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b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

STATE OF MINNESOTA

OFFICE OF THE ATTORNEY GENERAL

HUBERT H. HUMPHREY III
ATTORNEY GENERAL

102 STATE CAPITOL
ST. PAUL, MN 55155-1002
TELEPHONE: (612) 296-6196

July 25, 1997

TO: CLINTON ADMINISTRATION TOBACCO ANALYSTS

As you know, our Office has continued to analyze and raise questions about the inadequacy of the public health and other provisions of the Tobacco settlement proposal. Attorney General Hubert H. Humphrey III testified before the Senate Judiciary Committee last week, and will appear before the Senate Commerce Committee next week.

Attorney General Humphrey's statements reflect his continuing concerns with both the timing and content of the settlement proposals. Attached are the following documents for your review:

1. Attorney General Humphrey's July 16, 1997 Judiciary Testimony;

2. A Preliminary Analysis provided to the Judiciary Committee that focuses primarily on legal and policy concerns raised by the sweeping civil liability concessions granted to the Nation's number one killer industry; and

3. A broader draft analysis of the settlement, with comments and questions.

Our Office stands ready to help in any way that you would find useful. Please do not hesitate to contact me at (612) 296-2351.

Respectfully submitted,

LEE E. SHEEHY
Chief Deputy Attorney General

LES:gmm
Enclosures
c: Attorney General Hubert H. Humphrey III (w/o Encls.)

AG:31802 v1

TESTIMONY OF HUBERT H. HUMPHREY III
MINNESOTA ATTORNEY GENERAL
SENATE JUDICIARY COMMITTEE
JULY 16, 1997

Thank you, Senator Hatch and members of the Committee for convening these important hearings. Through your deliberations, and through the historic, ongoing litigation across the country, we have a once-in-a-lifetime opportunity to re-define America's love-hate relationship with the most deadly product in history.

We cannot squander this opportunity. I regret to say that this settlement proposal could become another sad chapter in the tobacco industry's long history of deception. For all its good intentions, the proposed settlement is a Trojan camel.

Wall Street has figured out who would benefit. Tobacco stocks soared 20% during the negotiations. Investment analysts say if you pass the deal, tobacco stocks will soar another 20. On top of that, they say the CEO of Philip Morris will personally make fifty million dollars on stock options if the deal goes through!

So, for forty years of lies, fraud, and conspiracy, the reward is a 40% increase in stock value, and millions of dollars for the CEOs. If that's punishment, I want some!

Three years ago, when I filed the second of the state tobacco lawsuits, I said this industry must change its ways forever. It must obey the laws that all other businesses obey. It must tell the truth. It must pay damages commensurate with the harm it has caused. It must answer for what it has done.

On May 2nd of this year, three weeks after the secret negotiations began, I wrote my attorney general colleagues a letter, setting out 14 searching questions I believe must be addressed in any proposed resolution -- beginning with the need for unfettered FDA jurisdiction over nicotine. Regrettably, the proposal fails to answer many of those questions.

Instead, I believe the settlement proposal is inherently flawed because it answers the wrong question. In essence, the negotiators asked themselves "How much regulation will this industry accept?" Mister Chairman, with the greatest respect to my good friend, Dick Blumenthal, and to my other colleagues, that may be an appropriate question to ask when you're settling lawsuits. But it's the wrong question to ask if you're establishing national health policy.

The question for the Congress is not "What is acceptable to the tobacco industry?", but rather, "What is best for America?"

Fortunately, we now have an alternative that helps us answer the right question. That alternative is the blueprint proposed by the distinguished panel convened by Doctors Koop and Kessler, which offers a template for a comprehensive tobacco policy for this country.

Here is a foundation from which to build a comprehensive national policy -- a policy that will give America what the public needs, not just what the tobacco companies want.

I suggest today that the bottom line for an effective and enduring national solution should be what I call "Koop-Kessler Plus."

I specifically want to call your attention to four of the Koop-Kessler Committee's most important recommendations -- recommendations which document clearly how the proposed settlement falls short. Plus, I urge you to insist that these companies pay far more money -- enough that they feel some pain for the outrageous wrongs they have committed.

1. FDA Authority

First, I agree with the Koop-Kessler Committee that there should be no giveback of the FDA's existing authority to regulate tobacco products as drug delivery devices, or its power over nicotine.

2. Civil and Criminal Liability

Second, I agree that "all currently available avenues of litigation, both civil and criminal, must be fully reserved (Koop-Kessler Report, page 16), with "no special rules of any kind, substantive or procedural" (Koop-Kessler Report, page E-3). The proposed settlement -- which eliminates class action suits, bars claims based on addiction, ends suits by insurance companies and union benefit plans, and bars punitive damages -- obviously fails that test.

3. Documents

Third, "all internal tobacco company documents that bear upon the public health must be disclosed " (Koop-Kessler Report, page 16), including a waiver of any claims of attorney-client privilege or work-product privilege (page E-3). This is crucial. In practical terms, the proposed settlement would let these companies conceal forever their smoking guns -- a million pages of top secret, and devastating, documents they have hidden for decades behind claims of attorney-client privilege.

4. State Preemption

Fourth, preemption of states' rights. I agree with the Koop-Kessler Committee that any legislation must include unambiguous non-preemption provisions, expressly protecting the power of states and cities to go beyond the federal standards (Koop-Kessler Report, page 16). Again, the proposed settlement falls far short and, in my view, would severely curtail the existing powers of states and cities.

5. The Money

Fifth, the "Plus" in my call for a "Koop-Kessler Plus" approach.

This industry must feel some financial pain. In contrast to this goal, the proposed settlement would guarantee them pain-free penalties: the companies would pass the penalties through to smokers in price increases and would even get to deduct them from their taxes!

The settlement also includes so-called "lookback" penalties, designed to "punish" the industry if it fails to reduce teen smoking rates. But even if the industry were to increase its illegal sales to kids, these penalties would amount to only about eight cents on a pack of cigarettes, an amount they will simply absorb as a cost of doing business. One CEO has already told the press he has no expectation of meeting the targeted reductions.

I believe it's an affront to justice to cut a deal that lets the tobacco cartel pass all of the pain through to its customers and to taxpayers. To achieve justice, the companies themselves and their shareholders must pay.

And, it ought to hurt!

These cases are not about money. But they are about justice -- justice for victims and their families, justice for taxpayers, justice for the public, and, yes, justice for the tobacco companies and their executives. That means the tobacco cartel must feel the sting of penalties for 40 years of lawbreaking.

Three hundred and sixty-eight billion dollars is a lot of money. It might even be called intoxicating. But sober investigation will show that, in fact, it is far short of what is needed to serve justice.

In putting a price-tag on the proposed settlement, my colleagues had only seen the tip of the iceberg of this industry's deceit. In Minnesota, we have collected two warehouses full of secret industry documents that my colleagues have not had a chance to examine. I believe that if the Congress examines those documents and understands the persuasiveness of the fraud, you will agree that the price must go up.

The proposed settlement would cost about fifty cents per pack of cigarettes. Other countries collect far more. The Koop-Kessler Committee calls for a two-dollar per pack increase, citing evidence this would cut teen smoking in half (Koop-Kessler Report, page B-7). A leading economic expert, Professor Jeffrey Harris of M.I.T., tells us the price could in fact be increased by $2 per pack, generating $800 billion over 25 years. Coupled with savings from reduced litigation and advertising expenses, this amount would be generated with minimal impact on the industry's overall profitability.

The bottom line: Congress should not settle for a mere 15 billion dollars per year, when justice demands and the industry can afford to pay a great deal more.

Finally, Senator Hatch, today I would like to propose a very specific, concrete step the Congress should take before you design a national tobacco policy that may stand as the law of our land for many years.

It is absolutely vital that you have the facts. This area is too important for the Congress to buy a pig-in-a-poke. Today I urge the Congress to subpoena the treasure trove of millions of secret industry documents that we have compiled in our Minnesota litigation.

