least confidence.

After "lead" next wk - pub health RPI will start making decisions.
Take about a week to get all briefing done.

Moore - Like to present it to Pres when I'm finished.
That's been promised to me from the beginning.

→ We're not going to be able to make our new long on FDA piece.
If you want us to change

Only thing not done by end of tomorrow | Pm done
Exact amt of $
Exact from - health effects of product

Tobacco –
settlement

4-10-97 Tobacco – Evening Meeting

Shalala – new + interesting ideas –
don't have leg lang
need to scrub real document – too many q's.
so many comms have juris – huge negotiation – taken apart –
very long time.
we can scrub these ideas, but That's diff from doing actual deal

EB – What's clearly not here?

BR – 1) If you want to ban cigarettes...
2) FDA jurisdiction tricky – too many hoops?
3) Coming to solution of tobacco related –
And you haven't solved international problem.

BCoon – enforcement prob –
for advert restrictions – need court decrees
↓
BC – They're agreeable to this –
binding on them.

JP – We're giving up ct to class them.

JP – High-wire act. A ton of stuff in here.
Desperation – coming from other provisions
Not going to get this w/out doing what BR is suggesting.

DS – Pres not well served by jumping on early when there's a long process to go.
Not respectful of demo process – stamping approval on secret deal

New parties can't be subject to consent decree.

Thurm/Corr

Doc - whole deal - libs.

1. Internal

HHS, DOT DOT, OMB

Ltr / State/USTR / USDA

? (cocktail party)

2. External

Go to Myer briefing - pub health comm.

Krog/Kessler

- Businessmen/retailers
- tobacco farmers

Hill strategy - consult w/ key players

Broader integrated deal as well

Mtg on Thurs or Fri -

assuming we get doc

Memo to EB -

process - who's going to go when

say where

Also need talking points

Tobacco —
settlement

4-10-97 Tobacco - Erskine Meeting

Agenda

Malala - new + interesting ideas -
don't have leg lang
need to scrub real document - too many q's.
so many comms have juris - huge negotiation - taken apart -
very long time
we can scrub these ideas, but that's diff from doing actual deal

EB - What's clearly not here?

BR - 1) If you want to ban cigarettes....
2) FDA jurisdiction recite - too many hoops?
3) In coming to valuation of tobacco stock -
And you haven't solved international problem.

BCoon - enforcement prob -
for advert vehicles - need court decrees
↓
members to BL - They're agreeable to this -
binding on them.

JP - We're giving up IT to class them.

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1. Internal

HHS, DOT DOT, OMB — Un / State/HHS / USDA

3 (workplace)

2. External

Go to Myers briefing - pub health comm.

Kraj/Kessler

- Businessmen/retailers

Hill strategy - consult w/ key players - tobacco farmers

Broader, integrated deal as well

Mtg on Thurs or Fri — Memo to EB —

assuming we get doc — process - who's going to go where/ say what

Also need talking points

Tobacco - settlement

Talking Points on Tobacco Settlement Talks

- The Administration is closely monitoring the settlement talks among the tobacco industry, state attorneys general, public health groups, and private lawyers. Any agreement would have to be passed by the Congress and signed by the President.

- We will carefully review any settlement that emerges from the discussions, and we will seek the advice of the public health community. As the President has said, in reviewing any settlement proposal, our focus will stay squarely on protecting kids and the public health.

Q: **Would you support a settlement that caps punitive damages? That seems to be the key stumbling block.**

A: I'm not going to speculate on any particular aspects of a potential settlement. The Administration proposed the toughest measures ever to protect children from tobacco, and we are fighting in the courts to see that those restrictions take effect. Our focus in reviewing any settlement will stay on protecting kids and the public health. The President has made it clear he is not going to agree to anything with respect to tobacco that jeopardizes the public health.

Q: **Senator Lott and others are urging quick closure to the talks. They say that the window of opportunity is closing. Is the Administration trying to help close the deal?**

A: No. Because any settlement will have a profound and lasting impact on the public health, the Administration will have to consider a settlement in a careful and thorough manner. There will be no rush to judgment and no precipitous action. We are not going to take a position on a proposal until the Administration and the public health community have fully reviewed it.

