

NLWJC - Kagan

DPC - Box 052 - Folder-005

**Tobacco-Settlement: Notes &
Memos [1]**

11682

Kagan

Loop-Kessler 7.9.97

Dr. Koop: David - I am among those who favor a settlement if the public health benefits outweigh what can be done thru reg, litigation, - legis.

FDA piece unacceptable, not the stumbling block it seems.

- Public health comm is not going to sit idly by + with abiding reduction of nicotine. Tobacco cos. may squeak

Only other thing David - I am worried about is penalties.

- graduated penalties - 3% triple, 5% quadruple

Except for those 2 things, everything else is settlement or budgeted

what we've done is easy, what Congress do is hard

Kessler: Only thing that matters is reduce # of people who smoke, esp kids

2 documents. We'd like to get you close to ours.

Cynical part of me - they want to be paid off, we want a general life

Should be dictated by industry negotiation

Niche. Performance stds. Another not real. 100s of other issues.

I have enormous faith in review. Have to be sure if it works.

VP: One conclusion - ^{FDA} limitations must be changed. Everything else open mind

Koop: I'm a doctor, not a lawyer

VP: What other shows stoppers

Koop: Industry controlled firms, can't change spots. What has industry already thought of to get around?

Kessler: Kessler has to look at the subtleties

Koop: 1) Ultimate price of cigs. 2) ~~tax~~ don't freeze allowances, need ability to do other things if those don't work.

Stamm: Don't use word 'settlement'. The answer may be fine.

Kessler: If you give up something, make sure pb. health will work.

VP: Theoretically an opt in public int. Cos. need incentive - finitely, predictability, certainty.

KOOP: Can't give them absolute certainty.

VP: 2 main load-bearing elements

KESSLER: Pub health needs to be rock solid. Performance side is all that matters.
Legal side

VP: Speaking personally, I don't want to give them anything. Speaking for the Admin, there is a theoretical settlement

KESSLER: Resolution, not settlement

VP: Continued litigation is enemy of public health certainty.
- How do you deal w/opponents of intl.?

KOOP: Don't overemphasize intl. See domestic conclusion before we take on the world.

KESSLER: 50% chance of Ch. 11 in 10 yrs.

→ Eliminate tax deduct. of tobacco advertising

KOOP: Falling dominoes

VP: CEA study on price vs. consumption

KESSLER: 70¢ excise tax. Need to look more broadly.

VP: Try to reduce # of uncertainties: Congress, industry

KOOP: People don't trust tobacco industry, can't be surprised. Had to find jury who'll convict.

KESSLER: Industry scientists, not lawyers. Real & for cessation. Paying lawyers ourselves want

AG's - 7.10.97

Gregoire: Took contraband from the comments. FDA gets to decide "significant"
- not 1% or 3%.
- CT shd defer to your expertise

Myers: Put agency on track early to deal w/ this. If hurdles... (willing to fix)
- designed to generate alternatives, give incentives for "safer" products
- need mix of regulatory with market forces [→ TALK TO MYERS re KOOP 1%]
- common-sense std - but diff legal a.
- Our goal was to get agmt on a concept.
- Yrs of litigation over stds of ~~product safety~~ or "reasonable assurance of safety" - hard to apply to tobacco
- industry says they have things they could do to make safer
- coming up w/ std you can apply

Gregoire: Contraband came from us. They wanted consumer acceptability. (= why BAT left)
We were focused on tar, not just nicotine - begin aimed to reduce risks
- more imp. issue is tar - too many addicts.
You may get petitions

Myers: Resources to agency to protect against Congress from coming down on him. ^{not} ^{accountants} ^{remember}
Reg. of nicotine will require LT effort to change pub. opinion.

Moore: Consent decree - Advertising.

Gregoire: → Meet w/ advertisers to back up consent decree.
Farmers - we want something, no consensus as to what

Moore: 1) Don't restrict crop insurance
2) \$ for alternative crops for farmers

Myers: Advertisers are in odd position, b/c these cos. do other things (Philip Morris)

Myers

(Donna asked about "extraordinary circumstances" on adverts)
Ads take yr or two to go into effect.
Wanted to prevent other loopholes - eg different ads
If agency saw loophole, could ask mfrs to do more.
- no rebate if mfrs said no.

Congress

Bring in 3 yrs to states + mfrs.

Shulka

No state by state data on smoking

Congress

Licensing = feds set min. stds, states have to enforce
How would you do this? We left yr flex.

Moore

Industry doesn't licensing.
Contract + enforcement is important

Myers

Industry made penalties, but cos. felt weak after
Took 5 days to get penalties at all.
72-58-67% over 10 yrs.
Ind. wanted state to have stds - 75-80-90.
- we needed cap on state penalties.

Clinton

Disclosure: As lamps insisted on it to see, industry in on disclosure.
Agmt makes all non-priv. docs to count.

Myers

Allow any citizen, group, or news media to ~~the~~ lobby standing to claim privileges
Industry waives procedural hurdles
Adopt's Min. privacy log model. Computerized databases

Ab, p. 3

Shelala: How much flex?

Moore: In some areas, not much. We don't trust them, they don't trust us.
- They can't lobby for weaker FDA auth.
- You'll lose BAT immed.

Myers: At this interim stage, as long as list is long & growing, won't get sthd. to go along.
As priorities get set, fix 1-2-3 (FDA, penalties, tax deducts)
- will do our own leg. draft.

Gregoire: Where we can make it less ambiguous, good. Can't come to them w/ 12 things, but crafting can fix some of those.

~~Moore~~
Moore

Bargaining window is the now & end of year
May settle FL. Won't settle in TX w/ no bill. By Minn.
Cases are 50:50 at trial, 70:30 on appeal.
LOTT - Leadership bill, start in phase, limited comm.
More adverse rulings expected.

Myers: Only 6 states have decent cases. Not many hurdles after Minn., then settle for less than nat. portion

Tobacco - Hearm Groups 7.11.97

Current, Range: What legislative? Before about recess.

Conson, lung: Skeptical. Use UK as basis of departure. ² Other flaws

Sawyer, Heart: Internal review due network. Highlight health.

Saffer, Cancer: Best opp. in our lifetime to shape tobacco. FDA + lookback. A lot of good there.
- By word - power on tobacco + health
- I'm lives now

Western, Pediatrics: Endorse self-interest in concept

Consider total ban on advertising. Even more substantially selective replacement for con-
Use state & to insure children - irony. Smoking pediatric health problem.
Don't close any legal avenues: passive + pre-natal smoking data only 10-15 yrs,
effect size - low level lead. Don't tie our hands

Myers: Historic opp. ^{on good} ~~to~~ ^{to} ~~of~~ ^{to} ~~test~~ ^{to} ~~who~~ ^{to} ~~stands~~ ^{to} ~~with~~ ^{to} ~~the~~ ^{to} ~~top~~ ^{to} ~~people~~ ^{to} ~~who~~ ^{to} ~~die~~
What's the best way to achieve that goal - that's the goal post
No editorial ownership - willing to strengthen if it can be enacted. Not more
reports on the staff, more headlines (kids smoking not going down)

FDA is non-negot. Easy for us to disagree, but we have to be realistic.
Not disseminated - need to ~~protect~~ ^{protect} effect shareholder value.
Penalties still increase over time. Paid for by foreign sales. That
may mean they're calling.
Targets need to come on - redefine the unacceptable over time.
Int'l is tough - but ~~for~~ ^{for} WHO, ³ ~~to~~ ^{to} ~~devel.~~ ^{to} ~~countries.~~ ^{to} ~~Topic~~ ^{to} ~~of~~ ^{to} ~~GATT~~
Attempting to generalize industry. Best way to generalize ind is no other smokers
→ Get congressional language to double 90% to that effect

Advisory, UCCIA

Public Health, p. 2

COSMAN: Opposed on grounds on new mkt. Hisp. #1 in 8th graders.
Joe Camel not our best export - in a mariachi band

Brown, Onyx: 4 major pts. : 1) Replacement of dollars for cultural efforts
2) Deep avoidance of black mkt issue (our comm. are dumping ground)
3) Taxes are regressive, earmark \$ to go back to our comm.
Not sure cessation will reach the poor
4) Children everywhere

GERMAN: Principles border the public health
We won't take position on settlement - focus on specific policies.
We see settlement as flawed ways to get people to stop. Need reg. + legislation
to affect indiv. choice.
Abs have got genie out of the bottle; can't go back. Historic moment.
Never a good time to do the wrong thing.

KLAUSS: More deaths from oral cancer than cervical cancer. Garagota.
1 in 4 US students use spit tobacco. Start as early as 5-6 yrs old
8 recomms: 1) FDA 2) Help ^{quit} ~~quit~~ (MUB who cry, use dirt + grass). 3) Educ
4) Labels

COSMAN: Minority comm. + abroad will be targets. Nat. American ceremonial smoking

BROWN: Cigars. Next drug of choice.

FIELDING: In LA, no majority. People don't understand the settlement. Bring public along.

CANCER: People like education + protecting kids. Punishes a non-issue

Public Health, p3

- Brown: Black preaches want to elim. the industry
- Graham: Objective of tobacco-free society. New mkt strategy might get over 21 to start.
- Selfrin -^A Settlement gives us best oppor. This addresses adult addicts. A lot of \$ could go to waste.
- Klars: Need to talk to grocery stores & gum makers
- Fielding: Worry about 18-25. We've been outsmarted before.
Troubled by Miss. settlement
- Garrison: Punitives as part of comprehensive strategy.

TOBACCO - ECONOMICS 7.11.97

CEA: Price up 62¢ excise tax. Pass thru of 100-125%.

Adult-only tobacco stores

Wall St. 18-5 buy; ~~even~~ 50-50 before deal.

Philip Morris move market settlement

85% of tobacco employ. in 5 states + P.Rico Va Ky NC Fl.

Antitrust immunity

Base payments on revenues, not profits

\$180 B, net \$368 B (180-240)

19% over 1st 7 yrs. - \$84 B 25% in 5 yrs., then trend after that.

Excise tax - \$44 B

GNP - \$60 B -

Present value - \$112 B

Soc. Sec - 2% increase by 2070

Medicaid a wash / SSI

Medicare is a zero

The dismal science

Ad ban cover only 50% of ad dollars

Total tax deductibility is non-starter

Tax impact is a wash, so deductibility doesn't affect budget

- ① Options paper on lock-backs
- ② Revenue/budget range
- ③ Options on revenue/profits
- ④ Reduced risk/FTC

Tobacco - Public Health 7.11.97

AMA

Substantial gains not imagined before. Historic 1st step, some risks
Advantages: 1) FDA gets express authority

- 2) Broadens regulatory option - eg advertising
- 3) Nat. licensing scheme
- 4) Retail price increase
- 5) \$1.5-2.5B for good things
- 1) FDA restrictions
- 2) Look backs
- 3) Liability

Concerns:

Recognize progress can't happen w/o industry

Anna Maria O'Keefe

Our bottom line is no settlement.

Tobacco industry spent \$200m lobbying 1997, 10m in campaign contributions. This deal would give industry what it wants most. States up 140%. Litigation. Mass. proves don't have to make concessions to industry. Pressure Press's place

Ned Baker, local

No position. Lot of success at local levels. Is this the best outcome?

Nancy Ruddy, press

Unprecedented opp. Amount of money in litigation looked ahead. Complexity.

Bonnie

HRC gave \$ to ASH. A floor, not a ceiling. Industry is vulnerable, can be probed. Get as many concerns addressed. Hidden TV ads. Only 5¢ on the \$. Int'l. ETS (bars, restaurants). Sign on EO making fed workplace smoke-free (Sullivan had it ready).

(*)

- Sullivan. California are sending us a letter on EO

Do OSHA reg. - working on it in 10 yrs. Maryland has done it.

Do investigation into product placement = a crime. (ask Hollywood what's going on?)

Public Health, p. 2

Prof. Dagnan
Liability

FDA piece is "the virus" - Subrogation - doesn't work

Something very important for tobacco is history to get tort reform. Last decaying. Ticker-type powder. Historical context - they got one heck of a good 1st offer from tobacco cos.

Miss. - tx about asked for paid lawyers' fees - funding the oppos.

The earth is moving - don't reject settlement, but keep moving. Don't worry.

Dr. Wm 90-1
ASTHO

We applaud vision of AAs who've brought us to the table; historic step,

transudas potential. 2 main issues

- 1) State + local health agencies - don't compromise on FDA. Must stress research
- 2) Enforcement measures. Co by co. penalties. Apply to ~~smoking~~ tobacco.

More funding for tobacco control.

Pub. health must take realistic approach to settlement. Not the end of ~~our~~ ^{our} ~~effort~~ ^{effort}.

W. L. Blodgett
Am & A

♀, not just kids. Can't separate children from adults - maternal health

No reason to allow ads to adults. Targeted marketing.

Terms like "Slim", "Direct Mail".

Well-funded smoke-free families program.

Louise & want-stop smoking. Help from govt. (Medicaid coverage?)

♀ who work in bars. (80% of wait staff; 53% of bartenders)

Int'l concerns - ♀ in developing countries. ~~What's the P. Manni - H. King - 22 ♀ smoke~~

Can't accept as sufficient. Skeptical of anything industry willing to sign.

State people ~~are~~ ^{are} angry bc been driven badly for 30 yrs, got hit on the ropes.

Fate Cleaver
Public Choice

Admin. - slide + proceed on this. Disclosure is central. No ingredient disclosure

Can't legitimate productly with us know what id. knows - read ad's playbook.

Barriers - have to know fully what ways are. Fed CTS more pro-tobacco than state CTS

3-judge panel - loss there is binding everywhere. Class action.

PUBLIC HEALTH, p. 3

Juane Smith,
AMA

Support K-K.
Protects ind's ability to make a profit. Giant step, but FDA.
1) what did cos really give up + 2) what did they get.

Dunlap

Harvard Law Conf., July 31st: Shd Tort law be on the table?
A little bit of glasnost - not enough even w/ 60s.
A system built on falsehood - a little truth undermines it

30B Revenue Increase
Revenues = 30B
~~Costs~~ Costs = 25B
Total = 5B
Plus = 40B
Costs =

Donne: Leave flex to protect future decisions

Bazelon: Preponderance of evidence stds

Ann Marie: Winston - "additive-free"

Bazelon: Contingency lawyers work had the govt backwards

Wmsan

Tobacco cos aren't going to cut of business. Be realistic. If it can be fixed, this is an opp. we'd hate to see missed.

Meyer Koplow, PM
Arthur Goldin, RTR
Jane Hickey, Werner Lipfert

Friday mtg w/CEOs
Wed - Hatch comm. hearing - Scruggs
- Tribe

DPC SR STAFF 7.14.97

CRIME

- RE
1. Brady event (Wed.)
 2. Gun tracing report (Sat.)
 3. Juvenile justice markup
 4. Sex offenders directive
 5. Crack

EDUC

- RE
1. Teacher ^{hiring} incentives (Thurs.)
 2. Big city symposium (Rahn → Daley) - Co, Mo, VT, MI
 3. \$ for testing
 4. Hispanic outreach

WR

1. Comm. service / 50% comp.
2. Work rates
3. DLC Conf.
4. Eli event mtg.
5. Grandmothers mtg.
6. Child care tax ideas
7. Child care reg.

HC

1. Immuniz - Satcher, registry
2. Needles
3. Pediatric labeling
4. FDA reform / comm.

Tobacco Excess 2.15.97

Carson: 3 goals: 1. Explain why 2. Answer Q's 3. Concluding dialogue

Why FDA - Industry position was that Congress needed to pass a ban, not FDA.

We're concerned about ban of tobacco products (concern over growers).
 P.H. health comm. insisted on "nicotine" instead

Science is still uncertain about health impact of reducing nicotine.

Didn't want to be able to sell abroad only (retrograde as confound)

Procedural safeguards were only part suggested by industry.

We proposed major spur to create less hazardous products. That's

a way to avoid confound. Cos. should compete to make

less hazardous products

- Didn't want FDA to regulate chemical etc but

- Allow FDA to permit edge for less hazardous products

- Turn over ^{of} any technology is (neutral). But fear of someone else developing ^{low risk is incentive}

- Could go way of buggywhips

(Probably people working on this as we speak.)

(RJR - mostly for)

- We wanted to ban only if met acceptability of alternatives, but Mett

said that was 3rd rat.

Wise

Attempt to put in words how to regulate FDA not control FDA at all

Koprow

Big collateral effects

- Industry position is not to stop FDA from ban. We know that's unacceptable

Procedural safeguards: we were prepared to walk thru mechanism to see

that complete record was made before the agency had to act on

the evidence. ~~Metts~~ Not needed to some specific existing provision

of AFA. Q is what is best way to do this.

Tribe to know more about the background record.

1/11/97

TOBACCO EXERCISES, p. 2

Koprow: lots of constituents other than tobacco. No restriction on non-tobacco constituents, Not looking for backdoor method to avoid regulation.

Davis: Nat. protocol, implementation?

Koprow: Contract not to engage in advertising etc. Enforceable against cos by feds, AGs, + other cos. Didn't want co. scrupulously adhering at disadvantage.

Wise: 2 probs: constitutional + competitive

Koprow: → They'll get us a list of what goes in the protocol.
Health claims can only be enforced against mgfrs. Others have immunity (incl. growers), but they have to live up to restrictions. Retaster can't make false claims, + can't sell new mkt entrant products w/o subjecting themselves to liability.
Reserve acct for new entrants for future claims; stays in acct for 40 yrs.
This is incentive to sign protocol + live by ad restrictions.
Industry will share judgments against other cos. (eg. Leggett had 15% in '60s, only 1.5% now). So no one would be left holding bag if bankruptcy.
Pay Leggett's upfront share of acct.
We're started to draft legislation.

Hickey: Drafters don't expect to withstand admin + Cong. review. Hodgepodge.
Industry lawyers don't expect to write legislation.

Korow: PM thinks ad restriction should be in legis. (advertisers)

RJR disagrees.

If we can demon. it's effective who legis we'd urge not to.

Anti-trust: no lawsuit against anybody but injrs.

State would apply civil lib. provision to cos. that sign or don't sign protocol.

Insurance industry has ^{liability} exclusions for injrs. Many spread to retail etc.

Protocol would include - legit. would say no outdoor ads etc.

BL: Secy shall be authorized to enter into protocol

Dorner: Document disclosure

Korow: Disclosure to the FDA. Take all documents sought by lawsuit + put in depository paid for by industry, + create log based on Minn. rules on basis of privilege.

CT is free to expose financial matters. Everything we could think of offer the way the privilege

Hearst asked about doing docs. before settlement is passed (Meyer will check.)

RJR: All relevant avail to the FDA. (including trading data.)

Korow: Industry's 1st posit. was adopt FDA rule. Abs included shift financial records. Industry suggested licensing scheme. We said we don't know how to drive

industry rates. We hope it will, but we don't know.

We'd agree not to earn a dime from any underage consumers. Abs created a formula which we think overstates the profits. We were going to use a formula that included quit rates. Industry agreed to 10 yr. (but hates it.)

Trying to achieve rates that are lower than margin rates

We're hoping that ads will have an effect, + enforcement of access restrictions

some counter-industry impact on leads. Price increases. (intraday impact)

Tobacco Execs, p. 4

Agreed to form new comm. to come

In bean reserv. sales. - ind. may have to get tough on distributors to get cooperation on access restrictions

Half-jokingly at PM to pay kids not to smoke. (check the penalties.)
we don't know how elastic incidence

Ind. does understand backlash against landing in kids hands

Dana: You may be open to other acceptability measures

Koplow: Yes

RJR: It could be refined.

Koplow: Price per pack is revenue-neutral. Reduced consumption is not.
PM has highest tax rate in America

Tobacco farmers 7.16.97

Kent

#1 crop, 25x soybeans, next highest crop. Microenter losing tobacco would be disaster - throw a letter. Not asking for handout 260k jobs = NC Farmers want to reduce teen smoking

Ky

This agent is good for tobacco, to stabilize the tobacco market. US small player - can't keep it out if we stop raising it altogether. Don't want to ask for much. Continue negotiation

Wayne Dilling GA

To this pt, all negot have been who growers. In all days, pants beef up. Now we got rights - that doesn't happen. Nothing could replace it.

Long Wooten NC

Worked for NC Sp Inventory 3 acres of tobacco; can't tear it from the fabric. Everything in start is designed to reduce consumption of tobacco. Cos. want some stability as they get to supply side. Growers want some stability, or some compensation as govt is eroded. Growers should be at the table. Govt of the world, not seller govt. Hold these reports at current levels. Cigarettes will be made whether US tobacco or not.

Mont

Nothing will go down sharply, but value of farms will go down. I hope it goes thru, but farmers should be left holding the bag.

Wayne Dilling VA

3rd generation tobacco growers. Seen in VA; top cash crop.

FL

Backbone of rural comms in N. Fl., used to be treated fairly

SC

They are shifting some uncertainty onto farmers, can't compete on other crops. Conversion program. One of best times for us to do something - the chance to help with health growers at same time.

Tobacco, p. 2

SC: Quotas established in 1940s, assigned to farms + historical production. Can't sell across ch. lines. A lot of tobacco land would go unfarmed.

Scenario: Do you agree w/ focus on kids? (more gradual reduction)

Ky: Agree that teen smoking is bad. Our fear is that you're going beyond teen smoking. Don't lose great opp. to reduce teen smoking.

Hint: Getting rid of ads really will reduce smoking. This kind of approach is essential. Get teen smoking as low as poss. Make sure farmers get treated right.

NC: We all have children, don't condone youth smoking.

SC: Sharp reduction at very beginning - 20% reduction. Tobacco is 5¢/pack.