Minnesota's lawsuit is unique. We have actually succeeded in compelling this industry to disgorge the documents it has long hidden from the public. Unlike any other case, public or private, we have forced the industry to create, under court supervision, two document warehouses into which we have forced them to deposit some 33 million pages of industry documents.

At the industry's insistence, the court has sealed those documents until we go to trial 180 days from today. Our team has been through them and, as our counsel likes to say, many of the things we have found aren't just smoking guns -- they're smoking howitzers! I cannot discuss the sealed documents, but I can give you an inkling by citing one document which was recently unsealed in connection with our ongoing motion practice.

This is a document from 1958. That's nineteen fifty-eight. It's a secret report by scientists who were sent to America by the British American Tobacco Company to study the scientific evidence about smoking and lung cancer. Here's what they knew six years before the first Surgeon General's Report:

> "Although there remains some doubt as to the proportion of the total lung cancer mortality which can fairly be attributed to smoking, scientific opinion in the U.S.A. does not now seriously doubt that the statistical correlation is real and reflects a cause and effect relationship."

(Report on Visit to U.S.A. and Canada, H.R. Bentley, D.G.I. Felton and W.W. Reid, June 11, 1958, page 8.)

That's what they knew in 1958. Six years later, when the Surgeon General first alleged a link to cancer, they were publicly outraged, -- outraged! -- at the very idea! Just three years ago, thirty-six years after they knew the truth, they were still coming before the House of Representatives and telling then-Congressman Wyden, under oath, -- under oath -- that smoking does not cause cancer.

That's one example out of 33 million pages.

This month we're closing in on the crown jewels of the conspiracy: more than one million pages of documents that have never left their secret vaults. Mr. Scruggs hasn't seen them. General Blumenthal doesn't have them. The Department of Justice doesn't have them.

Congress doesn't have them. These documents have been sheltered behind false claims of attorney-client privilege.

In our judgment, this is where the bodies are buried.

In recent weeks, we made history when we persuaded our judge that there is sufficient prima facie evidence of possible industry fraud and crime for the court to appoint a Special Master to review these secret documents in camera, to decide how many of them must be made public. That process is on a fast track. The Special Master is holding a hearing even as we speak today, and hopes to complete his review by mid-autumn.

But, the industry hopes desperately that you will act first, without seeing these documents. They want you to adopt the proposed settlement, which would terminate our lawsuit and squelch our efforts to get these documents. The proposed settlement, which purports to disclose the truth, would substitute a charade the industry tried to unsuccessfully foist on our court: a page-by-page, document-by-document mini-trial review that lets them stall disclosure for decades.

Mister Chairman, I believe you need these documents. You need to know what the industry knows about how to make cigarettes less hazardous -- and they know plenty. You need to know what the industry knows about manipulating nicotine, manipulating kids, and manipulating public policy. And they know plenty. You need to know whether they have intentionally lied to the Congress over the years. Only then will you be in a position to make good policy. Only then will you be in a position to decide what penalties are appropriate and whether they should be allowed to pass them on to their customers or deduct them on their taxes.

So, I ask the Committee to subpoena the key documents from our document depositories. Join us in prying loose the treasure trove of documents hidden behind false claims of privilege. We will be happy to work with you in going before Judge Fitzpatrick in St. Paul, to work within the framework of his protective orders, or to seek modifications if need be. We want to ensure that Congress can fashion effective national policy, so that this time we find real solutions and don't become victims of a Trojan camel.

AG:31058 v1

STATE OF MINNESOTA

OFFICE OF THE ATTORNEY GENERAL

HUBERT H. HUMPHREY III
ATTORNEY GENERAL

102 STATE CAPITOL
ST. PAUL, MN 55155-1002
TELEPHONE (612) 296-6196

TOBACCO PROPOSAL--PRELIMINARY ANALYSIS

July 18, 1997

This memorandum is a preliminary analysis of the issues raised by the proposed tobacco "settlement." The focus here is on the legal issues, but we have attempted to include major policy concerns where appropriate. The first section concentrates on the civil liability and disclosure issues, while the following sections analyze the regulatory provisions and the payment obligations built into the proposal.

I.
CIVIL LIABILITY PROVISIONS

Although many of these provisions do not come up until Title VIII of the June 20 proposal, clearly the primary consideration for the tobacco industry is the protection they would receive from liability, both from present lawsuits and from possible future claims.

A. KEY ELEMENTS OF THE PROPOSAL.

1. Termination of existing lawsuits.

Many existing lawsuits would simply be terminated, or, for all practical purposes, dismissed with prejudice by act of Congress:

- All present attorney general actions, all similar government actions (e.g., lawsuits brought by San Francisco and New York City), and all parens patriae actions;

- All present private class action lawsuits, including the post-Castano nicotine addiction cases.

The states and the private plaintiff classes, the groups who were at the negotiating table, would receive favorable financial treatment in the proposed legislation. Not faring as well in the proposed legislation are two other groups of pending lawsuits, who were not represented:

•Any third-party claims brought as class actions, whether based on subrogation or not.

•All other present "addiction"/dependence claims, which presumably includes individual claims using addiction evidence to avoid assumption of risk defenses.

Those cases will be terminated, and the state statutes and common law which permits them to proceed would be preempted, but it is not clear if they will share substantially in the financial package.

2. Restrictions on remaining present lawsuits.

The only existing lawsuits that would be permitted to continue would be claims of individuals brought by person claiming injury or heirs, not based on "addiction" or dependence;[1] third-party party (and similar) claims not based on subrogation pending as of June 9, 1997, and third-party payor (and similar) claims based on subrogation[2], but only of individual claims, not aggregates. [That is, a health insurer who paid the medical bills for an individual could file a subrogation claim against a tobacco manufacturer for that person, but could not do so for two or more individuals at the same time.]

Even those few remaining lawsuits, however, will be subject to serious restrictions:

•No punitive damages, ever, under any circumstances, based on past conduct.

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[1] Presumably, this means that plaintiffs could not assert "addiction" or dependence in their pleadings and proof, nor could they allege facts or introduce evidence of "addiction" or dependence as a response to an industry argument that the individual plaintiff assumed the risk. In effect, this would be a new federal exclusionary rule, applied to any litigation involving tobacco and health.

[2] This is of course a critical distinction for the tobacco industry. In subrogation cases, a "third party payor," typically an insurer who has paid a claim to an insured, is "subrogated" to the claims that insured individual might have against others for his injury or illness. For example, if Joe gets lung cancer from smoking, and Blue Cross pays his medical bills, Blue Cross might be able to assert a subrogation claim against the tobacco manufacturer, but then must "stand in the shoes" of Joe, which means that the tobacco company can argue, for example, that Joe assumed the risk. Third-party payor claims not based on subrogation, however, but instead based on fraud, antitrust violations, or intentional tortious conduct, like BCBSM's current case, do not face those same hurdles in court, and therefore are a much greater threat to the industry.

•No class actions, joinder, aggregations, consolidations, extrapolations, or "other devices to resolve cases other than on the basis of individual trials," without defendants' consent.

That means the courts would be unable to use many of the devices besides class action settlements they have used to help resolve "mass tort" cases, e.g. nonbinding "mini-trials," using hypothetical verdicts to induce settlements; judicial identification of "representative" plaintiffs that go to trial first, and set settlement or resolution pattern; statistical or sampling adjudication, where claimants agree to accept "averages" based on series of sample trials; or "science-only" trials to establish liability and general causation, often with epidemiological evidence, to be followed by individual adjudications (currently in progress in the silicone breast implant litigation). All of those innovations would be barred. If state courts refused to comply, the proposal calls for automatic removal to federal court, a new expansion of the jurisdiction of the federal judiciary.

•All industry defenses are preserved, including cigarette labeling act preemption defenses. There are no industry concessions on liability, causation, assumption of risk, or any other issue. There is likewise no limit on the availability of new preemption defenses based on greater FDA regulation.

•Any evidence of the development of "reduced risk" tobacco product after the effective date is neither admissible nor discoverable, another new exclusionary rule. [Note: The new Restatement on Products Liability emphasizes evidence of an ability to reduce risk not taken as the basis of liability.]

