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Tobacco-Attorneys General Proposed Settlement [2]

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mayo

Fax

Mayo Clinic Rochester
200 First Street Southwest
Rochester, Minnesota 55905

To: Mr. Jerry Mand Date: 7-29-97

Company: Fax: 202-456-6027

No. of Pages (including cover sheet): 9 Phone:

Delivery Instructions: ☐ Routine ☐ Urgent

Special Instructions:

From: Richard D. Hurt, M.D. Fax: 507-266-0038

Phone: 507-284-5161

Message:

mayo

Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
507-284-2511

Richard D. Hurt, M.D.
Director
Nicotine Dependence Center

July 29, 1997

Mr. Jerry Mand
The White House
Washington, DC 20500

Dear Mr. Mand:

Unfortunately, I did not get a chance to review the appendices to the proposed tobacco settlement and am getting ready to leave on vacation, thus will not get information to you in a timely manner. Attached is my assessment of the draft of the proposed settlement dated June 20, 1997, and the letter that I sent to Dr. John Slade concerning this. John had sent me a copy of the proposed resolution and asked for my response. I hope this is helpful in some way in your deliberations.

I will take the proposed settlement along with me and try to review in some detail the smoking cessation portion of the attachments and get an assessment back to you next week. I knew that you were on a short timeline and thus thought I should get something to you.

Sincerely,

Richard D. Hurt, M D.

RDH:nsp

Enclosure

July 7, 1997

John Slade, M.D.
Department of Medicine
St. Peter's Medical Center
254 Easton Avenue
New Brunswick, NJ 08903

Dear John:

Thank you for sending me the proposed resolution for the attorneys general/tobacco industry settlement. You are correct that this is an extremely complex document with so many nuances it is hard to grasp them all. The level of detail is obviously critical, but the phraseology and verbiage is also critical. This is clearly a document that has been prepared primarily by attorneys, and the meaning of some of it will only be evident to people with that background. Nonetheless, since this has a possibility of becoming law, it is critical for all of us to understand its implications and, when appropriate, seek further clarification so that there are no misunderstandings.

I just returned from a trip to Rio de Janeiro, Brazil, and came away even more concerned about this settlement agreement not including exports. The American tobacco industry is making tremendous inroads into Brazil using the techniques that this settlement document would prohibit in the USA. For example, during the Carnival season in Brazil, there are samples being freely given away to anyone who will take them, including underage people. Advertisements for Marlboro and Joe Camel are prevalent. The industry obviously recognizes that to retreat from the United States is acceptable as long as they can continue unimpeded in the rest of the world. Perhaps if the industry were truly held accountable in the U.S., they would not have the resources to do this to our fellow human beings around the world. This settlement as proposed does not mandate either full disclosure much less full accountability. I am quite disappointed in the document as it currently is written. Too much is given away for so little received.

Again, thank you for sending this to me. I have attached my assessment of the document up to the appendices.

Sincerely,

Richard D. Hurt, M.D.

RDH:nsp
Enclosure

Summary

There are some good points in the document and the negotiators obviously were able to extract from the industry concessions previously not given. However, I do not believe the proposal as is written would have the stated effect of dramatically reducing youth smoking rates in the United States. Furthermore, the proposed legislation would limit the FDA's ability to regulate the industry's linchpin, i.e., nicotine levels in cigarettes, for many years. I am also concerned that we are only talking about domestic products, and there is little, if any, mention of exports. Furthermore, cigars are not mentioned and should be included. Finally, the writers of the document seem to utilize existing standards as the "gold standards," i.e., the size of the Canadian warning labels, etc.; whereas, I believe that this is the opportunity to go beyond the current standards.

The following are specific comments:

Page 1, para 1: Why not include exports?

Para 2: The consensus about tobacco products causing harm spreads across scientific/medical communities and the tobacco industry itself, though they do not publicly acknowledge that. I believe that they have to do that.

Para 5: "Further, it is contemplated ..." This is the first hedge on words. Why should it be contemplated? It should be mandated!

Page 3, para 1: The FDA already has the power to regulate the levels of nicotine in tobacco products.

Para 2: I believe that they should be forced to release other internal documents relating to the health effects of tobacco products and not just internal laboratory research. As we saw from the Brown and Williamson papers, there was a lot of discussion about these issues at the highest levels of the tobacco industry. Full disclosure must be accomplished.

Page 4, para 4: They seem to lump all public health authorities and there is obviously disagreement amongst many of us.

Page 5, para 2: Were they a corporate good citizen, the tobacco industry could do all of this now without any legislation whatsoever.

Page 8, para 1: Why do we have to continue selling tobacco products in duty–free shops? In fact, why do we have duty-free shops to begin with? Why should travelers have this benefit when ordinary citizens do not? The use of the term new regime sounds like a government itself. Is there some particular reason this term was used rather than "under this agreement" or "under the terms of this legislation," etc.?

Para 3: Does this mean that no new brands can be introduced in the future?

Para 5: Who defines the adult–only facilities and publications?

Para 8: I assume that this means banning all coupons such as Camel dollars, Marlboro miles, etc.

Page 9, para 1: I assume that by tobacco brand they also would include a tobacco company. In other words, there could not be sponsorship by RJR or Philip Morris.

Para 4: It is impossible to design something to be inaccessible in or from the United States. There should be a total ban of such advertising on the internet.

Para 5: "...with a view toward minimizing the impact..." I think it should be toward eliminating the impact.

Para 7: I don't think it's a matter of just glamorizing tobacco use in the media, rather, having a higher rate of smoking in the movies than is the norm. We all know that when adolescents are asked to estimate the rate of smoking amongst their peers, they almost always over estimate it. The perception of smoking being more prevalent in the movies than it is in reality is not necessarily glamorizing, but it is the wrong message.

Page 10, para 1: To say that the information is misleading is incorrect. The information is what it is. The promotion of the image of a "safe cigarette" exploits that information.

Para 2: All exported U.S. cigarettes should carry the same labeling.

The warning about smoking during pregnancy could be changed to say it causes SIDS or causes your baby's death, and further down under the line that says tobacco smoke causes fatal lung disease, I would say that it causes lung cancer and emphysema. An additional warning could be that it causes fatal heart disease in nonsmokers. Those two statements would be more accurate given what we know.

Last para: Why not increase the percentage of covering? Why do it exactly like Canada?

Page 11, para 1: Let them do away with the boxes instead of restricting the space that can be used for the bigger health warnings. Boxes were not introduced until the 1950s. Remember the slogan "Filter, flavor, flip-top box" for Marlboro? According to this regulation what's to prohibit all cigarette manufacturers from converting to a flip-top box in order to keep the warning at a smaller size. Finally, why not use a larger warning label? Let the United States lead the way for a change rather than being in the position of following.

Para 5: Somehow they are treating the FDA rule as the "gold standard." I think we all know that this is just a beginning and should not be held up as the absolute standard by which all other things are measured.

Page 12, para 4: This simply can never be done, i.e., to determine whether minors are obtaining tobacco products through the mail. The simplest way to deal with this is to ban all such sales. There obviously are plenty of retail outlets for cigarette sales throughout the country.

Page 13: As we all know, the federal facilities and Indian reservations have lower prices. I think these prices should be raised so that the prices for a pack of cigarettes are comparable in all outlets.

Page 15, para 1: If the FDA set a reasonable time frame and the tobacco companies decided to litigate that, could they do it?

Para 3: Does the last sentence in this paragraph mean that traditional products could be forever produced?

Para 4: The way I read the middle part of this paragraph is that the FDA would never be able to eliminate nicotine yields. In the same sentence, it mentions the "possible elimination..." Who determines what constituents could be possibly eliminated? Would this be another point of contention and potential litigation?

Page 16, para 2: Does the right of judicial review simply mean that they have the right to bring this issue into court? Further in the same paragraph, they put the onus on the FDA about contraband and give the tobacco companies the right to sue or litigate. Experience has been that the tobacco companies will smuggle their own cigarettes across a boundary in order to smuggle them back into the country. Thus proving that smuggling will occur. As you know, this has happened in Canada and an official from the Brazilian National Cancer Institute stated it happens across the border from Paraguay to Brazil. What's to keep them from continuing to do this and accelerate the process in the future to forever eliminate the possibility of actually reducing the nicotine content in tobacco?

Para 3: Talks about examining, determining, and reviewing but there never is an action verb. If the FDA were to determine the level of nicotine that produces drug dependence, they should be able to act on that.

Para 4: I think that using the current measures for tar and nicotine are irrelevant and that tar delivery probably corresponds quite well with nicotine delivery.

Para 5: It's incredible to me that anyone would suggest 12 years to set safety standards, etc. So, the FDA can determine the dependence-producing nicotine level but can't act on it for 12 years? This is totally unacceptable.

Page 17, para 2: What is a Part 12 hearing? Here also is the recurring phrase, "with a right of judicial review." To me, the last part of the paragraph , "In the event any party files a petition..." means that this issue could be tied up in court for years.

Footnote 1: I assume that this mean that they can continue to sell the traditional tobacco products to adults, thus the nicotine level and tar levels would not be brought down across the board. Aren't we interested in protecting the adults too?

Page 18, para 1: What does this mean? Just sounds like legal jargon.

Para 7: I think the FDA should be able to demand any records that might have to do with nicotine or other possible health-related substances in tobacco smoke or in tobacco.

Para 9: It's hard to understand what this paragraph means. I'm not sure what regulation tobacco farmers are under except how much they can grow by their allotments.

Para 10: I think that we need to be able to see more than just "internal health research documents." There is need for full disclosure about what the tobacco companies knew and when they knew it, who they reported to and why they chose not to make these records public.

Page 19, para 1: They make the statement, "...manufacturers of medical devices generally would also...." Why generally? Why not just would? Most medical devices are a lot less dangerous than cigarettes and, therefore, the same if not more stringent rules should apply.

Para 4: Why should reconstituted tobacco be excluded? Doesn't reconstituted mean it was something else to begin with? The last sentence in this paragraph speaks to the issue of proprietary information, but they don't mention proprietary information until the bottom of page 20. I don't think we should let the manufacturer decide what should be disclosed to the public. The FDA should decide.

Para 5: Five years is too long. They can do this much more quickly. They either have the information already or they should devote some of their marketing dollars to do it since they will no longer be spending money on advertising.

Page 20, para 4: Here again is too much latitude for the industry to exempt from disclosure based on the manufacturer's decision. It also puts the onus on the FDA. In the drug business, safety (and efficacy) have to be proven by the manufacturer. The same should be true here. The tobacco company should have to prove ingredients they add to tobacco are safe.

Page 22, para 6: I don't think the words "...to promote efforts to attain..." are nearly strong enough. I would revise this to say, "...an authority to see that these standards are attained."

Para 9: This paragraph seems to imply that contract lobbyists are not currently responsible to the manufacturer. I find this hard to believe.

Para 10: Who sets the "strict procedures and federal oversight?"

Page 23, para 2: These fines are entirely too low. The per day per violation number should be at least $100,000 and the $200,000 total should be extended to $1,000,000. We mustn't forget that this industry makes billions of dollars (1 billion equals 1 thousand million).

Page 23 under the timeframe for sponsorships: December 31, 1998, is simply too long. This could be done very quickly even though it may cost the industry to do it.

Page 24, para 2: I also think that the levels for decline in underage smoking are set too low. The 30% should be moved up to 40%, the 50% should be moved up to 60%, and the 60% should be moved to 75% at year 10. The underage use of smokeless tobacco products should be the same as for cigarettes. In the "look-back" provision there is no indication that cigars are to be regulated. They should be included given the increased use among kids.

Para 3: Why should there be an annual cap? If they're not complying then they should be fined. In the last part of this paragraph it's unclear who would judge whether they had complied fully and made all efforts to achieve their targets. Is this not another point for litigation and delaying tactics?

Page 27, para 1: What is a facial constitutional challenge? This is another one of those terms that's entered into this that most of us do not understand.

Last para: It says that state proceedings to enforce the consent decrees may seek injunctive relief only and may not seek criminal or monetary sanctions. Why should they not be able to seek those types of sanctions? Otherwise, to get compliance they will have to go to court, which sounds to me to be another delaying tactic on the part of the industry.

Page 28, para 2: This seems to allow Congress to renege on the warnings on tobacco products. Does this mean the tobacco industry chips away year after year claiming that the consent decrees as well as other regulations are unfair, restrictive, "big brotherism," etc., and persuade Congress to renege on this agreement?

Page 32, item 3: Why should the Bureau of Alcohol, Tobacco, and Firearms retain physical authority over tobacco products? Since this is a drug delivery device, it should be under the FDA jurisdiction.

Item 8: I seem to recall that previously there was preemptive language on page 26. This paragraph seems to contradict that.