Hint: you see the quotas to reduce demand, compensated for it.

GA: Tobacco mkt on July 22 - children getting clothes. ♀ slide of smoke cigars, e-cigs, CT cigars.

TN: Don't know date when stopping smoking or stopping growing tobacco. Uncertainty.

Hint: Farmers need 1) keep tobacco program (quotas etc) 2) we want cos. to buy that crop. (boom this yr) 3) If consumption goes down, farmers get paid for their loss. Distortion opportunity

SC: Lower and. Anti-tobacco in Cong. If you have prob w/ cos, don't attack producer.

Sen. Dems - TOBACCO 7.18.97

BREARY: Concerned about trial lawyers + AGs. Some good - not a nickel in pocket
Worried that tobacco cos. may walk away.

BURMAN: A lot covered in this agent not covered in indiv. suits.

LANTIERO: Miss. is a disapp't. NJ AG. Ball's still at play.

FORD: Not for damn thing b/c the farmers aren't in it. Creative legal stance.
Acid rain. ETA std.

ROBB: Target youth, not adults.

BROWN: Medicare. Tax deduct.

WYON: What process to get this done? ^{Dems:}
1) POTUS has been incredibly quiet
2) Public health solution 3) Regulatory + trade policy > \$
- Don't target kids in Bangladesh to pay for struts here?
- USTR shouldn't treat tobacco like everything else

KENNEDY: Tobacco farmers, left out of profits. FDA changes unacceptable = most imp.
Lobbybackers. Don't deduct punitive damages.
We've missed the boat on the Medicare. PM convers. w/ RPK on youth smoking,
NOT going to take them at their word, when they're risking kids health
Can it be done this year? What needs to be done?

JACK REED: ~~Dem~~ They've invited us to legislate. Be detailed. Will strategy.

CONRAD: Lebow - not cost cos. anything

Tobacco Manufacturers 7.18.97

William: 25 yrs in HC, came to BRW to develop a safer cigarette. Had to be first in 191

ByDess: Brown/cancer research, honored to come to PM to develop less hazardous. Like want

esp. safer cigarette - could have been used 15 yrs ago. A shame. Powerful research. co. wanted to be first in world. One of most powerful in world. Mithras - removal. Filter techs. Cos. want to understand the loss in market share. Nobody in PM would present safer way if it meant losing market share.

DeNoble (long report)

Our job was to reduce nicotine from cig. Concerned about man-made or brittle to go to B. Vt. Medicine Millers. We found out also cardiovascular effects. Developed cig that reduces 80-90% of nicotine. Shut us down in 84 - killed our rats. Not talk favorable in court litigation.

Here (behavioral psych)

Could we demonstrate withdrawal syndrome. Self-admin. tobacco, no withdrawal. Found good drugs, but didn't know how to deal with it. They felt it would help improve acceptability, but co. not interested in improving quality. Exec: "We all know the addiction. I'd stick it in my arm in arm." Sidestream smoke.

DeNoble
ByDess
Wigard

Ind. has compartmentalized its research. Partner w/ someone in industry to do this. Drug development. Doctor all does relating to tech expertise, provided or not provided. [Rt scientist on 3-judge board?] The safe cig. "Hamlet."

One of major impediments to "safe" cigs is liability for other cigs. Journal of cardiovascular disease instead of concentrated. Does safer cig. become worse when smoked? Smoke more. How do they

Whistleblowers

Whiss: Can't have safe cig. if still enough nicotine to be hooked. Cf. auto industry 30-40 yrs ago - didn't shut them down, compelled them to improve.

Male: Smokeless RTR cig. is inherently product.

Wigard: Not going to eliminate smoking altogether. Engineers/prods - give choice. empire research base outside industry.

DeMable: Develop system just like drug ind. - monitor research etc. FDA police industry to create safer cig.

Male: Release of health + research docs. is critical to FDA

Whiss: Mgmt is the prob. Cig. could taste quite good (and it doesn't matter)

Wigard: Ind. has responded to every pub health charge. Not just a piece of paper when product inside. Fix FTC method. Ind. can take as long as it wants to do the cig. Nicotin-free cigs didn't sell. Cool temp - 200-1200°

DeMable: Ind. doesn't have to do the cig. Humor can take as long as it wants to do the cig. Ind. has manufactured drug-delivering devices, not the drug. Leg. looks for 9)

Wigard: New smokers are kids, start long before 18, any age of onset is 12-13

Whiss: Mr 50s, college. 60s, HS. 70s. early smokers. I don't think we had ban ads. Ad campaign to make fun of them. Ver. sim. cont. don't let off the hook.

Male: Corp. culture. DeMable - rats/loss. Wigard: sales/pubs, become part of the fold, individuals. Require them to develop reduced-risk cig.

Whiss: Criminal; evil. Male: freedom of choice. Oppose 12-year wait. Recommend combining devices to

UP: Spiritual issue, wrong side. Country's own spiritual health.

If not this deal, then what?

If not this deal, then what deal? That is the persistent question of those who recognize the fundamental flaws of the proposal on the table but fear losing a unique opportunity to harness the industry.

The answer is: No deal. As a matter of principle, there should be no concessions to the industry. As a matter of policy, we can expect to see exponentially more significant public health gains in the absence of a settlement. To reiterate: irrespective of legitimate desires to punish the industry, a "no deal" position will do more to advance public health than would any conceivable deal.

If there is a settlement, we get the terms of the settlement, and nothing more. An inevitable decompression effect will deflate the political momentum against the industry, and the media will turn its attention elsewhere. Meanwhile, the tobacco company lawyers, advertising agencies and marketing specialists will craft sneaky ways to circumvent the provisions of the settlement package. Other nations' regulatory record illustrates quite clearly that the industry is a moving target, able to elude the intended effect of almost any fixed set of regulations.

Without a settlement, the state and class action cases against the companies will proceed. There will be ever more document disclosures, leading to victories in court -- and in the court of public opinion. The ever-accelerating political momentum will create the climate in which stiff and sudden tax increases, along with other tobacco control measures, can be pushed through Congress, and FDA authority strengthened, or confirmed if necessary. The disclosures will spin off into more intensive and diverse criminal investigations and eventually prosecutions; these too will shift the political climate, facilitating Congressional passage of meaningful tax and regulatory reforms.

Meanwhile, the state attorneys general will continue to prosecute their cases, or settle them individually. In total, the states by themselves will win or settle for hundreds of billions of dollars, probably approaching the \$368 billion of the proposed deal, meaning the major, tangible benefit of the proposed deal -- the price increase to offset the companies' payment obligations -- will be achieved without making any concessions to the industry. The "most favored nation" clauses in the state settlements -- provisions establishing that early settling states automatically gain the regulatory benefits obtained by later settling states (such as Florida's billboard regulations), and included in the Mississippi and Florida settlements -- will provide an opportunity for a unique ratcheting-up process as the state cases unfold. The end result will be that the state cases exact most if not all of the regulatory accomplishments of the proposed deal.

The "no-deal" approach will achieve far more public health benefits than even a revised deal could hope to offer -- and it does so without sacrificing the rights of present and future victims of the industry, without undermining the vitality of the civil justice system (itself an absolutely critical public health protection system), without making concessions and giving "peace" to the industry

This is a realistic scenario. Stepping back from a micro-assessment of the provisions of the proposed deal helps make clear how quickly the ground is shifting in the tobacco control area and how short-sighted it would be to cut off the momentum against the industry.

As Attorney General Hubert Humphrey III said in June, "Six months ago, the private attorney who now reportedly represents 20 states said in the Wall Street Journal that the campaign against Big Tobacco had 'reached a high-water mark.' 'It's foolish not to settle now,' he was quoted as saying. If we'd settled then, we would have missed the historic settlement admissions by Liggett & Myers, the North Carolina judge's confirmation that nicotine is a drug and cigarettes are subject to full FDA regulation. We would have missed the Baltimore billboard cases, the Massachusetts additives case, and the sight of a retired senior executive of Philip Morris taking the fifth in one of four federal criminal grand jury proceedings."

This year has also witnessed:

- The disclosure by Congressman Waxman of Liggett documents detailing suppression of research the company thought would reduce harm from cigarettes by as much as 90 percent;
- The publication of new scientific research on the effects of second-hand smoke;
- The disclosure of the Florida documents;
- Revelations of BAT's consideration of marketing root-beer-flavored cigarettes;
- The filing of a new round of lawsuits against the tobacco companies by union health and welfare funds;
- R.J. Reynolds' withdrawal of Joe Camel from the U.S. market;
- The passage of a 15 cent tobacco tax (albeit one that will offset the companies liability under a settlement, if one is enacted);

- The deposed statements of the CEOs of Philip Morris and RJR that they believe smoking is deadly;
- A reversal of the tobacco company effort to defund FDA tobacco-related enforcement activities; and
- The settlement of the Mississippi and Florida cases for a combined sum of more than \$14 billion, the industry agreement to the "most favored nation" clauses in the settlements and the Florida advertising restrictions.

All of these developments have forced the tobacco industry on the run, and foreshadow the imposition of much more penetrating industry regulations, restrictions and punishments than we have allowed ourselves to contemplate in recent years. Collectively, they show that: there is much more to be learned about the industry's record of suppressing scientific research -- and publicity about scientific research -- on the hazards of smoking, as well as the industry's marketing-to-children strategies; there will be new emerging theories of tobacco company liability, based on emerging scientific evidence (e.g., second-hand smoke research), disclosed documents and legal innovations; while Big Tobacco maintains a firm hand on Congress, it is beginning to lose its grip; that cigarette tax increases can be pushed through Congress; and there is a ready alternative to a comprehensive deal -- prosecutions and selected settlements of the state cases.

The choice is not between a stagnant *status quo* and the terms of the settlement. Rather, it is between a dynamic current environment in which tobacco control forces are gaining ground daily and a settlement which will effectively freeze tobacco control efforts for the foreseeable future.

Ralph Nader, Robert Weissman

Sept. 9, 97

Bruce (Eleanor) /
HHS
1-2 pages
FYI

Tobacco - settlement -
notes + memos

DRAFT

1. FDA JURISDICTION

The proposed settlement assures jurisdiction over cigarettes and spit tobacco products, and places that authority with FDA. The settlement raises a number of issues about the scope of FDA's authority, including FDA's ability to regulate the nicotine content of these products.

The precise scope of FDA's authority beyond cigarettes and spit tobacco is not clear in the settlement. The word "etc." is actually used on page 13 of the settlement document to describe FDA's jurisdiction over tobacco products. What remains unclear is whether the agency remains free to investigate cigars and other tobacco products, and then assert jurisdiction and apply the final rule to cigars and these other products. (One of the negotiators of the settlement has stated that FDA would be permitted under the deal to investigate, assert jurisdiction, and apply the final rule to cigars and other tobacco products to the extent it is permitted to do so under current law.)

The settlement considerably alters FDA's authority over nicotine. New substantive and procedural obstacles would be placed in the agency's way before nicotine levels could be reduced or eliminated. The substantive hurdles include having to demonstrate: (1) a significant reduction in risk; (2) technological feasibility; and (3) that a significant demand for contraband will not be created. The contraband criterion has been heavily criticized by the President and many in the public health community. In addition, the safety standard apparently allows FDA only to consider the health risks to current smokers, which would prevent consideration of risks to future smokers and those affected by second-hand smoke. Furthermore, the agency would have to wait 12 years before it could eliminate nicotine. The new procedural burdens on the agency include having to employ "formal" rule making which is much more cumbersome and time-consuming than "informal" rule making procedures ordinarily used by FDA. The combined effect of the new substantive and procedural criteria would probably result in the agency receiving far less deference by a reviewing court if FDA's actions were challenged.

Of the new substantive criteria, the one that seems in principle to make sense is the safety standard. This provision is based on the concept of "risk reduction," rather than the current statute's notion of demonstrating safety and efficacy. It would probably need to be re-drafted to overcome the problems described above. Nevertheless, a "risk reduction" approach for products as dangerous and addictive as cigarettes and spit tobacco may provide FDA with more flexibility to address the problems associated with tobacco use.

Overall, however, current law enables FDA to address the nicotine issue unencumbered by the numerous substantive and procedural criteria included in the settlement. In any resulting court challenges under current law FDA would receive a fair degree of deference by reviewing courts. The new provisions in the settlement might effectively prevent or seriously delay a future FDA from reducing the nicotine content of tobacco products.

Options for consideration include: (1) codifying the agency's existing authority over tobacco products, as affirmed by the federal district court; and/or (2) converting the mandatory criteria in the settlement into mere "considerations" that FDA, in its discretion, could decide to evaluate in any agency action.

2. DISCLOSURE OF TOBACCO INDUSTRY DOCUMENTS

The settlement provides for the public disclosure of tobacco industry documents in a national tobacco industry document depository. The settlement further provides a mechanism by which there will be binding judicial determinations by a three-judge court regarding the disclosure of documents that the industry currently claims are protected as trade secrets or are protected by the attorney-client or attorney-work product privilege.

We have been told that the settlement is not intended to affect FDA's existing authority to request and inspect certain documents for regulatory purposes. However, the settlement's mechanism for reviewing privileged documents is extremely cumbersome and time-consuming, and it appears to be the mechanism that FDA would be subject to along with States, public and private litigants, other health officials, and the public. If the agency is required to follow the settlement's time-consuming procedures, it would make obtaining documents the agency has a legal right to in a timely fashion very difficult and could seriously hamper FDA's ability to meaningfully regulate tobacco products. This raises the question of whether there should be additional authority for FDA in this area. If there were to be an expansion of the settlement's terms, it would be important to seek subpoena authority for FDA, perhaps the only federal agency with major regulatory responsibility that does not currently have compulsory process.

The tobacco industry has historically gone to great lengths to protect the confidentiality of its documents, thereby concealing its actions and virtually all of its scientific information about its products, including their addictiveness. This secrecy has served the industry well and the protection of confidential documents is extremely important to the industry in this settlement. Because of the industry's history of secrecy, the issue of document disclosure has been debated publicly, and there are those who are emphatic that there should be no settlement until after all of the industry's documents have been disclosed and there is a more complete understanding of the true extent and nature of the industry's actions and scientific knowledge. Public health advocates argue that only when all the industry's information is public can the terms of the settlement be accurately evaluated and an informed decision be made whether to accept it.

In addition, if this settlement is adopted, the cases brought by the States will end, and the States will have to obtain documents by means of the settlement's mechanism. This is potentially very important because it would block the efforts of the State of Minnesota, which is in the process of piercing the industry's claims of privilege for its documents.

Finally, the Department of Justice questions the use of a three-judge panel to make disclosure determinations on both constitutional and policy grounds. In addition, serious reservations have been expressed about the fairness and appropriateness of a one-time nationally-binding determination of the public disclosability of these important documents.

3. REDUCED RISK PRODUCTS

The settlement contains provisions regarding the review and approval of “reduced risk” tobacco products. Under these provisions manufacturers would be allowed to make health claims if there were scientifically-based evidence that the product “significantly reduces the risk to health” from ordinary tobacco products. FDA is authorized to exempt such products from the advertising restrictions that apply to other tobacco products. There are also provisions that are designed to provide incentives to manufacturers to make reduced risk technology widely available, and FDA can require the introduction of such technology into the market after formal rulemaking. There are also provisions that give FDA authority to review the non-tobacco ingredients of cigarettes and prohibit its use unless the manufacturer can demonstrate that the ingredient is not harmful under the intended conditions of use. Manufacturers would also be required to disclose ingredients of tobacco products following rules similar to those used by food manufacturers.

Several serious issues are raised by the reduced risk provisions. First, the settlement appears to assume that reduced risk tobacco products can be developed and that these products should be marketed in the U.S. The public health community is split on this issue, and there are very strong opinions on both sides of the argument. This is a very complex question that should be the subject of vigorous national debate before being decided. That debate has not taken place, and it would be unwise and premature to settle such a momentous question in the settlement at this time. It would be more appropriate for the agency to decide that question in the future.

Second, while the settlement allows FDA to approve health claims for reduced risk products, it is counterintuitive to allow health claims for a product that is so inherently dangerous. It is hard to imagine what health claims could be scientifically substantiated and therefore approvable by the agency. There would be concern that these claims would be perceived by the public as meaning that the products are safe, as opposed to only marginally less dangerous. This perception could have the effect of deterring smokers from quitting or encouraging individuals to start. (There is a separate and more detailed discussion of health claims elsewhere.)

Third, FDA is concerned with the standard that the settlement imposes for determining whether a tobacco product poses less of a health risk. Instead of a scientific standard such as “reasonable assurance of safety and effectiveness” or “deleterious to health” which the agency currently uses, the settlement would have the agency determine what an “objective, reasonable consumer would believe pose[s] less of a health risk.” This is a much weaker and difficult to define standard that would provide little public health protection.

Fourth, it appears that reduced risk products would also be subject to mandatory categorization as Class II products. This is troubling because it limits the agency’s authority over such products before we even know what they are. It is inappropriate and premature to predetermine the class of these products before they have been developed and to remove the agency’s ability to determine how best to regulate such products based on their own safety and other characteristics. The agency strongly believes that it should retain its full current authority, and the flexibility that it provides, to determine how best to regulate each product.

Fifth, the settlement provisions under which the agency would require the introduction of reduced risk products are also troublesome because they are very vague. They impose a very daunting procedural requirement (formal rulemaking) that the agency must meet in order to take action. It is also not clear how the agency would determine that reduced risk products are technologically feasible.

Finally, there are several difficulties with the provisions regarding ingredient disclosure. The standard that is imposed for ingredient disclosure is the weaker food labeling requirement rather than the more stringent disclosure authority that is currently provided for devices. Under the food labeling rules, for example, many harmful ingredients could be hidden by using bland terms such as "flavoring." Further, the industry is given 5 years to provide available safety data regarding each ingredient (query whether the agency has the ability to require a manufacturer to develop data if none exist), while FDA is given 90 days to review all safety data. This is not only an inadequate amount of time for the agency to act, but the settlement provides that, if the agency fails to act within the specified time, the ingredient is deemed approved. This is an unworkable mechanism.

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4. Local-State Preemption/Federalism

Issues: 1) To what extent should federal standards and procedures preempt state law in the tobacco area?

Is it desirable to have separate standards and enforcement under federal and state law?

If separate state standards are permitted, could they be limited to provisions that are more restrictive than federal standards, i.e. federal standards would set the floor?

2) Do any of the provisions violate state sovereignty?

Background: The proposal is inconsistent in its statements about preemption although it appears to modify existing standards at least under current FDCA law and, perhaps, under other federal statutes. Under current law regarding preemption for devices under the FDCA, for example, certain state laws are preempted unless the state obtains an exemption from preemption. The proposal appears (i) to modify FDA's ability to grant exemptions and (ii) to heighten the burden on states seeking exemptions. The proposal appears to leave unaffected tobacco exclusion provisions in other statutes, such as the Federal Cigarette Labeling and Advertising Act, the Hazardous Substance Act, and the Toxic Substances Control Act.

Significant Relevant Considerations:

1) Preemption: First, any preemption changes should be no more limiting on law enforcement than existing law. Second, there should be no federal preemption under the FDCA of state tort actions relating to tobacco products. Third, from a public health perspective, it would be preferable, if Constitutional, to have federal regulations establish the floor, with states free to be more restrictive if they so choose in order to protect public health. Fourth, federal preemption is appropriate to maintain a uniform national standard in the areas of labeling and warnings. Fifth, consideration should be given to repealing exclusions for tobacco in the Federal Hazardous Substance Act and the Toxic Substances Control Act.

2) Federalism: In its recent ruling on the Brady bill, the Supreme Court significantly limited the authority of the federal government to direct state officials to administer or enforce a federal regulatory program. Thus, any provisions that anticipate state involvement in administration or enforcement should be evaluated as to whether they exceed the limits established by the Supreme Court.

7. LICENSING

The proposed settlement creates a licensing scheme for tobacco retailers that is intended to be administered by both federal and state authorities. Which level of government actually bears the responsibility for overseeing the program is unclear and needs to be clarified in any legislative language.

Licensing tobacco retailers is considered an important element of any comprehensive tobacco control effort. The ability to revoke a license and prevent a retailer from selling cigarettes or spit tobacco products is a powerful enforcement tool. FDA's objective is to be able to revoke a license if a retailer repeatedly sells tobacco products to minors. FDA is less interested in bearing the considerable responsibility for administering the licensing regime for more than 500,000 tobacco retailers.

According to SAMHSA, about thirty states have tobacco licensure requirements. There have been problems reported with the accuracy of retailer lists compiled by the states. Whatever current problems exist could probably be corrected with adequate resources.

Ideally, a licensing program would be administered by the states under guidelines established by the federal government. In this system, repeated violations of the federal prohibition against the sale of tobacco products to minors would trigger revocation of the retailer's license to sell the products. Further legal research is needed to ensure that this combined federal/state program can be done.

There are two other concerns raised by the licensing provision in the settlement. First, under the deal a license could only be revoked after ten illegal sales to minors in a two year period. This is an ineffective provision because it is extremely unlikely that ten compliance checks could be conducted on a single retailer in a two year time frame. Second, the settlement imposes a maximum penalty of \$50,000 on a corporation. FDA has been considering a "chain-based" enforcement strategy that could enable the agency to take action against regional or national chains that repeatedly sell tobacco products to minors. The monetary limit in the settlement is significantly lower than the \$1 million penalty FDA has the authority to impose under the civil money penalty provisions of the Food, Drug, and Cosmetic Act.

DRAFT**8. Civil Liability/Punitives/Immunity/Class Actions**

Issues: Whether ~~the incentives created by these provisions~~ will have the appropriate public health result, and whether it is appropriate to settle existing actions now.