•All claims against wholesalers, distributors, retailers, advertisers, attorneys, or anyone other than tobacco manufacturing companies, their successors and assigns, future fraudulent transferees, or "entities for suit designated to survive defunct manufacturer[s]," such as liquidating trusts, are dismissed and barred. The agreement specifically refers to "tobacco manufacturing companies," so arguably the non-tobacco assets of these companies are shielded from liability. All state law, whether statutory or common-law, creating those causes of action would be preempted by the new federal statute.

•All claims against insurers (not brought by tobacco manufacturers) are barred. State law causes of action would be preempted.

•All individual claims and all pre-June 9 third-party payor claims not based on subrogation (e.g. Blue Cross-Blue Shield of Minnesota's claim, some of the Taft-Hartley health and welfare fund claims) are subject to a $1 million annual payment cap, "unless

every other judgment/settlement can be satisfied within the annual aggregate cap." For example, if BCBSM were to get a $100 million judgment against the manufacturers, it might wait 100 years for payment, or possibly longer, because of the "global" liability cap.

•The industry would be covered by a global liability cap ranging from $2 billion in year one to $5 billion in years nine and later, adjusted by the Consumer Price Index (CPI) or 3% annually, whichever is greater, and adjusted downward or upward based on domestic sales volume (downward adjustment to be reduced by 25% of any increase in overall industry profits based on domestic tobacco sales). Individuals or third-party payors who secure judgments will have to wait in line for payment, if the cap amounts are reached in any particular year.

•All successful claims against any of five negotiating companies would be paid pursuant to a "joint sharing agreement for civil liability," to limit competitive impact. Any manufacturer with a judgment or settlement to pay would obtain an 80 cents-on-the-dollar credit against other required annual payments, which effectively pools the liability industry-wide.

•The five "protocol" manufacturers would be protected from joint and several liability based on non-protocol manufacturer liability, and would be entitled to severance from any case involving non-protocol manufacturer. For example, then, the surviving spouse of a Chesterfield and Winston smoker could not proceed jointly against Liggett and RJR Nabisco, but would have to proceed separately against each, with each defendant free to try to shift the blame to the other. Moreover, if Liggett were out of business or otherwise judgment-proof, RJR could not be held responsible anything more than its share of liability, no matter what the state law on joint and several liability might be.

3. Restrictions on future litigation.

Unlike present state and private class action plaintiffs, future claimants get no financial benefit from the proposed settlement[3], but their rights are severely restricted. They are subject to all of the restrictions listed above for the present lawsuits which survive--no punitives for past conduct, no class actions or "extrapolation," no claims against anyone except "tobacco

[3] Some of the private class action lawsuits may include future claimants within their proposed class definitions, and so the impact on future claims may be uncertain. Likewise, most future claimants would likely assert fraud or damage occurring prior to the date of the "settlement".

manufacturing companies," no "addiction"/dependence claims, no evidence of "reduced risk" products, no joint actions with non-participating manufacturers, annual individual case caps, and annual global liability caps. With the exception of the ban on punitive damages, all of these restriction extend to future claims, even if they are based on future conduct of the industry. In addition, there are other restrictions:

•No future prosecution of attorney general, parens patriae, or class actions, of any kind, ever, relating to tobacco and health.

•No third-party payor (or similar) claims not based on subrogation, of any kind, whether based on past, present, or future conduct of the industry. For example, all of the health and welfare fund cases filed in the last few weeks would be barred.[4]

•No aggregation of third-party subrogation cases. Any subrogation cases must proceed based on one individual at a time.

B. ANALYSIS OF PROPOSAL.

The civil justice system has four basic purposes: the disclosure of product hazards and corporate misconduct, fair compensation for victims, punishment, and deterrence from future misconduct. If this proposal is enacted, none of those purposes will be served. The full truth about what the tobacco industry knew and when they knew it will stay under wraps, most victims (except those whose lawyers negotiated the deal) will go uncompensated or face insurmountable hurdles to asserting their claims; the industry will escape financial punishment for past misconduct; and what is likely the only truly effective incentive for the industry to take greater account of the public health--the prospect of unlimited, unknowable liability--will be lost, all of this in perpetuity. In addition, the proposal makes considerable changes in the relationship between the states and the federal government, and raises a number of significant constitutional issues.

This analysis focuses on the following general subject areas:

--Background
--Settlement of present class actions

[4] The Presidential Commission appointed to allocate unused amounts under the caps is permitted to consider applications for compensation from third-party payors making nonsubrogation claims.

--Prospective prohibition of class actions and aggregation of claims
--Bar on punitive damages
--Liability caps
--Disclosure
--Constitutional issues

1. Background.

To understand the problems with the proposed legislation, it might be helpful to have a brief background on some of the developments in the law that have brought the tobacco industry to the bargaining table and have shaped this "settlement."

First of all are the changes in state products liability law that have tended to favor plaintiffs in the past twenty-five years: the expansion of strict liability (no proof of fault required), the recognition of new categories of compensable harms (e.g. compensation for fear of future injury), the increase in the level of compensatory damages, and the relaxation of standards for awarding punitive damages.[5] Closely related to that is the greater willingness of the courts to entertain claims brought by those suffering more indirect damages, including government and private third-party payors of health care costs.

Second has been the development of techniques for bringing groups of similar cases together, i.e. the development of "mass tort" litigation--asbestos, DES, Agent Orange, Dalkon Shield, Bendectin, silicone breast implants, nuclear testing, repetitive strain disorders, and so on. Before the 1980's, class action "mass tort" litigation was relatively rare. The Advisory Committee that drafted Fed. R. Civ. P. 23 [the federal class action rule] declared in the Rule Comments that a "'mass accident' . . . is ordinarily not appropriate for a class action" because of the presence of issues like causation and affirmative defenses like assumption of the risk that affect individual class members differently, and until the mid-1980's, the courts largely adhered

[5] Although there has been some judicial and legislative retrenchment of this trend, on other fronts, the trend continues. For example, the Restatement of Torts § 402A, which imposes liability on the manufacturers of "unreasonably dangerous" products used to contain comment i, which said that it only applied to articles "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics," with the primary example being tobacco. The current committee working on the third version of the Restatement has, however, now voted to delete the "tobacco exception," and that could be expected to have its influence on the courts.

to that position. In 1986, however, the Fifth Circuit affirmed class certification in an asbestos case, Jenkins v. Raymark Industries, 782 F.2d 468 (5th Cir. 1986), and then the courts around the country began to reverse themselves--in the Agent Orange cases, In re "Agent Orange" Prod. Liab. Litig., 818 F.2d 145 (2d Cir. 1987), cert. denied, 484 U.S. 1004 (1988), and then in the Dalkon Shield cases, In re A.H. Robins Co., 880 F.2d 709 (4th Cir.), cert. denied, 493 U.S. 959 (1989).[6] What changed the courts' minds on the mass tort class action was the sheer volume of cases filed, and the perceived need to aggregate the claims somehow to achieve some measure of "rough justice" for the claimants.

Out of that has come a predictable mass tort evolutionary cycle. In the early cases, defendants have the strategic, financial, and information advantage, and tend to win. As information comes out, however, the balance often begins to shift decisively to the plaintiffs.

At that point, particular "mass torts," e.g. asbestos, become recognized lawyer specializations, and the plaintiffs' attorneys who have invested time and money in becoming experts become highly motivated to search nationwide for new claimants to represent. The cases become highly interconnected, and a success in one case on, for example, causation, or avoiding assumption of the risk, affects similar cases across the country, and increases their settlement value. At that point, the number of claimants willing to sue can begin to increase exponentially. For example, "worst case" scenarios for the number of asbestos claimants were around 100,000 in the early 1980's, but had increased to 500,000 or 600,000 by the early 1990's. The defendant manufacturers turn to mass tort defense specialists and try to coordinate their efforts, e.g. the Center for Claims Resolution (CCR), the 21 nonbankrupt asbestos manufacturers with single counsel, to match the coordinated plaintiffs' bar. Once the courts see an avalanche of cases coming, they get consolidated, the responsible judges become "managerial," and they begin to explore aggregate techniques for getting at least the common issues of liability and causation (and sometimes punitive damages) resolved on a class basis.