Page 33, para 3: The last sentence also seems to be contradictory. I think the FDA should set the timeframe here and not have it put into the legislation.

Page 34, item B, 2: This again seems to be a delaying tactic so that it only applies after the first full year. Why not prorate this so if implemented after January they couldn't pay until 13 months later.

B, 3: In the public health trust, why doesn't this continue to increase over time?

B, 4: Does this mean that there is a 3% increase per year at a minimum, or if the CPI is larger than 3%, that is what is applied?

B, 5: They make the point of talking about relevant domestic tobacco product unit sales and relevant actual volume. What does relevant mean here? They also in the next to the last sentence speak about adult volume figures. Why only adult? Why not the underage market as well?

Page 35, para 2: I simply don't understand the statement that begins with "Any reduction in an annual payment...."

C, 1: Does this now include cigars? I think that it should.

Page 35, Q
This is anything but ordinary and necessary business expenses; therefore, this should come out of their after-tax dollars!

CAMPAIGN for TOBACCO-FREE Kids

TO: S. Buckingham, E. Chapnick, L. Crampton, B. Crain, D. Crane, S. Dickinson, J. Epstein, S. Hicks, A. Hyman, F. Karel, C. Kelley, R. Landry, D. Maier, D. Maple, J. Marx, T. Moreis, B. McHugh-Sanner, J. McKenna, J. O'Hara, M. Schoenfeld, D. Spitz, M. Tharp, B. Wooley, C. Yarborough, P. Yoxall

FROM: Kay Kahler Vose

DATE: June 13, 1997

SUBJECT: Negotiations with Tobacco Industry

Attached is a document produced by the Center that summarizes may of the points of agreement to date on public health issues in the ongoing negotiations between the tobacco industry and the attorneys general. The document contrasts the agreed-upon points with the provisions, or lack thereof, of the FDA Rule.

I hope you find this document helpful.

Please note that this document is not a final version. These are the agreed-upon provisions and they could change when an agreement is finalized. We will update you on any modifications.

Please call me with any questions.

06/13/97 4:22 PM
DRAFT

CAMPAIGN for TOBACCO-FREE Kids

Summary of public-health provisions that have been tentatively agreed to as part of the ongoing settlement talks with the Attorneys General, the tobacco industry and public health advocates.

1. Youth Access

The full substance of the August 28, 1996 FDA youth access provisions have been agreed upon.

The FDA rule:

- Bans sales to kids under 18;
- Requires proof of age;
- Limits, but does not ban vending machines;
- Limits self-service displays, but permits tobacco to be displayed on the counter;
- Establishes the minimum pack size at 20 and prohibits the sale of single cigarettes;
- Bans free sampling; and
- Uses FDA's normal enforcement tools with enforcement funding subject to annual Congressional appropriations.

In addition the tobacco industry has agreed to:

- A ban on all vending machines;
- The placement of tobacco products behind the counter and out of reach of consumers;
- Further restrictions of mail order sales, subject to conditions that demonstrate that an effective mechanism exists to restrict sales only to adults;
- A nationwide licensing system for all sellers of tobacco products with graduated penalties and license suspensions for violations of the youth access and marketing provisions to be established. The licensing system shall apply to all sellers of nicotine - containing tobacco products, including manufacturers, distributors, wholesalers, retailers and importers;
- Full funding from money paid by the tobacco industry for enforcement by FDA and state and local authorities;
- States and local governments would not be preempted from enacting stronger laws;

- Dual enforcement authority with both the FDA and state attorneys general, each being able to enforce these provisions. In addition, the FDA will have the power to contract with other state and local authorities to assist it to enforce the rules; and
- Enforcement to require unannounced, random stings.

2. Marketing and Advertising

The industry has agreed to the full substance of the August 28, 1996 FDA youth advertising and marketing provisions (which were struck down in Federal District court but which have been appealed):

The FDA rule before the court ruling:

- Text-only ads in youth oriented magazines and newspapers;
- Ban brand name event sponsorship;
- Limit billboards near schools and limit billboards to text only with no color;
- Ban use of non-tobacco brand names on tobacco products;
- Ban advertising on non-tobacco products, like clothing and gear;
- Ban offers of non-tobacco items or gifts based on proof of purchase; and
- Require ads to carry FDA-mandated statement of intended use.

In addition to the FDA provisions above, the industry has also agreed to:

- The elimination of all billboards and outdoor signs, including all signs in stadia and arenas and signs that face outwards in enclosed areas, such as stores;
- The elimination of all human images and cartoon characters from all advertising and from all cigarette packages;
- Additional restrictions on point of purchase advertising regarding the placement on point of purchase ads to limit their size and number, remove them from the line of sight of children and remove them from close proximity to candy and other goods likely to attract children;
- The elimination of internet advertising and the agreement on the use of whatever technology is available to make tobacco advertisements that are placed on the internet from foreign countries inaccessible in the US;
- The prohibition on product placement in movies and on TV;
- The prohibition on any payments or fees to celebrities to smoke in movies or on TV or to any other person or entity to glamorize tobacco use in movies or on TV, and the prohibition of any "in-kind" actions to accomplish any of these same purposes;

- Without limiting the FDA's normal authority, limits on the use of words, such as "light", that currently appear in some product names and that could be misinterpreted as health claims;
- Protection against First Amendment challenge: an agreement to consent to the placement of all of the advertising restrictions contained in the August 28, 1996 FDA rule plus the above noted restrictions in consent decrees to insulate the restrictions from First Amendment challenges by parties outside the tobacco industry;
- Dual enforcement authority with both the FDA and state attorneys general, each being able to enforce these provisions. In addition, the FDA will have the power to contract with other state and local authorities to assist it to enforce the rules; and
- Funding from the tobacco industry to pay the cost of enforcement for both FDA and the state authorities with enforcement power.

3. Public Education/Counter Advertising

The tentative agreement with the tobacco industry includes:

- Funds for the largest, most-sustained nationwide public education/counter advertising program ever done for tobacco or for any other public health hazard. The campaign would be similar to those campaigns in Massachusetts and California. The program would operate independent of the tobacco industry, which would have no say over the content or placement of the program. Funding for the program would be guaranteed, and to the extent possible, the program would be insulated from political pressure.

4. Health Warnings

- There would be a dramatic revision of the warning label system. The current system would be replaced with the far more specific, more detailed eight Canadian warnings.

  They include warnings, such as:

  - "WARNING: Cigarettes are Addictive";
  - "WARNING: Cigarettes Cause Cancer";
  - "WARNING: Smoking Can Kill You"; and
  - "WARNING: Tobacco Smoke Causes Fatal Lung Disease In Non- Smokers"
- The warnings on packages would be moved to the front of the cigarette package and the most prominent side of the smokeless tobacco product package.
- The warnings would appear in the Canadian format (the top of the front with white lettering on a black background). The warning would occupy at least 25 percent of the top of the front of the package. All warnings would appear simultaneously on tobacco packages and would be rotated quarterly on ads by brand.

5. Full Disclosure

Under the possible agreement:

- Decades of deception would come to an end and the industry would tell the truth about what it knows.
- All documents which would have been revealed through the litigation process would be made public and the industry would agree to make public its health-related research in the future.

6. Youth Smoking Targets

- The industry would be subject to penalties if youth tobacco use fails to drop by 30 percent in 5 years, 50 percent in 7 years and 60 percent in ten years. The penalty would be based on the value of a teen tobacco user to the industry over the lifetime of the individual. It would be worth approximately $80 million per percentage point by which the target was not met.

7. Funding for State and Local Tobacco Control Activity

Active state and local tobacco control efforts have been proven successful in reducing tobacco use. Current programs are under funded and funding for these programs is in jeopardy.

Under a possible agreement:

- State and local tobacco control activity modeled after the successful ASSIST program would be funded out of tobacco industry funds, permitting the ASSIST program to be funded in every state from these funds.

8. Tobacco Cessation

Under a possible agreement:

- Out of funds to be provided by the industry, funding would be provided for tobacco cessation programs and devices for those who want to quit and for whom cost is an issue. These funds would be available to individuals nationwide.

9. Protection from Environmental Tobacco Smoke

Under a possible agreement:

- Protection from environmental tobacco smoke would come from the enactment of the text of HR 3434 (the bill originally introduced by Congressman Waxman) that restricts tobacco use in public places and most workplaces to locations that are separately ventilated to the outside and through which non-smokers do not pass.

To avoid heavy opposition from the hospitality industry, restaurants (excluding fast food restaurants), casinos, bingo parlors, and bars would be exempted.

- The federal law would not preempt state and local governments from retaining or enacting more restrictive requirements governing ETS.

10. Monitoring Corporate Behavior

The tobacco industry has the most irresponsible corporate record of any industry in the United States. Currently, no mechanism exists to ensure that the industry complies with the letter or the spirit of existing law.

Under a possible agreement:

- Manufacturers would be required to develop detailed compliance plans describing how they intend to comply with the law and monitor their own employees behavior.
- Corporations would be required to set up incentive plans to encourage compliance and internal compliance checks to catch and report violations.
- Corporations would be required to establish a corporate code of behavior with outside monitors, a system of auditing, and reports to shareholders and the FDA.

11. General Authority of the FDA

FDA's authority over tobacco products as "drugs" and "devices" has been upheld by the trial court in North Carolina and is now on appeal. To date, the FDA has only sought to exercise its authority by establishing youth access and marketing rules, but it has far broader authority.

Under the tentative agreement:

- The judicial challenge by the tobacco industry would be dropped and FDA's authority explicitly recognized. Therefore, tobacco will continue to be categorized as a "drug" and a "device" under the Food, Drug and Cosmetic Act and the agency's authority to regulate the products as "restricted medical devices" will be recognized.
- FDA would exercise its normal authority to inspect, enter manufacturing plants, demand certain records and record keeping, and would have its normal enforcement authority.
- The tobacco industry would be required to provide FDA with all research it conducts and all non-public information it receives that relates to health, toxicity, addiction, drug dependence.
- In general, FDA's powers to regulate tobacco, including nicotine, would not be circumscribed. The details of this are still being negotiated.

12. Tobacco Industry Liability

The tobacco industry has lost only one court challenge in its history and only Liggett has actually paid any money in damages. Nonetheless, the tobacco industry faces unprecedented court challenges today. The issues about the tobacco industry's future liability are still being discussed, but several facts are already known if there is an agreement:

- The rights of individuals to sue will not be abridged.
- There will be no limits on individual judgments.
- Whether or not individuals have greater success in the future in court against the tobacco industry than they have had in the past, the tobacco industry will be required to pay billions of dollars to victims and public health causes for the harm done by their products.
- In return for the industry's commitment to pay several billion dollars a year, whether or not there are any judgments against it, it has been proposed to cap the overall damages the industry would pay through litigation in any one year. It is highly unlikely that this fund would be exhausted in any one year. However, if this were to occur, then payments to individuals winning cases against the industry would be extended over more than one year. This would not result in restricting the overall award an individual could receive, but it could lead to a delay in the total payment. Any money from the annual fund not won through litigation would then be transferred to national public health, anti-tobacco programs and would not revert to the tobacco industry
- While industry requests for broader protection are no longer on the table, there do remain unresolved issues concerning whether tobacco cases could be brought as class actions and whether preemptive damage claims to be paid out of the fund would be permitted.

Summary of Tobacco Settlement Proposal
-- DRAFT --

Industry Financial Commitment

Total commitment of about $370 billion over 10 years, including up-front commitment of $10 billion in "punitive damages" to HHS and annual payments as outlined below.

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

Public Health Provisions

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

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

Marketing and Advertising Codifies FDA rule. In addition, among other things: eliminates all billboards and outdoor signs; eliminates all human images and cartoon characters from all advertising and from all cigarette packages; places further restrictions on store placement of ads; prohibits product placement in movies and on TV. FDA and state attorneys general would have joint enforcement authority over these provisions, and industry would fund enforcement effort. May prohibit FDA from modifying agreed-to provisions for up to 7 years.

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

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

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

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

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

Industry Accountability and Disclosure

Youth Smoking Targets. The industry would be subject to penalties if youth tobacco use fails to drop by 30 percent in 5 years, 50 percent in 7 years and 60 percent in ten years. The penalty is $80 million per percentage point under target.

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

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

Liability

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

Settles all state Medicaid suits. Includes states that have not filed suits. Money distributed as outlined below.

Outline of Working Group Analyses

I. Brief description of issue area(s)

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

III. Long-term analysis without a settlement

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

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

IV. Long-term analysis with a settlement

ITWG 6/18

BNR - +28
Nancy Ann
Gips, Burson

EK -

1. FDA
2. Ad ED
3. ETS
4. Smk Cessation
5. Industry incentives/performance - affect on farmers
6. Litigation / Liability
7. Budget / Children's Health

KT - Posture - entirely neutral - not taking steps to promote settlemen

To set up a process - to begin work - ready to hit the ground.