Background: Under the settlement, current Attorney General actions, parens patriae, and class actions would be resolved by agreement and there would be no future prosecution of such actions, either for past or future conduct. Punitive damages for past conduct would be prohibited. The companies would pay a set amount each year to cover the cost of any judgments. The allocation of annual payments among manufacturers is unclear. If the annual payment is more than judgments entered, the money would be used for public health programs. Limits are imposed on the amount of damages that can be paid out each year. In addition, any part of an individual judgment that exceeds \$1 million will be paid only if all judgments under \$1 million have been paid. The extent of funds available to pay judgments, and how judgments would be prioritized is unclear.

Significant Relevant Considerations:

- Policy determinations need to be made regarding the relative importance of: compensating individual consumers; punishing companies; deterring companies; creating a fund for public health programs.

- A great number of risks and variables could affect the potential amount of the liability being settled. One significant unknown is the content of undisclosed tobacco company documents. The settlement would end numerous lawsuits at a time when many documents are still being withheld. Although plaintiffs' likelihood of success is uncertain, it is possible that documents could come to light that would warrant imposition of greater penalties than contemplated by this agreement.

- It is not clear that all of these restrictions are necessary to achieve tobacco "peace." The elimination of both punitive damages and class actions and other consolidation mechanisms is a significant concession, and should be carefully evaluated.

- The settlement imposes limits on lawsuits involving future action by the tobacco companies. This limitation may not create appropriate deterrence effects on future conduct, and could be detrimental to public health.

- FDA has traditionally opposed limits on tort liability because such liability has provided a separate system for consumer protection; the settlement could significantly reduce the deterrent effect of tort law with respect to tobacco products.

10. LOOK-BACK

Issue: Does the look-back provision act as an appropriate incentive for companies to reduce youth smoking?

Considerations: The proposed settlement contains a look-back provision with the stated purpose of providing economic incentives to tobacco firms to achieve "dramatic and immediate reductions in the number of underage consumers of tobacco products." Manufacturers would face a surcharge if tobacco-use reduction targets were not met- computed by comparing actual underage tobacco use with targeted reduction percentages. Manufacturers could petition FDA for partial abatement (75%) of the surcharge if they act in good faith (comply with the Act).

The proposed surcharge would be small in terms of the price of a pack of cigarettes (8 cents per pack)- due in part to a \$2 billion cap-and with a 75% abatement would result in only 2 cents per pack. In addition, the cost would be passed on the customers. This amount of penalty is not likely to provide a strong incentive for companies to reduce youth smoking. Moreover, because the penalty is assessed industry wide, and not on a company-by-company basis according to each firms youth sales, there exists no incentive for any one company to take extraordinary action to reduce its own youth market. This "free-rider" nature of the penalty is perhaps the most important aspect that must be modified.

The look back provision is based on the principle that the penalty should reflect the present discounted value of the profits earned by attracting youth smokers over and above the targeted number. But under those conditions it merely makes the industry indifferent to whether it meets the target or not. A larger penalty is required to achieve deterrence.

Options- In order to provide a proper penalty one or more of the following could be done:

- (1) Instead of setting the penalty at 1-for-1, make it a multiple of the profits - for example, the traditional treble damages.
- (2) Instead of computing the fine on an industry basis, the fines should be levied on a firm-by-firm basis to create the right incentives and to avoid the "free-rider" problem.
- (3) The look-back provision should be treated as a fine or penalty and not as a payment. This would insure that the amounts would not be tax deductible.
- (4) Don't dilute the penalty with abatements, either eliminate or greatly reduce the abatement or make it adjustable to create the proper incentives.
- (5) Instead of a one-size-fits-all penalty, structure the costs so that the penalty is lower the closer the companies get to the reduction targets. and/or
- (6) The penalty should not be reduced to avoid double counting. As it is now devised, the companies pay only once for the profits over time from each child. If, however, they were required to pay each year the child continued to smoke, then the incentive would exist to not induce the child to start and to convince him not to continue each year.

11. ANTITRUST

Issue: Are there elements of the settlement that promote collusion among the companies?

Consideration: The companies are required to make substantial annual payments and they are expected to collect those payments from smokers in the form of higher prices. By this device and others, they are encouraged to work together to achieve this goal. This and other collusion-facilitating aspects of the settlement, such as the ban on advertising and the restrictions on entry, will probably lead to a consolidation of market power and will most likely make the major tobacco companies far better off financially than they would be in the absence of a settlement.

As noted in another paper, FTC economists fear that the inspired collusion will lead to higher prices than mandated. To the extent that the settlement facilitates cooperative price fixing (it has language calling for an antitrust exemption), discourages entry, reduces advertising which largely leads to brand substitution, and raises the costs of output expansion, it could lead to price increases greater than the excise tax equivalent of the industry payment. Of course, this higher price would directly affect youth smoking by depressing the numbers of young people who will start smoking, and as such is a positive health result.

Thus, a greater than 1-for-1 pass through of industry payments could lead to a rise in industry profits, which would be incrementally taxed at only 25%.

Although the result will be higher prices which will likely lead to fewer smokers, economists generally consider collusion, per se, to be an inefficiency in the system, leading to other market ills.

AGRICULTURAL ISSUES

The proposed settlement is silent about the impact of the settlement on farmers and the rural economy in general. Yet, this is clearly an issue that Congress will address if any settlement proposal receives serious consideration on the Hill. A number of congressional Democrats and GOP Rep. Thomas Bliley have all signaled their intent to see that farmers' interests are taken into account. The depth of feeling on these issues should not be underestimated: tobacco is a powerful cultural force in the tobacco states (60,000 small farms) and its economic payoff -- as a cash crop, the net income from tobacco for a farmer is estimated at 20 to 25 times greater than soybeans -- is significant to the individuals involved.

In the White House meeting, Gov. Jim Hunt summarized the farmers' concerns as threefold:

- Maintain a market for tobacco products, i.e., as much financial stability as the companies are getting from the settlement
- Receive commitments from companies to buy certain amount of tobacco each year
- Get one-time payout to farmers if the equity of their tobacco allotments is reduced by reduced consumption

The Farm Bureau has floated a proposal for farmers to receive a one-time payout of \$7 billion to take into account the loss of equity as farmers' tobacco allotments lose value.

Considerations

Inherent contradictions/tensions mark any serious attempt to address farmers' concerns.

- o Maintaining market stability for farmers clashes head-on with a public health goal of reduction in use of tobacco products.
- o Maintaining an export market for U.S. tobacco clashes head-on with efforts by U.S. to support tobacco control efforts of other countries.
- o Replacing tobacco with other crops clashes head-on with reality no other crop can offer anywhere near the economic return. (In White House meeting, crop replacement was never mentioned by farmers as a real possibility).

Minorities and Special Populations

Background:

The proposed Agreement does not adequately address minority communities. Minority groups and other special populations suffer a disproportionate burden of tobacco-related disease and are among the greatest users of tobacco products. Nationally, black men are approximately 50% more likely to die of lung cancer than are white men. Smoking rates are highest among American Indian/Alaskan Natives (42%) and blacks (27%), as well as for those, regardless of race, who are living below the poverty level (35%).

Because of these differentials, minorities and special populations are the most likely groups to be affected by changes in tobacco control policies, such as those contained in the proposed Agreement. These changes can be expected to have a positive effect, provided that assurances are given that the programs and other benefits actually reach the communities most at risk. However, minority communities are often dependent on the tobacco industry for philanthropic support of civic, cultural and community activities. Accordingly, because of this heightened dependence on tobacco industry largesse, minority communities may experience a disproportionate adverse economic effect.

Issues Deserving Special Consideration:

- **Full Access to Programs and Services:** Minority groups and other special populations need to be assured full access to targeted, community-appropriate programs, media and smoking cessation services, particularly so that cost is not a barrier to accessing cessation services.
- **Research Focused on Racial and Gender Differences:** Tobacco research programs should explicitly address gender and racial differences in tobacco use and its sequelae. Inclusion of representative researchers should be emphasized.
- **Replacement Sponsorship:** Because minority communities are disproportionately dependent upon tobacco industry largesse and philanthropy, settlement funds allocated for replacing tobacco industry sponsorship should extend beyond sports sponsorship and include sponsorship for community, cultural and civic events.
- **Governance and Decision-making:** Explicit involvement of minority and ethnic communities is needed in governance and decision-making bodies established as a result of the proposed Agreement. In particular, the ability of communities to create more protective tobacco control ordinances must not be pre-empted.
- **Inclusion of Tribes:** In addressing Tribal issues, the proposed Agreement uses a formula based on tribal population as percent of state population. This does not provide adequate funds for successful program implementation, especially considering that Native Americans experience the nation's highest tobacco use rates.

Draft
(revised)

14. ADVERTISING PROVISIONS

The settlement generally codifies the advertising restrictions in FDA's final rule and thus removes the current uncertainty regarding the legal validity of those restrictions. The settlement makes several other additions that would strengthen the effect of the advertising provisions including a ban of all outdoor tobacco advertising and advertising on the Internet. The provisions concerning point of sale advertising, which limit the number of signs and restrict their location and size, offer a public health benefit by closing an important avenue of appeal to young people in retail establishments. Perhaps of greatest importance, the settlement would incorporate the advertising and marketing provisions in consent orders with the States that will be signed by the participating companies, so that, at least theoretically, those companies would be bound by the restrictions regardless of legal challenges (for example, by the advertising industry). However, it is unclear whether this approach would be constitutional.

Many of the remaining provisions, such as the elimination of human and cartoon images from advertisements in adult publications and in adult facilities, are of little value and merely reflect the industry's current practice (for example, the recent announcement that Cool Joe Camel is being retired from the marketing of Camel cigarettes by R.J. Reynolds). While the settlement's ban of direct and indirect payments for tobacco product placement in movies, television programs, and video games and its prohibition of payments that "glamorize" tobacco use sound positive, these provisions are of little worth because they are largely unenforceable.

The settlement preserves the ability of the industry to continue using the terms "light" and "low tar" as descriptors of existing and future brand lines. These terms, adopted by the industry in the 1970's, are very problematic because they were used to persuade millions of smokers that these products were in fact safer than so-called full strength cigarettes and are widely believed to have kept many smokers from quitting. These products now also comprise 71 percent of the American market. We have a substantial body of data that show that there is in fact a significantly increased risk of disease from these "light" and "low tar" products. The settlement thus preserves the industry's ability to use terms in its advertising that are now known to be false and misleading to the public and prohibits FDA from taking action against such advertising under its current authority in the Food, Drug, and Cosmetic Act. The only action the settlement allows FDA to take is to require a disclaimer stating that the products may not be less hazardous, but such disclaimers are ineffective with consumers.

Tobacco-Related Research

Summary of Workgroup Report

August 1, 1997

I. Purpose

As new resources for tobacco control become available from HHS agencies, state governments, and possibly the tobacco industry, a robust, comprehensive, and well-funded tobacco research program is essential to inform the development of new federal and state policies and guide the use of these public and private funds.

II. Priorities

"Tobacco-related medical research" is defined as research related to reducing tobacco use and reducing the burden of diseases caused by tobacco. A comprehensive research program should examine tobacco's impact on health, disease and quality of life, and include studies from six research categories defined by the Department as biomedical, clinical, behavioral, health services, public health and community, and surveillance/epidemiological research. Research must address issues at the national, state, local, and individual levels, and include studies of tobacco use among both youth and adults. Prioritization of research areas and the allocation of funds should be guided by the overriding principles of reducing tobacco use and reducing the burden of tobacco-related disease on society.

III. Funding

Research funding should be commensurate with the burden of disease and disability caused by tobacco use. The proposed settlement contains four potential funding sources, including 1) funds for activities to reduce tobacco usage, 2) funds for prevention and cessation research, 3) the Tobacco Use Cessation Trust Fund, and 4) the Public Health Trust Fund (PHT).

IV. Governance and Accountability

The PHT will be operated as an endowment fund, and the investment income from the fund will define the annual expenditures for tobacco-related research. Specifically, full capitalization of the trust fund should be achieved over a three year rather than an eight year period. A Presidentially appointed board of trustees, representing the interests of both the scientific and lay communities, should oversee the investment and fund disbursement of the PHT. Specific protections are needed to prevent new research funds from supplanting Congress' current appropriations to agencies engaged in tobacco-related research.

HEALTH INVESTMENTS

Summary of Workgroup Report

August 1, 1997

The charge of this workgroup is to develop appropriate priorities for Departmental spending of the Tobacco Settlement's unallocated, or residual, funds. Options focus on promoting health and quality of life by fostering prevention, control, and treatment of diseases, and closing gaps in health status.

I. Principles Guiding Health Investment Trust Fund Utilization

- A. The funds will be used for health-related purposes.
- B. Funds will be directed to priority populations in order to reduce disparities.
- C. A balance will be struck between strengthening existing efforts and establishing new initiatives.
- D. Funds may not be used to supplant existing expenditures.
- E. Funding decisions will be flexible in order to adjust for the uncertainty of this funding stream over time, and for changes in health priorities.
- F. The feasibility of investing of Trust Fund monies will be investigated.

II. Proposed Options For Funding (\$2-5 billion per option per year)

A. Pre to Three Program - Improving Prenatal Care and the Health Status of Children 0-3

This program would incorporate, and expand on, all 4 themes of the Children's Health Initiative and the relevant principles of the Department's Race Initiative for pregnant women and children 0-3 years old.

- ▶ Insurance expansion for pregnant women and children 0-3
- ▶ Outreach to Medicaid eligible pregnant women and children 0-3
- ▶ Expanded Healthy Start quality health care (Incorporating Health Home concept)
- ▶ Community-based programs for pregnant women and children 0-3
(Including developmental disabilities prevention, substance abuse and mental health services, immunization, injury prevention and screening programs)

B. School-Based Health Program

This program would expand the capacity of communities to provide school-based and school-linked health education and health services in areas of highest need.

C. Expanded Medicare Options

This program would include such features as grants to states for home and community-based care, reduced or eliminated 2 year waiting period for Medicare for the disabled, expanded respite care benefit, and cardiovascular disease prevention efforts.

D. Health Programs for Indian Tribes

This program would target urban Indian health, injury prevention, contract health services, women's and elder health, mental health services, inhalant abuse, oral health, diabetes prevention, sanitation facilities construction, maintenance and improvement, health care facilities construction, and tribal contract support.

F. Children's Health Initiative (Unchanged from its current form)

III. Accountability and Effectiveness

The success of these programs will hinge on the ability to analyze their effectiveness quickly, and modify them efficiently in order to keep pace with prevalent, often rapidly changing, health needs. Currently available monitoring systems are either too crude, or too limited in their scope, to effectively handle analysis of the proposed multi-billion dollar programs. Therefore, in addition to the programs listed above, Tobacco Settlement funds will be used to incorporate the latest scientific methods into surveillance and data analysis systems. Research into measures of quality care and cost-effectiveness also will be funded, and results will be incorporated into the proposals to ensure the use of relevant state-of-the-science health and financial outcomes measures.

IV. Governance

Funds will be placed in a trust fund(s) designated the "Health Investments Trust Fund(s)." A Board of Trustees with balanced membership from government, scientific, academic and lay communities, will be appointed by the President to oversee the dispersal of funds. An outside board will review Trust Fund activities on a regular basis.

DRAFT

SMOKING CESSATION & PUBLIC EDUCATION

Summary of Workgroup Report

August 1, 1997

The Workgroup believes effective programs to reduce tobacco use require a concerted, coordinated and synergistic effort at the national, state and community level. Programs should be targeted at both adult and youth tobacco users and non-users and at the environmental and social factors that encourage and support the use of tobacco. The desired outcomes of these programs are to prevent young people from starting to use tobacco, to help current tobacco users to quit, to protect the health of non-smokers by eliminating exposure to ETS, and to change the social and environmental factors that encourage and support the use of tobacco. Comprehensive programs based on these principles and funded at adequate levels have been shown to be effective in reducing per capita tobacco consumption.

I. Options and Recommendations for Use of Settlement in Smoking Cessation & Public Education

A comprehensive national and state level tobacco control program is proposed. It expands the range and intensity of existing programs and initiates new programs to fill the gaps and meet the needs of the nation. The program components include media, state/local programs, programs for special populations, school programs and cessation interventions, and includes surveillance and evaluation systems capable of not only assessing program outcomes and monitoring program performance but also of holding the tobacco industry accountable for its continued role in maintaining the use of tobacco among youth.

II. Funds Available

▶ Reduction in Tobacco Usage	\$ 5.325 billion
▶ Programs Like ASSIST	\$ 3.0 billion
▶ Tobacco Use Cessation Trust Fund	\$ 35.5 billion
▶ Public Education	\$ 12.5 billion
▶ Teams Fund	\$ 0.75 billion
▶ Public Health Trust Fund	\$ 25 billion
▶ Prevention/Cessation Research	\$ 2.5 billion

III. Sufficiency of Funds

While some line items allocations in the proposed Settlement are not sufficient for all above noted components, funds can be re-directed between these categories to adequately fund a comprehensive program.

IV. Key Issues to be Addressed and Areas for Potential Modification of Settlement

- ▶ **Administration of Settlement Funds.** The division of responsibility as outlined would present unique issues and challenges to DHHS for the implementation of a coordinated, synergistic effort.
- ▶ **Funding for ASSIST Like Programs.** The ASSIST level of funding is approximately \$1.2 million per state which will not provide for comprehensive programs within all states.
- ▶ **Additional Programs Are Needed.** The overall program should be considered as a nationwide effort involving activities through multiple agencies and organizations at all levels.
- ▶ **The Balance Between Media, Cessation, and Public Education Programs.** The funding levels in the Settlement are heavily weighted to cessation and media. A better balance is needed.
- ▶ **Implementation of the Tobacco Use Cessation Funds.** The Settlement proposes a program that would enable most tobacco users to receive assistance tailored to the needs to the individual smokers, and not limited to a single attempt. There are concerns about the value of spending the Settlement's proposed \$1 billion on a federal policy to reimburse insurers for cessation interventions.
- ▶ **Appropriate Allocation of Resources for Cessation and Public Education to Indian Tribes.** The Settlement treats Tribes like states, but the formula is based on tribal population as percent of state population, thus not providing adequate funds for successful program implementation.

DRAFT**17. National Protocol/Consent Decrees**

Issue: Whether the national protocol and consent decrees are legally permissible ways to help ensure compliance with the provisions of the settlement.

Background: The settlement has provisions for a "binding and enforceable national tobacco control Protocol" and consent decrees between the States and the participating tobacco companies. These provisions are very vague, but information in the settlement and from the negotiators indicates that they intended that the national protocol and each state consent decree would contain certain provisions of the settlement and be enforceable as contracts by the respective states. They are to allow the States to have independent enforcement authority, particularly in the event that enacted legislation is modified by a later Congress, or particular provisions are struck down on Constitutional grounds. In addition, some of the advertising restrictions that go beyond the FDA regulations and may be more vulnerable to Constitutional challenge, would only be in the protocol/consent decrees.

Significant Relevant Considerations:

- The national protocol and consent decrees do not appear to be effective mechanisms that would allow the federal government to direct enforcement activities, and conduct a national program to reduce tobacco use by young people. Individual consent decrees — would be enforceable only by the relevant signatory states in the jurisdictions in which they were entered, and not by the federal government.

- The federal government could not direct state enforcement activities conducted pursuant to the consent decrees. Federal legislation will need to be the source of obligations enforceable by federal action.

- The consent decrees/national protocol should be considered when evaluating the preemption provisions of the settlement, so as to ensure that the preemption provisions do not inappropriately constrain the states from enforcing the consent decrees/national protocol.

- The settlement's assumption that the use of consent decrees and/or a national protocol would eliminate the possibility of Constitutional challenge to the advertising provisions may be invalid. Moreover, if certain of the advertising restrictions are in federal law, they are particularly vulnerable to Constitutional challenge. On the other hand, if certain advertising restrictions (e.g., Internet advertising) are not in federal law, they will be less Constitutionally vulnerable, but may be broadly unenforceable and will likely be beyond federal enforcement reach.

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**18. ACCESS RESTRICTIONS: KEEPING TOBACCO
OUT OF CHILDREN'S HANDS**

FDA issued a number of access restrictions in the final rule including setting 18 as the federal minimum age of sale, requiring photo ID, eliminating free samples in person and through the mail, eliminating the sale of single cigarettes or "kiddie packs" (packs of less than 20 cigarettes), and limiting vending machines and self-service displays only to those areas where no one under 18 is present.

The proposed settlement seems to intend to codify all of the access measures in the final rule although the language used in the document is somewhat vague. (We have been told by one of the leading negotiators that the industry has agreed to use the exact language of the final rule and to include all the access provisions.)

In addition to incorporating the access provisions from the final rule, the settlement goes beyond the final rule and eliminates all vending machines and prohibits mail order sales. Further, in facilities where anyone under 18 may enter, the settlement requires all tobacco products to be placed out-of-reach of consumers, or, if on the counter, to not be visible or accessible to consumers. These are positive enhancements.

On the other hand, the proposed settlement freezes for five years any additional rule making. In the event that tobacco companies spend that period focusing on getting young people between the ages of 18 and 21 to begin smoking or using smokeless tobacco, the Agency would be blocked during this period from raising the federal minimum age.

Several options could be considered. First, the actual language from the final rule should be used rather than the vague language in the settlement. Second, it is worth considering whether to eliminate this adult-only exception altogether and thereby prohibit all self-service displays. (Since the final rule was issued, a number of tobacco companies and retailer organizations have been interested in greatly expanding the types of places that would be considered adult-only. This option would simplify matters and prevent the expansion of such facilities beyond what the agency intended.) Third, the freeze could be eliminated or limited to two years.