Tobacco - Settlement and Tobacco - Legislation

Sent to EK + return

PRELIMINARY IDEAS ON COVERAGE EXPANSIONS

OPTION	5-YR COSTS	COVERAGE	DISCUSSION
Premium Assistance for Workers between Jobs	$12 b ($2 b / yr)	3 million	All Americans are vulnerable to losing their health coverage when they lose their jobs Gives funds to States to make coverage affordable as well as accessible
Premium Assistance for New Workers (Age 18-24)	$10 b ($2 b / yr)	2 million	Addresses large problem: 23% of 18-20 year olds and 32% of 21-24 year olds are uninsured; also young adults were most likely affected by smoking advertising Gives funds to States to provide assistance to purchase basic benefits package
Helping Small Businesses Gain Insurance	$10 b ($2 b / yr)	1.5 million	Gives grants to states to develop voluntary purchasing cooperatives and provide premium assistance Addresses both issues of lack of access to group insurance and affordability of coverage for working families
Medicare buy-in for people age 60-64	$5 b ($1 b / yr)	0.5 million	Changes in companies retirement benefits policies as well as the high cost of insurance for older Americans has created a growing problem for this group Administered through Medicare which they will eventually join
Accelerate Self-Employed Deductibility **Extend Deductibility to Non-Group Coverage**	$15-20 b ($3 b / yr)	Negligible	Makes tax treatment of self-employed and individuals purchasing insurance in the non-group market equivalent to that of other workers Improves equity, not coverage
Increase public health funding	$5 b ($1 b / yr)	None	Helps uninsured and under-insured people through public providers rather than insurance Can target smokers or fund anti-smoking education

Note: Estimates are preliminary & rough; covered people includes only uninsured.

Bruce / Elena
You should read
- Elizabeth

Tobacco - settlement

COMMENTARY

By Mike France & John Carey

TOBACCO: DON'T JUMP AT THIS DEAL

America now has an unprecedented opportunity to save millions of lives. With public outrage at Big Tobacco hitting all-time highs, and the industry's power sinking to new lows, it appears to be politically feasible—for the first time ever—to impose a powerful regulatory regime on cigarettes, one of the world's deadliest consumer products.

But there's a risk that the country will blow this historic opportunity. Well-publicized peace talks are now under way over the future of tobacco. Unfortunately, these negotiations—and the public debate—are dominated by three groups that do not necessarily have society's best interests at heart: the industry, plaintiffs' lawyers, and attorneys general from 24 states that have sued manufacturers. Rather than focusing on the regulation of tobacco, these players have put the bulk of their energy into developing a $250 billion to $300 billion fund that would compensate the industry's alleged victims. It's clear what they find appealing about such a deal: Plaintiffs' lawyers stand to make hundreds of millions; the industry wants to limit its liability and stabilize its stock valuations; and the state AGs will be able to crow about the billions they have won for their states.

ILLUSTRATIONS BY JEFFREY SMITH

TEMPTATION. But these peace talks are worrisome. While it's tempting to grab the industry's billions now, the price for such a mammoth compensation fund will be far too high. In exchange for a share of tobacco's profits, the powerful lawyers at the bargaining table may have to trade off the right to fully regulate everything from tobacco advertising to nicotine content. While the attorneys would obtain tougher limits than those that currently exist, there are already signs that they would fall far short of what is needed to seriously slash tobacco use. Then America's hands would be tied, since the negotiators want to cement their deal in congressional legislation. Says former Food & Drug Administration Commissioner David A. Kessler: "We can't afford to buy into a system that looks good today but may turn out not to be effective."

Kessler is right. While there may come a time when settlement talks are appropriate, now isn't it. The public-health community, unprepared for the speed with which Big Tobacco's political power has crumbled, still has to do some serious thinking about the right way to cut tobacco use. Moreover, the wrong parties are at the table. The industry, the AGs, and the plaintiffs' lawyers share a strong financial interest in striking a deal that focuses on compensating Big Tobacco's victims rather than regulating it in the future. While paying money to smokers and states that have shouldered huge Medicaid bills may one day be desirable, it isn't the top priority.

Instead, it is far more important to take immediate steps to raise cigarette taxes, curb tobacco advertising, and accelerate the campaign to ban smoking in public places. Only after these goals have been achieved should the issue of a compensation fund be addressed. "If there is only a limited amount of money available, it's always better to use that money to prevent future loss than to compensate people for past loss—as cruel as that choice may seem to be," says Jeffrey O'Connell, a professor at the University of Virginia law school and expert in injury-compensation plans.