DG - Would working groups consult outside groups.

Int'l

BC - Boundaries? Will we look beyond the settlement?

EK - Irresponsible not to look beyond scope of settlement.

MZ - Groups track deal - PR - Mtgs will create momentum

KT - BC - Risks of starting before we receive a settlement document.

DG - Proper size of $ settlement.

MZ - FDA / advertising

KT - Koop/Kessler - McCurry

BNR - Need to maintain our own timetable.

There aren't many grown ups left in the process.

DAK - 3¢ days?

Where should hrs process fit in

1. Regulation of nicotine
   Safer cigarettes — less addictive
   — less toxic (Ca, CHD)

1a. Advertising.

2. ETS

3. Farmers.

4. Smoking cessation

5. Public education

➢ Assess world w/o ~~of~~ settlement.
   Litigation - what's possible — torts
   — states
   Bankruptcy

Reduction of smoking
- kids don't start
- more adults quitting
- safer product
- fewer addicted

➢ Assess world with settlement.

Affect of peace in tobacco wars

Distribution of $ - public interest

- # of grass roots local groups that are affected by the settle

- Good corporate citizen

Youth Smokers ETS

Econ / Ind
Corporate
Structure

Reg of NAC

KW

313 - 663-8412

▸ Ultimate solution - removing nicotine

- paper → alternate nicotine delivery system. non-dangerous / minimally dangerous

eg. gum - looks bad, tastes bad

Must be much ~~before~~ more consumer friendly.

Sol Shifman (Pitt.) — 5% chippers → 18% (Warner) non-daily smokers

↓ Why

nicotine altern

↓

work place restrictions ?

Jay Winston (Harvard - Medical Policy) —

Smoking - scene continuity

Real world -

1. Nicotine alternatives - more attractive, widely available
2. Access + Advertising +
   - $1B/yr counter advertising
3. Price up $30B/yr

We don't know — need process

Wall Street — stock values will go up no matter. Stability.

Int'l — UICC - Int'l Ca Control

Can NEC or CEA calculate the proper size of a settlement.

Justice must successfully complete prosecutions.

- Give them enducement to develop less hazardous produc
  Always going to max profits - maintain addiction.
  Channel energy into less hazardous products.
  Liability system in this instance has caused them to keep a more hazardous project
- Send some CEOs to prison.
- Most appalling case of market going wrong they must pay a price.

BL BNR
+17

I FDA - spelled out framework for nic regulation
for 10yrs - gradual reduction but not elimination.
a- sig reduction in health risk b. - tech feasible c- feasible-won't create black market

Matt
OAK-OK

FDA + on access & advertising

Performance stnd - 3Φ%-5 5Φ%-7 6Φ%-1Φ
$8ΦM/percentage pt.

- Waxman. 2d hand smoke except bars & restaurants
- Nothing on intl. - Price/pg-left to market 15Bfund → 5Φ4

II Civil Justice- most matters off the table

1. No class actions - maybe splinter
2. Punitive - still open - split large - Symbolic Issue -
✓ 3. Lawyer Fees. one time deal-from ind - TBD by former Fed Judge

III $$: Industry - low 2s for ~~25~~ 25 yrs

AGs - 375 — might go beyond ~~25~~ 25 yrs.

HHS $1-1.5B/yr advertising
research WHO
farmers - $150M
$300M enforcement

ramp 1Φ up
8 1Φ 12 16 15B/yr
6 8 1Φ 16
payout

increases over time

1-1.5B/yr cessation

4B tort fund

7-8B to states - fund child health

After 10yrs - could eliminate ingredients if
A- B- C-

If there isn't a global settlement - there may be state by state settlements.

DAK

1. Public Health Benefit

2. What are we giving up.

3. $ - so much - staggering - distorts thinking.
uncomfortable - why is so much going to compensate smokers & lawyers.

---

1. Industry is getting something fundamental for their long-term survival.
But it is not enough to not go to #2.

2. If the industry is getting fundamental change - the public health should receive the same.
If we are going to enact the framework for 25-30 yrs there needs to be more thinking about the package.
Fundamentally will bring down smoking.
We need the 100% solution.

3. A lot depends on where the $ go.

Financial predictability.
Tish - Stay in business - diminishing domestic market expanding int'l market.

Politics - Deal -
\ No Deal - sustains coalitions

BNR - Create a 5 yr horizon

DES

BNR Kevin Mitch Raab

Toby Corr

Elana

DES → POTUS "cannot" comment on immunity

→ Ordering to look for another part of the statute to do advertising restricting

DES
- As much fun as he possibly can
- as big as it comes, doesn't get much better

RJR - Very pleased struck down advertising
disappointed

Myers - Single most devastating loss industry has ever suffered.

BNR - ~~Someone~~ Mitch please collect validators stmts.

DES
- It's a victory for FDA, but our line ~~s~~ should be:
- Huge victory for POTUS

BNR - Do you have to, ok we can live w that.

"Other conditions" doesn't sustain ad restrictions. Judge didn't say anything about the 1st amdt. Greensboro fraud too pumped to figure if another part of the statute.

- Chevron, Chevron, Chevron

Don't know what other section, to do ads. We have taken our best shot - we need to appeal.

June 18, 1997

Tobacco Talks Snag, Walkout Hinted

A.P. INDEXES: TOP STORIES | NEWS | BUSINESS | SPORTS | ENTERTAINMENT

Filed at 2:15 a.m. EDT

By The Associated Press

WASHINGTON (AP) -- Tobacco talks have hit the biggest impasse yet, as negotiators issue what may be a final ultimatum demanding strict government nicotine control and ``punishment'' of the cigarette industry.

Mississippi Attorney General Michael Moore said Tuesday he had refused industry calls for protection against paying punitive damages to sick smokers and called ``most contentious'' the fight over Food and Drug Administration nicotine regulations.

``The tobacco industry must be punished for past misconduct, must maintain their liability for the future ... and nicotine has to be regulated by the FDA,'' Moore said. ``They will give us what we want, or we will go to trial.''

``They are going to really and truly hurt,'' pledged Florida Attorney General Bob Butterworth, angry that tobacco companies were even resisting calls to admit their products are dangerous.

One source said tobacco foes could walk away from the talks as early as today unless the industry offers a viable counteroffer.

But privately, one negotiator said a faction still is pushing a compromise: a lump-sum payment that is part of the estimated $300 billion settlement, to go either to the states or for some ``good deed'' such as health care for uninsured children. The industry then would be liable only for punitive damages in the future.

``It's not a cave-in,'' said one person close to the talks. ``It's a settlement for past conduct.''

Few attorneys were openly backing any compromise, said Connecticut Attorney General Richard Blumenthal. ``The talks are as tense as we've ever seen.''

On the FDA issue, cigarette-makers were pushing to make the agency win congressional permission before it could ever ban nicotine. The FDA also would have to meet certain standards showing it had proof that even lowering nicotine levels would help public health, said one source. Also, tobacco companies are resisting letting the government fully oversee the development

of allegedly safer cigarettes, said the source.

``We are at a roadblock,'' said Washington Attorney General Christine Gregoire. ``Clearly we've got a problem now, and unless and until they meet the needs of the attorneys general, we're going home.

``They're concerned they may have to develop safer cigarettes ... or nonaddictive products,'' added Butterworth.

Calling the talks ``very rocky,'' Mississippi's Moore said at the White House Tuesday that he was running out of negotiating time: His trial, the first of 37 state suits seeking to recover Medicaid funds spent treating sick smokers, begins July 7.

The tobacco industry declined comment.

Also Tuesday, tobacco manufacturer R.J. Reynolds went to federal court in Raleigh, N.C., to protect its Joe Camel advertising campaign that the Federal Trade Commission claimed was engineered to create a new generation of smokers. In its complaint, RJR accused the FTC and the Clinton administration of conducting a coordinated campaign of intimidation.

Under the proposed deal, cigarette-makers would accept numerous advertising and other curbs in return for such legal protections as a $4 billion cap on the compensatory damages the industry would pay sick smokers in any one year and a ban on future class-action lawsuits.

While juries have never forced the industry to pay punitive damages, tobacco companies fear a coming tide of litigation in which punitive damages might be ordered. Also, compensatory damages paid to sick smokers are fully tax-deductible for the company, while punitive damages are not.

Minnesota Attorney General Hubert Humphrey III began lobbying Congress Tuesday on behalf of several states worried that the proposed deal is too soft. Any deal is subject to congressional approval.

``They're trying to rush this through before we realize we've had our pockets picked,'' complained Humphrey, particularly upset that the settlement as written would seal thousands of the industry's most secret documents -- papers that a Minnesota judge even now is considering making public in Humphrey's lawsuit.

Just last week, some similar secret papers revealed that No. 5 cigarette-maker Liggett Group stifled an allegedly less-cancerous cigarette in the 1970s.

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Smoke Signals: Omens of Tobacco Truce Are in the Air

By Bruce Ingersoll
And Michael K. Frisby
Staff Reporters of The Wall Street Journal

WASHINGTON – Is a truce at hand in the tobacco wars?

The cigarette industry has fought for decades against legions of antitobacco lawyers and now is girding for a court battle with federal regulators. But since the November elections, some of the combatants have indicated they may be willing to light up the peace pipe. Factions on both sides have signaled growing interest in striking a historic deal: In return for Congress's granting immunity from future liability suits, the industry would accept the Food and Drug Administration's landmark regulations to curb underaged use of tobacco.

There are numerous indications that they aren't just blowing smoke. This month, Steven F. Goldstone, chief executive officer of **RJR Nabisco Holdings** Corp., reiterated his call for a legislative settlement. Meantime, Thomas Hale Boggs Jr., one of Washington's superlobbyists, has been sounding out leading antitobacco lawyers about the prospects for a deal. His involvement is particularly significant because he represents both tobacco clients and the Association of Trial Lawyers of America.

Possible Advisory Panel

Mr. Boggs also has participated in discussions about appointing an advisory panel of political veterans – retiring Alabama Sen. Howell Heflin, former Senate Majority Leader Howard Baker and Leon Panetta, the departing White House chief of staff – to help broker a legislative compromise that would pass muster with the industry, the plaintiff's bar, smoking foes, the Clinton administration and lawmakers. Sen. Heflin confirms that such a troika is under consideration, but insists it's "premature" to discuss it. Mr. Boggs declines to comment.

At this point, nobody in the administration appears ready to take up the tobacco issue. At the White House, senior officials say that they know nothing about a "three-wise-men" plan, and that Mr. Panetta isn't interested in any peace-making role. They also insist that striking a deal with Big Tobacco isn't a presidential priority. The White House hasn't even found a successor for the chief staffer on tobacco issues, Jennifer O'Connor, who took another administration job last fall.

When tobacco lobbyists call Mr. Panetta, as they have in recent months, his message to them has been: "We want to get kids to stop smoking. We've gone about it the best way we can to make that happen. Do you have a better idea?"

But White House officials caution that the industry shouldn't interpret that to mean Mr. Clinton might be willing to deal. Having fought the battle over FDA regulations last year and won, they say, why would he revisit it? Where is the political upside? The officials say they can envision the president's returning to the matter only if legislation begins moving in Congress. Then, the administration might weigh in with suggestions on the measure's objectives and wording.

In Congress there is equally strong reluctance to take the initiative on tobacco. Last year nobody on Capitol Hill moved to protect the tobacco industry from FDA regulation. What's more, nobody was willing to embrace a proposed watered-down version of the FDA regulations offered by **Philip Morris** Cos., largely because the No. 1 cigarette maker only had the industry support of **U.S. Tobacco** Co.

Executives say the industry remains divided on how to proceed with any settlement. On Dec. 5, the Tobacco Institute trade group asked its members for suggestions about a compromise. But mighty Philip Morris reportedly declined to respond, and the proposal wasn't on the Tobacco Institute's Dec. 12 executive committee agenda. The institute declined to comment on its internal workings, and a Philip Morris spokesman said the proposal wasn't on the agenda for reasons that had nothing to do with the company.

Proposal Fails

A sweeping proposal to settle future liability issues advanced by Mississippi Attorney General Mike Moore and trial lawyer Richard Scruggs also went nowhere last year, largely because of overwhelming opposition from health groups and other attorneys general. The proposal would have immunized cigarette makers against liability suits for 15 years and spared them from FDA regulation in return for multibillion-dollar payments to reimburse several states for health costs. The lack of unanimity was more than enough to dissuade Mr. Scruggs's brother-in-law, Senate Majority Leader Trent Lott, from sponsoring such a settlement.