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19. PROTECTING THE GOVERNMENT'S ABILITY TO RESPOND TO CHANGING CIRCUMSTANCES

FDA currently has the ability through informal rulemaking and other mechanisms specified in the Federal Food, Drug, and Cosmetic Act to impose additional requirements on cigarettes and smokeless tobacco should the Agency find that they are necessary to protect children and adolescents from tobacco.

For example, the Agency now has the ability to raise the minimum age of sale from 18 to 19, 20, or 21 if it found that industry practices were resulting in dramatic increases in new smokers among these groups. Or, it could limit new types of advertising not currently employed by the industry if it found that these forms of advertising were influencing children's tobacco use. Additionally, the Agency could limit the types of retailers that could sell tobacco, add new warnings to the packaging or labeling of tobacco products, or require plain packaging. The Agency held back from taking these steps in the final regulation but always recognized that it had the ability to take such actions in the future.

Informal rule making also could be employed quickly and efficiently to correct or clarify any provisions in the final rule. If, for example, the exemption from advertising restrictions for "adult-only" publications was being vastly overused to permit all forms of advertising in publications read by young people, the Agency could eliminate this exemption. Furthermore, in the event that FDA found that other tobacco products such as cigars met the definition of a drug or device under the Act, the Agency could assert jurisdiction over them and subject them to the same regulations as cigarettes and smokeless tobacco.

The government's flexibility to respond to new tobacco industry practices or other factors resulting in increased tobacco use among young people is vital to the Administration's long-term ability to protect young people from tobacco. It gives the tobacco industry an enormous advantage if the government is unable to issue new rules as needed.

Under the proposed settlement, the Agency is frozen for five years from taking any additional action except in "extraordinary conditions." This freeze will permit the tobacco industry to initiate new access or advertising practices secure in the knowledge that the government is prevented from doing anything to respond for a period of five years. Five years is a considerable length of time in the advertising world. (For example, from the time R.J.Reynolds introduced Joe Camel until it Camel's popularity among children soared was only a few years.)

While the five-year-freeze is specified in the proposed settlement, the document does not affirm the Agency's ability after five years to issue new regulations. If legislation incorporates all of the current regulations but fails to expressly reserve to the Agency the ability to issue new regulations through informal rule making and other mechanisms specified in the statute, it might give the impression that Congress has identified all the restrictions it believes are necessary and that FDA cannot issue take any additional actions.

Options for addressing the above concerns include: limiting the freeze to two years, eliminating the freeze altogether, and expressly reserving for FDA the authority to issue new rules.

20. COUNTER-ADVERTISING: REACHING YOUNG PEOPLE

Counter-advertising is a vital element of any comprehensive tobacco control program. It is not enough to reduce the barrage of advertising and promotional messages young people receive that encourage them to smoke cigarettes or use smokeless tobacco. Young people need positive messages to help them reject pro-tobacco messages and to choose not to use tobacco. In addition, counter-advertising is useful in motivating people to quit smoking and to foster support for smoke-free environments. The most effective nationwide counter-advertising program is one that combines multi-media efforts with school-based and community-based programs. It should have national, state, and local components. (To this end, CDC is including a \$50 million counter-advertising component to its 'FY'98 budget request.)

The Food, Drug, and Cosmetic Act (section 518(a)) provides a mechanism for FDA to require manufacturers to notify users and potential users of an unreasonable risk posed by a product. In the preamble to the final rule, FDA indicated that this notification process might be an appropriate means to require tobacco manufacturers to fund multi-media campaigns to educate children and adolescents about the risks associated with tobacco products. The process for requiring companies to undertake this effort would consist of the Agency notifying companies of its intent to require such action, providing an opportunity for a hearing, and, if necessary, imposing a "notification order." The Agency has not yet taken this action.

The proposed settlement provides for the establishment of a public education program which the industry would fund annually for \$500 million. It does not appear to place restrictions on the type of educational messages that could be developed. It authorizes the Secretary of Health and Human Services to establish a public education program to "discourage and deglamorize the use of tobacco products," and to make grants to state health departments to assist in carrying out these programs. — However, it seems to provide primary authority to an independent non-profit organization. It is unclear the extent to which the Secretary would oversee the counter-advertising program.

In the event that this settlement were finalized, it would seem to decrease the need for FDA to use its authority to require companies to fund an additional campaign. The amount of the funding, the immediacy of the availability of funds, and the lack of restrictions on the type of messages are clearly favorable.

Although \$500 million is far more than the government has ever had to undertake counter-advertising, it may be somewhat less than the amount needed for a coordinated national/state/local campaign. (For example, if a national campaign were modeled on the Massachusetts' campaign, it would require approximately \$600 million annually.)

Options to consider include: increasing to \$600 million annually the amount of the counter-advertising campaign and, if an independent organization is formed to oversee the program, ensuring that such an organization receives overall direction or guidance from the Department. Alternatively, consideration should be given to having the program run by the Department so as to be able to coordinate media efforts with other prevention and cessation activities.

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23. Enforcement/Penalties

Issue: Should enforcement mechanisms and penalty provisions in existing law be strengthened or otherwise be changed?

Background: Current enforcement authority is found in the Federal Food Drug and Cosmetic Act and Title 18 of the United States Code. In addition, states are required to enforce their laws concerning the sale of tobacco products to minors in order to receive federal substance abuse block grants. The proposed settlement contains certain new provisions, but is unclear as to whether existing penalty provisions would be retained, diminished, or enhanced.

Significant relevant considerations: Any proposal should clarify that existing sanctions and penalties are either retained or form a threshold for developing new, enhanced provisions. Unlike the proposal, any new provisions should not restrict broad-based action, such as enforcement against "chains" for sales violation, with an unduly low corporate cap. That is, the government should be able to combine the individual fines for a large number of violations against the same corporate entity without being limited by a maximum fine per company. The government may also want to use this settlement opportunity to enhance existing authority with other provisions, for example:

- raising the FDCA civil money penalty maximum, currently \$15,000 per violation, \$1,000,000 per proceeding;
- giving FDA full subpoena power; or
- streamlining civil money penalty procedures to allow for ticketing by FDA. Currently, FDA must provide for an opportunity for a hearing before assessing a fine. It may be preferable to first issue a ticket and then provide an opportunity to appeal.

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Monitoring, Evaluation, and Program Accountability

Background:

All proposed program efforts (i.e., media, community, school, cessation activities, and minors' access advertising restriction provisions) will require a comprehensive monitoring and evaluation system to assess program impact at the state, major metropolitan, and media market levels.

Because the nature and complexity of these needs will place unprecedented and urgent demands on current systems, existing health information systems must be strengthened. Otherwise, it will not be possible to determine if intended public health effects are being achieved. New levels of monitoring and evaluation capacity at the Federal and State level are required, especially in view of the erosion in our public health infrastructure over the last two decades.

While the monitoring of adult smoking behaviors at the national and state levels, and of youth smoking at the national level is well established, major gaps in data collection and evaluation systems remain. Monitoring youth smoking is incomplete at the state level, and needs to be expanded to major media markets. Little infrastructure for evaluating the provision of cessation interventions exists, and mechanisms to hold the tobacco industry accountable (e.g., advertising that influences youth, or tactics that hamper effective minors' access restrictions) are needed.

Issues Deserving Special Consideration:

- **Expanding Current Survey Mechanisms.** Current monitoring and evaluation activities need to be expanded at the national, state, and local levels, as well as in major media markets, to incorporate: 1) tobacco-related knowledge, attitudes, and behaviors (e.g., detailed descriptions of brand preference, the incidence of initiation and cessation of various tobacco-use behaviors, and observation and reactions to both anti- and pro-tobacco media messages) among adults and youth; 2) exposures to both anti- and pro-tobacco programs and messages (e.g., anti-smoking advertisements, tobacco's portrayal on television and in the movies, attempts by the industry to circumvent advertising restrictions); 3) relevant policies, ordinances, and laws, and their enforcement; 4) biomarkers indicative of exposure to tobacco and tobacco smoke; and 5) current and future tobacco products' composition and design, including laboratory analyses of tobacco and tobacco smoke and their constituents in body fluids.
- **Coordination of Efforts.** The monitoring and evaluation system will need to function in a coordinated fashion. Currently most activities are being conducted by CDC, with SAMHSA, NIDA, FDA, NCI, and others also conducting monitoring and evaluation work.
- **Allocation and Sufficiency of Funding.** Funding for these activities should be assured and allocated separately from those allocated for research. Furthermore, CDC estimates that approximately \$270 million annually will be needed to conduct the required activities.
- **Expedited Clearance Mechanisms.** The dynamic and rapid need for monitoring data will require expedited mechanisms for clearance of surveys and for funding of evaluation projects. Applied research projects to guide timely modification of intervention efforts also need expedited review and funding.

26. HEALTH CLAIMS

The proposed settlement envisions that conventional and so-called "less hazardous tobacco products" would be able to make health claims in labeling and advertising. The deal also preserves the industry's ability to make "light" and "low tar" claims as long as such claims are accompanied by a disclaimer elsewhere on the label or in an advertisement. Serious questions have been raised about the public health benefit of these provisions and about the wisdom of deciding this issue now (as opposed to letting FDA decide at a future time whether to permit these claims).

The first fundamental issue that must be addressed is whether claims should even be allowed for tobacco products that pose reduced risks but are still dangerous and addictive. There are some in the public health community who believe there is a role for such claims. However, important lessons from the history of "light" and "low tar" marketing efforts are quite relevant here. Filtered "light" cigarettes sold over the last 30 years may have reduced tar and nicotine deliveries, but there was no concomitant reduction in the death and disease associated with tobacco use as result of these marketing innovations (perhaps because smokers simply smoked more cigarettes or inhaled more deeply). As we look toward the next 30 years we must remember that every single cigarette on the market today, regardless of its nicotine level, is capable of both creating and sustaining addiction. It is arguable whether health claims should be permitted for innovations that may reduce the risk of products that nonetheless remain deadly and addictive.

The second fundamental issue is the vagueness of the health claims provision in the settlement. Under the deal, "scientifically-based health claims" would be permitted for "less hazardous tobacco products." These terms are not defined, hence there is no way to know what the negotiators meant. One party to the negotiations has stated that it would be up to FDA to determine what these terms mean. Until legislative language is drafted and enacted into law, it is unclear whether FDA would indeed have that discretion and authority.

The third fundamental issue raised by the settlement is the provision that allows claims for "less hazardous tobacco products" to be exempt from the advertising restrictions in the legislation if FDA finds that such advertising would reduce harm and promote public health. Even if FDA retains the discretion to make these determinations, the wisdom of the provision remains debatable.

The fourth fundamental issue is addressed in the "Advertising Provisions" analysis that discusses the impact of the "grand fathering" of certain "light" and "low tar" claims. As stated in that analysis, FDA would be unable to eliminate the use of these misleading terms as long as they were accompanied by relatively ineffective disclaimers.

- Volume
- International
- ETS
- Liability / trust fund

Spending (child care)
 smoking
 conv. stores

anti-trust
 smokeless

5/12 Raids MTS -

Tob - nr - notes + memo
 To Do:

- (1) MTS w/ DeWine / Abraham
- (2) Took language on approps

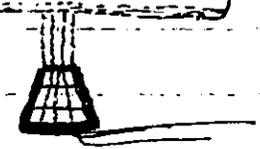
1. smokeless

// International
 still in process

Free
 cigarette penalties
 - extrajurisdictionality
 center
 duty free

2. Liability

Trust acct w/in larger trust fund



- Volume

ch

- International - no fee; no to dept; no duty-free; army-band; existing DoD ETS language w/ support; extrajurisdiction.

- No new spending

- New baseline focus (w/ our survey)

?? - 50/50 trust fund

- Bureaucracies

- Spending

- menu - 700 pop names
- fix quotas in bud window + out year.

opt-out

ETS - 2 yr w/ equiv health protection

multilateral report w/ smoking.

(non-profit corp)
 vending machines
 documents
 accessibility passed

No partner/affiliate/
 atty / agent
 Amends to reduced risk/
 addiction

ETS -
 OSHA - as effective band as health.

7/4 50%

new baseline - give to ind.

Tost:

- running #s on CPI/390

- smokeless (vot adj)
- survey - #25m

McCasin
Hollings
Kerry
Staff:

- Vets: give to Hegel?

Tob - vet - notes + memos
and
Tob - vet - legislative outreach

(Lott)

<u>With us</u>	<u>Maybe</u>	<u>Unlikely</u>	<u>Out</u>
• McCl	← ? Bond	• Auer	Hubel Hubel
• Chaffee	Bonnett	Kyl - (Vets)	Nichols
1 Guter - (itD)	← ? Campbell	• Curiale	Ashcraft
• Gettys	<u>Dwyer</u> - Abraham	Adams	Roth
• Snow	(Vets) - Murkowski	Roberts	Gram
• Collins	██████████	Gregg (??)	Dominici
• Lujan -	Brownback	Warner	Shelby
1 Dewine	Cochran	Thompson	Fankhauser
• D'Amato	[7]	Hegel - (Vets)	Brown
██████████		Hubel	Coats
• Mack - (itD)		Hubel	Craig
1 Kirt - (itD)		Smith, Bob	Euzi
1 Stivers		Thurmond	Faircloth
1 Specter			Holmes
• Crassley			Grans
G. Smith			LaHue
			Keeney
			██████████
			McConnell
			Susiano
			Thomas

Hollings -
Ferd -
Robb -
McLund -

Feinstein -
Mucilli -
Poreaux - OK

Tues:

8:30: McCain meets w/ parliamentarian

ho. after come in: file closure w/ vote on Thurs.
McC modifies his bill
~~all time on tab. spent w/ McC~~

Ask for years + ways.

All time spent talking on amendment (Durbin)
etc.

It was to table from Gramm, vote - then
McCain amends

File closure

1. Ask for years + ways
- 1.5. Modification of Main Amend.
2. Durbin withdraws
3. sub in vets. for Gramm
4. If win, we ^{celebrate} + 4 career studies

If lose, 2nd degree w/ ? ;
stall; do budget point
~~Reopen point of order~~

no votes until closure

File closure

- Ask for years + ways.
- Modification
- Talk
- ?? Budget point of order -
(postpones Durbin)

OR NOT

TO DO'S

See Josh stuff

- a. Smokers adjustment
- b. Survey - #s + decaying
- c. #s on CPI - why not do

- McC 1. Check w/ maybes
2. Get modification together for Monday
3. Get D + Tax on AGI to do better -
price impact of settlements
4. Draft 2nd degrees
- e.g. with timing + hope of
marriage tax (2)
- e.g. veterans (2)
- e.g. drugs (simple)

[us]

Leahy: smurfling

5-15 Tobacco - Amendments

Dem

1. Lookback (Dunlin)
2. International? (Wyden)
(funding floor)
3. \$1.50 (Conrad) (Kerry back-up)
4. Child care (Kerry/Bond)
5. Deductibility of ads (Feed)
↳ incurris w/ bill?
6. Cigars (Dunlin)
7. Class size?? (Murray)
8. Anti-smuggling - \$ to cops
(Leahy)

Repubs

1. Wipe out cap (w broader?)
(Cress)
2. Veterans
(Ricketts/McCain)
3. ETS - state opt-out
4. Nicotine / products - FDA
5. ATF - eliminate role
6. Atty fees
7. Roth tax cut (self-employed)
8. Make whole thing subj to
approps. (Revenue)
9. Lookback for drugs (Ashcroft) -
Pub health → drugs
Research drug czar / needles /
crack
10. FDA - black market finding
11. Black mkt price trigger
12. Earmark NIH \$ to tobacco
(Pettit)

Talk to Biden
Leahy re drugs

Ask Justice: Take cut
fed cause of action?
or give it a check?
no preclusion of st ct action

Ask Justice:
Need language to
address Minn +
other settled states
Pt. of sale for adult-only
etc. - put in T. 14 only. OK?

Filibuster threat: at least
4 Repubs
Monitor money:
appropriations look (OMB)

5/12. MTS w. SR/IS

1. Smokeless fix - Harkin talking to Ford

1:1:1

change de minimis exception

take out de min. exceptie for cigarettes

Tot. ser.
notes + memos

2. International - Harkin talking to Wyden

Get rid of: entering restrictions abroad

excise fee

prohibit on duty free sales

expanded Doffett

3. Amendments - Republican

a. Second-hand smoke - \$ only; grant program
only for kids + others

b. Attorney's fees

c. Ding vote - laws on nicotine/product/retail

d. Hatch substitute for whole bill

e. Cut down on price - to June 2016

f. Ship liability (weys)

g. Czar, Cwendell on drugs - cocaine/needles/monthly drug czar

h. Lupan - harm

i. Ashcroft - liability protections for charities, hosp. devices

j. Put all extra \$ into Medicare / tax cut

4. Amends - Dem

a. Czar substitute

b. \$1.5B

c. ETS - hosp.

d. Child Care

e. Cigars

f. Lookback

g. Liability

h. Tax deductibility of advert.

2:15 - McCain hideout

(acceptability panel)

Take off: blow cap before 20,
in exchange for more \$ in
lookbacks.

Obama

McCain

Vol adj

Vol adj

Unit score cor. of

Int'l

No new spending

Env. stre

Needs reassurance that at
end of process, people will
be reasonable.

Need opt-out on ETS

No new ent. spending

Supplying - pres certif

17 bureaucracies

MTG w/ Sen. McCain + Hollings

McC: International - Ask EB to talk to Wyden

Finance to take Hollings amend.

States have to receive their \$

(Wicks) - now at 65¢ - 75¢ - no lookback)

Bureaucracies - being trimmed - so can go

No new entitlement spending ("In agreement.")

Vend machs have to be scaled back

Convenience store. Already have ad. camp. in can.

Last thing we need:

Threshold - in say act in this area.

EB: Camel's horn in tent?

TR: ^{no} late on floor - NOT an mfr's amend. EB Mfr's am.

Allow states to make part of licensing scheme - something about punishing kids.

Volume adj - in 1st year -

Sec. hand smoke - Chafu/Hahn - grant programs
grants

Direct spending safeguards - OMB standard language

Black market - Pres. vetif / expedited procedures

EB: encourage ind to cheat

Tax fund - how financed + paid out

Spending - how much? Direct or appropriated?

tax deduction for health insurance

Parent cos / addicts / fed on st c. of act -

give them up? hold on? negotiable?

Shlager - maybe allow this to be an amendment -
for anti-liab ~~exp~~ crowd.
McLain - can definitely hold off long until late

EB: Lohbachs

Smokeless - Schlager: work in progress
Int'l - look what's coming from left.

State funding - money (ITR - tax relief)

Bureaucracies - whatever we can do.

ITR: need help \$ w/ pub health comm.

New emts - discuss in context of all of it.

Consensus - agree no other enemies, but have to be
very careful.

VAI adj - big deal to ind; 5-10m
big size; to discuss

Sec had smoke - big difference. By imp to us
opt-out

hosp ind exclusions

(OSAAA involvement)

Smuggling - willing to be cooperative

don't want to create incentives for industry

Hollings: can't yield to the pressure

has to figure something better

BR - penalty on ind. if caught smuggling

Spencer - tax debate we've done

Peab

if had to have one,
resolve all together | money

JR: have to pay attn to govs.

EB: discretionary menu

Loebach

ind cap. \$6

\$500 per smoker in co. surcharge, starting
from lit smoker, outside cap.

strengthen link btw 20% miss + loss of liab

Liability

only if cos return to table

No parent/affiliate protection

& Lillian 80-80

S. b. of up-hunt #

JR: 80-80 is right / not 80-20

Protection

5 McCain/Kerry/Hollings - talk with

1. Payments - v. adj. (incl. inflation adjustment)
 how does this affect ourselves?

2. Survey cost =

Also "deeming" language
 maybe some other
 time?
 NAS review
 thing cosmetic?

3. Inf. adjustment
 CPI / 3%

4. Veterans - Specter / Rockefeller

1L over 5

Med: 600m over 5 - out of prevention

5. Cession ~~not~~ programs =

incl. vets

6-2 - Mtg w/ Daschle

Pues will say: not preferable us --
but will not ignore veto threat, or
take strong stand.

TD: Doesn't want to blast. Potentially
worse version - but blast whole idea

Marriage penalty - in an alternative

we have to give them something to vote for.

Proposed Amendments:
Craig - Gov
Attorneys
Farmers

2 substitutes: Hatch
Wickles

Dem amendments: Durbin
Reed
Kerry

8-29 cur - cur of Hoppe:

go of amend. - have to get through... don't go for closure

Harold substitute
Dunnick - Nicholas - 1/2

lot of dry stuff - beyond CC

Another attorney amend

Roth tax cur

Gramm " "

Crandall - Craig

too early - harden cur says.

We said: commitment not to go off tobacco

when will rest of work get done?

Why 12 Dems also voted for cur was the bill?

That's why closure vote on Tues. in one week so imp.

- Cleaver
- G... ..
- Harkin
- Hollup
- Johnson
- Kohl
- Leahy
- Levin
- Max Baucus
- Murray
- Robb
- Wyden

Have to decide whether makes sense to offer closure a week early.

Roth tax cut - self-employed has lots of support in Dem caucus

Other part raises q's about employers dropping coverage

protect you from marriage tax cut? maybe, maybe not.

Leahy + Gramm vote Mon or Tues. Gramm may not come down all that far - may not be so willing to compromise. Hard to know.

5/6

Attorneys General

Ind. needs reassurance -

stop them from going into Third year

need concision - as McC on liability -

hard to know how/when.