Taking tougher steps to prevent future smoking is possible right now—without conceding anything to the industry. An enormous legal hurdle to regulation fell on Apr. 25, when a North Carolina federal judge declared that the FDA has jurisdiction over tobacco. If the decision is upheld on appeal, as

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many legal experts expect, the FDA could accelerate its attack on teenage smoking—and begin thinking about such dramatic future steps as requiring reductions in the amount of nicotine in cigarettes. Before striking an irreversible deal with the industry, let's see what the FDA can do first.

What, specifically, should be done? Looking forward, policymakers should be guided by some fundamental principles. University of Michigan tobacco policy expert Kenneth E. Warner, for instance, advocates four key rights: All Americans have the right to breathe air not tainted with tobacco smoke at work and in public places; addicted smokers deserve more help to quit; children and teenagers have the right to an environment free of ads and other inducements to use tobacco; adults who are well-informed about all the risks should have the right to use tobacco.

We would add to Warner's list another important right, dear to the hearts of Americans: the right to sue manufacturers of dangerous products.

TAX HIKE. We must, of course, be careful to respect freedom of choice, also a cherished American value. If restrictions are placed on people's smokes, critics wonder, what will be next? "Before I jump on the tobacco bandwagon, I want to know why aren't caffeine, chocolate, sugar on there, too," grumbles Lawrence W. Schonbrun, a Berkeley (Calif.) attorney who fights excessive class-action lawyers' fees.

Keeping all these principles in mind, here are some steps worth taking. For starters, the most effective way to prevent smoking is to raise the tax on cigarettes. A 10% rise in the cost of tobacco sends sales down 4%—and among youths, the drop is higher, perhaps as much as 12%. "Kids are sensitive to price, if not to risk," explains health economist Willard G. Manning of the University of Minnesota (table, page 112). We should heed the recommendation of smoking foes for a major nationwide tax increase—about $2 per pack, to roughly $4.50. From an international perspective, that's still not very high: A pack costs $4.80 in Britain. But it would be enough to discourage children and push millions of adults to cut back or quit. Admittedly, new taxes are a hard sell in Congress, but polls show that Big Tobacco is a pariah to a majority of Americans, so cigarette taxes may be a breed apart. Some key Republicans have signed onto a bill that would modestly raise cigarette levies, and a record number of states are considering boosts. The billions of dollars raised could be used to fund education programs and hard-hitting antismoking campaigns. Such revenues might eventually fall as consumption does, but that's the point, after all.

Another effective tool: strict curbs on ads and promotions aimed at kids. Right now, America's youth are bombarded with merchandise offers, clever ads in magazines and on billboards, and alluring store displays—a barely regulated free-for-all. That's just what the FDA was trying to curb when it announced new ad restrictions last fall. U.S. District Judge William L. Osteen blocked the FDA's ad limits in his recent ruling, but the U.S. Supreme Court on Apr. 28 endorsed the government's right to regulate commercial speech for the public good—a sign that some restrictions on tobacco marketing are likely to be tolerated.

That's welcome news. More than 90% of current smokers begin puffing before the age of 18, and in recent years such enticements as cartoon characters and free merchandise have helped boost smoking by kids. Typically, they're well aware of the hazards of smoking, and they never intend to make it a lifelong habit. But before they reach adulthood, they're hooked. "The big problem is that kids underestimate the addictive power of nicotine," explains Neal Benowitz, an addiction expert at the University of California at San Francisco Medical School.

The message that smoking is cool also comes from secondary-source promotion through the mass media, such as Hollywood movies. There is a deliberate industry-funded effort to get cigarettes placed in movies and TV shows. "We're getting killed in the entertainment media," laments Gregory Connolly, director of the tobacco-control project at Massachusetts' Public Health Dept. It's a tough problem to solve, given the First Amendment. But it's worth trying to jawbone Hollywood into deglamorizing smoking.

We also need to push companies and local government to

the past, rather than on preventing future smokers

WHAT WE SHOULD DO ABOUT TOBACCO

POSTPONE THE SETTLEMENT TALKS Current negotiations amount to a backroom deal by lawyers and would give away too much to industry and hobble our ability to regulate in the future.

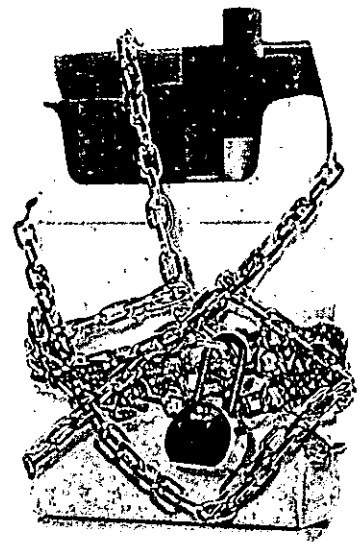
BAN ADVERTISING AND PROMOTION AIMED AT KIDS Without trampling the First Amendment, we need to keep the industry from hooking smokers early.