Mr. Scruggs, for one, believes the legal campaign against Big Tobacco has reached a high-water mark. "It's foolish not to settle now," he asserts. But some industry critics doubt that any proposal akin to the one that he and Mr. Moore shopped around last year can succeed. "Why should the tobacco industry be immune, given the harm they've caused?" asks Matt Myers, executive vice president for the National Center for Tobacco-Free Kids.

Loss of Allies

In the House, meantime, Virginia Republican Thomas J. Bliley has made it clear to colleagues that he doesn't want to be known as "the congressman from Philip Morris." In a Dec. 9 speech, the House Commerce Committee chairman left tobacco off his legislative agenda. "You're not going to move legislation unless the administration signs on," he said.

Heating Up

August 1995
Food and Drug Administration proposes to ban tobacco sales to young people under age 18 and to sharply curtail industry advertising

March 1996
Liggett Group enters first-ever settlement of tobacco lawsuits.

August 1996
Brown & Williamson Tobacco Co. loses a landmark $750,000 jury verdict in Florida case.

February 28, 1997
FDA ban on tobacco sales to minors is scheduled to take effect

Some in the industry hope the administration might be more amenable to a legislative compromise in the second term than it was in the first. The antitobacco movement will soon lose two important allies – FDA Commissioner David Kessler and Harold Ickes, White House deputy chief of staff. Dr. Kessler's departure raises the possibility of a successor more willing to compromise.

Mr. Panetta, who is going home to California next month, has advocated seeking a peaceful resolution with the cigarette manufacturers, but his aides say he has no interest in serving on any peace-making troika. His successor, North Carolina investment banker Erskine Bowles, isn't expected to differ much from Mr. Panetta. As a tobacco-state native, however, Mr. Bowles has a better understanding of the industry's grave problems.

Cigarette manufacturers clearly are on the defensive. In March, **Liggett Group** broke ranks with the rest of the industry and agreed to a multimillion-dollar settlement of several large liability cases. In August, the industry's courtroom invincibility was shattered when Norwood Wilner, a Jacksonville, Fla., plaintiff's lawyer, won a shocking $750,000 judgment against Brown & Williamson Tobacco Corp., prompting other lawyers to go after the industry. Much more costly setbacks may be in the offing. Sixteen states have suits pending against the industry to recoup billions of dollars in Medicaid outlays for smoking-related illnesses.

For now, the industry is focused on its Feb. 28 showdown with the FDA – despite the conciliatory remarks of RJR's Mr. Goldstone in a Dec. 10 appearance before fellow CEOs. The industry has asked a federal judge in Greensboro, N.C., to block the FDA's ban on tobacco sales to smokers under 18 years old and its advertising restrictions.

"We believe the case against the FDA is best made in court," said Thomas Lauria, spokesman for the Washington-based Tobacco Institute.

The impending court battle hasn't diminished the swirl of rumors about a possible legislative compromise. A few weeks ago, John Angell, a top Panetta aide, telephoned Mr. Boggs, the superlobbyist, to find out what all the fuss was about, according to the White House. Mr. Boggs believes, according to several accounts, that the rumors began after Hugh Rodham Jr., a Florida antitobacco lawyer, discussed the industry's huge liability problem with his brother-in-law, President Clinton, over Thanksgiving at Camp David.

Circulating among trial lawyers, however, is a different version of the call, which has Mr. Angell calling Mr. Boggs to take soundings on the attitudes of leading antitobacco attorneys toward a legislative settlement.

Wendell Gauthier, a New Orleans trial lawyer who has assembled a team of 60 lawyers for a massive class-action suit against Big Tobacco, confirms that Mr. Boggs contacted him about 10 days ago. He says he told Mr. Boggs that any settlement with the cigarette manufacturers would have to codify the FDA regulations.

"Our fight with those rascals has to do with them targeting the kids," says Mr. Gauthier. "Settlement discussions are probably premature. We are going to have to have some trials first."

–Milo Geyelin and Suein L. Hwang in New York contributed to this article.

Trie Often Paid Visits To the White House

By a Wall Street Journal *Staff Reporter*

WASHINGTON – Yah Lin Trie, the longtime friend of President Clinton now embroiled in controversy over fund raising, has visited the White House between 22 and 38 times.

On 13 occasions Mr. Trie, who is known as Charlie, was cleared into the White House by presidential aide Mark Middleton, who in 1995 left the White House and began seeking business deals in Asia with Mr. Trie.

The entry figures, released last night by the White House, are based on a preliminary review of Secret Service records. Some of the visits were for social events, but the purpose of most of the visits wasn't disclosed.

Mr. Trie raised more than $600,000 in questionable contributions for Mr. Clinton's legal-defense fund, but the gifts were rejected. Much of the money came from followers of a Taiwanese religious organization.

National Journal, April 12, 1997
p. 719

A WHITE HOUSE ROLE IN A TOBACCO SETTLEMENT?

If asked to step in, the White House will try to facilitate a so-called global settlement of the mounting legal assaults against the tobacco industry. But President Clinton's point man on the issue, deputy counsel Bruce R. Lindsey, warns that with several major anti-tobacco lawsuits due to go to court this summer, the time for reaching such an agreement is running short.

"We stand ready to try to be helpful if all the parties believe that is a useful role for us," Lindsey said in an interview. Right now, the tobacco companies and their adversaries "are getting to know each other still and aren't ready to put their cards on the table," Lindsey said. "If they get close [to a settlement], there may come a time when we can weigh in and help move the discussions along, but we aren't there yet, at least in my judgment."

The White House lawyer and close adviser to President Clinton said he has had "regular and frequent contact" with several of the 22 state attorneys general who have filed lawsuits seeking reimbursement for their states' Medicaid costs for treating smoking-related diseases. Lindsey said he also has been in touch with attorneys representing plaintiffs in class action suits against tobacco companies, public health activists and representatives of the major tobacco firms, including members of a newly assembled team of Washington lawyers and public relation experts hired by the industry to help seek a comprehensive legal and regulatory settlement. *(For more on the industry team, see NJ issue 2/15/97, p. 327.)*

Lindsey declined to identify his contacts, but he outlined the general points that the Administration would like to see included in a negotiated agreement to settle the massive lawsuits facing the tobacco industry and to reach an accord on the future regulation of the sale of cigarettes.

He emphasized that the Administration's priority is to reduce smoking among children and speculated that tobacco companies might comply with that objective if the authority of the Food and Drug Administration (FDA) to regulate cigarette sales is restricted. "We're prepared to talk about some sort of limitation on FDA's jurisdiction," Lindsey said. "If they will join with us, we will in some way legislatively guarantee that our goal is not to drive cigarettes out of business."

He also said that plaintiffs in class action suits against the tobacco companies should share in any financial compensation that the industry agrees to pay in a blanket settlement of its lawsuits.

"I think there would have to be a division between individual claimants and states so that we felt like individual claimants were participating to some reasonable extent in the settlement," Lindsey said. He added that some portion of big tobacco's payout should go for an anti-youth-smoking education and advertising campaign.

But if such a deal is to be cut, it probably will have to be done soon. Mississippi's landmark suit to recoup hundreds of millions dollars spent in state Medicaid funds for treating smoking-related illnesses is scheduled to begin on July 7. A similar case in Florida will go to court in August.

"There is some sense that the best opportunity for settlement is between now and June," Lindsey said. After that, the focus of lawyers on both sides will shift to litigation. As Lindsey noted, "It's hard, after being in a courtroom all day, to that night continue to have friendly discussions about a settlement." —James A. Barnes

COMMENTARY

By Mike France & John Carey

TOBACCO: DON'T JUMP AT THIS DEAL

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

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

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

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

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

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

The lawyers at the table are focusing too much on

ILLUSTRATIONS BY JEFFREY SMITH

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

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

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

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

Keeping all these principles in mind, here are some steps worth taking. For starters, the most effective way to prevent smoking is to raise the tax on cigarettes. A 10% rise in the cost of tobacco sends sales down 4%—and among youths, the drop is higher, perhaps as much as 12%. "Kids are sensitive to price, if not to risk," explains health economist Willard G. Manning of the University of Minnesota (table, page 112). We should heed the recommendation of smoking foes for a major nationwide tax increase—about $2 per pack, to roughly $4.50.

From an international perspective, that's still not very high: A pack costs $4.80 in Britain. But it would be enough to discourage children and push millions of adults to cut back or quit. Admittedly, new taxes are a hard sell in Congress, but polls show that Big Tobacco is a pariah to a majority of Americans, so cigarette taxes may be a breed apart. Some key Republicans have signed onto a bill that would modestly raise cigarette levies, and a record number of states are considering boosts. The billions of dollars raised could be used to fund education programs and hard-hitting antismoking campaigns. Such revenues might eventually fall as consumption does, but that's the point, after all.

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

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

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

We also need to push companies and local government to

the past, rather than on preventing future smokers

WHAT WE SHOULD DO ABOUT TOBACCO

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

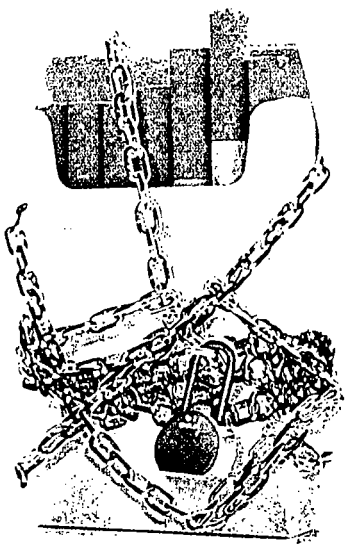
BAN ADVERTISING AND PROMOTION AIMED AT KIDS Without trampling the First Amendment, we need to keep the industry from hooking smokers early.

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

THE POWER OF TAXES

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

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

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

COMMENTARY

By Mike France & John Carey

TOBACCO: DON'T JUMP AT THIS DEAL

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

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

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

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

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

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

The lawyers at the table are focusing too much on

ILLUSTRATIONS BY JEFFREY SMITH

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

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

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

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

Keeping all these principles in mind, here are some steps worth taking. For starters, the most effective way to prevent smoking is to raise the tax on cigarettes. A 10% rise in the cost of tobacco sends sales down 4%—and among youths, the drop is higher, perhaps as much as 12%. "Kids are sensitive to price, if not to risk," explains health economist Willard G. Manning of the University of Minnesota (table, page 112). We should heed the recommendation of smoking foes for a major nationwide tax increase—about $2 per pack, to roughly $4.50.

From an international perspective, that's still not very high: A pack costs $4.80 in Britain. But it would be enough to discourage children and push millions of adults to cut back or quit. Admittedly, new taxes are a hard sell in Congress, but polls show that Big Tobacco is a pariah to a majority of Americans, so cigarette taxes may be a breed apart. Some key Republicans have signed onto a bill that would modestly raise cigarette levies, and a record number of states are considering boosts. The billions of dollars raised could be used to fund education programs and hard-hitting antismoking campaigns. Such revenues might eventually fall as consumption does, but that's the point, after all.

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

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

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

We also need to push companies and local government to

...he past, rather than on preventing future smokers

WHAT WE SHOULD DO ABOUT TOBACCO

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

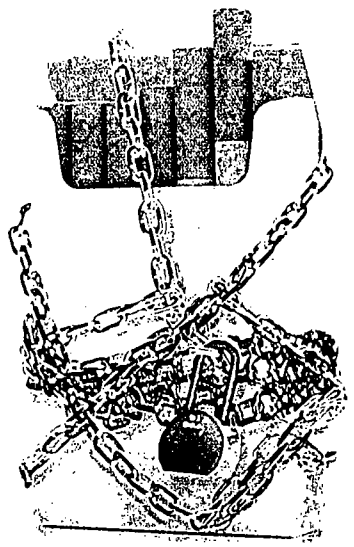
BAN ADVERTISING AND PROMOTION AIMED AT KIDS Without trampling the First Amendment, we need to keep the industry from hooking smokers early.

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

THE POWER OF TAXES

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

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

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

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CAMPAIGN for TOBACCO-FREE Kids

TO: S. Buckingham, E. Chapnick, L. Crampton, B. Crain, D. Crane, S. Dickinson, J. Epstein, S. Hicks, A. Hyman, F. Karel, C. Kelley, R. Landry, D. Maier, D. Maple, J. Marx, T. Moreis, B. McHugh-Sanner, J. McKenna, J. O'Hara, M. Schoenfeld, D. Spitz, M. Tharp, B. Wooley, C. Yarborough, P. Yoxall

FROM: Kay Kahler Vose

DATE: June 13, 1997

SUBJECT: Negotiations with Tobacco Industry

Attached is a document produced by the Center that summarizes may of the points of agreement to date on public health issues in the ongoing negotiations between the tobacco industry and the attorneys general. The document contrasts the agreed-upon points with the provisions, or lack thereof, of the FDA Rule.