Ind is / ~~Regime~~ commenced if doesn't get better than McC.

CG: Export provisions - give something to industry
meaningful - and not taboo subject

2-tier T.14 - some minimum of protection if you do X.

more protection if you do Y.

→ that they
don't have to
do new.

e.g.
(total ad ban)
(size of pack)
(internat - age shift)

8/11

Tob Prices Mtg

1. Why we might be different:

(from ST/CTO):	smuggling	st excise taxes
(some have only vol effect -	mark up	toothback
some have indep price effect	city share	export fees
(which itself has a feedback		liability.
vol effect)):		

2. Smokeless

Good policy and helps lower the price

1:1:1 - so cost will no longer equal for de min for mouth but not chew -- still quality there.

de min also lets imports, new entrants of look.

1:1:1 w/ de min - 72¢ for mouth; 28¢ for chew (incl. ad val.)

" w/out de min - each \$1.10 → but then have to add ad val → \$1.34

(Covad had 1:1:1)

Push for this + work down de min threshold (Covad didn't have this)

- ① de min should be only for smokeless - bad for imports, so good for Ford
- ② lower thresholds to get cost in - maybe diff threshold for chew + mouth

Tues - Hatch - price hearing (Black, Feldman, Myers (!!))

letter go up to Hatch - hope, tonight

Wed - Hatch - constitutionality?

CMB letter, twisting May 1 letter

THE WHITE HOUSE
WASHINGTON

May 10, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Elena Kagan

SUBJECT: Tobacco Negotiations

This memorandum reviews what we need to get out of our negotiations with Senators McCain and Hollings; what we can give up; and some ideas on opening positions and trades. Negotiations are not scheduled to begin until Tuesday, so we can meet Monday to discuss these ideas and any other questions you might have. We also would like to go over spending issues, including the public health programs and the state menu; OMB is currently preparing some tables for this discussion.

I. What we need**A. Lookback Penalties (pp. 345-61).**

The most important (and most difficult) concession we need to secure in these discussions is to strengthen the lookback penalties by increasing the cap and adding a company-by-company component. Along with liability, this is the number-one concern for Conrad, Waxman, and many public health advocates. But Hollings and the industry will vehemently resist any increase in penalties as a backdoor way to drive up the price of a bill they think costs too much already. McCain might have given us these changes in committee, but Hollings said no.

In its current form, the McCain bill includes industrywide penalties of up to \$3.6 billion, the precise equivalent of a 20% miss. Instead of a company-specific penalty, the McCain bill includes a provision that could theoretically deny liability protection to a company that missed the targets by more than 20% -- but in its current form the provision is meaningless.

In an earlier memo, we described three options on how to meet our concerns: (1) raise the cap to \$4-5 billion, and add a company-specific penalty of \$500 per youth smoker; (2) raise the cap to \$4-5 billion, and add a company-specific penalty of \$20 million per percentage point (the virtual equivalent of \$500 per youth smoker); or (3) raise the cap to \$5 billion, with companies paying the first \$4 billion on the basis of adult market share and the last \$1 billion on the basis of youth market share. These are the options you described to McCain in your office. We offered to explain these options in more detail to John Raidt, but he has yet to take us up on it.

We now think we have an even better idea that stacks these approaches in a way that might sound more attractive to the public health community but also fits more neatly into the current McCain bill. Here's how it would work: The first 20% would be paid industrywide, as in McCain. Once the industry-wide level was reached, any company that missed by more than 20% would be assessed an uncapped company-specific penalty of \$500 for each youth smoker beyond the 20% miss. Under this scheme, there is no cap on penalties - just an industrywide tier for the first 20% and a company-specific tier beyond 20%. But because the company-specific component is reasonable, and doesn't kick in until 20%, there's no need for a cap because it won't put anybody out of business. Treasury estimates that even if youth smoking didn't decline at all, and companies had to pay for a 60% miss in year 10, Philip Morris would pay a company-specific penalty of less than \$500 million.

Waxman will never be satisfied with these amounts, and whatever we get will suffer by comparison to the Meehan-Hansen bill, with over \$1.00 a pack in company-specific penalties. But being able to say we have penalties that are uncapped with a company-specific component will go a long way with the rest of the public health crowd. Moreover, it only requires one change in the McCain bill: replacing the current unworkable company-specific provision linking a 20% miss to liability protection with our company-specific idea. We might be able to convince Hollings that such a trade isn't so bad from the industry's standpoint. (The public health community doesn't seem to care about the current provision, but industry analysts were somewhat alarmed by it.)

To end up with this plan, we recommend staking-out an opening bargaining position that is somewhat stronger: for example, raising the industry cap to \$5 billion, and adding an uncapped company-specific penalty of \$500 for every youth smoker (not just the ones above a 20% miss). (We could start at \$750, although that is more than we discussed with McCain.) Another idea we could raise to frighten Hollings (and eventually relent on) is the prospect of seeking to strengthen the link between a 20% miss and loss of liability protection.

B. Environmental Tobacco Smoke (ETS) (pp. 415-20).

The McCain bill generally requires owners of "public facilities" (defined as any building "regularly entered by 10 or more individuals at least one day per week") to prohibit smoking except in specially designated smoking areas that accord with specified ventilation requirements. The bill excludes from this general prohibition buildings used for residential purposes and -- in the so-called hospitality exception -- buildings used as a "restaurant (other than a fast food restaurant), bar, private club, hotel guest room or common area, casino, bingo parlor, tobacconist's shop, or prison." The bill further provides -- in the so-called opt-out clause -- that none of the ETS provisions shall apply to any state that "by law, provides that [they] shall not apply to that State."

Our goal is to remove the opt-out clause, which the agencies (OSHA, EPA, HHS) and the public health community agree very substantially diminishes the value of an otherwise fairly

strong ETS provision. The tobacco industry does not much care about this section of the bill; the original June 20th settlement did not include any state opt-out, instead simply setting a national standard. For some Republicans, however, the issue is ideological; the opt-out clause is a way of resisting federal (worse yet, OSHA) regulation. We should not underestimate how difficult it will be to remove this provision -- but we also should not underestimate the importance of this issue to the public health community and the need for us to come out with a solid win.

The agencies and public health community also would like us to fight the breadth of the hospitality exception -- particularly its coverage of non-fast food restaurants and casinos, which are often the most unhealthy of all public facilities; the agencies have suggested phasing in (over a period of five or so years) the application of the bill's ETS provisions to these facilities. Subjecting restaurants and casinos to the bill's ETS provisions, however, would add yet another set of powerful interest groups to the many already fighting tobacco legislation. If ~~we~~ were to succeed in accomplishing this objective, we might soon regret it.

In thinking about the ETS issue, you should note that the Chafee-Harkin bill adopts a very different approach, which is much more amenable to Republicans. Rather than prescribing a national standard for public facilities, Chafee-Harkin would provide grants to states and building owners for progressively lowering exposure-levels. At the same time, Chafee-Harkin would provide funds for outreach and education regarding the health effects of ETS on children, which primarily occurs in their own homes. Some of the agencies think that a program of this kind, assuming adequate funding, could have substantial health benefits; EPA in particular is very supportive of the focus on children, and would like us to press for funds for this purpose wholly independent of the public facility standard. The public health community, however, is focused on a national standard and will give us little credit on the ETS issue unless we emerge with the standard currently in the McCain legislation minus the opt-out provision.

In light of all the above, we recommend an opening position that demands both the removal of the opt-out clause and the elimination or narrowing of the hospitality exception. We can then bargain down solely to the removal of the opt-out clause. We would not initially mention the use of incentive grants, because McCain is likely to jump on that suggestion as an alternative to a national standard. At an appropriate time, however, we may want to suggest the addition of a grant program to a national standard, so as to make it less of an unfunded mandate. If such a funding stream becomes part of the ETS provisions, we should try to include some grants for outreach and education relating to ETS's effects on children.

C. Antitrust Exemption (pp. 628-29).

The McCain bill exempts from the antitrust laws any concerted action among tobacco manufacturers if it is for purposes of (1) entering into and complying with the agreements (protocols, consent decrees, etc.) presumed to exist between the manufacturers and the federal and state governments; (2) refusing to deal with a distributor or retailer who offers products to underage persons or otherwise fails to comply with the requirements of the law; and (3) carrying

out any plan to reduce the use of tobacco products by teens if the Attorney General has determined that the plan is "appropriate as part of the effort to reduce the use of tobacco products by underage individuals and will not have the effect of unduly restraining competition."

The Antitrust Division hates antitrust exemptions, and this one is no exception. The Division worries that any antitrust exemption, no matter how carefully drafted, will tend to facilitate anticompetitive behavior in an industry, including price-fixing. In response to the argument that anticompetitive behavior will only increase prices, which is what we want with regard to tobacco products, the Division notes that it does so by allowing the tobacco companies to unduly enrich themselves, which is hardly the mechanism most consistent with public health interests. Moreover, the Division believes that the McCain bill is not carefully drafted; rather than specifying clearly and precisely what kinds of concerted action tobacco manufacturers can undertake in what circumstances, the bill countenances concerted action of any kind whenever intended to facilitate several generally defined purposes. (With regard to lack of specificity, provision (1) above is particularly troubling.) Finally, the Division objects strenuously to the regulatory role assigned to the Attorney General by the McCain bill, noting that (1) she has no expertise in determining what efforts will reduce youth smoking and (2) the involvement of law enforcement officers in policy matters of this kind would set an unfortunate precedent.

Although the Division's general inclination is to oppose any and all antitrust exemptions, it also acknowledges that in limited circumstances, an agreement among tobacco manufacturers could facilitate efforts to reduce youth smoking without imposing any real harm. (The Division believes that the strongest case for an antitrust exemption is in a bill without company-specific lookback penalties, because such a bill has little way of containing free-riding other than by facilitating industry-wide agreements.) The Department is accordingly drafting a carefully limited exemption that we could substitute for the McCain language. We should have this new language on Monday.

We recommend an opening position that calls for the elimination of the antitrust exemption. We may not encounter much resistance to this position. If we do, we should revert to the Antitrust Division's new language. The difference between eliminating the provision and substituting our own language is not worth terribly much -- to our own agencies, to the public health community, or to Democratic members of Congress.

D. Liability Issues (pp. 431-51).

In addition to the annual liability cap, the McCain bill contains a number of less high-profile liability provisions that Sen. Conrad has been trying to highlight. The bill settles not only the state suits (as the Conrad bill itself does), but also the so-called "Castano suits" -- i.e., the class actions brought by Stan Chesley and others alleging the harm of addiction (not tobacco-related disease) and requesting a remedy of cessation services (not compensatory damages). The bill also bars suits by cities or counties located in states that have recovered funds under the Act. Perhaps most important, the bill prevents plaintiffs with tobacco-related claims from suing any

entity other than the tobacco manufacturer, including parents and affiliates, officers and directors, and other persons involved in the distribution chain (e.g., distributors, wholesalers, retailers). Finally, the bill provides that in claims against manufacturers, evidence relating to reduced risk products developed after enactment of the legislation shall be neither admissible nor discoverable.

We should insist, as an initial matter, that liability limitations go only to companies that "return to the table" -- i.e., companies that sign a protocol with the federal government agreeing to abide by the bill's terms, as well as the additional, otherwise unconstitutional advertising restrictions. As you recall, we have given McCain's staff a set of changes designed to make the bill work regardless whether the companies agree to participate. In this set of changes, we put the liability protections into the portion of the bill -- and only into the portion of the bill -- that applies to willing parties (so-called participating manufacturers). We have reason to believe that McCain agrees with this structure, but do not know Hollings' views. If we need to, we should insist on the point: a company should not get liability protections if it has not agreed to accept the bill's terms without challenge and to adopt additional advertising restrictions.

As to the content of the liability protections, we want to have another conversation with Conrad's staff, but we are inclined to think that you should raise only the issue of parent and affiliate liability. The Justice Department largely supports the rationale of the other provisions: the Castano plaintiffs, like the states, were well-represented at the bargaining table, and the funds for cessation in the bill represent recovery for their claims; the preemption of local claims where a state already has collected funds prevents double recovery; the protection of entities down the distribution chain encourages companies to deal with participating manufacturers and effectively prevents them from challenging the bill's advertising provisions; and the reduced risk rule encourages the development of safer products. The Department has some suggested changes to the language in these provisions, but we suspect we can make these changes on the staff level. The single liability limit that seems troubling in concept -- and to which Conrad has most strongly objected -- is the protection of parents and affiliates of manufacturers, which would protect these entities from tobacco-related suit even when they have committed an independent wrong. Bruce Lindsey agrees that we should be able to remove this provision.

II. What we can give away

A. Volume Adjustment.

The most valuable concession we can make in these discussions is to allow the annual payments to be adjusted for volume in the first five years (the current volume adjustment doesn't begin until after year 6). This change would give the industry the certainty of knowing that the annual payments won't increase cigarette prices by more than \$1.10 a pack, even if volume plunges. It could also reduce available revenue in the 5-year budget window by \$5-10 billion. But it is a concession we almost certainly have to make in order to keep Joint Tax from scoring the McCain bill as an increase of \$2 a pack. (Joint Tax is currently assuming higher retail

markups and other factors that will keep the price around \$1.50 even with a volume adjustment.)

In the first five years, the McCain bill provides for fixed payments by tobacco manufacturers of \$93 billion (plus a \$10 billion voluntary upfront payment). We estimate that these payment levels will reduce consumption by 23% and result in an effective real price increase of \$1.10 per pack by 2003. Beginning in 2005, the McCain bill would adjust these payments as consumption rises or falls, thereby keeping the per pack cost constant.

The industry and Wall Street were quick to criticize this approach as a death spiral, because the companies would still have to pay \$93 billion over 5 years even though they expect consumption to drop nearly twice as fast as we projected. Our \$1.10 is based on consumption at 17.7 billion packs in 2003. If consumption fell to 13 billion packs, as many analysts predict, that would rise to \$1.50. The industry also argues that at those prices, black market sales would significantly reduce legal consumption, driving the price of the settlement per pack higher still.

The major drawback of a volume adjustment is that instead of locking in \$65 billion over 5 years, we'll end up with somewhat less. Joint Tax is likely to assume a larger drop in consumption than Treasury, so with fewer packs sold, \$1.10 a pack will bring in less money. (We've asked OMB and Treasury to prepare a memo for you on where they think Joint Tax will come out, based on our meeting last week.)

We propose a volume adjustment that begins in year 2, and would be based on the difference in the prior year between actual volume and our estimated levels (essentially, a correction of our previously estimated volume adjustment). This approach will keep the price per pack constant at \$1.10, while keeping projected industry payments as close as possible to our budget numbers.

B. International Provisions (pp. 583-7, 599-628).

The McCain bill currently contains a number of provisions on international tobacco control proposed by Sen. Wyden. The bill would broaden the current prohibition (the "Doggett provision") on using federal funds to promote tobacco products in such a way as to interfere with the government's ability to negotiate general tariff reductions. The bill also would impose the marketing, advertising, and labeling restrictions applying in this country to U.S. companies, or their affiliates or subsidiaries, operating overseas. Finally, the bill would impose a clearly unconstitutional 2-cent per-pack export fee.

Everyone in the room will dislike these provisions. McCain thinks they're silly; Hollings thinks they're detestable; and our own agencies object to everything noted above except the requirement that U.S. tobacco companies operating abroad use the same or substantially similar labels (most already do). As you know from listening to Rep. Pelosi, however, these provisions are very popular among liberal Democrats, elite opinion-makers, and the public health community. They believe that without these provisions, this legislation may simply export our

tobacco problem to other nations.

Our bargaining position with respect to this issue is hardly optimal, because McCain and Hollings know our own opinion of these provisions. But in light of who supports these provisions, we cannot give them up without getting something substantial for them. Indeed, even if we do effect a good exchange, we may want to keep this part of the bargain out of the text of the manager's amendment. McCain's staff has suggested, for their own reasons, that the best way to deal with this issue may be through a pre-rigged floor amendment (*i.e.*, an amendment we would agree to support). Although this approach forces us to reveal our view of the international provisions, it also insulates us from the charge that we have given away these provisions in what could be characterized as a backroom negotiation.

C. Attorneys' Fees Limitations (pp. 451-54).

The McCain bill has one provision relating to attorney's fees. This provision submits to arbitration, to the extent consistent with private agreements, any fee dispute arising from "litigation affected by, or legal services that . . . resulted in, this Act" -- *i.e.*, the state suits and the Castano actions. Under the provision, the arbitration panel makes an award to the lawyer after considering criteria such as the time the case required, the difficulty it involved, and the risk it imposed on the attorney. This provision is exactly what the lawyers in these cases want; it does nothing for the many Republicans who would like to limit fee awards.

One way to respond to this desire is to impose a presumptive cap of \$250 per hour on the awards that the arbitration panel could make. Under this provision, the arbitration panel could decide that the circumstances were sufficiently unusual as to call for more than \$250 per hour, but generally would make awards within the cap. Such a provision would substantially (*i.e.*, by millions and millions of dollars) cut into the awards of the Castano and state lawyers, to the extent that their preexisting contracts do not specify other fee arrangements. (The Justice Department believes that attorneys for only 15 states -- the four that have already settled and 11 others -- have contractual rights that could trump such a statutory provision; we do not know about the lawyers for the Castano plaintiffs.)

We do not know whether McCain will raise the issue of attorneys fees; he does not seem to care much about it personally, but to the extent he is negotiating for his Caucus, he might well do so. If he does, we should offer the above proposal; even if he does not, we should probably look for an opportunity to suggest a trade involving this kind of provision. McCain might want to go further, imposing still more stringent limits on the lawyers in the state and Castano suits, or imposing limits on the lawyers in any tobacco legislation, now or in the future. We should not accept the latter kind of proposal in this negotiation, because our own caucus (including Sen. Hollings) would view it as pro-tobacco, anti-trial lawyers, and anti-consumers.

Smaller Issues and Trades

We are meeting with McCain's and Hollings' staff on Monday morning to discuss a number of design issues that we hope can be resolved without the principals. These include (1) how much to charge smokeless manufacturers; (2) how to structure the \$6.5 billion liability fund; (3) licensing and anti-smuggling provisions; (4) document disclosure provisions; (5) inflation adjustments and other technical pricing issues; (6) whether and how to reduce the 17 so-called new federal bureaucracies; (7) whether and how to provide funds for asbestosis victims; and (8) how to restructure the bill to make it effective regardless whether the companies return to the table. If we need to bump any of these issues up to the principals' level, we will let you know quickly.

Assuming the issues for the principals are as stated above, we think the following trade-offs make some sense: (1) strengthened lookbacks in exchange for a volume adjustment and elimination of the provision to remove liability caps; (2) strengthened ETS provision in exchange for amendment of the international provisions; (3) elimination of the antitrust exemption and parent company protection in exchange for attorneys' fees limitations; and (4) as we will discuss further tomorrow, full funding for public health programs and a good state menu in exchange for our agreement to no new entitlement spending.

THE WHITE HOUSE
WASHINGTON

May 12, 1998

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Elena Kagan

SUBJECT: Tobacco Negotiations Status Report

Erskine, Larry, and we held a series of meetings today in an attempt to reach agreement with Sen. McCain on a manager's amendment to his tobacco bill. Although we have not yet nailed down a deal with McCain, our discussions with him were very fruitful. In later discussions, Sen. Daschle indicated real enthusiasm for the deal that we believe we can make. As explained further below, however, Sen. Conrad expressed severe disappointment on several issues.

The key features of the manager's amendment under discussion are as follows:

1. Price. As you know, the McCain bill imposes payments of about \$65 billion over the next five years. OMB has calculated that these payments, when passed on to price, will increase the price of a pack of cigarettes by \$1.10. We expect, however, that CBO will say tomorrow that if the McCain bill becomes law, the price of a pack of cigarettes will rise by over \$2 in the next five years. A large part of this price differential reflects disparate assumptions about how much the volume of cigarettes sold will decline in this period. (The more consumption declines, the larger the per-pack price increase necessary to make the annual industry payments.)

To combat the new CBO figures, which will tend to support the industry's recent arguments, we would agree in the manager's amendment to incorporate an explicit "volume adjustment" in the first five years of the McCain bill. (There is already an explicit volume adjustment after year six; prior to this point, OMB's estimates about volume reduction were taken into account in setting the annual payments, but there is no correction mechanism if OMB is wrong.) This volume adjustment would ensure that the price increase attributable to the annual industry payments would not exceed \$1.10 per pack, no matter how much volume declines. (CBO assumptions regarding additional factors, such as wholesale and retail mark-ups and state excise tax increases, should bring the total price increase to about \$1.50 in five years.) The downside of this approach is that if CBO is right about how steeply consumption will fall, a volume adjustment will bring down the total revenue generated by the bill -- OMB estimates by between \$5 and \$10 billion in the first five years.

Sen. Conrad is worried that if we go this route, we will wind up with far less revenue than is necessary to fund what people expect from a tobacco bill. It is unclear, however, what Sen.

Conrad would do to respond to the forthcoming CBO estimates. He seems to want to insist on an \$1.50 per pack excise tax, but CBO would score that as above \$2 as well, rendering this approach utterly impractical.

2. Lookbacks. As you recall, the McCain bill has industry-wide lookback penalties capped at approximately \$3.5 billion per year, with no company-specific penalties at all. We have gotten McCain and Hollings to agree to raise the cap on industry-wide penalties to \$4 billion. We have also gotten them to add a company-specific penalty wholly outside the cap of \$1000 per child for every child by which the company misses its youth smoking targets. This figure represents twice the lifetime profits that a company earns from any youth smoker. Finally, we have gotten McCain and Hollings to agree to strengthen the provision linking a 20 percent miss to the loss of liability protection. Under the current provision, when a company misses by more than 20 percent, the government must show that a company committed affirmative misconduct in order to trigger the loss of liability provisions. Under the new provision, when a company misses by this amount, the tobacco company will have to show both that it did not engage in affirmative misconduct and that it used best efforts to reduce youth smoking in order to escape the loss of liability protections.