RAISE TAXES Boost the price of cigarettes—by as much as $2 a pack—to dramatically cut sales, especially to kids.

EXPAND SMOKE-FREE WORKPLACES AND PUBLIC AREAS Studies show that when a company bans indoor smoking, nearly 25% of its smokers quit and others cut back. More states need to sign on.

DISCLOSE ALL INGREDIENTS Adults could make more reasoned decisions. Now many smokers think "lite" cigarettes are safer than nicotine patches.

KEEP FDA ON THE CASE Current rules barring tobacco sales to kids are only a start. We need a strong regulatory hand that could impose further restrictions.



make everything from offices to sections of restaurants smoke-free. "It's the most effective single intervention," says Stanton A. Glantz, a prominent antitobacco activist. When a company bans smoking, about one-quarter of smokers quit, and the rest cut back 20%. But we have a long way to go. A new Massachusetts survey shows that in 1995, 35% of companies in the state still didn't have such a ban—and Massachusetts is one of the more enlightened states on this issue.

Individuals should be free to smoke, of course. But full disclosure of all the ingredients in tobacco—and their effects—is crucial if people are to make more rational choices. Massachusetts officials, using recent focus groups, discovered that a majority of smokers believe "lite" cigarettes offered a safer way to quit than nicotine patches did. That's because the patches come with an extensive list of warnings about their dangers, while cigarettes, despite containing a bevy of more toxic ingredients, say next to nothing about their dangers.

HOOKED. We may also want to consider the controversial idea of reducing the level of nicotine in cigarettes. That could conceivably allow teenagers to experiment with tobacco without getting hooked. It would also take away the most compelling reason for adult smoking. "We've largely won the public-health battle if we take the nicotine out of cigarettes," says a former FDA lawyer.

True, there's the problem of 48 million Americans still addicted to the drug. Heavy smokers would have to smoke more to get their daily nicotine fixes. And it might encourage bootlegging of stronger foreign brands. But patches, gum, or other delivery systems could be just as effective in satisfying the craving, without many of the health risks.

Naturally, any course of action needs flexibility, fine-tuning, and plenty of debate. And it's wise to remember that in the case of even the most well-meaning regulations, the industry has a history of turning the laws to its advantage. After the 1971 ban on radio and TV tobacco ads, for example, companies rebounded with a series of strategies—from merchandise giveaways to sports sponsorships—that reached impressionable youth.

Once a strong regulatory scheme is in place, then it may be time to move on to the issue of compensating Big Tobacco's victims. But beforehand, society needs to reach a consensus on how much money smokers really deserve. After all, the vast majority knew of the risks of cigarettes and therefore contributed to their own injuries. So is it fair to force the industry to pay for their full medical expenses?

There's also reason to believe that any compensation scheme for tobacco victims would be a mess. The crux of the problem: Smoking causes a wide variety of health ailments, but it is not the sole cause of any of them. If a compensation scheme tries too hard to separate legitimate claimants from illegitimate ones—weighing factors such as how long they smoked—it will burn up every penny in the fund. But without some guidelines, millions of people could be eligible for money—reducing the average payout to a fraction of most victims' medical expenses and lost wages.

Given these flaws, it may never be worth handing the industry blanket immunity from liability solely in exchange for a compensation fund. There's no reason to deprive people of their day in court, especially since the FDA's recent triumph in court has reduced the need to provide the tobacco industry legal protection in exchange for cooperation.

America is at a crucial crossroads. The tobacco industry is on the run, and there is a unique opportunity to shape the future. Let's not rush into a lawyer-driven deal that sacrifices this once-in-a-lifetime chance to kick the tobacco habit.

Mike France covers legal affairs from New York, and John Carey reports on health from Washington.