I hope you find this document helpful.

Please note that this document is not a final version. These are the agreed-upon provisions and they could change when an agreement is finalized. We will update you on any modifications.

Please call me with any questions.

06/13/97 4:22 PM
DRAFT

CAMPAIGN for TOBACCO-FREE Kids

Summary of public-health provisions that have been tentatively agreed to as part of the ongoing settlement talks with the Attorneys General, the tobacco industry and public health advocates.

1. Youth Access

The full substance of the August 28, 1996 FDA youth access provisions have been agreed upon.

The FDA rule:

- Bans sales to kids under 18;
- Requires proof of age;
- Limits, but does not ban vending machines;
- Limits self-service displays, but permits tobacco to be displayed on the counter;
- Establishes the minimum pack size at 20 and prohibits the sale of single cigarettes;
- Bans free sampling; and
- Uses FDA's normal enforcement tools with enforcement funding subject to annual Congressional appropriations.

In addition the tobacco industry has agreed to:

- A ban on all vending machines;
- The placement of tobacco products behind the counter and out of reach of consumers;
- Further restrictions of mail order sales, subject to conditions that demonstrate that an effective mechanism exists to restrict sales only to adults;
- A nationwide licensing system for all sellers of tobacco products with graduated penalties and license suspensions for violations of the youth access and marketing provisions to be established. The licensing system shall apply to all sellers of nicotine - containing tobacco products, including manufacturers, distributors, wholesalers, retailers and importers;
- Full funding from money paid by the tobacco industry for enforcement by FDA and state and local authorities;
- States and local governments would not be preempted from enacting stronger laws;

- Dual enforcement authority with both the FDA and state attorneys general, each being able to enforce these provisions. In addition, the FDA will have the power to contract with other state and local authorities to assist it to enforce the rules; and
- Enforcement to require unannounced, random stings.

2. Marketing and Advertising

The industry has agreed to the full substance of the August 28, 1996 FDA youth advertising and marketing provisions (which were struck down in Federal District court but which have been appealed):

The FDA rule before the court ruling:

- Text-only ads in youth oriented magazines and newspapers;
- Ban brand name event sponsorship;
- Limit billboards near schools and limit billboards to text only with no color;
- Ban use of non-tobacco brand names on tobacco products;
- Ban advertising on non-tobacco products, like clothing and gear;
- Ban offers of non-tobacco items or gifts based on proof of purchase; and
- Require ads to carry FDA-mandated statement of intended use.

In addition to the FDA provisions above, the industry has also agreed to:

- The elimination of all billboards and outdoor signs, including all signs in stadia and arenas and signs that face outwards in enclosed areas, such as stores;
- The elimination of all human images and cartoon characters from all advertising and from all cigarette packages;
- Additional restrictions on point of purchase advertising regarding the placement on point of purchase ads to limit their size and number, remove them from the line of sight of children and remove them from close proximity to candy and other goods likely to attract children;
- The elimination of internet advertising and the agreement on the use of whatever technology is available to make tobacco advertisements that are placed on the internet from foreign countries inaccessible in the US;
- The prohibition on product placement in movies and on TV;
- The prohibition on any payments or fees to celebrities to smoke in movies or on TV or to any other person or entity to glamorize tobacco use in movies or on TV, and the prohibition of any "in-kind" actions to accomplish any of these same purposes;

- Without limiting the FDA's normal authority, limits on the use of words, such as "light", that currently appear in some product names and that could be misinterpreted as health claims;
- Protection against First Amendment challenge: an agreement to consent to the placement of all of the advertising restrictions contained in the August 28, 1996 FDA rule plus the above noted restrictions in consent decrees to insulate the restrictions from First Amendment challenges by parties outside the tobacco industry;
- Dual enforcement authority with both the FDA and state attorneys general, each being able to enforce these provisions. In addition, the FDA will have the power to contract with other state and local authorities to assist it to enforce the rules; and
- Funding from the tobacco industry to pay the cost of enforcement for both FDA and the state authorities with enforcement power.

3. Public Education/Counter Advertising

The tentative agreement with the tobacco industry includes:

- Funds for the largest, most-sustained nationwide public education/counter advertising program ever done for tobacco or for any other public health hazard. The campaign would be similar to those campaigns in Massachusetts and California. The program would operate independent of the tobacco industry, which would have no say over the content or placement of the program. Funding for the program would be guaranteed, and to the extent possible, the program would be insulated from political pressure.

4. Health Warnings

- There would be a dramatic revision of the warning label system. The current system would be replaced with the far more specific, more detailed eight Canadian warnings.

  They include warnings, such as:

  - "WARNING: Cigarettes are Addictive";
  - "WARNING: Cigarettes Cause Cancer";
  - "WARNING: Smoking Can Kill You"; and
  - "WARNING: Tobacco Smoke Causes Fatal Lung Disease In Non- Smokers"
- The warnings on packages would be moved to the front of the cigarette package and the most prominent side of the smokeless tobacco product package.
- The warnings would appear in the Canadian format (the top of the front with white lettering on a black background). The warning would occupy at least 25 percent of the top of the front of the package. All warnings would appear simultaneously on tobacco packages and would be rotated quarterly on ads by brand.

5. Full Disclosure

Under the possible agreement:

- Decades of deception would come to an end and the industry would tell the truth about what it knows.
- All documents which would have been revealed through the litigation process would be made public and the industry would agree to make public its health-related research in the future.

6. Youth Smoking Targets

- The industry would be subject to penalties if youth tobacco use fails to drop by 30 percent in 5 years, 50 percent in 7 years and 60 percent in ten years. The penalty would be based on the value of a teen tobacco user to the industry over the lifetime of the individual. It would be worth approximately $80 million per percentage point by which the target was not met.

7. Funding for State and Local Tobacco Control Activity

Active state and local tobacco control efforts have been proven successful in reducing tobacco use. Current programs are under funded and funding for these programs is in jeopardy.

Under a possible agreement:

- State and local tobacco control activity modeled after the successful ASSIST program would be funded out of tobacco industry funds, permitting the ASSIST program to be funded in every state from these funds.

8. Tobacco Cessation

Under a possible agreement:

- Out of funds to be provided by the industry, funding would be provided for tobacco cessation programs and devices for those who want to quit and for whom cost is an issue. These funds would be available to individuals nationwide.

9. Protection from Environmental Tobacco Smoke

Under a possible agreement:

- Protection from environmental tobacco smoke would come from the enactment of the text of HR 3434 (the bill originally introduced by Congressman Waxman) that restricts tobacco use in public places and most workplaces to locations that are separately ventilated to the outside and through which non-smokers do not pass.

To avoid heavy opposition from the hospitality industry, restaurants (excluding fast food restaurants), casinos, bingo parlors, and bars would be exempted.

- The federal law would not preempt state and local governments from retaining or enacting more restrictive requirements governing ETS.

10. Monitoring Corporate Behavior

The tobacco industry has the most irresponsible corporate record of any industry in the United States. Currently, no mechanism exists to ensure that the industry complies with the letter or the spirit of existing law.

Under a possible agreement:

- Manufacturers would be required to develop detailed compliance plans describing how they intend to comply with the law and monitor their own employees behavior.
- Corporations would be required to set up incentive plans to encourage compliance and internal compliance checks to catch and report violations.
- Corporations would be required to establish a corporate code of behavior with outside monitors, a system of auditing, and reports to shareholders and the FDA.

11. General Authority of the FDA

FDA's authority over tobacco products as "drugs" and "devices" has been upheld by the trial court in North Carolina and is now on appeal. To date, the FDA has only sought to exercise its authority by establishing youth access and marketing rules, but it has far broader authority.

Under the tentative agreement:

- The judicial challenge by the tobacco industry would be dropped and FDA's authority explicitly recognized. Therefore, tobacco will continue to be categorized as a "drug" and a "device" under the Food, Drug and Cosmetic Act and the agency's authority to regulate the products as "restricted medical devices" will be recognized.
- FDA would exercise its normal authority to inspect, enter manufacturing plants, demand certain records and record keeping, and would have its normal enforcement authority.
- The tobacco industry would be required to provide FDA with all research it conducts and all non-public information it receives that relates to health, toxicity, addiction, drug dependence.
- In general, FDA's powers to regulate tobacco, including nicotine, would not be circumscribed. The details of this are still being negotiated.

12. Tobacco Industry Liability

The tobacco industry has lost only one court challenge in its history and only Liggett has actually paid any money in damages. Nonetheless, the tobacco industry faces unprecedented court challenges today. The issues about the tobacco industry's future liability are still being discussed, but several facts are already known if there is an agreement:

- The rights of individuals to sue will not be abridged.
- There will be no limits on individual judgments.
- Whether or not individuals have greater success in the future in court against the tobacco industry than they have had in the past, the tobacco industry will be required to pay billions of dollars to victims and public health causes for the harm done by their products.
- In return for the industry's commitment to pay several billion dollars a year, whether or not there are any judgments against it, it has been proposed to cap the overall damages the industry would pay through litigation in any one year. It is highly unlikely that this fund would be exhausted in any one year. However, if this were to occur, then payments to individuals winning cases against the industry would be extended over more than one year. This would not result in restricting the overall award an individual could receive, but it could lead to a delay in the total payment. Any money from the annual fund not won through litigation would then be transferred to national public health, anti-tobacco programs and would not revert to the tobacco industry
- While industry requests for broader protection are no longer on the table, there do remain unresolved issues concerning whether tobacco cases could be brought as class actions and whether preemptive damage claims to be paid out of the fund would be permitted.

10TH STORY of Level 1 printed in FULL format.

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SECTION: NATIONAL; TOBACCO WARS: THE THIEF and the THIRD WAVE; Pg. 1A

LENGTH: 6671 words

HEADLINE: CAN THIS MAN TAME TOBACCO?

BYLINE: DAVID BARSTOW

DATELINE: PASCAGOULA, Miss.

BODY:

Last of two parts

From the looks of his law office lobby - cheap tiling, vinyl chairs, a signless entrance across from a thrift store - it is tempting to underestimate Dickie Scruggs, to write him off as a hick lawyer in over his head, too dumb or too pig-headed to realize that Big Tobacco can't be beat, at least not by the likes of him and his gum-chewing receptionist.

Look closer. Notice the framed photograph on the wall. The one that shows a Navy fighter pilot and his A-6 Intruder, the one he flew from an aircraft carrier in the Mediterranean as the Middle East exploded into war in the early '70s.

The Russians were there, too, with their new destroyer and its seemingly invincible air defenses. But then Lt. Dickie Scruggs dreamed up a way to sneak his Intruder under the destroyer's radar.

The Navy awarded Scruggs a commendation for his tactical ingenuity.

"I like trying to figure out ways to do things that can't be done," Scruggs says.

It is a story worth remembering now that Scruggs has his sights fixed on another seemingly invincible target, the nation's tobacco industry. How invincible? Despite overwhelming evidence that cigarettes kill when used exactly as directed, despite government estimates that cigarettes cause more American deaths than drugs, drunken driving, homicide, suicide, fire and AIDS combined, the industry has never paid a penny in damages to a smoker. Not one red cent.

Hundreds of attorneys are flocking to this holy war against Big Tobacco, with more joining by the day. It is a vast struggle, a Lexus jihad that has spilled into dozens of courtrooms in dozens of states. Almost daily, it produces dizzying, often contradictory news, expertly spun by both sides.

Other attorneys grab more headlines, but it is Scruggs who stands at the center of what is called the Third Wave of tobacco litigation.

He represents more than half of the attorneys general among the 22 who have sued tobacco, including Florida's Bob Butterworth. He represents the most important industry whistle-blowers. He was instrumental in last month's stunning Liggett settlement.

He has the best political connections, the fastest Lear jet.

So don't underestimate Dickie Scruggs, or his receptionist.

For more than 30 years, the tobacco industry has crushed lawsuit after lawsuit - more than 800 in all - with an elegantly simple defense:

Smoking is a matter of personal choice.

Everyone knows the risks.

So if you choose to smoke, you alone are responsible for the consequences.

You could sum it up on a bubble gum wrapper.

But Scruggs figured it might be possible to evade tobacco's traditional defense, to sneak under the radar. So did his friend, Mississippi Attorney General Mike Moore, and a growing network of plaintiff attorneys.

The key lay in avoiding the question of personal responsibility, in finding a way to "step out of the smoker's shoes." This is what a Miami attorney was attempting with a lawsuit by flight attendants who claimed second-hand cabin smoke made them sick. It wasn't their choice to inhale.

But Scruggs and Moore planned a more radical end-run around the personal-choice defense.

Why not sue on behalf of the state?