Sen. Daschle was supportive of this agreement, but Sen. Conrad thought the provision on company-specific lookbacks is weak. His own proposal would impose far more onerous company-specific penalties, perhaps as much as ten or twenty times higher. We believe penalties of this magnitude would ensure that the companies never return to the bargaining table; we also could not possibly convince McCain and Hollings to accept company-specific penalties of this magnitude.

3. Liability. As you recall, the McCain bill provides for an annual liability cap of \$6.5 billion, while avoiding the question of whether this money comes from the annual industry payments or from other industry assets. McCain has now agreed to push the liability cap to \$8 billion, the exact amount of the Harkin-Chafee liability cap. (As you recall, you said you would sign Harkin-Chafee.) We have tentatively agreed that (1) half of the upfront payment that the industry makes will go to pay legal judgments and (2) when that amount is depleted, half the amount of judgments will come from the annual payments and half from other assets of the liable company(ies).

Another, perhaps even more tricky set of issues has arisen around other liability provisions in McCain. First, the legislation provides that suits for tobacco related disease can be brought only against a tobacco product manufacturer, and not against a wide variety of other parties, including their parents and affiliates; officers, directors, employees, agents, or attorneys; importers, distributors, wholesalers, and retailers; suppliers of component or constituent parts; growers; and insurers. We have succeeded in removing this liability protection for parents and affiliates. We do not think anyone cares about removing protection for growers, suppliers, or parties down the distribution chain. Conrad, however, has objected strongly to giving liability protection to attorneys, and we are trying to remove this provision. We may also try to remove

the protection for officers, directors, employees, agents, and insurers.

Second, the McCain bill settles the Castano lawsuits, which are lawsuits brought on behalf of addicted (but not ill) persons for cessation services. We have succeeded in ensuring that the language in the bill does not at all affect the ability of plaintiffs claiming injury from disease to use evidence of addiction in their lawsuit. (Evidence of addiction generally would come in to these suits in response to the industry's charge that the plaintiff chose to smoke and thus assumed the risk of injury.) As currently written, however, the bill does bar all future claims based solely on addiction. The rationale for this provision is that the legislation itself provides funds for cessation services -- the exact remedy that addicted (but not ill) persons seek. Conrad, however, wants to continue to allow these claims in the future. We do not believe this result can be accomplished while settling the Castano lawsuits, which many Senators would like to do.

Third, the McCain bill provides that no evidence relating to reduced-risk tobacco products is admissible in suits alleging harm from tobacco-related disease. The rationale for this provision, which is very similar to one of the federal rules of evidence, is to assure manufacturers that their development of safer products will not come back to haunt them in a legal proceeding. We have succeeded in narrowing this provision somewhat (so that such evidence, although not admissible at trial, will be discoverable), but apparently not enough for Conrad. We intend to take another run at this provision tomorrow, not because we think Conrad is right, but because we think the liability cap will be easier to maintain if we remove as many objections to other liability protections as possible.

4. Second-Hand Smoke. As you recall, the current McCain bill has a strong environmental tobacco smoke (ETS) provision, but gives states the opportunity to opt out of it entirely. We have tentatively agreed to maintain the opportunity for an opt-out, but only if the state is able to demonstrate to OSHA that it has an ETS standard at least as protective of public health as the federal standard. This compromise, if it holds up, should get us all we need on this issue.

5. International. We think that Sens. McCain, Hollings, and Wyden have agreed to eliminate many of the international provisions in the current McCain bill. (Wyden was their original sponsor.) Under this agreement, the manager's amendment would eliminate the 2 cents per pack export fee, eliminate extraterritorial restrictions on advertising and marketing, and eliminate restrictions on tobacco products in duty-free stores and on military bases. The provisions would continue to fund international tobacco control efforts and would establish a mechanism for multi-lateral negotiations on tobacco marketing and advertising.

6. Spending. We have yet to have a full discussion of spending with McCain, but we believe we can convince him to divide money among (1) the states, (2) public health money (cessation, prevention, counteradvertising, etc.), (3) health research, and (4) farmers. We doubt we can convince McCain to earmark any of the state money to the specific programs we proposed in our budget -- child care and class size reduction. We think, however, that he will

agree that states must use a portion of their money (representing the federal government's share of Medicaid recoveries) on programs appearing on a specified menu. We are currently developing an agreed-upon menu with the NGA; we hope it will include between 8 and 12 health and children's programs, including child care and class size reduction.

7. Bureaucracies. As you know, the industry and other opponents of the McCain legislation have accused it of setting up 17 new federal "bureaucracies." (Charts purporting to illustrate the legislation -- similar to those used in the health care debate -- are appearing all over.) We succeeded today in eliminating all of these 17 supposed bureaucracies, leaving a stripped-down, much simpler bill.

8. Farmers. We agreed to give Sen. Hollings help in ensuring passage of the LEAF Act. Hollings is worried that he will lose a vote on the floor to substitute Sen. Lugar's farming plan for his own. As you know, Lugar's plan would buy out all tobacco farmers and then end the tobacco price support system; Hollings's plan would compensate tobacco farmers for any loss suffered as a result of legislation (through buyouts and/or subsidies), while keeping the price support system in place.

Please let us know if you have any thoughts on, or objections to, what we are doing in these negotiations.

copies
Reed
Kagan
Bowles
Stein

22:58

BIRMINGHAM STAFF ADVANCE

P.001

Tobacco - notes + memos

THE WHITE HOUSE
WASHINGTON

98 MAY 14 AM 12:19

May 12, 1998

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Elena Kagan

5-14-98

SUBJECT: Tobacco Negotiations Status Report

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✓ 1. Price. As you know, the McCain bill imposes payments of about \$65 billion over the next five years. OMB has calculated that these payments, when passed on to price, will increase the price of a pack of cigarettes by \$1.10. We expect, however, that CBO will say tomorrow that if the McCain bill becomes law, the price of a pack of cigarettes will rise by over \$2 in the next five years. A large part of this price differential reflects disparate assumptions about how much the volume of cigarettes sold will decline in this period. (The more consumption declines, the larger the per-pack price increase necessary to make the annual industry payments.)

To combat the new CBO figures, which will tend to support the industry's recent arguments, we would agree in the manager's amendment to incorporate an explicit "volume adjustment" in the first five years of the McCain bill. (There is already an explicit volume adjustment after year six; prior to this point, OMB's estimates about volume reduction were taken into account in setting the annual payments, but there is no correction mechanism if OMB is wrong.) This volume adjustment would ensure that the price increase attributable to the annual industry payments would not exceed \$1.10 per pack, no matter how much volume declines. (CBO assumptions regarding additional factors, such as wholesale and retail mark-ups and state excise tax increases, should bring the total price increase to about \$1.50 in five years.) The downside of this approach is that if CBO is right about how steeply consumption will fall, a volume adjustment will bring down the total revenue generated by the bill -- OMB estimates by between \$5 and \$10 billion in the first five years.

Sen. Conrad is worried that if we go this route, we will wind up with far less revenue than is necessary to fund what people expect from a tobacco bill. It is unclear, however, what Sen.



5-14-98

Conrad would do to respond to the forthcoming CBO estimates. He seems to want to insist on an \$1.50 per pack excise tax, but CBO would score that as above \$2 as well, rendering this approach utterly impractical.

2. Lookbacks. As you recall, the McCain bill has industry-wide lookback penalties capped at approximately \$3.5 billion per year, with no company-specific penalties at all. We have gotten McCain and Hollings to agree to raise the cap on industry-wide penalties to \$4 billion. We have also gotten them to add a company-specific penalty wholly outside the cap of \$1000 per child for every child by which the company misses its youth smoking targets. This figure represents twice the lifetime profits that a company earns from any youth smoker. Finally, we have gotten McCain and Hollings to agree to strengthen the provision linking a 20 percent miss to the loss of liability protection. Under the current provision, when a company misses by more than 20 percent, the government must show that a company committed affirmative misconduct in order to trigger the loss of liability provisions. Under the new provision, when a company misses by this amount, the tobacco company will have to show both that it did not engage in affirmative misconduct and that it used best efforts to reduce youth smoking in order to escape the loss of liability protections.

OK

Sen. Daschle was supportive of this agreement, but Sen. Conrad thought the provision on company-specific lookbacks is weak. His own proposal would impose far more onerous company-specific penalties, perhaps as much as ten or twenty times higher. We believe penalties of this magnitude would ensure that the companies never return to the bargaining table; we also could not possibly convince McCain and Hollings to accept company-specific penalties of this magnitude.

OK

3. Liability. As you recall, the McCain bill provides for an annual liability cap of \$6.5 billion, while avoiding the question of whether this money comes from the annual industry payments or from other industry assets. McCain has now agreed to push the liability cap to \$8 billion, the exact amount of the Harkin-Chafee liability cap. (As you recall, you said you would sign Harkin-Chafee.) We have tentatively agreed that (1) half of the upfront payment that the industry makes will go to pay legal judgments and (2) when that amount is depleted, half the amount of judgments will come from the annual payments and half from other assets of the liable company(ies).

Another, perhaps even more tricky set of issues has arisen around other liability provisions in McCain. First, the legislation provides that suits for tobacco related disease can be brought only against a tobacco product manufacturer, and not against a wide variety of other parties, including their parents and affiliates; officers, directors, employees, agents, or attorneys; importers, distributors, wholesalers, and retailers; suppliers of component or constituent parts; growers; and insurers. We have succeeded in removing this liability protection for parents and affiliates. We do not think anyone cares about removing protection for growers, suppliers, or parties down the distribution chain. Conrad, however, has objected strongly to giving liability protection to attorneys, and we are trying to remove this provision. We may also try to remove

Want
to
protect
for
families
down
distribution
chain

McCain
5-14-98

5-14-98

3

the protection for officers, directors, employees, agents, and insurers.

Second, the McCain bill settles the Castano lawsuits, which are lawsuits brought on behalf of addicted (but not ill) persons for cessation services. We have succeeded in ensuring that the language in the bill does not at all affect the ability of plaintiffs claiming injury from disease to use evidence of addiction in their lawsuit. (Evidence of addiction generally would come in to these suits in response to the industry's charge that the plaintiff chose to smoke and thus assumed the risk of injury.) As currently written, however, the bill does bar all future claims based solely on addiction. The rationale for this provision is that the legislation itself provides funds for cessation services -- the exact remedy that addicted (but not ill) persons seek. Conrad, however, wants to continue to allow these claims in the future. We do not believe this result can be accomplished while settling the Castano lawsuits, which many Senators would like to do.

Third, the McCain bill provides that no evidence relating to reduced-risk tobacco products is admissible in suits alleging harm from tobacco-related disease. The rationale for this provision, which is very similar to one of the federal rules of evidence, is to assure manufacturers that their development of safer products will not come back to haunt them in a legal proceeding. We have succeeded in narrowing this provision somewhat (so that such evidence, although not admissible at trial, will be discoverable), but apparently not enough for Conrad. We intend to take another run at this provision tomorrow, not because we think Conrad is right, but because we think the liability cap will be easier to maintain if we remove as many objections to other liability protections as possible.

4. Second-Hand Smoke. As you recall, the current McCain bill has a strong environmental tobacco smoke (ETS) provision, but gives states the opportunity to opt out of it entirely. We have tentatively agreed to maintain the opportunity for an opt-out, but only if the state is able to demonstrate to OSHA that it has an ETS standard at least as protective of public health as the federal standard. This compromise, if it holds up, should get us all we need on this issue.

5. International. We think that Sens. McCain, Hollings, and Wyden have agreed to eliminate many of the international provisions in the current McCain bill. (Wyden was their original sponsor.) Under this agreement, the manager's amendment would eliminate the 2 cents per pack export fee, eliminate extraterritorial restrictions on advertising and marketing, and eliminate restrictions on tobacco products in duty-free stores and on military bases. The provisions would continue to fund international tobacco control efforts and would establish a mechanism for multi-lateral negotiations on tobacco marketing and advertising.

6. Spending. We have yet to have a full discussion of spending with McCain, but we believe we can convince him to divide money among (1) the states, (2) public health money (cessation, prevention, counteradvertising, etc.), (3) health research, and (4) farmers. We doubt we can convince McCain to earmark any of the state money to the specific programs we proposed in our budget -- child care and class size reduction. We think, however, that he will

5-14-98

agree that states must use a portion of their money (representing the federal government's share of Medicaid recoveries) on programs appearing on a specified menu. We are currently developing an agreed-upon menu with the NGA; we hope it will include between 8 and 12 health and children's programs, including child care and class size reduction.

Handwritten scribble

7. Bureaucracies. As you know, the industry and other opponents of the McCain legislation have accused it of setting up 17 new federal "bureaucracies." (Charts purporting to illustrate the legislation -- similar to those used in the health care debate -- are appearing all over.) We succeeded today in eliminating all of these 17 supposed bureaucracies, leaving a stripped-down, much simpler bill.

8. Farmers. We agreed to give Sen. Hollings help in ensuring passage of the LEAF Act. Hollings is worried that he will lose a vote on the floor to substitute Sen. Lugar's farming plan for his own. As you know, Lugar's plan would buy out all tobacco farmers and then end the tobacco price support system; Hollings's plan would compensate tobacco farmers for any loss suffered as a result of legislation (through buyouts and/or subsidies), while keeping the price support system in place.

Please let us know if you have any thoughts on, or objections to, what we are doing in these negotiations.

*Lugar's Plan
not really
fair to farmers
too good
but summer*

Mtg w/ Reidt / Shleger

1. International

Flow? Manager's Amend?

Get as far as can w/ Wyden

Count votes - can win on floor?

(STR likes Lec. of 100/150 prob)

2. Fitch IV - OK what goes in? - substance

concept paper → 3. Tr. Fund - 10b up - ⁵ in: 50/50 after that - reduce pay by \$1 for \$2 injud.

4. Smokeless - Ivan / → go to Fund - try to sell 1:1:1

de minimis ⁵ Licensing - get to STR / Treasury: retailers - only buy from license get rid of trustees

HHS to write → Bureaucracies - HHS - to figure out how much to jump - come up w/ simple lang.

Documents - Make it apply to everyone.

Funding - sub it, across-bd non-compliance Ivan / Louye

FDA retailer -

Asbestos - Finding ^{re link} btw asbestos + ^{smoking}. Trustees report asbestos from act.

Spending - Mandatory; based on 90% of fund; some oversight -

Tr. Fund - put in budget rationale for what we're spending - continued need for

Role for appropriators?

Med ^{Med} Waiting for advice on 90% of pub. health spending.

give them language

- Local preemptive - give meaningless language.

- Addictive claims - narrow the language

go to state ct?



Cynthia A. Rice

05/14/98 08:08:50 PM

Record Type: Record

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

cc:

Subject: Before Sen. Kerry will commit to McCain, he wants our commitment

that we will in our SAP say the Administration support his amendment earmarking 50 percent of the federal share of the state dollars for child care.

Per David Kass, they've been asked tonight to sign a letter supporting the McCain bill, and they want our commitment on this SAP item first.



Cynthia A. Rice

05/14/98 09:18:21 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Laura Emmett/WHO/EOP, Cynthia Dailard/OPD/EOP
cc:
Subject: Answers to Bruce's Questions from Last Night

1) **Volume adjustment options** -- Josh, Jon, and Karl will have paper shortly, and are ready to discuss.

2) **Youth lookback surcharge survey** -- By 10:00 am I will have from Gary Claxton language adjusting the base year for the lookback survey and proposing other technical changes (i.e., the survey specifications that should substitute for the Univ. of Michigan language now in the bill). HHS recommends that we provide a credit towards the youth smoking targets based on how much we think the price increase would have reduced youth smoking.

3) **Effect of State Settlements** -- Currently, every state is included in the bill unless they opt out. However, the way the language is written now, TX, FL, and MS could probably get paid twice if a) they did not opt out of the bill and b) they argued successfully in court that the federal legislation is not "substantially similar" to their agreements. Minnesota's settlement agreement does not include this disputable "substantially similar" language, but instead makes clear that companies will get a credit against settlement payments owed Minnesota for funds the state receives due to federal tobacco-related legislation which are "(i) unrestricted as to their use, or (ii) are restricted to any form of health care or to any use related to tobacco." DOJ is preparing language ASAP to fix this possible double dipping problem.

4) **Castano Lawyers** -- Section 704(c) of the bill (p. 440-441) settles the Castano suits and establishes a 3-person arbitration panel to award attorneys fees and expenses. Participating manufacturers pay the awards made by the arbitration panel -- outside of anything they pay in the annual assessment.

5) **Document Depository** -- DOJ has no objections to making the document depository a non-profit entity.

6) **International funding language** -- as you asked, we faxed to Hollings staff the language OMB drafted authorizing \$200 million a year for international tobacco control efforts, which allows the President to transfer to any agency funds appropriated for this purpose.

Mt. / Bill Cur re Dennis + Tob

Loebach

- a. slightly tougher goals - Koop/Kessler goals_L?⁷
- b. Same %age reductions in smokeless?
- c. Company specific - and tougher

They think 15¢^{FM}; is this right?

what does cap mean? ___¢ per pack?

McCain = ___ ¢ per pack

\$500 per - too little - just take profit out - not

2¢ per pack for 1090

3¢ per pack for next 1090

cap??

Env Tobacco Smoke -

Opt. cur - none

Restaurants - ?? let's get something for it.

Clarity - str + loc can be tougher.

Preemptive -

Make clear - 40¢ restriction on more adverts

OSTA (states where fed got regulator -

make sure state can adopt stricter smoking laws)

anything beyond labelling itself.

Check whether we need change.

Advertisements -

3 kinds

I said: don't put in middle ground.

No deductibility for making if an ad violator. The rules

(I said: seems reasonable)

Tack Reed amend.

(Thursday - mbw mtg)

David O.

International - Hollings / Ford / Wyden - working on reaching ag.
reas. that }
this is } • prohibiting promotion of exports
problematic } • code of conduct

Issue: what comes out / not what comes in

Price

1.50 over 3 yrs.

Take it back

Per pack - not as assessment (w/ volume reduction)
??

→ Penalty for not passing through. Leave in

Up-front payment. Leave in.

Uses of money -

Memo - child care, ed, children's health

MOE

Not annual appropriation - spent automatically

Law Enforcement

give our assets to Leahy -
sit down with him.

(Make sure not
inconsistent w/
Wyden)

Liability

what about these other legal rules?

Also: addictive claims

→ Corporate parents

▶ Paul J. Weinstein Jr.
05/11/98 03:45:43 PM
.....

Record Type: Record

To: Elena Kagan/OPD/EOP
cc: Bruce N. Reed/OPD/EOP, Cynthia A. Rice/OPD/EOP, Cynthia Dailard/OPD/EOP
Subject: Re: HR 3534 

This bill would amend the Unfunded Mandates Reform Act to do two things: 1) would require CBO to do an analysis on any legislation that would impose a private sector mandate of over \$100 million annually; 2) would require that any tax increase included in legislation be offset by a tax decrease (including tobacco). If either of these provisions were not met, the legislation would be subject to a point of order in the House of Representatives.

OMB is not sure they want to do a SAP because of concern that the Administration would be taking a position on a bill that is centered around a change in House floor rules. However, I believe that is shortsighted. We have taken positions on bill like this before, including the original Unfunded Mandates Reform Act which Sally Katzen and I helped write. Another example is the Congressional Accountability Act. Secondly, this bill is about more than a change in House rules, it also impacts national policy (taxes).

I recommend you discuss with Sally Katzen. Apparently EPA is interested in doing a SAP because of the impact on Superfund taxes. The bill will be on the House floor Wednesday.

Tob - per -
notes + memos

THE WHITE HOUSE
WASHINGTON

May 6, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
SUBJECT: Response to Governor Hunt's Concerns

Here is a brief analysis of the issues Gov. Hunt raised with you. Some of the industry's charges are exaggerated, but others are legitimate, and can be addressed.

1. Only 2% of smokers are underage. This is one of Goldstone's main talking points, but it is incorrect. About 10% of current smokers in America are underage – and 90% of adult smokers started while they were teens. The basis for Goldstone's charge is that underage smokers represent only 2% of overall cigarette consumption. That is because the typical underage smoker consumes only a few cigarettes a day, while adults average about a pack a day.

2. The McCain bill will increase cigarette prices to \$5 a pack. Hunt gave you an analysis by Martin Feldman of Salomon Smith Barney, the most pessimistic analyst on Wall Street. Feldman contends that under the McCain bill, adult volume will drop 40% in 5 years (Treasury and CBO assume a 30% drop), turning \$1.10 into \$1.50. He also assumes a 60-cent markup by wholesalers and retailers, which Treasury, CBO, and most Wall Street analysts strongly dispute. Finally, he assumes that the industry pays the maximum in lookback penalties (about 35 cents in his model) on the theory that adult volume will decline dramatically but teen smoking will stay flat. Treasury and OMB are developing a volume adjustment/correction mechanism for us to propose in negotiations that will make it more difficult for Feldman and other analysts to spin out these disaster scenarios. (With a volume adjustment, the McCain bill would essentially impose a \$1.10 excise tax; without a volume adjustment, each company would have to make a set annual payment no matter how many cigarettes they sell.) You may not want to tell Hunt just yet that we're prepared to give them a volume adjustment, but you can tell him we're looking at it.