THE POWER OF TAXES

A recent study shows the strong correlation between high cigarette taxes and reduced consumption, especially among young people:

PROPOSED TAX INCREASE	REDUCTION IN NUMBER OF YOUTH WHO SMOKE	REDUCTION IN CIGARETTE CONSUMPTION BY YOUTH
$1.00	**25%**	**50%**
$2.00	**40%**	**70%**

DATA: CHALOUPKA & GROSSMAN FOR NATIONAL BUREAU OF ECONOMIC RESEARCH, BW

PHOTOGRAPH OF CIGARETTE BOX BY TED MORRISON; PHOTO ILLUSTRATION BY JOHN BLACKFORD

Tobacco - settlement

CAMPAIGN for TOBACCO-FREE Kids

NATIONAL CENTER FOR TOBACCO-FREE KIDS

TO: Bruce Lindsay, Bruce Reed

FROM: Matthew Myers
Executive Vice President and General Counsel

DATE: April 29, 1997

SUBJECT: Summary of Status of Discussions on FDA Related Issues

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As you requested, the following is a summary of the discussions that have taken place with the tobacco industry concerning FDA related issues and closely related other public health issues. These discussions all took place prior to the decision in Greensboro and, therefore, do not reflect any modifications in light of Judge Osteen's decision.

1. Youth Access

The industry agreed to the full substance of the August 28 FDA youth access provisions under the authority of the FDA. In addition, the industry agreed to:

A. A ban on all vending machines;
B. The placement of tobacco products behind the counter and out of reach of consumers
C. The prohibition of mail order sales, unless the industry can convince us that they have an effective mechanism to restrict sales to adults;
D. Parallel enforcement authority with state attorneys general and the power of FDA to contract with other state and local authorities to enforce the rules;
E. Enforcement to include unannounced, random stings;
F. Funding from the tobacco industry to pay the cost of enforcement for both FDA and the state authorities with enforcement power;
G. A nationwide licensing system for all sellers of tobacco products with a system of graduated penalties and license suspension.;
H. The power of FDA to augment and modify these rules after a set period of time not to exceed 7 years;
I. States and local governments would not be preempted from enacting stronger laws.

2. Marketing and Advertising

The industry agreed to the full substance of the August 28 FDA advertising and marketing provisions under the authority of the FDA. In addition, the industry agreed to:

A. The elimination 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, including on cigarette packages;
C. Additional restrictions on point of purchase advertising regarding the placement on point of purchase ads to limit their size and remove them from the line of sight of children and from close proximity to candy and other goods likely to attract children;
D. The elimination of internet advertising and the agreement on the use of whatever technology is available to restrict access to tobacco advertisements that are placed on the internet from foreign countries;
E. The prohibition on product placement in movies and on TV and the prohibition on any payments or fees to celebrities to smoke in movies or on TV or to otherwise glamorize tobacco use;
F. 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 First Amendment challenges by parties outside the tobacco industry
G. The power of FDA to augment and modify these rules after a set period of time not to exceed 7 years

3. Public Education/Counter Advertising

This issue was not directly addressed in the final FDA Rule. The industry has agreed to provide funds for a major nationwide public education/counter advertising program similar to those found in Massachusetts and California. It was agreed that the industry would have no say over the content or placement of the program, that the funding would be guaranteed, and that, 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.

Better get IA involved on this too.
Best not for it to be by your entity?

4. Health Warnings

FDA does not have authority over package warnings. The industry has agreed to a revision of the warning label system. They have agreed to replace our current

warnings with the more specific, more detailed Canadian warnings (probably with attribution to the Surgeon General), including a warning on addiction, to move the warnings to the front of the cigarette package (and the most prominent side of the smokeless tobacco product package). Discussions were continuing on the exact format of the warning. We were pushing for the Canadian format (25% of the top of the front with white lettering on a black background. They last offered 20% of the front with black lettering on a white background).

5. Performance Standards

The concept of performance standards are implied in the FDA Rule, but only with regard to the modification or supplementation of the youth access and marketing restrictions. Discussions with the industry have also focused on performance standards tied to economic sanctions if youth smoking rate reduction targets are not met. The concept has been agreed to although the exact formula is still being discussed.

6. Funding for State and Local Tobacco Control Activity

It has been agreed in principle that state and local tobacco control activity modeled after the successful ASSIST program would come out of tobacco industry funds. While the exact amount has not been discussed with the tobacco industry, discussions among our side would permit the ASSIST program to be fully funded in every state from these funds.

7. Tobacco Cessation

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 the cost is an issue.

8. Protection from Environmental Tobacco Smoke

Discussion of protection from environmental tobacco smoke has not reached a final conclusion. Preliminary discussion has indicated a tentative agreement to restrict tobacco use in public places and virtually all workplaces to locations that are separately ventilated to the outside and through which non smokers need not pass. To avoid heavy opposition from the hospitality industry, restaurants and bars would probably be exempted, but state and local governments would be permitted to enact more restrictive requirements governing these and all other areas. This would replace the need for OSHA to complete its difficult and controversial rulemaking.

