Erskine memo -- timetables change
First step is world without settlement -- get started
First meeting

- convene larger group (30 people)
- process and goals --
- convene working groups (assign leads)
    1. FDA regulation of product, access, and labeling
    2. Advertising restrictions / public education
    3. Environmental tobacco smoke
    4. Smoking cessation
    5. Farmers
    6. Liability and litigation

Also

-- CEA starts industry analysis (need CEA at meeting?)
-- USTR/HHS start review of interenational policy; trends (need USTR at meeting?)

- Ask for paper by (Monday?)

Advance work

- Bruce calls Kevin
- Jerry calls FDA, others
- Eliz calls treasury, OSHA

Pending work

- Principles

- When paper arrives
    - Drafting and enforcement issues in codifying a potential agreement
    - Analysis of specific settlement provisions

Master Schedule

~~Labor cont — Tues 10~~

7/28 Mon 12 - Mtg. mtg / Cigar:
7/29 Tues 10-11 Labor Cont. < 11:30 >

7/30 Wed. 10:30 Nichols
5:00 Legal

7/31 Thurs. Hold 9:30 Tobacco Event < >
AMA 10:30 press conf.
5:15 Matt Myers

8/1 Friday 1:30-3:00 Retailer · ad mtg
3-4:30 public health grps.

Outstanding

? Liggett 10 Tuesday 2:30 Tues 5th Bonnie
Humphrey
Members mtg. < Wed — Friday

J Aug 5 2:30 Liggett.

DPC Meeting Agenda
August 7, 1997

Public Health (FDA, BD BAN, etc)		
~~FDA Jurisdiction~~	1	DONNA
Youth Smoking Penalties	2	YELLEN (Summers)
Legal Issues	4	HUNGER
Budget Issues	5	RAINES / SUMMERS
Farmers	6	GLICKMAN
Environmental Tobacco Smoke	3	ALEXIS
~~Advertising~~		
Intl.	7	TARULLO

Pub Health
ETS
BUDGET ← LEGAL
FARMERS
PENALTIES
INTL

6

Erskine memo -- timetables change
First step is world without settlement -- get started
First meeting

- convene larger group (30 people)
- process and goals --
- convene working groups (assign leads)
    1. FDA regulation of product, access, and labeling : WH - HHS FDA - DOJ - JRM
    2. Advertising restrictions / public education : WH - HHS/FDA - DOJ - ED
    3. Environmental tobacco smoke : WH - OSHA - HHS - EPA - ED
    4. Smoking cessation : HHS (CDC, NIH) - JRM
    5. ~~Farmers~~ : USDA - DOL - NEC - CARP
    6. Liability and litigation : DOJ - HHS ~~EPA~~ EK - NEC — disclosure
    7. Industry analysis + incentives : NEC/CEA/USDA/DOT (Mark Mazur) — performance

Budget / Civil Litig. 1. Health group (Chris)

Also

-- CEA starts industry analysis (need CEA at meeting?)
-- USTR/HHS start review of international policy; trends (need USTR at meeting?)

- Ask for paper by (Monday?)

Advance work

- Bruce calls Kevin, Janet, Gene, Summers
- Jerry calls FDA, others
- Eliz calls Treasury, OSHA
- Elena calls DOJ

Pending work

- Principles

- When paper arrives
    - Drafting and enforcement issues in codifying a potential agreement
    - Analysis of specific settlement provisions

June 11, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Bruce Lindsey
Rahm Emanuel

SUBJECT: Tobacco Settlement Review Process

We have reached agreement with HHS on a process to review and evaluate the possible tobacco settlement with relevant agencies, to seek input from the public health community, and to present recommendations to the President. Our goal is to prepare a memo for the President later this month that: (1) defines the public health and public interest objectives of a global settlement; (2) weighs the settlement's strengths and weaknesses against those objectives and proposes possible modifications; (3) assesses the likely reactions of the public health community and other affected parties; and (4) lays out options for how to respond to a settlement announcement.

Interagency Review

This review will be carried out by (1) our existing tobacco group, which will examine the public health and liability issues, and (2) a DPC-NEC health care team led by Chris Jennings, which will assess how to spend recovered Medicaid revenues. These teams will look at the Administration's overall public health and public interest goals; what will happen with the proposed settlement, what will happen with no settlement; and what changes we might want in any global settlement.

o Public Health and Liability Team

We expect to receive a draft of the possible settlement documents tomorrow or Friday from Attorney General Mike Moore. We will hold a White House meeting Friday or Monday with representatives from the major agencies (HHS, Justice, Treasury, USDA, Labor, OMB) and White House offices (DPC, NEC, OVP, OSTP, Counsel, Leg. Affairs, Intergovernmental, Public Liaison) to begin review of these documents. The principal issues will be:

1. FDA regulation of product, access, and labeling
2. Advertising restrictions / public education
3. Environmental tobacco smoke
4. Smoking cessation

5. Farmers
6. Liability and litigation
7. Drafting and enforcement issues in codifying a potential agreement

We will ask these representatives to respond with preliminary recommendations by Thursday, June 19. At the same time, we will ask a smaller group of agencies (HHS, USTR, State, Commerce, NEC, NSC, DPC) for their views on U.S. responsibility in addressing the growth of smoking worldwide.

o Medicaid Spending/Children's Health Team

Chris Jennings' group (HHS, Treasury, Labor, OMB, DPC, NEC) will begin meeting tomorrow to explore options for using the Federal government's share of recovered Medicaid funds for health care investments. This is an effort we had already planned to undertake to evaluate Hatch-Kennedy or similar legislation.

Outreach

Over the next two weeks, we will reach out to public health organizations and individuals and to members of Congress. Key public health contacts include: Action on Smoking and Health; American Cancer Society; American Heart Association; American Medical Association; American Academy of Pediatrics; American Public Health Association; Americans for Nonsmokers' Rights; National Center for Tobacco-Free Kids; Dr. Kessler; and Dr. Koop. We will also meet with other affected parties (states, farmers, small businesses) as appropriate.

Schedule

We have planned the following schedule, but note that adherence to this timetable is highly dependent on agency cooperation.

June 12:	Teams begin meeting.
June 18:	Teams report back with initial findings and outstanding issues.
Week of June 16:	White House and HHS host meetings with public health groups.
Week of June 23:	Develop options for outstanding issues; hold principals meeting.
June 27:	Send memo to the President.

Mike Moore told us today that the parties to the negotiations will meet Monday and try to reach agreement by mid-week.

Erskine memo -- timetables change
First step is world without settlement -- get started
First meeting

- convene larger group (30 people)
- process and goals --
- convene working groups (assign leads)
    1. FDA regulation of product, access, and labeling
    2. Advertising restrictions / public education
    3. Environmental tobacco smoke
    4. Smoking cessation
    5. Farmers
    6. Liability and litigation

Also

-- CEA starts industry analysis (need CEA at meeting?)
-- USTR/HHS start review of interenational policy; trends (need USTR at meeting?)

- Ask for paper by (Monday?)

Advance work

- Bruce calls Kevin
- Jerry calls FDA, others
- Eliz calls treasury, OSHA

Pending work

- Principles

- When paper arrives
    - Drafting and enforcement issues in codifying a potential agreement
    - Analysis of specific settlement provisions

--- DRAFT --- 6/24 **Tobacco Working Groups**

I. Regulatory Issues (Elena Kagan)
White House: DPC, OMB, OVP, NEC; Agencies: HHS, DOJ, DOL, GSA, EPA, Treasury

A. FDA regulation of product, access, advertising and labeling (HHS/FDA)

B. Environmental tobacco smoke (DPC/OSHA)

II. Program and Budget Issues (Chris Jennings)
White House: DPC, OMB, NEC, OVP; Agencies: HHS, Treasury, Labor USDA

A. Children's Health Care (DPC/NEC)

B. Education (including grass roots programs) (DPC/HHS)

C. Smoking Cessation (DPC/HHS)

D. Nicotine Research (OSTP/HHS)

III. Legal Issues (Elena Kagan)
White House: DPC, OVP, DOJ, HHS, Treasury

IV. Industry Performance and Accountability (Bruce Reed)
White House: DPC, NEC, CEA, OVP; Agencies: HHS, Treasury, DOL, USDA, USTR, State

A. Economic Analysis (including farmers, international markets)

B. Targets, penalties, incentives

~~CONFIDENTIAL~~

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

TO: Kevin Thurm
Deputy Secretary

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

RE: Summary of Discussions on FDA-related Issues

DATE: June 4, 1997

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

1. Youth Access - The industry would agree to the full substance of the August 28 FDA youth access provisions. In addition, the industry would agree to the following:

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

in enforcing the rules;

H. Enforcement would include unannounced, random stings;

I. The tobacco industry would pay the cost of enforcement for both FDA and the state authorities with enforcement power.

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

A. The eliminations of all billboards and outdoor signs, including all signs in stadiums and arenas and signs in enclosed areas, such as stores that face outwards;

B. The elimination of all human images and cartoon characters from all advertising and from all cigarette packages;

C. Additional restrictions on point of purchase advertising regarding the placement of point of purchase ads to limit their size and number, remove them from the line of sight of children and remove them from the close proximity to candy and other goods likely to attract children. The exact details of these restrictions have yet to be resolved. There has also been discussion of restricting point of sale advertising in stores within 1000 feet of schools and playgrounds to price lists;