Third has been the growing availability of statutory causes of action, enforceable either by state government or by "private attorneys general," for violations of antitrust and consumer fraud laws, and the increasing possibility of recovering substantial penalties and damages under

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[6] Some have suggested that the U.S. Supreme Court's recent decision in Amchem Products v. Windsor [Georgine], 65 U.S.L.W. 4635, 1997 WL 345149 (U.S., June 25, 1997) will significantly limit the availability of the "mass tort" class action. To the contrary, what the Court did in Amchem is reject "futures only" class settlements, where future claims are sacrificed for present claims, and direct the courts to use subclasses to avoid single law firms representing different groups with directly conflicting interests.

those statutes. In Minnesota, for example, the legislature has eliminated the "indirect purchaser" and "pass through" defenses to antitrust;[7] and has granted broad private standing to enforce the unfair discrimination and competition, deceptive trade practices, and false statement in advertising statutes. Moreover, the Minnesota courts have very broadly construed these provisions to enhance consumer protection, expanding the connection between conduct and injury necessary to permit suit, rejecting efforts to elevate the standard of proof, and ordering a wide range of remedies, including restitution, disgorgement of unjust enrichment, multiple civil penalties[8], and attorney fees. See State v. Alpine Air Products, Inc., 500 N.W.2d 788 (Minn. 1993); see also State ex rel. Humphrey v. Philip Morris, Inc., 551 N.W.2d 490 (Minn. 1996)(Court upholding availability of these theories and remedies to both public and private plaintiffs in tobacco case).

Fourth has been the production of industry documents through discovery that show an arguably unprecedented pattern of unlawful conduct. In the Minnesota case, the industry has produced some 33 million pages of documents, held in storage depositories in Minneapolis and London, and in early May 1997, the judge ruled that Minnesota had made a threshold showing that it was entitled to see nearly 250,000 documents and over one million pages under the exception to the attorney-client privilege applicable when a crime or fraud may have been committed. Those documents are currently under in camera review by a special master, with rulings expected later this year. As that information comes forward, in Minnesota's litigation and then across the country, the informational advantage favoring the industry will have shifted considerably.

All of these trends have done a great deal to shift the balance of power from defendants to plaintiffs in these cases, at least in certain states. Unfortunately, some of these developments--particularly the development of the mass tort settlement class action have also created the circumstances for collusion--"repeat players," all with an incentive to settle early[9]; often a single

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[7] 1984 Minn. Laws, sec. 458, sec. 1 (response to Illinois Brick Co. v. Illinois, 431 U.S. 720, 97 S.Ct. 2061 (1977)).

[8] Minnesota authorizes $25,000 civil penalties per violation of the consumer fraud laws, and $50,000 per violation of the antitrust laws, and the courts have construed "violation" to allow for the multiplication of penalties for patterns of illegal conduct.

[9] For plaintiffs' counsel, early settlement can mean early, and substantial fees, with less investment of time and resources. For defendants, early settlement can preclude tipping of the balance of power to plaintiffs, can avoid the perils of bankruptcy, and can provide all of the spinoff benefits of greater certainty about liability. For courts, early settlement is a way to clear the docket, and to avoid a mind-numbing series of near-identical trials on the same subject.

forum with a judge eager to get a "global" settlement; and passive future claimants whose rights can be affected without their knowing it.[10] As a result, the courts have had to confront (and have sometimes embraced) inventory settlements, where plaintiffs' counsel get present clients and themselves favorable terms, in exchange for "global" settlement of all future claims on terms favorable to defendants; double-dipping, where plaintiffs' counsel get class attorney fees, plus later fees for representing individuals in negotiated claims resolution process; front-loading claim funds, so present claimants and fees are taken care of early, at expense of future claimants, eligibility restrictions and illusory benefits.[11]

The ultimate result is the Georgine process:[12] defendants facing uncertain and potentially devastating liability contact certain plaintiffs' class counsel (who they have likely worked with before, and who they know have a strong incentive to settle early) before lawsuits are filed, reach "global" agreement favorable to current clients but unfavorable to future claimants, and then file a complaint, motion for class certification, and settlement with a receptive court, all on the same day.

With the U.S. Supreme Court's decision in Georgine the last week of this past Term, fewer federal courts will approve mass tort settlement class actions, and no court could or would approve the kind of settlement negotiated by the attorneys general and the private class counsel--

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[10] Many commentators have written about this topic. E.g. Coffee, Class Wars: The Dilemma of the Mass Tort Class Action, 95 Colum. L. Rev. 1344 (1995). A letter signed by 144 law professors to the Judicial Conference's Rules Committee, opposing Rule 23 amendments which would expressly sanction settlement class actions, in a section called "Inviting Collusion," says that the rule change would "license[] a regime under which plaintiffs' lawyers are encouraged to compete to sell out the claims of people in order to gain the defendant's acquiescence to a ... class." Their view was cited in Justice Ginsburg's opinion for the Court in Amchem Products v. Windsor [Georgine], 65 U.S.L.W. 4635, 1997 WL 345149 (U.S., June 25, 1997).

[11] Prof. Carrington has identified what he calls "significant wealth transfers" inherent in settlement class actions--the shift in the burden of the transactions costs of evaluating individual claims from the defendants to the claimants, the transfer of wealth from those with stronger cases to those with weaker ones, and the transfer of wealth to leading class action lawyers "who amass large fortunes in short periods at the bar" from lawyers who would otherwise present the claims of individual clients. See letter of Paul D. Carrington to Judicial Conference Rules Committee, cited in Amchem, at ____.

[12] Georgine is the asbestos settlement which the U.S. Supreme Court recently rejected in Amchem Products, Inc. v. Windsor.

paying off present claimants in exchange for limiting the rights of future claimants.[13] Hence, the issue goes to Congress, which may have greater power to adjust the rights of different classes of individuals on this kind of macro level[14], but which must also face the fundamental due process and equal protection issues that were not directly addressed in Georgine.

2. Settlement of present class actions.

The proposal calls for all present class action lawsuits involving tobacco and health to be "legislatively settled," without any further discussion. At present, there are somewhere between 15 and 20 Castano-like class actions pending in state courts around the country, there is the Florida secondhand smoke lawsuit on behalf of a class of flight attendants, where the trial is now underway, and there are a number of third-party payor actions filed before the June 9 cutoff which are proceeding on at least a purported class basis.

Although the public information about this is limited, the idea of a legislatively-imposed settlement of the present class actions raises a number of obvious concerns and questions:

- How many people are included in the purported classes? Do the post-Castano class action lawsuits include most or all of the smokers that were in the original federal court class definition? Do they include potential future claimants as well as present claimants? Will even the limited rights to sue supposedly preserved in the "settlement" be extinguished or limited further by these "side agreements"?

- Is it intended that this be a "no opt out" settlement for class members (as in the Ahearn asbestos settlement negotiated by many of these same lawyers)?[15] If class members can opt out, are they governed by all other restrictions on future claimants?

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[13] Indeed, Congress recognized this issue in 1994, when it adopted amendments to the Bankruptcy Code to allow bankruptcy courts to consider and preclude future tort claims against the bankrupt entity. Congress insisted that any such resolution must meet two standards--future claimants must be treated in a manner similar to present claimants, and there must be assurance that there are funds available to pay their claims. 11 U.S.C. § 524(g), (h) (1994), as amended by section 111, Bankruptcy Reform Act of 1994.

[14] Still open is the question of whether the federal courts can exercise jurisdiction over future claimants, who may not have standing sufficient to satisfy Article III justiciability requirements.

[15] See In re Asbestos Litigation: Flanagan v. Ahearn, 90 F.3d 963 (5th Cir. 1996). The approval of that "futures only" class settlement is now highly questionable after Georgine.