3. The industry has a 24-month inventory of domestic tobacco, and won't need to buy any more from U.S. farmers if adult consumption plunges. This is a legitimate concern. The industry definitely has domestic inventory – one of the reasons farmers are so anxious for a settlement is that the companies don't appear to be buying much tobacco at auction this year. (I doubt they have two years' worth, but that won't stop the companies from

telling farmers as much.) If U.S. consumption drops more dramatically than we project, we could see lean tobacco auctions for the next few years. The best counter to Hunt's argument is that with the LEAF Act in place, a lot of farmers will get out of the business, and those who don't will have virtually guaranteed incomes anyway. We can also try to include the Etheridge provision requiring companies to maintain current purchases of domestic tobacco – although that can only survive GATT if it's a voluntary agreement by the companies.

4. The McCain bill includes an unconstitutional 2-cent-a-pack tax on exports, and includes other restrictions on foreign advertising and duty-free sales that don't make sense. Hunt is right, and we are working with Hollings and Ford to fix these provisions.

5. RJR has \$20 billion in debt. Treasury says that RJR has \$7 billion in debt and preferred stock, but has a \$10.2 billion asset in Nabisco holdings. Later this week, they will give you a new, more detailed analysis of Wall Street's views on the companies' financial condition.

6. Because the McCain bill requires the industry to pay \$115 billion over 5 years, but has no volume adjustment in the first 5 years, accounting rules will force all companies to book their share of \$115 billion on day one. The five-year number is more like \$100 billion (with the government netting only \$60-70 billion because of scoring conventions), but the basic concern is real. Moody's and other analysts share Hunt's view that without a volume adjustment, the payments would have to be treated like debt. That is one of the reasons why Treasury and OMB have come around to the idea of a volume adjustment.

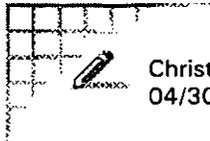
7. If the companies go broke, industry stockholders will lose \$150 billion, and the Dow will plummet, triggering an Asian-style financial crisis. When Treasury completes its new analysis, you can judge the bankruptcy risk for yourself. Although Philip Morris is a component of the Dow, the risk to the stock market seems rather small, since Wall Street currently values the tobacco companies' domestic operations at close to zero.

8. Philip Morris has \$100 billion in market cap, 155,000 employees worldwide, and \$6 billion in exports. Hunt is right: PM is the 6th most profitable Fortune 500 company. It will be the last tobacco company to go out of business.

9. A Cornell study shows that price increases have little or no impact on youth smoking. This is true, but almost every other study shows that price does have a significant impact. Treasury has compiled a survey of major studies. Our estimate of a 32% drop from \$1.10 is at the conservative end of the scale. The CBO model projects a 34% drop. Others range from 28% to 65%. The truth is, there has never been a price shock of this magnitude in the U.S., so we don't really know what will happen – but almost all the experts assume teen smoking will drop a lot. The experience in other countries is mixed: in England, teen smoking has continued despite high prices, but in Canada, which may be culturally more similar to the U.S., price increases cut teen

smoking in half (before concerns about smuggling led the government to roll back the price).

10. Canada and Sweden rolled back price increases because of smuggling and a black market. Canada's experience proves Shalala's point that there can only be a black market if the companies know about it. When Canada increased cigarette taxes, exports of Canadian cigarettes suddenly skyrocketed from 100 million packs a year to *700 million* packs a year. Hunt is also right about Sweden, which just cut taxes 27% in an effort to curb smuggling. Our proposed regulatory scheme, largely incorporated in McCain's bill, should reduce the threat of smuggling significantly by creating a closed distribution system, marking cigarettes for export, and imposing tough penalties for violations.



Christopher C. Jennings
04/30/98 07:34:42 PM

Record Type: Record

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

cc:

Subject: Chiles

Just was talking to Gary Claxton about another matter and he asked me to forward on a message to you guys. When Gary met with Governor Chiles' staff today, they made a pitch for us to use the Governor to help push the tobacco bill. I asked if the Governor was now in the position of strongly pushing for a Federal bill and Gary said the Chiles' staff said yes.

At any rate, Gary just wanted to make sure you guys knew this. Just making another one of my major contributions to the tobacco bill...

cj

Tob - sec - notes + memos EK
and
Tob - sec - public health outreach

THE WHITE HOUSE
WASHINGTON

April 15, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Meeting with C. Everett Koop

As you know, we are aiming for a strong, comprehensive tobacco bill that meets our core public health objectives and that the industry might swallow in the end. Without industry consent, some provisions in comprehensive legislation (i.e., the most far-reaching advertising restrictions) would be impossible, while other provisions (e.g., narrower advertising restrictions and look-back penalties) would be in litigation for years. We should not compromise our objectives to secure that consent, but at the same time we should not ask for more than we need to achieve our public health goals and in the process destroy any chance of industry acquiescence.

With the overwhelming vote in favor of the McCain legislation in the Senate Commerce Committee and the subsequent announcement of the tobacco industry that it will fight this legislation, we have entered into a new phase of our effort to procure a comprehensive tobacco bill to reduce youth smoking. The Commerce Committee vote two weeks ago brought new momentum to this legislative effort, and the industry's response should only add to that momentum, by making it even harder for Members of Congress to block legislation, lest they look as if they are doing the industry's bidding.

Given this growing momentum, we thought it made sense for you to meet with Dr. Koop, given his high visibility on this issue. Over the past two weeks he has been critical publicly of the McCain bill, particularly with regard to the lack of company specific lookback penalties, and due to the liability cap. Specifically, he has said that the bill's programs to reduce the number of children who smoke are too weak, and its protections of the tobacco industry are too strong. He believes that the price per pack of cigarettes needs to be raised by \$2 to prevent teens from smoking, instead of the \$1.10 contained in the bill.

Your goal for this meeting should be to persuade him that we need to work hard, and work together, in order to ensure passage of comprehensive tobacco legislation that achieves our public health goals. At the same time, he needs to understand that we should be reasonable in our demands, and ensure that we don't demand too much, lest the entire legislative effort should fall apart. If Koop raises his concerns, you may want to say:

- The McCain bill represents dramatic progress. The 19-1 vote in the Senate Commerce Committee shows that we have real momentum in both parties to pass comprehensive tobacco legislation this year.

- You have done a tremendous job over the past few decades of alerting Americans to the dangers of smoking, and we very much appreciate your ongoing efforts to reduce youth smoking.
- We agree that we need to strengthen the lookback penalties, and we will continue to work with Congress toward achieving that goal. However, we also believe that we need to be reasonable in our demands.
- We will work hard to make sure the public health programs such as cessation and counter-advertising get funding.
- We have to work every bit as hard to protect the programs we have already made on FDA and other issues. Our #1 enemy is a skinny bill.

Tob - ser - notes + memos
aid
Tob - ser - legislative ahead

THE WHITE HOUSE
WASHINGTON

April 17, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Meeting with Senator Daschle

As you know, we believe the best way to get a strong, comprehensive bill that meets our core public health objectives is to engage in negotiations with Senators Lott, Daschle, McCain, and Hollings that are designed to produce an agreed-upon bill to go to the Senate floor. The greatest danger we face is chaos on the Senate floor, in which some amendments roll back what we already have achieved (e.g., on FDA jurisdiction), while other amendments make the bill essentially unpassable (e.g., by stripping all liability protections while increasing the overall price of the deal).

The goal of this meeting should be to make clear to Senator Daschle that we want to negotiate before going to the floor. He needs to understand that we should be reasonable in our demands, and ensure that we don't demand too much, lest the entire legislative effort should fall apart. You may want to say:

- The McCain bill represents dramatic progress. The 19-1 vote in the Senate-Commerce Committee shows that we have real momentum in both parties to pass comprehensive tobacco legislation this year.
- The best way to put pressure on the Republicans is to get an overwhelming vote for a good bill in the Senate, and beat Gingrich over the head with it until the House acts.
- We do want to strengthen the bill -- but we need to be reasonable in our demands.
- We have a lot to lose from chaos on the floor: a Jeffords amendment to weaken FDA; a Lugar amendment to gut farmers; party line votes on how to spend the money.
- Our #1 enemy is a skinny bill, one that raises the price of cigarettes without restricting advertising or including public health efforts. We need to push for improvements we can achieve while protecting the progress we have already make on FDA and other issues.
- We should seek to:
 1. Strengthen the penalties, by including a company-specific component, and increasing the industry-wide surcharge cap above \$3.5 billion.
 2. Ensure spending on research, public health, and farmers, and press for spending on child care and education (or at least a menu including these programs).

3. Eliminate the antitrust exemption.
4. Eliminate the "opt-out" provision that allows states to adopt weaker environmental tobacco smoke, or second-hand smoke, laws.

Reed
Kagan
3/20/98

Tobacco - mt -
notes + memos

THE WHITE HOUSE
WASHINGTON

April 9, 1998

4-9-98

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Elena Kagan

SUBJECT: McCain Legislation

With the overwhelming vote in favor of the McCain legislation in the Senate Commerce Committee and the subsequent announcement of the tobacco industry that it will fight this legislation, we have entered into a new phase of our effort to procure a comprehensive tobacco bill to reduce youth smoking. The Commerce Committee vote last week brought new momentum to this legislative effort. The industry's response should only add to that momentum, by making it even harder for Members of Congress to block legislation, lest they look as if they are doing the industry's bidding.

The broad consensus among your advisors is that we should aim for a strong, comprehensive bill that meets our core public health objectives and that the industry might reluctantly swallow in the end. Without industry consent, some provisions in comprehensive legislation (i.e., the most far-reaching advertising restrictions) would be impossible, while other provisions (e.g., narrower advertising restrictions and lookback penalties) would be in litigation for years. We should not compromise our objectives to secure that consent, but at the same time we should not ask for more than we need to achieve our public health goals and in the process destroy any chance of industry acquiescence. In any event, most of your advisors believe that efforts to push the price too far would be counterproductive, because tobacco-state Democrats will join with Republicans to derail a bill that goes as far as some in the public health community might like. Instead, we should try to address the aspects of the McCain bill that are most important to us and to securing broad Democratic support.

Your advisors also agree that the best way to get this kind of bill is to engage in negotiations with Senators Lott, Daschle, McCain, and Hollings that are designed to produce an agreed-upon bill to go to the Senate floor. The greatest danger we face is chaos on the Senate floor, in which some amendments roll back what we already have achieved (e.g., on FDA jurisdiction), while other amendments make the bill essentially unpassable (e.g., by stripping all liability protections while increasing the overall price of the deal).

We recommend against direct discussions with the industry at this stage; we doubt they would level with us anyway. Assuming Senator Hollings is in the room, we should have a decent sense of the industry's concerns, and of course we have more-than-adequate lines of communication to the public health community.



We list below several aspects of the McCain legislation in which we should seek changes during these negotiations. Note that FDA jurisdiction does not appear on this list; we were able to reach an agreement on this issue with Senators McCain and Frist, prior to the Commerce Committee vote, that satisfies all our regulatory needs and objectives.

I. Youth Lookback Penalties

We already have said that Congress must strengthen the lookback penalties in the McCain legislation, by incorporating some company-specific penalties and raising the cap on the industry surcharge. The incorporation of some company-specific penalties is a core demand of the public health community, and is strongly supported by HHS and Treasury. Such penalties, however, may be unacceptable to the industry, and especially to Phillip Morris because of its disproportionately large share of the youth market. (Unlike industrywide penalties, which can be passed on in the form of higher prices, company-specific penalties come straight out of a company's profits.) Bruce Lindsey has noted that even if we need to make demands in this area, we should not let the issue of company-specific penalties become grounds for vetoing the bill. We agree, but think it is important to try to find a way to address this issue.

agreed

A number of approaches are available, and we should not now tie ourselves down to any of them. A company-specific penalty developed by Treasury and HHS would impose a \$500 fee for every child by which a company misses the targets (i.e., if a company misses the target by 10,000 children, it would pay a fee of \$5,000,000). This per-child surcharge represents the present value of the profits a company would gain from addicting a teenager over his lifetime. Treasury estimates that the total cost of this penalty -- i.e., across all companies -- could reach as much as \$500 million a year. Another approach, probably more acceptable to the industry, would be to allow suits between companies for redistribution of the industry-wide penalty. Such indemnification suits would create a potential for transforming the industry surcharge into a company-specific penalty scheme, without increasing the overall cost of the penalty provisions. We will continue to try to develop creative solutions in this area so that we can enter negotiations with a range of proposals.

Raising the cap on industry-wide penalties is obviously an easier matter. We would suggest proposing a change from the current \$3.5 billion to \$4 to \$5 billion if possible.

II. Price per Pack and Spending

Price per Pack

We should not demand any increase in the McCain bill's funding levels in the first five years, because McCain essentially adopted our own budget numbers (while adding a \$10 billion up-front payment). We recommend waiting until CBO scores the McCain bill before deciding whether to seek any increase in funding levels in later years. (McCain has asked CBO to score his bill by the time Congress returns.) Congressional scorekeepers may well estimate that the

yearly payments in the bill will increase the price of cigarettes not by the \$1.10 we estimated, but by the \$1.50 that the public health community has most often demanded. The higher figure may result from assumptions by CBO that (1) states will use the opportunity to increase state excise taxes, further reducing the number of packs sold and (2) the bill will significantly increase the black market for cigarettes, resulting in fewer than expected packs sold through the legitimate retail market. By reducing the number of expected packs sold, both of these changes would increase the per-pack price estimate, because the annual industry payment set in legislation would be spread among fewer packs. Once we know the actual per-pack price increase calculated by Congressional scorekeepers, we will be in a better position to determine whether we should push for a small increase in funding levels after the fifth year.

Spending

We hope for bipartisan consensus on much of the spending: we think Members could agree on approximately \$10 billion over 5 years for farmers; \$10 billion for prevention, cessation, counteradvertising, FDA enforcement, and other public health programs; \$10-15 billion for research (the Republicans may want to limit these funds to NIH); and \$20-25 billion for states. This distribution leaves about \$15 billion on the table, which Republicans will want to spend on Medicare or tax cuts and Democrats will want to spend on programs like child care and school construction.

One issue will concern the use of the state money. Our budget earmarked 57 percent of the state funding for child care, class size, and Medicaid outreach initiatives. As we go forward, we should argue at a minimum for a menu of state programs, such as child care and education, on which states would have to use a significant portion of their funds. For example, in the Harkin-Chafee bill, half of the state funds must be spent on one of 20 listed programs, which include child care, K-12 education, Medicaid, the Child Health Insurance Program, and Head Start.

Another issue, more important in the out-years, concerns the amount of money allocated to paying legal judgments. The June 20th settlement put only a few billion dollars into the tort fund in the first five years, on the theory that lawsuits against the industry would take some time to come to judgment. Congress may well use the same assumption, given competing spending priorities. But once this initial grace period is concluded, Congress must figure out how to fund legal judgments. The June 20th settlement placed a \$5 billion annual cap on judgments, with \$4 billion coming from the industry's base payments to the government and \$1 billion (a kind of copayment) from the defendant companies' coffers. The McCain bill establishes a \$6.5 billion cap; McCain contemplated that \$5.2 would come from the industry's base payments, with \$1.3 as a copayment, but his bill does not actually address this issue. Some in the public health world may begin to call for the entire amount to be paid by the companies, outside of their payments to the government. This change, however, would add an enormous amount to the total cost of the deal and could doom prospects for legislation. Room for a tort fund thus will have to be found in the out-years by squeezing some of the spending listed above.

III. Antitrust Exemption

The McCain bill contains antitrust exemptions for the tobacco industry that are not necessary to achieve the goals of the legislation and may have serious anticompetitive effects. As written, the bill exempts any and all agreements designed to "reduce the use of tobacco products by underage individuals." This exemption could cover (among other things) price-fixing agreements of all sorts. The Department of Justice believes strongly, and we agree, that we should oppose all antitrust exemptions, except possibly for a narrowly-drawn exemption designed to allow companies to agree to restrict their advertising and marketing to children.

Me
OK

IV. International Tobacco Control Efforts

As part of the public health spending noted above, we believe we should include significant funding (\$200 million a year) for international tobacco control efforts. These funds should be spent on both governmental and non-governmental efforts to promote public health and smoking prevention efforts abroad.

The McCain bill has several additional international provisions that we would like to change so that they do not interfere with our diplomatic and trade priorities. For example, although we support the bill's effort to prohibit U.S. government support for promotion of tobacco overseas, we need to ensure that the language does not interfere with USTR's ability to negotiate tariff reductions or interfere with treatment of other products. In addition, the McCain bill contains a provision that the State Department and HHS consider problematic and unenforceable, which would require U.S. companies to abide by the new labeling and advertising requirements when doing business in other countries. The industry strongly objects to these provisions for a different reason, because it views them as a real threat to its international operations.

V. Environmental Tobacco Smoke

The McCain bill would exempt the hospitality industry (restaurants, bars, casinos, etc.) from its environmental tobacco smoke provisions, which ban smoking, except in enclosed and specially ventilated areas, in public facilities. In addition, the bill would allow individual states to "opt out" of all of the provisions, even if the state had no ETS protections of its own. Although HHS strongly opposes the hospitality exception (workers in the hospitality industry face grave risks from second-hand smoke), we doubt it is politically feasible to remove it. We should, however, try hard to eliminate the state opt-out provision, which could leave many of the nation's citizens without any protection from ETS. Alternatively, we might consider pushing the Harkin-Chafee approach to this issue, which rather than imposing a ban would provide funds to States that progressively reduce exposure to ETS.

4-13-08

VI. Liability Provisions

We believe we should adhere to the basic structure of the liability provisions in the McCain legislation. If we need to make these provisions a bit tougher, we can try to raise the cap from the current \$6.5 billion to the \$8 billion contained in Harkin-Chafee. Note, however, that doing so only compounds the budgetary issues surrounding the tort fund noted earlier in this memo: to the extent that money for tort judgments come from the industry's payments to the government, that money squeezes out funds for public health and other priorities; conversely, to the extent that money for tort judgments comes over and above the industry's payments to the government, the expected cost of the deal to the industry increases.

AC 7
AC 7
(We should either tighten it (by linking the cap only to objective measures) or discard it entirely. Especially if we try to make the liability provisions tougher in other areas, agreeing to eliminate the provision may prove useful.

VII. Constitutional Issues

(The Department of Justice is prepared to recommend changes to the advertising, marketing, and other speech-related provisions of the legislation in the event that the industry does not sign protocols agreeing to these restrictions. The Department also would like us to press for the elimination of all provisions regulating non-commercial speech, such as one that forbids companies from lobbying Congress, regardless whether the companies offer agreement.

agru

Conclusion

In summary, we would recommend seeking these improvements:

Youth Lookback Penalties

- Incorporate some company-specific component in the penalty scheme
- Increase the industry-wide surcharge cap from \$3.5 billion to between \$4 and \$5 billion

Price and Spending

- No change in annual payment amounts in first five years; wait until CBO scores before deciding whether to seek later changes
- Ensure spending on research, public health, and farmers, press for spending on child care and education, or at least a menu including these programs

Antitrust Exemption

- Eliminate the antitrust exemption

International Tobacco Control

- Support funding for governmental and non-governmental organizations
- Narrow provision prohibiting U.S. support for promotion of tobacco overseas to ensure it does not interfere with USTR authority to negotiate treaties
- Remove requirement that companies must abide by new labeling and marketing requirements when operating overseas

Environmental Tobacco Smoke

- Eliminate "opt-out" provision that allows states to adopt weaker laws

Liability

- Retain basic structure of liability priorities
- Consider modifying level of cap and relation of cap to youth reduction targets

Constitutional Issues

- Recommend changes to minimize Constitutional difficulties

Senate Panel Would Preempt Cities' Right to Sue Big Tobacco; Commerce Committee Approves Plan With No Clear Local Role

by Kristin E. Cormier

A settlement as approved by a Senate committee last week would preempt every local government's legal right to sue tobacco companies. As it stands this measure protects tobacco companies from suits by cities to recover the tobacco-related Medicaid expenses footed by communities.

The Senate Commerce Committee approved "The Tobacco Products Control Act of 1998" (S. 1415) in a 19-1 vote late last Wednesday. The bill, introduced by Commerce Committee Chairman John McCain (R-Ariz.) would implement a Global Tobacco Settlement that would limit tobacco companies' limited legal liability in exchange for tobacco advertising restrictions and a half-trillion dollars in payments.

Local government lawsuits would be extinguished in the settlement without any direct funding mechanism to compensate cities and towns for money paid in Medicaid expenditures as well as the cost of indigent care.

It would preempt some local authority with regard to cigarette and tobacco use and it leaves unresolved what, if any, new unfunded mandates would be imposed on cities and towns to enforce the bill's provisions.

The bill would cap tobacco company liability at \$6.5 billion annually and raise the tax on packages of cigarettes to \$1.10 over five years. The tobacco companies would be required to pay \$516 billion over 25 years to cover legal damages as well as for anti-smoking, education, and research programs.

The Food and Drug Administration would gain expanded authority to regulate nicotine as a drug. Targets for reduction in youth smoking would be set at 60 percent over 10 years by this legislation.

San Francisco City Attorney, Louise Renne, who actively lobbied prior to the mark-up in

attempts to protect local governments against federal preemption and to have a funding mechanism implemented in the legislation for local government compensation of unique and substantial health care costs incurred in serving individuals with tobacco-related diseases said, "Local governments were an early driving force in suing the tobacco industry. San Francisco alone sued before 10 of the state attorneys general. Local governments are key to the successful implementation of any federal tobacco legislation. Local governments need to be protected from having their lawsuits extinguished by this legislation." Renne along with National Association of Counties President and Hennepin County Board of Commissioner Chair Randy Johnson met with Clinton Administration officials two weeks ago to discuss local government concerns in the tobacco legislation.