D. The elimination of internet advertising and the agreement on the use of whatever technology is available to make tobacco advertisements that are placed on the internet from foreign countries inaccessible in the US;

E. The prohibition on product placement in movies and on TV, the prohibition on any payments or fees to celebrities to smoke in movies or on TV or to any other person or entity to glamorize tobacco use in movies or on TV, and the prohibition of any "in-kind" actions to accomplish any of these same purposes;

F. While these provisions will be enacted into legislation, FDA would be given the administrative authority to augment and modify these rules after a set period of time, not to exceed 7 years, to further reduce tobacco use among minors;

G. An agreement to consent to the placement of all of the advertising restrictions contained in the August 28 FDA Rule plus the above noted restrictions in private binding agreements and/or in consent decrees to insulate the restrictions from the First Amendent challenges by parties outside the tobacco industry;

H. FDA would have the primary authority over the enactment of regulations concerning these provisions and full enforcement authority over them. However, there would be dual enforcement authority with both the FDA and state attorneys general, each being able to enforce these provisions and, in addition, the FDA would have the power to contact with other state and local authorities to assist it to enforce the rules;

I. The tobacco industry would pay the cost of enforcement for both FDA and the state authorities with enforcement power;

J. The portion of these advertising and marketing restrictions that relate to purely local advertising would not preempt stronger state and local laws.

3. Public Education Counter Advertising - Funds would be provided for a major nationwide public education/counter advertising program similar to those found in Massachusetts and California. The program would operate independent of the tobacco industry which would have no say over the content or placement of the advertisements. Funding for the program would be guaranteed, and to the extent possible, the program would be insulated from political pressure. The program could be administered by FDA, the CDC, or an independent entity.

4. Health Warnings - While FDA does have authority to require tobacco companies to provide health information to consumers in a variety of ways, FDA does not have authority over the current warnings on the package. The industry would agree to a revision of the warning label system, replacing the current warnings with the more specific, more detailed Canadian warnings including a warning on addictions. The warnings would be moved to the front of the cigarette package (and the most prominent side of the smokeless tobacco product package). The warnings would appear in the Canadian format (the top of the front with white lettering on a black background) and occupy at least 25% of the top of the front of the package.

5. Performance Standards - The concept of performance standards are implied in the FDA Rule, but only with regard to the modification or the supplementation of the youth access and marketing restrictions. Discussion with the industry have also focused on performance standards tied to economic sanctions if youth smoking rate reduction targets are not met. The industry would be subject to penalties if youth tobacco use failed to drop by 30% in 5 years, 50% in 7 years and 60% in ten years. The penalty would be based on the value of a teenaged tobacco user to the industry over the lifetime of the teenager. It would be worth approximately $80 million per percentage point by which the target was not met.

6. Funding for State and Local Tobacco Control Activity - State and local tobacco control activity modeled after the successful ASSIST program would be funded out of tobacco industry funds. While the exact amount had not been agreed to, we expect the ASSIST program would be funded in every state from these funds.

7. Tobacco Cessation - Out of the funds to be provided by the industry, funding would be provided for tobacco cessation programs and devices for those who want to quit and for whom the cost is an issue. The Secretary of HHS would be authorized to set standards and procedures for the approval of cessation programs and devices.

8. Protection from Environmental Tobacco Smoke - Protection from environmental tobacco smoke would come from the enactment of the text of HR 3434 (originally introduced by Congressman Waxman) that restricts tobacco use in public places and most workplaces to locations that are separately ventilated to the outside and through which non smokers do not pass. Restaurants (excluding fast food restaurants) and bars would be exempted but

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

9. General Authority of the FDA

A. Tobacco products would have the same definition as contained in the FDA Rule. Jurisdiction would also cover Roll Your Own, Little Cigars, Fine Cut, etc.

B. Tobacco would continue to be categorized as a "drug" and a "device" under the Food, Drug and Cosmetic Act. The agency's authority to regulate the products as "restricted medical devices" would be explicitly recognized and tobacco products would be classified as a subcategory of a Class II device pursuant to Sec 513 of the Act. The Food, Drug and Cosmetic Act would apply to these products as provided by the Act and the amendments to the Act contained herein.

C. The Class II Classification would permit the FDA to require product modification of tobacco products, including the regulation of nicotine content, and would provide that the sale of tobacco products to adults in the form that conforms to Performance Standards established for tobacco products pursuant to Sec 514 shall be permitted notwithstanding Secs. 516, 502j and 518e. Until the establishment of the Performance Standards under Sec 514, the FDA would not prohibit the sale and manufacture of traditional tobacco products now on the market to adults solely because they are inherently dangerous or because they have not previously been approved as new drugs.