•Is it intended that the attorneys will negotiate some kind of administrative compensation scheme for present claimants? If so, how will different kinds of claims (e.g. serious lung cancer now vs. pre-cancer indicators vs. fear of cancer and so on) be decided, and by whom? Will any new compensation system be available to future claimants? If so, what assurances are there that the fund will be adequate to pay those claims as well?

•If future claims have been sacrificed to benefit present claimants, do negotiators have a conflict of interest that raises ethical concerns? Obviously, those losing otherwise viable claims were not consulted by the negotiators.

•What are the proposed class attorney fee arrangements, and are they appropriate?

We will not be able to provide answers to these questions until we have more detail about these "side" agreements, but these are good questions to at least start the inquiry.

3. Impact of prohibition on class actions or other aggregation of claims.

Under current rules, in order to proceed as a class action, several criteria must be met: numerosity, commonality, typicality, and adequate representation, Fed. R. Civ. P. 23(a), and the court must be able to find "that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action if superior to other available methods for the fair and efficient adjudication of the controversy." Id., 23(b)(3). To make that determination, judges are to consider: (1) the interests of members of the class in individually controlling the prosecution or defense of separate actions; (2) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (3) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (4) the difficulties likely to be encountered in the management of a class action.

Therefore, what the proposal recommends is that, even for cases where there are too many claimants to join them all, where the questions of law or fact in common predominate over the individual issues, where the representative claims are typical, where the representation is adequate, where the individual interest in controlling claims is limited, the litigation history suggests class treatment, it is desirable to concentrate the cases in one forum, and the class action is manageable, even under all those circumstances, the class action device will be barred anyway, even if only used for particular issues. Moreover, all of the other techniques for aggregating claims will be barred as well.

On balance, the prohibition on class actions and claim aggregation will likely have the following effects:

•It will discourage most potential victims from filing suit, and few law firms will choose to make the financial and human capital investment necessary to become expert in bringing these cases and going out and getting an inventory of plaintiffs. The costs of litigation against the tobacco industry are high, the evidentiary burden is substantial (for example, epidemiological evidence is much more likely to be admitted in class or representative cases than in individual cases, even though it can be highly probative on issues of causation), and realistically, those costs can only be borne by lawyers who might be able to share in class damages awards. Even a plaintiff with $1 million in damages would have difficulty getting an attorney, since few lawyers, under normal contingency fee arrangements, could make such a case pay with the kind of aggressive defense typical of the tobacco industry.

•If the history of other "mass tort" litigation is a guide, most claimants do not come forward until the liability picture has tipped decisively toward plaintiffs, which is much less likely if class or consolidated litigation is precluded.

•Even, however, if the number of individual tobacco cases remains high, and even if, with new evidence and successful trial strategies, the balance shifts toward plaintiffs, and the avalanche of cases the industry fears comes to pass, the prohibition on class and aggregative procedures simply guarantees that the courts would not be able to manage the caseload except on defendants' terms, either by dismissing cases, delaying their prosecution, or forcing settlements favorable to defendants. Consolidation in single forums, representative cases, consolidated liability, causation, or punitive trials, statistical sampling, "reversed bifurcation," and other innovative techniques would be unavailable to the judiciary. Therefore, even if the cases continue, the likelihood of fair results is very low, and would only get worse as future claimants come into the picture.

4. Bar on punitive damages.

An absolute bar on punitives for past conduct, no matter how egregious the conduct, preempting all applicable state law on the issue, would be an extraordinary decision on the part of Congress.[16] Particularly with class and consolidated actions prohibited, punitive damages attached to individual claims may be the only way to attract attorneys to these cases, and the threat of punitives certainly would be the only way the civil justice system could still serve its deterrent purpose.

[16] In comparison, the products liability reform bill vetoed by the President last year would have imposed a $250,000 punitives cap (or twice the economic damages) in an individual case.

There is, of course, a case to be made against unlimited punitive damages, particularly the prospect of repeated punitive awards in whole series of similar cases that end up killing rather than just stinging the offending companies. Some judges have therefore used class actions to resolve punitive damages claims together, and, conceptually, a single or a series of aggregated punitive damages award against the tobacco industry could be justified.

Of course, such an award would actually have to punish the industry, that is, be high enough to affect shareholder equity significantly, and with restrictions to make it less likely that the punitive liability could be laid off on either consumers, insurers, or taxpayers. Clearly, the figures contained in the proposed settlement and the requirement that those payments be passed through to consumers through a per-pack charge do not meet those criteria, on any level.

5. Liability caps.

With the restrictions on the kind of litigation the industry may face, the liability caps may well be largely immaterial. Nevertheless, there are concerns to be raised:

•Precedent: No other industry has a global liability cap, not even those with per-case caps like the vaccine manufacturers. If Congress is prepared to offer that to tobacco, they can expect other industries with liability concerns to seek similar or better treatment.

•By definition, of course, all global liability or "case flow" caps discourage and discriminate against future claimants in favor of present ones, because of the prospect of payment delay.

•With liability caps and industry liability pooling arrangements in place, any adverse liability experience for any particular company is unlikely to have any competitive impact, so the threat of competitive consequences for misconduct or set of incentives is removed.

•The value to the industry of certainty about liability, even at very high figures, would be difficult to underestimate: increases in shareholder value, reallocation of management focus, removal of "fraudulent conveyance" barriers to tobacco "spin-offs," greater or more secure access to long-term financing, and so on.

•If Congress were to remove the limits on class or consolidated actions, or eliminate or modify the punitive damages bar, the $2-5 billion annual payments would likely be low. It would initially be less than 2% of what CDC estimates the total annual harm to be, and could easily be consumed by only a handful of judgments, e.g. the Florida flight attendants' secondhand smoke case, or a single union health and welfare fund case. Prior "mass tort" settlement funds have invariably proven to be inadequately funded, and become insolvent quickly once the liability picture shifts toward plaintiffs. If the fund

becomes insolvent, the possibility of successful constitutional challenges to the abrogation of common-law rights becomes greater.

•The payment levels contemplated by the proposal are, of course, much less than what the industry can afford, particularly with the appreciation in stock prices (20% during the negotiations alone), continued growth in international sales and the revenue-raising elements built right into the proposal:

- ♦Mandatory pass-through of costs to consumers through price increases
- ♦Tax deductibility of all costs, whether punitive in nature or not
- ♦Reduction in advertising expenses [current level: $6 billion annually]
- ♦Reduction in legal expenses.

Several analyses have concluded that the industry could increase prices by $2 a pack or more without sacrificing any significant profitability from decreased demand. Such a figure would generate at least $32 billion a year, again without affecting either shareholder equity or industry profitability.

6. Disclosure.

The proposal establishes a new centralized document depository in Washington, D.C., which will contain the documents produced so far in the Minnesota litigation.[17] Those documents will be available to Congress, state and federal agencies, and the public under certain conditions.

The industry, however, would be permitted to withhold any document for which it asserts attorney-client privilege, work product, or trade secret protection.[18] They would be permitted to conduct a new document-by-document review of everything previously withheld on grounds of privilege (hundreds of thousands of documents, over 1 million pages), and then create new privilege logs for that data.

At that undetermined future date, when the new industry review is completed, anyone who wishes to challenge the industry's continued assertion of privilege or trade secret must file a claim with a new three-judge panel of Article III judges appointed by the Judicial Conference. The decision will be binding on all state and federal courts in all litigation in the United States,

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[17] Or in any other case, although the Minnesota discovery effort has been the most comprehensive.

[18] Compare the present situation in Minnesota, where the judge and a special master are conducting an in camera review of those documents under the "crime/fraud" exception to the attorney-client privilege.

and may be reviewed only by a certiorari petition to the U.S. Supreme Court under 28 U.S.C. § 1254. The only exception would be for disputes that have already been "resolved" by other state or federal courts prior to the time the three-judge panel has had the opportunity to review privilege claims.[19]

The panel will review claims of privilege or trade secret protection, not according to applicable state law, but rather under the ABA/ALI Model Rules and/or federal common law with respect to privilege, and the Uniform Trade Secrets Act with respect to trade secrecy. The panel may appoint tobacco industry-funded special masters, and, if the decision is to order disclosure, the panel can consider awarding costs, fees, or other sanctions.