The bill was criticized by members of both the public health community and the tobacco industry. Many committee members voted to approve the legislation in the Commerce Committee, but noted that there were still issues that would have to be hammered out on the floor of the Senate.

Local Government Concerns

The McCain bill does provide some protection of local government control and grants to localities and states for health related programs. The bill does not include a repeal of a thirty year old law, the Federal Cigarette and Advertising Act, which prevents states and localities from imposing stricter laws controlling tobacco. Also, states and local governments would not be able to provide any stronger requirements relating to performance standards, premarket approval, adulteration, misbranding, registration, reporting, good manufacturing standards, reduced risk products, or

Comparison of Tobacco Settlement and McCain Bill

ISSUE	JUNE 20, 1997 SETTLEMENT	MCCAIN BILL
PRICE INCREASE	No cigarette price increase	Would place a per-pack fee on cigarettes, starting at 63 cents in 1999 and increases to \$1.10 over five years
INDUSTRY PAYMENTS	\$368.5 billion over 25 years	\$516 billion over 25 years according to McCain's \$374 billion over 25 years according to the tobacco industry
LEGAL PROTECTION	Would provide industry immunity from class-action and similar lawsuits, although individuals could still sue for actual damages from past tobacco use.	Would cap liability at \$6.5 billion a year and would settle attorney general lawsuits and current major class-action cases. No bar on mass lawsuits of punitive damages.
FEDERAL REGULATION	Broad authority for FDA regulation of tobacco products.	Broad authority for FDA regulation of tobacco products.
YOUTH SMOKING	Broad restrictions on advertising and marketing to youth. If youth smoking fails to drop 30 percent in five years, 50 percent in seven years, and 60 percent in 10 years, industry would be fined about \$80 million for each percentage point short of the goal.	Broad restrictions on advertising and marketing to youth. Penalties of up to \$3.5 billion a year if companies fail to meet targets to reduce youth smoking by 60 percent in 10 years.
LOCAL GOVERNMENT COMPENSATION FOR LAWSUITS	Local government suits would be extinguished by the agreement.	Local government suits would be extinguished by the legislation.

other areas relating to safety of tobacco products. The Food and Drug Administration (FDA) would retain control over these provisions, but states and localities could obtain waivers to control these areas from the Secretary of Health and Human Services in certain circumstances.

The bill would provide several grant opportunities for local governments to receive funds to support anti-tobacco education and cessation efforts. The amounts of these grants will not be solidified until the bill reaches the floor of the Senate.

The legislation also provides for a state, tribal, and federal licensing program that the FDA would draft. The FDA would draft model state programs in consultation with state and local officials. It is unclear how the enforcement program would operate, thus it will likely also be considered on the Senate floor with a number of outstanding issues.

Sen. Wendell Ford (D-Ky.) was successful in rolling in his LEAF Act, that would provide assistance to farmers. Ford's

provision creates a Tobacco Community Revitalization Trust Fund, provides assistance in economic development grants, worker transition, and quota payments tobacco reliant communities. Additionally, it would provide farmers with educational and economic assistance to learn another trade and provides immunity to tobacco producers and warehouse owners.

Full Senate Consideration

Commerce Committee Chairman McCain noted that the Clinton Administration, the Commerce Committee, and other Senate Committee Chairmen would work in coming weeks to solidify the legislation before it reaches the floor for a vote. A provision regarding international control of tobacco and global protection of children from tobacco introduced by Sen. Ron Wyden (D-Ore.) was left for more consideration in coming weeks by the Clinton Administration and Committee members.

Spending provisions were not

Local governments' last chance to be considered for inclusion in the settlement will be during the floor debate.

supposed to be considered in the committee debate, but the panel did pass a non-binding "Sense of the Senate" resolution that included compensation to states for Medicare and Medicaid costs, the Federal Black Lung Program, tobacco farmers and their communities, the Tobacco and Asbestos Trust Fund, child care and child care development, clinical trials for cancer research at the National Institutes of Health, and Medicaid health insurance for children.

The Senate is expected to take up this legislation soon. The full Senate will be expected to debate many issues, including how the settlement money will be spent and immunity. Local governments' last chance to be considered for inclusion in the settlement will be during the floor debate.

Native American Issues

Also Thursday, the Senate Indian Affairs Committee approved a measure (S. 1791) that would give tribal governments the responsibility for enforcement of tobacco regulations and provide funds to assist tribes with enforcement and reimburse them for the costs of smoking related illnesses. Native Americans would retain the right to use tobacco for traditional or ceremonial purposes. ■

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FYI re: Cities
and Tobacco

For Distribution

From: Mickey Ibarra,
IGA X 07060

Tob - ser - preemptia

Tob - sec - notes + memos EK
and
Tob - sec - public health research

THE WHITE HOUSE
WASHINGTON

April 15, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Meeting with C. Everett Koop

As you know, we are aiming for a strong, comprehensive tobacco bill that meets our core public health objectives and that the industry might swallow in the end. Without industry consent, some provisions in comprehensive legislation (i.e., the most far-reaching advertising restrictions) would be impossible, while other provisions (e.g., narrower advertising restrictions and look-back penalties) would be in litigation for years. We should not compromise our objectives to secure that consent, but at the same time we should not ask for more than we need to achieve our public health goals and in the process destroy any chance of industry acquiescence.

With the overwhelming vote in favor of the McCain legislation in the Senate Commerce Committee and the subsequent announcement of the tobacco industry that it will fight this legislation, we have entered into a new phase of our effort to procure a comprehensive tobacco bill to reduce youth smoking. The Commerce Committee vote two weeks ago brought new momentum to this legislative effort, and the industry's response should only add to that momentum, by making it even harder for Members of Congress to block legislation, lest they look as if they are doing the industry's bidding.

Given this growing momentum, we thought it made sense for you to meet with Dr. Koop, given his high visibility on this issue. Over the past two weeks he has been critical publicly of the McCain bill, particularly with regard to the lack of company specific lookback penalties, and due to the liability cap. Specifically, he has said that the bill's programs to reduce the number of children who smoke are too weak, and its protections of the tobacco industry are too strong. He believes that the price per pack of cigarettes needs to be raised by \$2 to prevent teens from smoking, instead of the \$1.10 contained in the bill.

Your goal for this meeting should be to persuade him that we need to work hard, and work together, in order to ensure passage of comprehensive tobacco legislation that achieves our public health goals. At the same time, he needs to understand that we should be reasonable in our demands, and ensure that we don't demand too much, lest the entire legislative effort should fall apart. If Koop raises his concerns, you may want to say:

- The McCain bill represents dramatic progress. The 19-1 vote in the Senate Commerce Committee shows that we have real momentum in both parties to pass comprehensive tobacco legislation this year.

- You have done a tremendous job over the past few decades of alerting Americans to the dangers of smoking, and we very much appreciate your ongoing efforts to reduce youth smoking.
- We agree that we need to strengthen the lookback penalties, and we will continue to work with Congress toward achieving that goal. However, we also believe that we need to be reasonable in our demands.
- We will work hard to make sure the public health programs such as cessation and counter-advertising get funding.
- We have to work every bit as hard to protect the programs we have already made on FDA and other issues. Our #1 enemy is a skinny bill.



Cynthia A. Rice

04/07/98 01:57:51 PM

Record Type: Record

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

cc: Laura Emmett/WHO/EOP, Cynthia Dailard/OPD/EOP, Thomas L. Freedman/OPD/EOP, Mary L. Smith/OPD/EOP

Subject: I saw Ivan after my international meeting

He said they'd be happy to get any and all bill clean-up comments -- late in the week would work. They are trying to complete language by the end of next week. He lamented how they're getting "killed" by the industry.

He said Hollings and McCain are doing a S.C. tobacco event on Friday. Jacoby and I told him the President will be in Kentucky on Thursday -- Ivan said we should invite McCain and that we need to work to keep McCain bought in. I did not tell Ivan, but now wonder if I should have, that Ford will be part of our Thursday event.

Not reviewed
Never used

Tob-ser - notes + memos

THE WHITE HOUSE
WASHINGTON

March 31, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Meeting with Senator McCain

As you know, Senator McCain has provided great leadership in the Commerce Committee to draft a bipartisan bill that will move us significantly closer to enacting comprehensive tobacco legislation. We believe his bill will lay a strong foundation for further action, but also has room for improvement. Here are some areas that need further work:

Penalties for Companies Missing Youth Smoking Targets

- We believe it is critically important that individual companies have financial incentives to meet the youth smoking reduction targets. This means that a company that misses the youth smoking targets by 40 percent will pay a higher penalty than a company that misses by 10 percent.
- Industry-wide penalties, while important, are not a substitute for company specific penalties. Since industry penalties are imposed on all firms at once, companies can pass them on to consumers -- thus raising the price of cigarettes more (and reducing youth smoking more) but without providing companies with a financial incentive to do more to reduce youth smoking.
- Reducing youth smoking is our bottom line and we must make it the industries' bottom line -- that is why we need company specific penalties.

Environmental Tobacco Smoke

- When the President announced his five principles for comprehensive tobacco legislation, he said progress toward other public health goals should include limiting exposure to environmental tobacco smoke in work sites and public places.
- We have serious concerns about this bill's provision which would allow individual States to "opt out" of the national smoke-free environment policy. This undermines and significantly weakens the national ETS standard by creating a patchwork system where states could decide to adopt weaker laws or decide against taking any action, leaving people with little or no protections from the hazards of environmental tobacco smoke.

Anti-Trust Exemption

- We are extremely skeptical of including antitrust exemptions for tobacco manufacturers in comprehensive legislation, which this bill does. In particular, we would strongly oppose any exemptions that would allow price fixing agreements.
- We have left open the possibility, depending on other provisions in the legislation and any settlements, of allowing a very limited anti-trust exemption to facilitate efforts to restrict advertising to minors.

Public Health Spending

We would encourage the chairman to include core public health investments in his bill, including:

- Prevention and Education Funds (\$400 a year for CDC state, community and national efforts, and \$200 million a year for school based efforts);
- Counteradvertising (\$500 million a year for CDC);
- Youth Smoking Surveys (\$200 million a year for HHS);
- Full funding of the Administration's proposed Research Fund for America which includes an increasing the NIH budget to \$14.8 billion and the National Science Foundation budget to \$3.8 billion; and
- An additional Fund for Tobacco-Related Research (\$1 billion a year for NIH-CDC-ACHPR).

Liability

- As you know, our position on liability is clear: unless we are imposing tough penalties on the tobacco companies and doing everything in our power to reduce youth smoking, this Administration will not consider proposals to give the tobacco companies protection from liability. As we have said many times, reasonable limits on liability will not be a deal breaker in a bill that meets all of the president's principles, but first, we have to get that kind of bill.
- We understand that there are concerns being raised about how the \$6.5 billion liability cap is structured in this bill. I can only say that because we have not proposed a cap, we do not have views on this issue.

Background

The proposed settlement would require a portion of the company's annual payments to be set aside for a tort fund. If companies were found liable in court, this fund would be used to pay the judgment. Companies would have to pay a copayment in order to draw from the tort fund. If court claims did not use up the entire fund, it would revert to the federal government for public health uses. Claims that were too large to be paid in one year would be rolled over into the next year. Senator McCain has proposed this same basic structure, but with a higher cap (\$6.5 billion rather than \$5 billion). The settlement also relieved the companies from future class action and punitive damages, which McCain has chosen not to do.

Currently, some Democrats, such as Rep. Waxman, and members of the public health community are protesting this structure. They say that the companies' payments into the tort fund should be in addition to the regular annual payment, and that this structure unfairly pits federal health programs against plaintiffs. While we have not taken a public position on this matter, we generally believe that the settlement structure strikes the right balance. If the companies are found liable for damages, the plaintiffs would receive the funds; if such suits are not successful, then we should fund more public health programs.

- 1) Treaty scheme - liability
- 2) Authority
- 3) Waxman

Conv. w/ Matt Myers 3/22

sep chapter

same broad range

same ent. auth.

Koop - call directly.

Kessler -

Both are - almost ~~in~~ inseparable

e.g. access, advertising, document disclosure

Desperately imp^{by us} to have sep. chapter -

go through - maybe list

everything.

include:

a few from d+d title

incorp by ref. / then say
"in addition"

make clear - free to elim nico.

def of tobacco product - has to
be broad.

narrower preemptive provision

Don't leave to West~~moreland~~.

= Tell McC staff =

Talk to Koop/Kessler



Cynthia A. Rice

04/02/98 07:13:43 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP
cc: Cynthia Dailard/OPD/EOP, Laura Emmett/WHO/EOP
Subject: Next steps on tobacco

Next Steps with McCain and Hollings

Have either of you spoken to John or Ivan about next steps?

On technical amendments, you may want to ask them if they need anything more from us -- we sent them technicals on Tuesday (which they didn't incorporate into the package handed out -- Ivan indicated they were too rushed), and yesterday they said they would probably need our help on the final price language.

There are several policy issues they've indicated that they'd like to work on before the floor -- perhaps for a managers' amendment? They are:

International issues (they want a Tuesday am mtg with us, Hollings, Ford, & Wyden staff)
Licensing/Anti-smuggling -- (McCain staff told me they'd like to discuss post-markup)

And then there are several areas where our agencies would like to push for changes:

Constitutional issues -- in particular, to urge them to strip the lobbying ban
Liability -- DOJ says the provisions are so poorly drafted as to be nearly meaningless
Penalties -- there are various technical changes Gruber has in mind

Talking Points and Q&A

I have asked the agencies to produce our best talking points and Q&A on the following topics:

Penalties
Price/Youth Smoking Estimates
ETS
Antitrust
Bankruptcy
Smuggling/Black Market

Scoring

I just sent Cathy a note about having a meeting on this tomorrow. I assume its us, Josh, and Gruber?

3-6 Tobacco notes

2-3 PP

Penalties

Defense of youth estimates

ETS (OSMA)

Anti-trust

Bankruptcy

Smuggling + Black Market

Comments on amendments

Comments on McCain bill

International - Wyden / Fwd / Hollings

tomorrow morning

Harkin-Chafee has good language.

Problems: Access / labeling restrictions

Doppert trade language - would prevent reduction of tariffs

pre-meets today - internal

then w/ Fwd / Hollings

See how Chafee Harkin language would work on printing.

More calling for limit

Close to working out farmers problems -
wasting. In inty w/ Ford + Helms

Kennedy OK w/ deductibility of payment
on Conrad bill
Poreaux will support liab limits
press for a cap (at least)

2-3-78 Tobacco - lawyers mtg

List of witnesses - Hyde

Panel 1 - David Ogden -

Panel 2 - Myer Koplin

Gail Nantz

Shirley Humphrey

Dr Albert Munster - Long Assn

Panel 3 - Prof James Foster - U IU LS

(neg)

John O'Keefe - Columbia

Robt Rubin - Stanford

(neg)

Richard Deynard - Northeastern

(neg)

Steve Cassin - asbestos lawyer.

Diana Schacht
(Hyde)

Early March - went to make up
civil lib/atty fees / antitrust
some sort of rebuttal to Biley -

Casper - Perry Application

Moore - Pres has to call Biley -

Fall apart in 2 wks - not be able to put together.

W. O. #

#

DeRay/Brook v Arney/Girlich

Promise to give cover. (June 20 - Lindsey)

Thurs - docs - preparation to minorities -
Congress to bring up.

Conrad - to call for summit?

3/16 Tobacco principals

Stiv: Dems now want us to not incomplete bill. They'll CC

Dasch: They engage LOTT in floor

< Get something out! >

Bu: This week - Tethrds make-up

(Even Dasch agree)

New draft today

Nichols - prop cut bad floor amendments - incl. Tethrds bill on FDA.

→ Specific language on budget

Budget resolution - steps all bad

Public events next wk -

Speech next wk?

(S) - 25th - GW

costs of smoking

med costs / productivity

(more detailed Treasury study)

VPR state-by-state health

bill

2 venues

Mar 23 - probably

April 2 - high levels

(cabinet)

81st - smokeless event -

Camden park -

Shalala

THE WHITE HOUSE
WASHINGTON

March 6, 1998

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed

SUBJECT: Tobacco Strategy

Over the past two weeks, we have met with Erskine, OVP, NEC, OMB, HHS, Treasury, and Justice to develop an aggressive communications plan to help turn up the heat on Congress to pass comprehensive bipartisan tobacco legislation this year. We have also begun extensive, high-level meetings on the Hill. This memo outlines our communications and legislative strategy to get a bill done by late summer.

Communications Strategy

We are organizing a series of events for you and others, including House and Senate Democrats, to make the point that Congress should not go home without passing comprehensive tobacco legislation.

Our message is simple: Every day Congress fails to pass tobacco legislation, 3,000 kids start smoking and 1,000 will die early as a result. We can dramatically reduce teen smoking and save a million lives over the next 5 years if we pass our budget proposal now.

We must continue to stress that we need a comprehensive, not piecemeal, approach that raises the price of cigarettes by up to \$1.50 a pack over the next ten years, expressly confirms the FDA authority to regulate tobacco products, gets tobacco companies out of the business of marketing to children, furthers public health research and goals, and protects tobacco farmers and their communities.

In the next week, we plan to underscore our commitment to bipartisan, comprehensive legislation in several ways:

- In your March 7th radio address, you can challenge the Congress not to go home this year without passing legislation that will dramatically reduce teen smoking. In issuing this challenge, you can note that Congress has as few as 70 working days left, and that 1,000 people will die from smoking on each of those days.

- On Sunday, March 8th, The Washington Post is planning to begin a three day series chronicling the tobacco wars from the drafting of the FDA rule to the present. We hope this series will underscore our long commitment to this issue and the urgent need for action.
- On March 9th, in your speech to the AMA on health care quality, you can laud the doctors' support for comprehensive tobacco legislation. Senator Jeffords is currently scheduled to mark up a bill on FDA jurisdiction on the same day, providing us with an opportunity to underscore the importance of the tough advertising and access restrictions in our FDA rule and the need for legislation that reaffirms the FDA's authority to regulate tobacco.
- When Senators Chafee, Harkin, and Graham announce their bipartisan plan -- probably during the week of the 9th -- we hope the Vice President can appear with them and express support for the bill.
- On March 11th, the Democratic leadership will announce a countdown calendar to emphasize that on every day that passes without enacting tobacco legislation, 3,000 kids will start smoking, causing 1,000 to die a premature death. Rep. Fazio may introduce a slightly revised version of Senator Conrad's bill on the same day.
- In a March 12th speech to the attorneys' general, you can announce state-by-state numbers of how many lives will be saved by comprehensive tobacco legislation. We expect the industry to release more documents on this day, in response to a subpoena from Rep. Bliley, and you also can refer to these documents.
- On March 13th, we would like to leak a political memo on the popularity of tobacco legislation. We are working to line up a pollster.
- On Saturday, March 14th, the Vice President will convene a regional tobacco roundtable in Boston, inviting key members of Congress (Kennedy, Chafee, Jeffords).
- Secretary Shalala will meet with editorial boards throughout the week to explain our goals and priorities.

Legislative Strategy

We are using the weeks before the Congressional recess in early April to lay the groundwork for negotiating comprehensive tobacco legislation. We have been (1) attacking Republican plans to enact piecemeal legislation; (2) praising comprehensive bills, such as Senator Conrad's, which meet your principles; and (3) meeting extensively with key Democrats and Republicans in both the House and Senate. Yesterday, Erskine, Larry, and I met with Sens. McCain and Mack, Sen. Conrad and his Democratic Tobacco Task Force, and Rep. Waxman. Next week, we plan to meet with Sens. Domenici, Chafee, Nickles, and Hatch, Rep. Bliley, and the House Democratic Tobacco Task Force.

We believe we are making real progress in the Senate. Two serious bipartisan efforts have emerged. As you know, Senators Chafee, Harkin, and Graham are collaborating on a bill; we expect them to announce it as soon as they can get another Republican (perhaps Lugar) on board. Although the Senators are still working, we think the bill will include a \$1.50 price increase, tough youth smoking penalties, good provisions on FDA jurisdiction, and a cap on annual damages (but no other liability limits). The bill may very well get the support of significant players in the public health community, including General Koop.

At the same time, Senator McCain is leading an effort -- blessed by Trent Lott -- to report a comprehensive bill out of the Commerce Committee. McCain is talking extensively with Senators Breaux, Wyden, and Hollings, as well as with Republicans on the Committee. McCain is currently working off a draft bill that has significant weaknesses, especially with regard to price and FDA jurisdiction. There is little doubt, however, that McCain would like our support and that he is listening carefully to our concerns. Some Democrats in the Senate are concerned that McCain will be able to cut a deal with Commerce Committee Democrats too fast. We will make clear to the committee Democrats that they should work with McCain to improve his bill, but should not sign on to any bill that does not meet all our principles.

The House remains inactive. Bliley has held some hearings and may try to draft legislation, but prospects for a Bliley-Waxman collaboration now seem slight. The House Republican leadership is interested in tobacco revenue to pay for tax cuts, but has done nothing to spur legislative action. We hope that the increased momentum in the Senate will carry over to the House, and in our meetings next week we will try to jog key members.

One early and important skirmish will take place over the budget resolution. We need to make sure Congress includes a reserve fund that keeps the door open for us to use receipts from tobacco legislation for the purposes outlined in our budget.

Ultimately, our communications and legislative strategies converge on the same basic point: The Republicans fear that we will get the credit if tobacco legislation passes, and that they will get the blame if it does not. We need to make the price of not passing a bill too much for their side to bear, and the value of getting it done too great for our side to pass up.