D. FDA would exercise its normal authority to inspect, enter manufacturing plants, demand certain records and record keeping, and would have its normal enforcement authority. Industry information would be given the same proprietary protection as information from other industries.

E. The tobacco industry would be required to provide FDA with all research it conducts and all non-public information it receives that relates to health, toxicity, addiction, drug dependence, etcetera, and the FDA would have the power to subpoena such information.

F. FDA would have the authority to require a new system for testing and disclosure of nicotine, tar, and other product and smoke constituents that FDA determines the public should know to protect the public health. This authority would be transferred from the FTC and would include the authority to require additional package and advertising disclosures established after an APA rule making. The FDA would have the authority to require tar and nicotine disclosures on both the

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

G. With regard to non tobacco ingredients:

- No such ingredient would be permitted unless the industry demonstrates that it is not hazardous under the proposed conditions of use as it would be used in the tobacco product. The burden would be on the industry to provide FDA with such data pursuant to a rule promulgated by the agency. As the agency does for other products, it would set up a standard of the type of testing of each ingredient based upon the "best available evidence" and information provided. Once the industry provides such information and data, the FDA would be required to review it and make a determination in a time certain as to whether it meets the agency's safety standards. The safety standard would apply to new ingredients immediately, but there would be a five year grace period for ingredients already in tobacco products on the date of enactment. However, nothing would be done to undermine the Massachusetts disclosure law and its requirements in the interim period.

- The industry would be required to provide FDA with a list of ingredients (including those in paper and filter as well as other product components) by brand and by quantity in each brand, subject to the same confidentiality protections given to other industries for similar information.

- FDA would be permiteed to requre 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 authorty 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, resonable 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 resonable fee, to cross license all such technology, but only to those companies also covered by the same obligations. Procedural protections would be built in to resolve license fee disputes, if the private parties can't agree among themselves first. If the technology reported to the FDA is in the early develoment stages, the manufacturer would be provided confidentiality protection during the development process.

J. To further the public health, to promote the production of "reduced risk" tobacco products, and to minimize the harm to the public by insuring that the best available, feasible safety technology becomes the industry standard, the FDA would have the authority to promulgate Performance Standards to govern product modification pursuant to Sec 514 of the Act:

- For a period of no less than ten years following the effective date of the Act, the Product Performance Standard would be governed by the following principles: The agency would be permitted to adopt performance standards that require the modification of existing tobacco products, including the gradual reduction, but not the elimination of other constituents or other harmful components of the product, based upon the demonstration that the modification: a) would result in a significant reduction of the health risks associated with such products to the consumer, b) is technologically feasible, and c) given the number of dependent tobacco product users and the lack of alternatives that are available that are

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

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

The authority to require such product modification could be exercised upon a showing of "substantial evidence", based upon the administrative record developed through a formal rule making subject to the Administrative Procedures Act, with the right of judicial review, and any such modification shall be subject to the current procedures of the Regulatory Reform Act of 1996 to provide time and a process for Congress to intervene should it so choose.

- Separate from the requirements of the Sec 514 Performance Standard noted above, the agency would also have the authority to promulgate ceilings on tar and nicotine yields in tobacco products that gradually reduce but do not eliminate the presence of these constituents over the 10 year time period pursuant to agreed upon levels, unless the agency finds that the reduction would not reduce mortality and morbidity.

- The agency would also have the authority to mandate the introduction of "less hazardous tobacco products" that are technologically feasible, after a formal rule making subject to the Administrative Procedures Act with the right of judicial review. The goal of any rule mandating the introduction into the marketplace of "less hazardous tobacco products" for which the technology exists is to guarantee that a mechanism exists to insure that products which appear to hold out the hope of reducing risk are actually tested and made available in the marketplace and not held back.

- After the initial ten year period, the agency would be permitted to set product safety standards that go beyond the standards it is authorized to set pursuant to the above noted principles and procedures and, if it does so, it shall be guided by the following expanded principles: The agency would be permitted to require the alteration of tobacco products then being marketed, including the elimination of nicotine and any other demonstrated harmful component of the product, provided: a) the safety standard would result in a significant overall reduction of the health risks to the nation associated with tobacco products, b) the modification is technologically feasible, and c) given the number of dependent tobacco users then in existence and the availability and demonstrated market acceptance of alternated products then on the market, the modification would not result in the creation of a significant market in contraband products that do not meet the safety standard. In determining the overall health benefit of a change, the agency may

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

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

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

cc: Elena Kagan