The likely result of these provisions is that the discovery process nearing completion in Minnesota would be short-circuited, and jurisdiction wrested from our state court system to the new three-judge federal panel. Meanwhile, any surviving or prospective litigation would presumably have to continue while litigation in the new federal forum over document production takes place. If one of the central goals of the civil justice system is to force disclosure of product hazards and industry misconduct, this proposal is a significant step backward.

7. Constitutional issues.

Our research is still quite preliminary on these issues, and we have reached no conclusions, but some of the major constitutional questions presented by this proposal should be relatively obvious:

(a.) Tenth Amendment [or more precisely, the Constitution's system of "dual sovereignty"]: The source of authority for Congress to take these actions would presumably be the Commerce Clause, and obviously the authority of Congress to regulate commerce among the states and, under the Supremacy Clause, to preempt conflicting state laws, remains substantial. The Supreme Court has, however, now made it clear that, despite that authority, the federal government may not commandeer the states to accomplish federal purposes. Printz v. United States, No. 95-1478 (U.S., June 27, 1997)(Brady Act); New York v. United States, 505 U.S. 144 (1992)(Low-Level Radioactive Waste Policy Amendments). The proposal would have Congress directing the 50 state court systems to, in effect, change their rules of civil procedure and their rules of evidence governing state-law claims. If state courts refuse to comply, the consequence then is that the federal courts take jurisdiction through removal[20], although how these state law claims would, absent diversity, become claims arising under the "laws of the United States"

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[19] "Resolved" is undefined, but presumably that means appeals have been exhausted.

[20] We presume this is intended to fit this provision within the exception contained in New York, allowing the federal government to order states to implement regulatory programs, if states can opt out and a federal agency steps in to take the enforcement responsibility.

under the well-pleaded complaint rule and therefore come within the federal courts' Article III, section 2 authority is not completely clear.

State courts of course have to comply with federal law, but Congress directing them how and under what circumstances to adjudicate state-law cases might be a qualitatively different assertion of federal power, and raise significant Tenth Amendment and constitutional federalism concerns. Of course, even if the courts did not strike the statute down, the proper scope of federal preemption of state legislation, state court rules, and state causes of action, both statutory and common-law, and the precedent of that policy decision, are certainly topics Congress should consider.

(b.) Due process/equal protection: The proposal would substantially restrict citizen access to the courts, and would eliminate or curtail a number of both pending and prospective state court claims. In particular, at least two elements of the proposal raise substantive due process concerns--the elimination of entire causes of action and the granting of immunity without substitute avenues of redress, and the possibility of claimants being bound by legislatively imposed "settlements" without an effective opportunity to opt out. Likewise, distinctions in the treatment of claimants based solely on the time of filing (present vs. future) may raise equal protection issues, particularly when it involves quasi-fundamental rights such as access to courts.

The Supreme Court has noted that "statutes limiting liability are relatively commonplace and have consistently been enforced by the courts," Duke Power Co. v. Carolina Environmental Study Group, 438 U.S. 59, 88 n. 32, 98 S.Ct. 2620, 2638 n. 32 (1978), and that the "Constitution does not forbid the creation of new rights, or the abolition of old ones recognized by the common law, to obtain a permissible legislative object." Id. (upholding nuclear industry liability limits in Price-Anderson Act); see also Cipollone v. Liggett Group, Inc., 505 U.S. 504, 530-31, 112 S.Ct. 2608, 2625 (1992) (allowing preemption of state failure-to-warn claims).

There are limits, however. The Court has expressed its hostility to the idea of Congress setting aside final judgments, on the grounds that the "Constitution's separation of legislative and judicial powers denies it the authority to do so." Plaut v. Spendthrift Farm, Inc., 115 S.Ct. 1447, 1463 (1995). Moreover, the Court has at least left open the question of whether the due process clause requires some reasonably just substitute for common-law rights replaced by a new federal statute. Duke Power, 438 U.S. at 93, 98 S.Ct. at 2640-41. As Justice White noted in a dissent from dismissal of an appeal in 1985, "[w]hether due process requires a legislatively enacted compensation scheme to be a quid pro quo for the common-law or state-law remedy it replaces, and if so, how adequate it must be, appears to be an issue unresolved by this Court, and one which is dividing the appellate and highest courts of several States." Fein v. Permanente Medical Group, 474 U.S. 892, 894-95, 106 S.Ct. 214, 216 (1985)(White, J.); see also Pruneyard Shopping Center v. Robins, 447 U.S. 74, 94, 100 S.Ct. 2035, 2047 (1980)(Marshall, J., concurring); Cipollone, 505 U.S. at 541, 112 S.Ct. at 2630 (1992) (Blackmun, J., concurring in part and dissenting in part, joined by Souter, J. and Kennedy, J.) Depending on the

circumstances governing present and future claimants, that issue may be tested if this proposal is enacted into law.

(c.) Right to a jury trial: The Seventh Amendment provides that "[i]n suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved." This would apply only to actions in federal court, but again there is the question of whether Congress can direct states to eliminate their own right to a jury trial in state-law cases. In the federal court cases, the Supreme Court has held that Congress cannot take away that right if the cause of action is legal and if it involves a matter of "private right." Granfinanciera, S.A. v. Nordberg, 492 U.S. 33, 109 S.Ct. 2782 (1989); see also Atlas Roofing Co. v. OSHRC, 430 U.S. 442, 97 S.Ct. 1261 (1977). Of course, the courts have been divided on whether damages limitations violate the Seventh Amendment, and particularly when the limits extend to compensatory and out-of-pocket damages, some courts might be more likely to find an infringement of the right to a jury trial. If the proposed private class action "legislative settlements" include mandatory, "cram down," "no opt out" arrangements, that may also raise significant Seventh Amendment issues.

(d.) First Amendment: Obviously, the advertising and marketing restrictions raise "commercial speech" issues. See generally 44 Liquormart, Inc. v. Rhode Island, 116 S.Ct. 1495 (1996); Central Hudson Gas & Electric Corp. v. Public Service Comm'n, 447 U.S. 557 (1980). The proponents of the "settlement" claim that by incorporating the manufacturers' waiver of First Amendment rights in consent decrees that they can insulate the new rules from First Amendment review. Given the relatively relaxed nature of First Amendment standing, however, and the number of different, non-tobacco parties who have an interest in challenging content-based marketing restrictions, it seems likely that the First Amendment issues will be resolved judicially, no matter how hard the parties try to keep those questions away from the courts.

II.
FDA

A. FDA PRODUCT SAFETY STANDARDS.

The FDA has asserted jurisdiction to regulate nicotine as a "drug" and tobacco products as drug delivery "devices," and Judge Osteen in North Carolina ruled that the courts should defer to that judgment. Coyne Beahm, Inc. v. FDA, Civ. No. 95CV00591 (M.D.N.C. April 25, 1997). Under the proposal, however, unlike any other "drug" or "device," the FDA would not have authority to ban, 21 USC § 360f, deem as misbranded, 21 USC § 352(j), or recall, 21 USC § 360h(e), tobacco products under current statutory health standards. Likewise, FDA would be able to promulgate performance standards to regulate the contents of the product, as they can with any drug, but only subject to the following special restrictions:

•No elimination, and no non-"gradual" reduction of nicotine yields for no fewer than twelve years;

•No reduction in nicotine, and no elimination of "other constituents or other harmful components" unless FDA can find the modification: (a) will result in a significant reduction of the health risks associated with such products to consumers thereof [cf. current standard--to provide reasonable assurance of safe and effective performance]; (b) is technologically feasible; and (c) will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard.