After all, no state ever chose to smoke a single cigarette. Yet the state foots the bill, through Medicaid payments, for thousands of smokers too poor to pay for their own medical care.

The client wouldn't be some guy who smoked for 40 years and now expected to be rewarded for his stupidity. And they could seek billions in Medicaid reimbursements, not just a few million for a single smoker.

A team of attorneys began drafting Mississippi's Medicaid lawsuit, the first of its kind in the nation.

Then, to everyone's shock and surprise, a thief named Merrell Williams stepped from the wilderness with 4,000 pages of dynamite.

Williams had been hired as a paralegal for the Brown & Williamson Tobacco Corp. to help sort through millions of pages of company documents. He was supposed to guard the company's secrets. Instead, he spent four years stealing them.

In April 1994, as Mississippi's complaint was getting its finishing touches, Williams dumped his documents in Scruggs' lap.

A fancy new legal theory was one thing. New facts - facts that destroyed the central tenets of tobacco's defense - were quite another. Recall the bubble gum wrapper:

Smoking is a matter of personal choice.

Williams stole documents in which tobacco executives and scientists described nicotine as a highly addictive drug.

Everyone knows the risks.

Williams stole documents that showed the extraordinary lengths tobacco executives went to hide the risks.

So if you choose to smoke, you alone are responsible for the consequences.

Williams stole documents that showed tobacco executives were scared silly of the consequences of being open and honest with smokers.

Tobacco executives have the best public relations advice money can buy, and when they look jurors in the eye and say there's no proof smoking causes cancer, they make it sound like a sincere disagreement over science. But with his stash of documents, Williams saw himself like Toto tugging back the curtain to reveal the great and all-powerful Oz as a fraud.

The documents energized Scruggs and his team. They would not be paid by Mississippi for their work - unless they won. Their percentage of the verdict would make them rich. But if they lost, they'd be ruined. It was a huge gamble.

Now they knew their opponents' hole cards.

There was one hitch. The documents were stolen goods. Actually, it was worse than that. Many of the documents were written by or to Brown & Williamson's lawyers, meaning they were subject to that sacred shield of lawyering - the attorney-client privilege.

Like the priest's confessional, this is supposed to protect the confidentiality of all communications between attorneys and their clients.

Once Brown & Williamson got wind that Merrell Williams possessed stolen documents, it obtained a court order preventing him from revealing them to anyone, even his own attorney. Williams handed the documents to Scruggs in direct violation of this order.

"What the hell we gonna do with these things?" Scruggs asked Mike Moore.

One thing they sure as hell were not going to do: Return them to their rightful owners. The documents, they reasoned, contained evidence of an ongoing fraud, and even the attorney-client privilege doesn't protect that.

Scruggs loaded the documents into his Lear jet, and flew them to Washington D.C. into the waiting arms of tobacco's chief nemesis in Congress, Henry Waxman.

Waxman had just completed hearings in which he asked seven CEOs of major tobacco companies to answer, under oath, whether nicotine is addictive. One by one, the CEOs had said no.

"We had to put 'em in his hands," Scruggs says.

Scruggs also recognized the potential for the documents to reshape public and political attitudes toward the tobacco industry. He could imagine the headlines.

Philip J. Hilts, a New York Times reporter who covered tobacco issues, got a phone call from a government source who invited Hilts to his home to look at some documents.

On May 7, 1994, Hilts published the first of several front-page stories based on the stolen documents. The headline:

"Tobacco Company was Silent on Hazards."

Five days later, a "Mr. Butts" sent a set of the documents to Dr. Stanton A. Glantz, a University of California, San Francisco professor and a leading critic of the tobacco industry. Glantz placed the documents in the university library's archives, for public examination.

Before Brown & Williamson even knew what hit it, the documents were out to the world.

The company reacted with a fury, flinging subpoenas like confetti. They even subpoenaed Waxman.

The company dispatched private investigators to stake out the University of California, San Francisco library, and more lawyers to demand that the documents be removed from the archives.

The company would spend millions in legal fees and private investigators to keep the genie in the bottle - mostly to no avail.

Killing the Waxman subpoena, U.S. District Judge Harold H. Greene called the company's reaction "high-handed" and "patently crafted to harass those who would reveal facts concerning Brown & Williamson's knowledge of the health hazards of tobacco."

Tommy Sandefur, Brown & Williamson's hot-tempered CEO, lashed out at Scruggs and Williams in testimony to Congress.

"I'm not concerned about the information itself," Sandefur said of the documents. "I'm concerned about the process, saying it's okay to steal, saying it's okay to accept stolen property, saying it's okay to violate the rights of confidentiality with legal counsel, saying it's okay to return to an age of McCarthyism when black-listing and vilification of honest and respectable people were sanctioned for the sake of advancing a political agenda."

Sandefur received a warm reception from several Republicans on the committee. Rep. Mike Bilirakis, R-Palm Harbor, complimented Sandefur's "courage."

But the damage spread.

Dr. David Kessler, the commissioner of the U.S. Food and Drug Administration, said he was considering regulating the nicotine in cigarettes as a drug. The documents convinced him to press forward.

The Justice Department wanted to present the documents to federal grand juries investigating whether the tobacco CEOs committed fraud and perjury in their testimony to Waxman's committee.

The Journal of the American Medical Association devoted an entire issue to a scholarly analysis of Williams' documents. The University of California, San Francisco library posted every one of the Brown & Williamson documents on the Internet. (More than 100,000 Internet users have looked at them.)

The attention on Williams' documents inspired other insiders to come forward. William Farone, a top Philip Morris researcher, said the company manipulated nicotine levels to keep smokers hooked. Philip Morris employee Jerome Rivers described how the company used gas chromatographs to measure nicotine levels hourly in the manufacturing process.

On May 23, 1994, a month after Williams handed his boxes to Scruggs, Mississippi became the first state to sue the tobacco industry for the reimbursement of Medicaid funds.

That summer, Joint Resolution No. 367 was proposed in the U.S. House of Representatives. A public relations ploy, the resolution called for Congress to award a "Congressional Medal of Appreciation for Public Spirit to the courageous citizen who made the concealed documents public."

The resolution did not pass.

Days after presenting the crown jewels of tobacco litigation to Scruggs, Merrell Williams made a cash offer for a $ 109,600 home in Ocean Springs. On the sales contract, he gave a false social security number. The real buyer turned out to be something called M&S Enterprises. Two months later M&S Enterprises deeded the house to Williams.

In other words, Williams got a free house.

His mystery benefactor? Dickie Scruggs. M&S was a limited partnership of his making. Why would Scruggs give away a house?

"It was my impression that he wanted to be very helpful to me," Williams says.

There seemed no end to the attorney's generosity. Williams mentioned to Scruggs he was trying to start a business taking tourists on night sails to the gulf islands.

"Well, he just popped up with, "Let's go see my banker and talk to him,' " Williams recalls.

Williams walked out of Sunburst Bank in Ocean Springs with a $ 22,000 loan guaranteed by Scruggs, which he used to buy a 30-foot Morgan.

The business was a flop; Williams didn't make a single loan payment. Scruggs took care of it.

Scruggs co-signed a $ 10,000 loan so Williams could buy himself a used Ford Mustang; he co-signed a $ 12,000 loan so Williams could buy his daughter a new Dodge Neon; he co-signed a $ 6,000 loan so Williams could pay his taxes.

Scruggs got him a $ 3,000 a month job as a paralegal for a New Orleans firm. Williams was paid even if he didn't show up for work, which was good because he didn't do a speck of work for the firm for an entire year. When that job ended, Scruggs began paying him $ 3,000 a month out his own pocket, payments he still makes.

To do what?

"Well, I am probably one of two or three people in the world who know more about this (industry) than anybody else, and I am ready and available to be a consultant if I'm ever asked," Williams has said.

Has that happened?

"No. But if he calls me, I would answer the phone."

Brown & Williamson has a different view of these events, a view it is pursuing in a federal lawsuit against Scruggs and Williams. The company accuses Scruggs of lavishing goodies on Williams to induce him to hand over his cache of stolen documents.

"The man's got the best life he's ever had trading off of his thievery," says Brown & Williamson's attorney, Gordon A. Smith.

Williams and Scruggs deny it. Williams says he told Scruggs - "perhaps in a pitiful way" - that he felt scared for himself and his kids, and that a nice house, a house in his name, would help him keep custody rights to his daughters through their college years. "A private witness protection program," he calls it.

Scruggs says his generosity has been "mischaracterized and made to look like it was some sort of a bribe or payoff.

"I wanted to basically hide Merrell, as opposed to hide the transaction. We knew that the tobacco industry would be following us, would be spying on everything we did, looking at everything we did, and I just didn't want a big glaring billboard pointing to Merrell Williams being in Ocean Springs, Miss."

And then: "It sounds like a lot of money, but it wasn't to me. I thought the guy'd done a real brave thing. He was in a lot of trouble, and needed some safe harbor."

Would he have been so giving if Williams hadn't coughed up the documents?

"That's a hard question. I don't know."

Scruggs doesn't need this fight, at least not for the money. Never mind the spartan decor of his law office lobby. He lives in a waterfront mansion and owns a 61-foot Hatteras cruiser. He races his J-35 sailboat, called Gunsmoke, off Key West every year.

He parks his Lear jet at an itsy-bitsy airstrip a few miles north of this shipyard and oil refinery town. The airstrip is named the Trent Lott International Airport, after Pascagoula's favorite son, the Senate Majority Leader. A staunch defender of the tobacco industry and recipient of tobacco campaign contributions, Lott is Scruggs' brother-in-law.

Like so many Third Wave lawyers, Scruggs made his millions suing asbestos companies. Many of his asbestos clients work at the shipyard. Even now, they beat a steady path to his office to check on their asbestos settlements.

"We've got (asbestos) money coming in through the end of the century," Scruggs says.

So why has Scruggs shelled out more than $ 3.5- million of his own money on tobacco litigation? What does he want?

Start with what he doesn't want. He doesn't want to save the world, or kill the tobacco industry, or spend the rest of his life wrestling tobacco lawyers.

What he wants, he says, is a deal. A sweet deal. A once-in-a-lifetime deal, the sort that makes your heart race and palms sweat at the very thought of it. What he wants, he says, is a grand compromise, a national armistice that settles the tobacco wars for decades to come.

"There must be an endgame."

What Scruggs has in mind would work something like this:

Tobacco pays a ton of money, as much as $ 500-billion over 20 or so years. The money reimburses state Medicaid costs, compensates individual smokers, funds independent research and pays for "countermarketing" on the dangers of

smoking.

Oh yes, let's not forget the lawyers. "We don't want to be the pied pipers of the world - get rid of all the rats and not get paid," Scruggs says.

What does tobacco get in return? Freedom from the most severe FDA regulation. A cap on damages in pending cases. Immunity from just about all smoker lawsuits for decades to come. All of it blessed by Congress in national legislation. (Here's where the brother-in-law comes in handy.)

Everyone would walk away with something.

What's the alternative? he asks. Protracted trench warfare? An asbestos scenario in which tobacco starts losing cases, prompting every eager attorney in the country to rush the courthouse?

"I mean, 400,000 people die every year prematurely from smoking. If you took one year's worth of lawsuits, they (tobacco) could not pay it, they could not defend it," Scruggs says.

"That would put 'em into bankruptcy and then there would be no winners."

Still, $ 500-billion is a lot of money, even for an industry that turned an estimated $ 8-billion profit last year. But Scruggs thinks greed will carry the day. Stock analysts say a settlement will trigger a sharp rise in the market value of tobacco stocks - at least $ 60-billion for Philip Morris alone. Tobacco executives with stock options would make small fortunes.

Downturns in the stock market only help Scruggs' deal-making strategy.

To him, each new whistle-blower, each new lawsuit, each damaging headline, each attack from the White House or Congress, each new Justice Department subpoena, is a way to hammer tobacco stock prices lower. One unfavorable ruling by the Mississippi Supreme Court last month sent Philip Morris' stock tumbling 8 percent in a day.

"With that sort of instability and volatility in tobacco stock prices, these guys have got to come to grips with their business," Scruggs says. "Their shareholders are not going to permit that to go on."

It's the domino theory: The Brown & Williamson documents beget lawsuits, which begets the specter of financial catastrophe, which begets lower stock prices, which begets a settlement.

"The whole idea is to use the combination of all these state actions to leverage these guys into a position to try to resolve it nationally."

Last fall, in a Jacksonville courtroom, the tobacco industry got its first taste of how miserable life can be when a plaintiff is armed with the Brown & Williamson documents.

The case was just the type tobacco had been winning for years. Grady Carter, a 66-year-old former air traffic controller, had contracted lung cancer after

smoking Lucky Strikes and Tareytons for 44 years. Warned over and over about the dangers of smoking, he kept smoking and even sought out a doctor who smoked so he wouldn't be lectured. Now he wanted Brown & Williamson to pay up. He wanted $ 1.5-million.