9. Public Disclosure/ Public Position on Tobacco and health Issues/Corporate Behavior

Documents: This remains a somewhat open issue. The industry has agreed to disclose all internal health research related documents. There has been discussion

about disclosing internal memoranda which contain any reference to health, toxicity, addiction, drug dependence, and marketing to kids, but no final resolution.

Public Position on Health Issues: The industry has said it does not intend to make a public admission as Liggett did in its settlement, but has also said that it will no longer challenge the scientific conclusions about the causal link between tobacco use and disease and nicotine and addiction. The enforcement mechanism and form of this new posture is still unclear and needs to be worked out.

Corporate behavior: There has been talk about requiring the adoption of a corporate code of behavior with outside monitors, reports on steps the company is taking to comply with the FDA rules, financial incentives and disincentives for employees who comply or are found to encourage noncompliance. These would be modeled after agreements entered into in the environmental areas with corporations charged with violations of the environmental laws.

10. General Authority of the FDA

It was agreed that FDA would be the agency with primary authority over tobacco and that the FDA's authority would be as extensive as the authority it exercises over products like drugs and medical devices. Prior to the Greensboro decision, it was envisioned that a separate chapter would be created for tobacco that would not be intended to cut back the agency's authority, but would be intended to also address specific issues related to tobacco.

Whether a separate chapter makes sense in light of the Greensboro decision should be revisited, but whether a new chapter is created or not, it still makes sense to specifically address some issues specific to tobacco.

The discussions produced broad agreement over FDA control subject to one condition, that FDA authority not result in a ban on the manufacture and sale of tobacco products to adults - directly or indirectly. The following is not necessarily inclusive:

A. It was agreed that FDA's normal authority to inspect, enter manufacturing plants, demand certain recording keeping, enforcement, etcetera would apply;
B. It was agreed that the industry would be required to provide FDA with all research it conducted and all information it received that relates to health, toxicity, addiction, drug dependence, etcetera and that the industry would have the power to subpoena such information;
C. With regard to non tobacco ingredients,
    - the industry agreed that no such ingredient should be permitted unless it has been tested and proven safe when used 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. The 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.

- The industry would be required to provide FDA with a list of ingredients by brand and by quantity in each brand.
- FDA would be permitted to require the public disclosure of ingredient information as it does for foods in a manner that does not disclose trade secrets, i.e. 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 on foods.

D. FDA would be given the authority to require a new system for testing and disclosure of nicotine, tar, and other factors that FDA determines that the public should know to protect the public health.

E. FDA would have its typical authority over the manufacturing of the product, including the establishment of Good Manufacturing Practicing Standards, product quality criteria, pesticide residue standards, etc.

F. Products sold that a reasonable consumer would believe pose less of a health risk. It was agreed that FDA should have specific broad authority over any product that a consumer would reasonably believe poses a reduced health risk. This includes products ranging from traditional low tar products to higher technology products like Eclipse and could, if FDA so desired, include Alternate Nicotine Delivery Devices that do not contain tobacco. It was agreed that

- the manufacturer would be barred from saying anything about such a product that could be reasonably be interpreted to state or imply a reduced health risk unless the manufacturer had proven to FDA that the product scientifically did in fact "significantly reduce the risk to health" from ordinary tobacco products 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 advertisement from being used to expand or prevent the contraction of the marketplace.
- The industry would be required to notify FDA of any technology that reduced the risk form tobacco products and to cross license all such technology
- The industry raised its desire to explore a system to provide incentives to produce less hazardous products. No detailed discussion has taken place or agreement reached on this concept.

G. Regulation of the tobacco components of the product, including but not limited to nicotine. It was agreed that FDA must have the authority to regulate and require the modification of the tobacco components of the product to protect the public health *subject to the condition that such product regulation could not be used to produce a de facto ban.* Details of this important issue had only been explored in the most preliminary way. *Emphasis in the discussions was placed on the authority of FDA to regulate nicotine and not on imposing a particular long term answer with what to do about nicotine.*

H. Enforcement - FDA would have its normal enforcement authority. It would be supplemented by Parallel enforcement with 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 believed had violated their obligations under the Act.

Tobacco - settlement

4-30 Tobacco mtg

3:00 – 1/2 to notes (all)

1/2 for indiv claims

testing (?)

tar/nicotine levels

authority – no benefit