•New procedural requirements: formal rulemaking under APA[21] (trial-type hearings, right to introduce direct and rebuttal evidence through oral testimony, right to cross-examination, agency decision based on "substantial evidence" developed at the hearing), burden of proof on FDA for all findings, cf. 21 CFR § 12.86, full judicial review under less deferential standard (not "arbitrary and capricious" but "deference to extent to which matter at issue is within Agency's field of expertise"), and Congressional "regulatory reform" review.

•Other new requirements after 12 years, when FDA could eliminate nicotine or other harmful ingredients: same new substantive standards, "preponderance of evidence" burden, rather than "substantial evidence," manufacturer [apparently, each and every single manufacturer] can select rulemaking process, judicial review of original decision and all subsequent petitions to amend, minimum two-year phase-in [cf. current one-year or earlier], and Congressional review.

These restrictions, of course, apply to no other "drug" or "device," and they impose a virtually impossible burden for FDA to overcome, both the substantive standards and the procedural requirements. They are also directly contrary to the negotiators' publicly stated goals and what the Koop-Kessler Commission recommends: full and unfettered FDA authority to do whatever is necessary under current statutory authority to solve the problems of tobacco and the public health.

B. MARKETING AND ADVERTISING RESTRICTIONS.

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[21] The proposal refers to the Administrative Procedures Act, presumably 5 USC §§ 556, 557, although the FDA has its own "Part 12" hearing process, 21 CFR pt. 12, which is also quite formal but perhaps less so than the formal process described in the APA. Under current law, however, FDA uses notice-and-comment rulemaking, 5 USC § 553, to promulgate performance standards, which allows them to incorporate their expertise and what they have learned from all sources to craft the rule, rather than serving as the impartial arbiter at a trial-type hearing.

The proposal incorporates existing FDA regulations, and adds prohibitions on the use of human images and cartoon characters, extends the advertising ban to stadia and ads directed outside from retail locations, further restricts point of sale ads, bans movie and TV product placement payments, and the direct or indirect "glamorization" of tobacco use in media appeals to minors.

The effectiveness and significance of advertising and marketing restrictions remains controversial, but the following additional issues should be noted:

- The proposed regulations go beyond current FDA regulation, but they do not necessarily expand the FDA's current authority to regulate.

- No penalties are provided for violations--no civil penalties, no actual damages, no attorney fees, no private enforcement standing.

- Some of the restrictions may be illusory. For example, the point-of-sale advertising restrictions would permit outlets such as convenience stores to display ten 2' x 2' signs--40 square feet of point-of-sale advertising messages.

- FDA would be prohibited except under "extraordinary circumstances" to alter the restrictions for five years. With the burden of proof on the agency, and the opportunity for litigation that presents, that might limit their ability to regulate, for example, direct mail, which appears to be the tobacco industry's next advertising frontier.

- The proposal would continue to permit brand logo advertising on the package, with teens being particularly brand sensitive.

- Finally, no matter what is included in consent decrees, nonparties to the agreements cannot be bound by them, and will be able to raise any applicable First Amendment arguments.

C. WARNINGS, LABELING, AND PACKAGING.

The proposal provides new, rotating warning on cigarettes and smokeless packages. The warnings would occupy 25% of the front package panel [smaller on certain flip-top boxes]. The FDA would be required to promulgate rules governing the testing, reporting and disclosure of tobacco smoke constituents.

Again, as with advertising and marketing restrictions, the issue of whether warning labels deter smoking is controversial. There are other critical points, however:

•The preemption language in the Federal Cigarette Labeling and Advertising Act would not be repealed.

•The rulemaking proceeding provides another opportunity to dispute, litigate, delay, and possibly dilute the proposed standards.

•The new warnings may well strengthen the industry's assumption of risk defense in individual cases, and may therefore benefit the industry more than consumers.

D. LICENSING OF RETAIL TOBACCO PRODUCT SELLERS.

The proposal would mandate minimum federal standards for licensing, to be enforced by federal, state, and local authorities and funded by the industry payments. Anyone selling tobacco products directly to consumers would need a license, and the penalties for violations are set forth in appendix II.

The primary problem with this provision is preemption. The penalty scheme would expressly preempt more stringent state and local sanctions, such as the ones recently signed into law in Minnesota. Moreover, the substantive law here may not be adequate; arguably, it is only a return to programs like Philip Morris's "retailer sanctions" program, which was notably ineffective.

E. NON-TOBACCO INGREDIENTS.

Under the proposal, manufacturers would disclose ingredient information to the public "under regulations comparable to what current federal law requires for food products." They would also provide confidential lists of added ingredients, substances and compounds to FDA, by quantity in each brand. Manufacturers would have five years, for each ingredient, to provide a safety assessment, consistent with new regulations to be promulgated. The FDA then has 90 days to approve or disapprove; the failure to disapprove constitutes approval. Not all ingredients would have to be publicly disclosed under the food laws, and nondisclosable information would be kept confidential. Companies would be required to adopt procedures for the selection, testing, and use of ingredients.

Although this would give FDA clearer statutory authority, the proposal imposes significant obstacles, which would make effective regulation nearly impossible:

•Five years for the industry to analyze what they likely already know, and then 90 days for the FDA to digest and review the mountain of documentation that would likely be produced is unbalanced. A much shorter time frame should be imposed on the industry, with FDA given the authority to act without restriction as reliable information becomes available.

•There is ambiguity about whether the ingredient disclosure requirements refer to the components of tobacco, or the components of tobacco smoke. Some non-tobacco ingredients are perfectly safe if eaten, but harmful if burned and inhaled.

•There is a five-year preemption of state content disclosure laws, such as those enacted in Massachusetts and Minnesota. [The preemption language is in Title V.]

III.
COMPLIANCE AND CORPORATE CULTURE

The proposal would require the industry to create annually reviewed compliance plans to identify ways to reduce youth consumption, and provide incentives for the development of reduced risk products, to protect whistleblowers as permitted by current federal law, to promulgate corporate principles, designate compliance officers, and report to shareholders on progress, to inform lobbyists about the new requirements and limit their activities except as expressly authorized by the manufacturers, and to subject individual companies to fines and "scarlet letter" advertising for breach of their obligations.

The substantive change in this section is the requirement that the Tobacco Institute and the Council for Tobacco Research be disbanded, a remedy that is consistent with antitrust practice in similar cases. The regulations to prevent re-formation of these groups may be inadequate, however:

•No requirement that records be turned over to receiver (or FDA), who would in turn disclose evidence of misconduct;

•No regulatory or public interest representation on any new group's board; and

•No open records and visitation rights for DOJ, FTC, or states.

IV.
"LOOK BACK" PROVISIONS AND STATE ENFORCEMENT INCENTIVES

A. CONTENTS OF PROPOSAL.

Title II of the proposal contains three provisions intended to reduce youth smoking:

•Targets for the reduction of underage tobacco use, with separate criteria for cigarettes and smokeless tobacco. The targets are based on a "base percentage" of underage smokers age 13 and up who smoke (in the case of cigarettes) on a daily basis.

•Sanctions, in the form of "mandatory" FDA-imposed surcharges for failure to meet the targets. The sanctions are subject to rebates for good-faith attempt to comply.

•A state enforcement scheme, including funding for enforcement, but also significant sanctions for states where the tobacco industry fails to meet youth access reduction targets.

The tobacco use reduction targets are:

	Year 5	Year 7	Year 10
Cigarettes	30%	50%	60%
Smokeless	25%	35%	45%

Reduction will be measured from estimated levels over the last decade.

B. ANALYSIS.

Although the stated purpose is "to achieve dramatic and immediate reductions in the number of underage consumers," the targeted reductions are neither dramatic nor immediate.

•The target reduction levels are too low. The baseline percentage--those children age 13-17 who smoke every day--is artificially low, compared to the data collected by the CDC's Youth Risk Behavior Surveillance System (YRBSS), which indicate that 35% of students in grades 9 through 12 have smoked at least once in the last thirty days, and that 16% have smoked on 20 or more of the last 30 days. The YRBBS does not have a category for daily users under 18.