The tobacco attorneys trotted out their tried and true personal-choice defense. No tobacco executive ever put a gun to Carter's head and made him smoke. He made the choice. He knew the risks. He is responsible. Wall Street stock analysts predicted another tobacco victory.

The jury began deliberations. On their first vote, four of the six jurors sided with Brown & Williamson's personal-choice defense. In the minority was the jury foreman, a retired postal supervisor named Sam Gaskins, who suggested a way to break the deadlock: Let's read the Brown & Williamson documents.

Carter's attorney, Norwood "Woody" Wilner, had submitted 21 of the documents into evidence. The jurors began to read. They began to get angry. One of the jurors, a smoker, looked up from a report and said, "If I'd known all this, maybe it would be different."

Soon, tobacco had no defenders left on the jury. "They could see in black and white what had happened," Gaskins says of the deliberations. "It was total hypocrisy."

Each juror wrote a dollar figure on a piece of paper. They added up the numbers, divided by six, rounded off, and that's how they decided that Brown & Williamson should pay the Carters $ 750,000, the largest verdict ever against a tobacco company.

Wall Street was stunned. Philip Morris, which wasn't even a defendant, lost $ 11-billion in its market value that day when its stock price plunged 14 percent.

Scruggs and the other Third Wave attorneys were stunned, too. They had thought that the only way to beat tobacco was to "step out of the smoker's shoes." But Woody Wilner - a lawyer who had never tried a tobacco case before, who often came to court on a bicycle - stood in Grady Carter's shoes and stomped Big Tobacco.

Wilner was just getting started. He has filed claims against tobacco on behalf of hundreds of smokers. (His second tobacco trial begins today in Jacksonville.) Wilner intends to pound away with the Brown & Williamson documents in all his cases.

Stanley Rosenblatt is the Miami attorney behind two key class-action suits. He represents an estimated 60,000 flight attendants who say second-hand smoke made them sick. He also represents roughly 500,000 Florida smokers who say they are addicted. He is using the documents.

A group of 60 major product liability firms has filed class-action suits in multiple states. Those firms are using the documents.

In Florida's Medicaid lawsuit, the first big fight was over Williams' documents. Florida's lawyers filed 833 pages of them with the court

clerk - ostensibly to have Brown & Williamson validate them. But another purpose was to generate damaging media coverage. Robert Montgomery Jr., Florida's lead trial attorney, told the judge that he sent copies of his motion - documents and all - to every media outlet he could think of. "If I missed one," he said, "I should not have."

In Washington, FDA Commissioner David Kessler wanted to declare nicotine a dangerous, addictive drug and propose tough new regulations on tobacco products. He needed his boss' approval for a step of that magnitude. He showed Williams' handiwork and other internal documents to President Clinton.

"These are their words?" Clinton asked.

Kessler got his green light - and Candidate Clinton got a poll-pleasing applause line.

Gordon A. Smith is the Brown & Williamson lawyer dealing with the Merrell Williams mess.

He has been relentless, pursuing Williams and the Brown & Williamson documents in court after court for nearly three years. Once, during a contentious deposition, Williams demanded that Smith back away from him because he felt intimidated by Smith's body language.

"I'll see him in hell," Williams says bitterly of the man he calls "my Torquemada."

Over a Village Inn breakfast of grits and huevos rancheros, Smith hardly looks the part of tobacco's grand inquisitor.

His jacket won't quite button over his spreading mid-section. He allows that he was nervous about looking foolish when Mike Wallace interviewed him on 60 Minutes. A tennis fanatic and diehard Georgia Bulldog, he comes across like an aging frat boy.

But he is passionate and serious when the topic turns to Merrell Williams.

"His job, understand, was to preserve the very documents that he stole. His job was to collect them and to categorize them so that they would be available in lawsuits," says Smith, a partner in Atlanta's largest law firm, King & Spalding.

"He didn't choose to be a whistle-blower or hero. He chose to steal 'em to try and make money."

As for the documents, Smith says their significance has been overblown. Just because company attorneys wrote memos about ditching damaging research, that doesn't mean the advice was followed. Sure, tobacco executives may have called nicotine addictive, but that's a meaningless label.

"People have known forever that it's hard to quit," he says. "It's a word game."

The stolen documents, he says, give an incomplete picture of Brown & Williamson. He is anxious to put them in context, to explain their true meaning and significance. He'd love to . . . but he can't.

Why not?

Because he is defending something even more important - the principle that what a client tells an attorney is inviolate. If he were to discuss the documents in detail, that might suggest that his is waiving the attorney-client privilege.

"Because of the theft, we are put in the position of being unable to respond to what the plaintiffs are talking about in the press," he says.

"It's terribly unfair."

A settlement will be a tough sell.

For tobacco executives, a key question is: Why should we pay tens of billions of dollars to settle when all we face right now, if you get down to it, is one puny $ 750,000 verdict. That's barely lunch money to us.

For many long-time tobacco opponents, there's this: How can we make a deal with criminals who addicted our children to their deadly poison just to make a buck? Let's lock 'em up instead.

"I don't think there's a soul in the public health community who agrees with Dickie's deal," says Richard Daynard, president of Northeastern University's Tobacco Products Liability Project.

So like some intrepid Middle East diplomat, Scruggs logs thousands of miles a month in his Lear jet, shuttling across the country at 360 mph in search of the two ingredients crucial to a settlement - leverage and consensus.

Leverage came with last month's settlement with Liggett Group Inc., the smallest of the nation's five major cigarette makers. The settlement, which Scruggs helped negotiate, strengthens his hand three ways: tobacco stocks plunged with the news; Liggett confessed that it marketed an addictive, cancer-causing product to children; Liggett pledged to release hundreds of incriminating industry documents.

Consensus is building among the attorneys general and the Third Wave lawyers on the shape of their settlement demands. Tobacco executives have signaled their openness to a settlement in filings with the Securities and Exchange Commission.

"All this is is playing the odds," Scruggs says. "What we're doing, and what we've done from the beginning is try to position the litigation and the tobacco control movement to keep us in a position to win if we get lucky."

Stanley Rosenblatt scoffs at the idea of a settlement. "It won't happen," he says. Why is he so sure? Because in six years of relentless trench warfare against hordes of tobacco attorneys, there has never been a single syllable

uttered about settlement.

"They haven't offered 10 cents," Rosenblatt says.

He has only one objective: "To win the biggest possible judgment I can."

Another obstacle is time. In June, Rosenblatt's flight attendant case is to begin in Miami. In July, the first of the state Medicaid trials is scheduled to start in Mississippi. Florida's case follows in August, Texas in September.

Scruggs: "If they wait till we beat 'em, then the deal won't be possible. There will be too much blood in the water."

Imagine two battleships a hundred yards apart, blasting away at each other with every gun. Then ramming each other for good measure.

Already, the approaching trials are producing epic clashes. It is bitter, fratricidal lawyering, with tobacco's attorneys disparaged as ruthless mercenaries for an Evil Empire and plaintiffs' attorneys demonized as self-righteous bloodsuckers.

At many court hearings, the tobacco industry sends 40 or more attorneys. Shock troops in Gucci. They jet in from Houston, Denver, New York, Washington, Atlanta, Miami and happily ring up billable hours for an industry that spends an estimated $ 600- million a year in legal fees.

Heavy hitters are dispatched to even the smallest skirmishes. Howard Acosta, a St. Petersburg lawyer who has filed lawsuits for more than 100 smokers, recalls a recent court hearing in which one of the main arguments was over the meaning of the words "less hazardous."

His opponent: Benjamin H. Hill III, past president of the Florida Bar.

In most lawsuits, a witness deposition takes less than a day. In one tobacco case, industry attorneys grilled a plaintiff's scientist 22 days.

So what is it like to defend an industry blamed for 420,000 deaths a year?

"Well, my wife still loves me," says Steve Krigbaum, a West Palm Beach tobacco attorney who is responsible for digging up damaging information to use against the state of Florida.

By contrast, plaintiff's attorneys swell with moral indignation as they tell you that 3,000 kids start smoking each day, and a third will die from smoking-related illnesses.

"This is good versus evil," says Tampa attorney Steve Yerrid, a member of the "Dream Team" of litigation hot shots on Florida's Medicaid suit. ("We don't have too many Dennis Rodmans," he says. "We have a lot of Michael Jordans.")

Like many of his brethren, Yerrid has a personal score to settle. His mother, a two-pack-a-day smoker, died of a stroke at 67. Yerrid found her in

bed, eyes open, a cigarette in the bedside table ashtray. His father was told to quit smoking after his stroke at 56. He couldn't. He was dead at 58.

"I have an emotional ache to try this case." he says.

A financial ache, too. If Florida were to win a $ 1-billion verdict against tobacco, the dozen or so Dream Team members would split about $ 250-million in legal fees.

"To say we're not in it for the money would not be true," Yerrid says.

Given the stakes and the egos, everything about the Third Wave litigation is done on a grand Gone With the Wind scale.

Trial attorneys typically line up a few experts for a case. The Dream Team has retained 55 experts, some with resumes 30 pages long. They have experts in advertising, neonatology, biomedical ethics, addiction, pharmacology, health care costs - even military disinformation.

Their cleanup hitter is former Surgeon General C. Everett Koop.

Tobacco attorneys, meanwhile, concede nothing and attack at every level. They deny in court that cigarettes are addictive or even "habituating." They deny cigarettes cause emphysema or cancer or anything else. Research that says otherwise is invalid, or flawed, or misinterpreted. Statistics are proof of nothing. Animal experiments are proof of nothing. And on and on.

"It's the four-dog defense to the guy who's bitten by your dog," Scruggs says.

"First of all, I don't have a dog. And if I had a dog, it doesn't bite. And if I had a dog and it did bite, then it didn't bite you. And if I had a dog and it bit, and it bit you, then you provoked the dog."

Tobacco companies have produced 25-million pages of discovery material to plaintiffs. It's all stored in a special, high-security repository in Minnesota. The states demand more.

Mississippi's lawyers asked for every government official who had received a gift from Philip Morris since 1989. The company produced a list of 119 public servants, from Crowell Armstrong ($ 600) to Clyde V. Woodfield ($ 400).

Tobacco has been no less thorough.

Since October, tobacco has paid a couple dozen legal assistants and lawyers to do nothing but read state records in Tallahassee. They've reviewed more than 10-million papers and counting.

Steve Krigbaum, the tobacco attorney supervising the researchers, says the state is burying his people with millions of pages of junk to divert their attention from the good stuff. The state Department of Corrections produced dozens and dozens of boxes of records. Krigbaum's researchers scoured every box and found a measly 100 pages worth copying.

Oddly enough, Krigbaum says, the boxes didn't contain any records describing how the state prison system made its own cigarettes in the '70s, then gave them to inmates for free.

Which brings us to tobacco's main defense in the Medicaid suits:

Hypocrisy.

The states tax tobacco, subsidize tobacco farmers, invest pension funds in tobacco stocks, and sell tobacco products in their prisons and mental hospitals. They've even peddled cigarettes to minors in juvenile detention centers.

Hypocrisy.

Gov. Lawton Chiles hews tobacco. Former Gov. Bob Graham signed proclamations declaring Pride in Tobacco Week. "Whereas, tobacco is a major source of tax revenue for the state of Florida . . ."

Hypocrisy.

The states claim that tobacco has quietly paid huge sums to prominent scientists to produce the research results it wants. Well, tobacco can point to Dr. John H. Pierce, who took $ 600,000 in government grants for research that concluded: "Cigarette advertising encourages youth to smoke and should be banned."

Hypocrisy.

Then there's Dr. Paul Fischer, famous for research that concluded 91 percent of 6-year-olds recognize Joe Camel, the same as Mickey Mouse.

It turns out - oops! - that the 91 percent figure was based on interviews with just 23 kids from one school in Georgia.

From his velvet exile in Ocean Springs, Merrell Williams is watching the battle unfold.

He has two dogs, Riley and Tina, but few friends. His neighbors have no idea who he is, or what he did. Most of his visitors are reporters. Fred Francis of NBC has been by. The Los Angeles Times. A BBC crew.

He tracks tobacco stocks obsessively on the Internet and gets by on blood pressure pills, anti-depressants, and an occasional tranquilizer. There are good days, days when he sails on the outgoing tide with his new girlfriend. But some nights he drinks too much. He says he nearly had a nervous breakdown after enduring a dozen or so depositions with tobacco attorneys.

"They were pounding me with rubber hoses," he says with typical flair.

His suspicions of the tobacco industry are bottomless. He thinks his phone may be tapped, and he's had his house swept for listening devices. He couldn't believe it when none were found. (Though tobacco's investigators have snapped

surveillance photographs of Williams.)

He swears the tobacco industry tried to terminate him. It happened when he was out for his morning walk. A sniper's bullet whizzed by his head, he says. At least, it sounded like a bullet. Tobacco lawyers scoff at the allegation, saying he's trying to gin up interest from Hollywood.

Don't think for a minute that the tobacco industry has forgotten Merrell Williams. Brown & Williamson executives say they want his hide in jail - six months, at least, for contempt of court. Plus they want his house, his car, his boat, his daughter's car - every single dime he has made off the 4,000 pages of documents he stole.

He has been paid $ 15,000 for a six-month option on his life story, but he figures his story is worth at least $ 200,000 for an "M.O.W." - movie of the week.

"There is no question that I am going to make a lot of money off of the movies."

He thinks Dustin Hoffman, another obsessive method actor, could do him justice. Yes, say those who know and like Williams, Dustin Hoffman would be just right.

In the 1992 movie Hero, Hoffman played a shiftless, self-absorbed petty crook who, inexplicably, rushes into a crashed airliner and rescues dozens of strangers from flames. How far is that from Merrell Williams, a lifelong screw-up who, at great personal risk, endeavored to save lives by stealing the tobacco industry's darkest secrets?

Fencing with Merrell

Brown and Williamson Tobacco Corp. sued Merrell Williams for stealing company documents. When tobacco attorney Gordon Smith has taken his pretrial testimony, Williams hasn't made things easy. Some excerpts:

Williams takes back some of his testimony:

Smith: So you testified earlier that you had browsed the Internet and done legal research for Ms. Ardoin and that was not true, correct?

Williams: I am recanting on that point, yes.

Smith: It's not true?

Williams: The truth has just been told to you. I did not have the Internet on my computer.

Smith: And you just told me that you did essentially no work for Ardoin & Tanet, correct?

Williams: That's exactly correct.

Smith: So you were paid $ 3,000 a month from June of 1994 through June of 1995 and you performed no services?

Williams: That's correct.

Smith: Can you tell me why someone would pay you, why, to your understanding, you were paid $ 3,000 a month to do nothing?

Williams: Because I'm a good-looking son of a bitch. How about that?

Smith: And what three books are you writing?

Williams: Well, I'm writing about you right now, and you gentlemen right here, and you, and the attacks on the - by the tobacco industry.

Smith: I'm sorry. The what?

Williams: The attacks.

Smith: On?

Williams: A professional defendant.

Smith: You?

Williams: Yes.

Smith: That's Book No. 1. What's Book No. 2?

Williams: Trying to survive the attacks of the tobacco industry.

Smith: That's a separate book?

Williams: Well, it's in a format. It's not quite finished.

Smith: All right. Book No. 3?

Williams: Bypass surgery and the tobacco industry, and how to love your enemy, story of a foot soldier.

Smith: Is that the title?

Williams: Yes. Working title, all of them.

Williams complains that Smith is sitting too close:

Williams: You've deposed me many times and I appreciate the strategy of your body language, but if you don't mind, would you kind of keep a distance from me a little bit? ...

Smith: I want you to be comfortable. I want your best testimony.

Williams: Well, you have a very high torso, and you tend to move it toward me like this. And it's a very minor point, I realize with you, but it seems to be that you're pressing on me a little bit.

Smith: I'll try to sit back.

Williams: I like a little social space, a little private space.

Smith: During this deposition, you have described a $ 100 to $ 150 amount of money provided to you by Mr. Scruggs. You've testified that he provided you $ 3,000 in cash. You've testified that he co-signed on a $ 10,000 loan, a $ 12,000 loan, a $ 22,000 loan, which has now been paid off, and he co-signed on a $ 6,000 loan, and he's deeded to you a $ 105,000 house. What has Mr. Scruggs told you about why he wanted to help you and why he did these things for you, if anything?

Williams: Nothing.

Smith: Not a thing?

Williams: Not that I can recall.

Williams says somebody fired a gunshot at him. He suspects it was somebody from some tobacco company law firm:

Smith: And you don't know who shot, who pulled the trigger, do you?

Williams: No. But I don't know who killed Kennedy, either.

Smith: You don't know that they weren't shooting at a squirrel in a tree, do you?

Williams: It came pretty close to me.

Smith: Well, you don't know that anybody was shooting at you, though, do you? You don't know what they were shooting at?

Williams: It's pretty hard, when you're on the Ocean Springs track, to believe they were shooting at a squirrel.

Smith: You heard a shot. Did you see where the bullet hit?

Williams: It's hard to find a bullet.

Smith: Do you know where it hit?

Williams: It came close to my head.

Smith: How do you know that?

Williams: I felt it.

Smith: You felt the bullet go by?

Williams: I felt a whiz. ...

Smith: No other witnesses to this?

Williams: No. There was nobody on the track.

Smith: Did you report this incident to the police?

Williams: No, I did not.

GRAPHIC: COLOR PHOTO, ANDREW INNERARITY, (9); BLACK AND WHITE PHOTO, ANDREW INNERARITY, (2); COLOR GRAPH; Dickie Scruggs with his Lear jet and his cell-phone in West Palm Beach.; Merrell Williams driving his Mustang.; Williams on his sailboat.; Gordon Smith; Merrell Williams; Scruggs napping on his jet.; Members of the Florida team are Bob Butterworth, Steve Yerrid, Scruggs, Robert Montgomery Jr., Wayne Hogan, Kim Tucker and Mike Maher.; Boxes of state records in Tallahassee.; Norwood "Woody" Wilner; Tommy Sandefur; Merrell Williams; fever graphs follow the stock prices of Philip Morris and Brown and Williamson from March 7 until afer March 19, with March 12 and 19 highlighted

LANGUAGE: ENGLISH

LOAD-DATE: April 8, 1997

June 11, 1997

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed
Bruce Lindsey
Rahm Emanuel

SUBJECT: Tobacco Settlement Review Process

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

Interagency Review

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

o Public Health and Liability Team

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

1. FDA regulation of product, access, and labeling
2. Advertising restrictions / public education
3. Environmental tobacco smoke
4. Smoking cessation
5. Farmers
6. Liability and litigation
7. Drafting and enforcement issues in codifying a potential agreement

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

o Medicaid Spending/Children's Health Team

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

Outreach

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

Schedule

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

June 12: Teams begin meeting.
June 18: Teams report back with initial findings and outstanding issues.
Week of June 16: White House and HHS host meetings with public

health groups.

Week of June 23: Develop options for outstanding issues; hold principals meeting.

June 27: Send memo to the President.

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

Talking Points on Tobacco Settlement Talks

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

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

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

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

Q. Have you started to review the deal?

A. We have begun a process for reviewing the provisions that have been under discussion. We expect to spend the next couple of weeks analyzing the details as they emerge, and consulting with the public health community and others.

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

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

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

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

Outline of Working Group Papers on Baseline Activities

I. Brief description of issue area(s)

II. Public health/public interest goals (e.g., affect on kid smokers, adult smokers, addictiveness/safety of product, recovering Medicaid costs)

Long-term

III. Actions absent a settlement

A. Current/Planned activities (expected benefits; timing; litigation risk)

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

IV. Critical Issues

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

- convene larger group (30 people)
- process and goals --
- convene working groups (assign leads)
    1. FDA regulation of product, access, and labeling URM
    2. Advertising restrictions / public education
    3. Environmental tobacco smoke
    4. Smoking cessation URM
    ~~5. Farmers~~
    6. Liability and litigation
    5. Industry 7. $

Also

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

- Ask for paper by (Monday?)

Advance work

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

Pending work

- Principles

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

TO: Kevin Thurm
Deputy Secretary

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

RE: Summary of Discussions on FDA-related Issues

DATE: June 4, 1997

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

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

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

in enforcing the rules;

H. Enforcement would include unannounced, random stings;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9. General Authority of the FDA

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

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

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

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

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

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

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

G. With regard to non tobacco ingredients:

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

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

- FDA would be permiteed to requre the public disclosure of ingredients information as it does for foods in a manner that does not disclose trade secrets, (i.e., a flavoring that had been tested and approved as safe for use in a burning tobacco product could be identified in the same manner as flavorings are disclosed in foods.) This is the same standard for public disclosure provided in the Massachusetts disclosure law. During the five year grace period, the industry would not be required to publicly disclose confidential, proprietary information concerning these flavorings and spices.

H. FDA would have its typical authorty over the manufacturing of the product, including the establishment of Good Manufacturing Practice Standards, product quality criteria, pesticide residue standards, etc. Tobacco farmers would face no greater regulatory burden than the producers of other raw products regulated by the federal government.

I. Products sold that an objective, resonable consumer would believe pose less of a health risk:

- tobacco product manufacturers would be barred from making claims that could reasonably be interpreted to state or imply a reduced health risk unless the

manufacturer had demonstrated to FDA that the product scientifically did in fact "significantly reduce the risk to health" from ordinary tobacco products[1] and in that case,

- FDA would have to approve all claims (direct or implied), as well as the content and placement of any such advertisements, to prevent the public from being mislead and to prevent the contraction of, the marketplace.

- For less hazardous products, FDA would be authorized to permit scientifically based specific health claims and to permit exceptions to the advertising restrictions that apply to other products if FDA determines that such advertising would reduce harm and promote the public health. The FDA would promulgate a rule to govern how these determinations would be made.

- The industry would be required to notify FDA of any technology that reduces the risk from tobacco products and, for a commercially resonable fee, to cross license all such technology, but only to those companies also covered by the same obligations. Procedural protections would be built in to resolve license fee disputes, if the private parties can't agree among themselves first. If the technology reported to the FDA is in the early develoment stages, the manufacturer would be provided confidentiality protection during the development process.

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

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

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

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

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

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

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

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

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

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

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

cc: Elena Kagan

The Advisory Committee on Tobacco Policy and Public Health

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

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

June 10, 1997

Bill Clinton
President of the United States
The White House

Dear Mr. President,

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

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

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

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

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

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

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

Sincerely yours,

C. Everett Koop, M.D.

David A. Kessler, M.D.

The New York Times
Op-Ed

June 4, 1997

Smoked Out

By C. EVERETT KOOP and DAVID KESSLER

WASHINGTON -- The problem with the settlement talks between the tobacco industry and the states which are suing it is that the focus is on the wrong subjects: money and immunity. The money is for victims, lawyers and the states; immunity from lawsuits is for the tobacco industry, which is seeking long-term financial security. That's not what should be driving our national policy.

The goal of any settlement must be reducing the number of people who smoke, now and in the future. Compensating victims doesn't do that. Paying lawyers doesn't do that. Limiting the industry's liability certainly doesn't do that. Right now, there are two choices: Let the fight continue on many fronts or reach a broad settlement. In either event, the only acceptable outcome is one that assures the eventual decline of tobacco use.

About 50 million Americans are addicted to nicotine. One third will die a smoker's death, which means they will die prematurely. We must help these people because they became addicted at a time when the tobacco industry said that nicotine was not addictive and that its products were not harmful.

We know that prohibition won't work.

But we should try to phase out tobacco use over the next several decades. There are three ways to do this: Prevent young people from smoking, help adults break their habits and manufacture the products so that they are not addictive.

Tomorrow, the Advisory Committee on Tobacco Policy and Public Health, a independent panel of public health advocates, will meet to figure out how to reach these goals. As the committee's co-chairmen, we hope our discussion will be broader and more open than the current closed-door settlement talks and that the panel may be able to suggest an effective national policy.

In the end, of course, the tobacco industry must be held accountable. When defending itself in front of a jury, the industry usually brings up individual responsibility.

But what about the individuals who make up the industry? It is time that they, too, show some responsibility.

C. Everett Koop was Surgeon General from 1981-1989. David Kessler was Commissioner of the Food and Drug Administration from 1990-1997.

MMWR 5-23-97

Cigarette smoking remains the leading preventable cause of death in the United States. The same methods and data sources that were used to calculate the 1990 SAM and YPLL (2)** were used for the 1990-1994 calculations, which indicated that 2,153,700 deaths (1,393,200 men and 760,400 women; total annual average: 430,700 deaths) were attributed to smoking (19.5% of all deaths). A total of 906,600 of these deaths resulted from cardiovascular diseases; 778,700, from neoplasms; 454,800, from nonmalignant respiratory diseases; 7900, from diseases among infants; and 5500, from smoking-related fires. Lung cancer (616,800 deaths), ischemic heart disease (IHD) (490,000 deaths), and chronic airway obstruction (270,100 deaths) accounted for most deaths. During 1990-1994, cigarette smoking resulted in 5,732,900 YPLL before age 65 years and in 28,606,000 YPLL to life expectancy.