Moreover, even if a different base percentage were used, the targets are low. We have supported the following goals--20% reduction after two years, with annual 20% reductions thereafter until the sixth year, when the final 10% target would be achieved.

Penalties would be $1 per pack for the first violation, rising an extra dollar for consecutive years' violations, with the revenue targeted to tobacco enforcement and education.

•The first "look back" measurement is late. For the same five years when FDA regulations would be frozen and state content disclosure laws preempted, there would be no incentive for reducing youth smoking.

•The permissible FDA surcharge would not discourage the tobacco industry from marketing to children. The combination of the following factors make the "look back" penalties inadequate:

- The $2 billion yearly cap on penalties;
- The full tax deductibility of the penalty amounts;
- The "joint and several liability" of the manufacturers, payable in proportion to market share, which eliminates individual brand or manufacturer accountability and even creates an incentive for some of the companies to gain a disproportionate share of the youth market.
- The availability of abatements of the surcharge if the industry has "acted in good faith and in full compliance with" applicable law, and "pursued all reasonably available measures" to meet the target. Litigation over any abatement petition delays the distribution of the money to state and local public health agencies.

•The state enforcement incentives would penalize the states for tobacco industry misconduct. Under Appendix VI, states must conduct a youth access enforcement campaign which includes a no-sales-to-minors act; random, unannounced inspections of retailers at least monthly; at least 250 such inspections per year for each million of population; annual reports to the FDA; and designation of a "single state agency" accountable for results.

That is all appropriate, but the proposal also provides for a reduction in grant money to the states if the tobacco industry does not meet the targeted goals. Since the sanctions will leave ample incentive for the industry to continue to sell to kids, subjecting state enforcement mechanisms to reduced funding precisely where the industry's marketing to kids is most effective does not seem to be sound policy.

V.
PENALTIES AND ENFORCEMENT

The legislation would be enforceable by the states and the federal government (and FDA could contract authority to the states). States could proceed under consumer protection "or

similar statute[s]" but could not "impose obligations or requirements beyond those imposed by the legislation (except where it does not specifically preempt additional state-law obligations), and would be limited to" penalties provided. Moreover, state enforcement proceedings under the Act or "predicated on conduct violating the Act" would be removable to federal court.

Certain terms would also be included in consent decrees--marketing restrictions, trade association dissolution, lobbying restrictions, tobacco smoke constituent and ingredient disclosure, money payment obligations for the states' "reasonable shares" and similar terms. Excluded are product design and testing, manufacturing standards, and the "look back" provisions. The states, however, would only be entitled to seek injunctive relief for violations

Difficulties with this provision include the following:

•Preemption: This is unclear, but it appears that state consumer protection enforcement would go to federal court, be limited in its breadth and interpretation by the substance of the new federal act, and be limited by the penalties of the Act.

•Federalism: The removal provisions are an unwarranted infringement on state sovereignty and expansion of federal court jurisdiction.

•Limits on remedies: The injunctive-relief-only provision discourages state enforcement, and removes the deterrent effect of civil penalties, damages, and possible fee and cost recovery.

VI.
ENVIRONMENTAL TOBACCO SMOKE

The proposal would establish minimum federal standards for smoking in public places and workplaces, without preempting stricter state or local standards. A "public place" is any building "regularly entered by ten or more individuals at least one day per week." Smoking would only be allowed in areas with a direct outside exhaust, maintained at negative pressure compared to surrounding areas, and with no recirculation of air.

No employee would be required to enter a smoking area while smoking is occurring. Bars and restaurants, except fast food establishments, are exempt. OSHA would be required to issue and enforce standards, with enforcement funded from industry payments.

These provisions retreat from the indoor air quality (IAQ) standard OSHA noticed in April 1994 in the following ways:

•The OSHA standard would cover restaurants, bars and hotels; the settlement would exempt them [except for "fast food restaurants" catering largely to minors].

•The OSHA standard would require enclosed ventilated areas under negative pressure, i.e. separate rooms for smoking. The settlement does not require the smoking areas to be separately enclosed.

•The OSHA standard would require posted signs stating that smoking is restricted to designated areas; the settlement does not.

•The OSHA standard would apply to "all indoor nonindustrial work environments"; the settlement would only apply to "public places."

In addition, the costs of enforcement would come out of the total settlement fund, which would reduce the amount available for victims.

VII.
SCOPE AND EFFECT

Title V of the proposal contains two major difficulties:

•It limits the proposal to "all product sold in U.S. commerce," which means that, despite Congress's constitutional authority under the Foreign Commerce Clause, international marketing is left unregulated.

•It purports to preserve state and local authority, but it in fact preempts state and local authority in several respects:

- ♦ It preempts more restrictive state and local youth access and retailer licensing laws, and preempts harsher state and local penalties;
- ♦ It preserves FDCA preemption of state advertising restrictions.
- ♦ It curtails state ability to set manufacturing performance standards.
- ♦ It freezes state content disclosure laws for five years after its effective date (achieving in Congress what the industry has not been able to achieve in some state legislatures and in the courts).

VIII.
INDUSTRY PAYMENTS

The cash value of the "settlement" has been advertised as $368.5 billion over 25 years, which is an arbitrary number because the payments and the limitations on the civil justice system and state law continue in perpetuity. The basic elements of the proposal are as follows:

•When the President signs the bill, the industry makes a $10 billion lump sum cash payment, which appears to go to the states [allocation to be determined later].

•On December 31, 1998[22], $8.5 billion--a $6 billion "base amount" and $2.5 billion for a new public health trust.

•After that, the payment schedule looks like this:

Year	2	3	4	5	6	7	8	9	10+
Base	$7B	8	10	10	12.5	12.5	12.5	15	15
Trust	$2.5B	3.5	4	5	2.5	2.5	2.5	-	-
Total	$9.5B	11.5	14	15	15	15	15	15	15

Payments will increase by 3% or CPI each year, whichever is greater, applied to the previous year's payment. If the volume of sales decreases from 1996 levels, then payments are reduced, with the possibility of an increase back if profitability increases despite the volume decline. Payments would also have priority in bankruptcy, and the industry could not reject its payment obligations in a bankruptcy reorganization.

Two other salient points:

•The legislation would "provide" that all industry payments "be reflected in the prices manufacturers charge for tobacco products," which means passed through to tobacco consumers. This is essentially a new antitrust exemption for tobacco pricing.

•None of the payments will be deemed fines or penalties, and all payments (including expressly the youth lookback penalties) are deemed to be ordinary and necessary business expenses and therefore tax deductible. With the projected reductions in advertising expenses and legal costs, most of the payment amounts will either come out of new industry savings or from taxpayers, with the balance passed through to consumers. The risk to manufacturer assets and equity appears to be virtually zero.

Likewise, as described above in the civil liability discussion, the sharing of the liability on a participating industry basis (plus the credit against scheduled payment amounts) removes any competitive consequences from adverse litigation outcomes, and reduces substantially any incentive to change industry practices.

[22] This would be the date if the legislation passed in 1997; if not, the date would be December 31, 1999.

In addition, also as described above, given the ability of the industry to pay and to pass through the costs of any new payment obligation, the amount of the payment obligations is quite low. Again, the relevant comparison figure would be the $32 billion a year that a $2 a pack increase would generate, plus an any assessment based on assets and outstanding capitalization.

AG:31072 v1

STATE OF MINNESOTA

Office of the Attorney General

TO	:	HUBERT H. HUMPHREY, III Attorney General	DATE	:	July 23, 1997
FROM	:	THOMAS F. PURSELL Senior Counsel	PHONE	:	296-7579 (Voice) 297-7206 (TDD)
SUBJECT	:	Legal and Policy Issues in the Proposed Tobacco Settlement			

INTRODUCTION

This memorandum analyzes the proposed settlement negotiated by the tobacco companies, several state attorneys general, and private class action lawyers. I have regretfully concluded that the settlement is not in the public interest - it falls short on substance; it is full of subtle preemptions of state authority and procedural advantages for the tobacco companies; it will create a host of fact questions which will let the industry litigate forever over details while regulators remain frozen during what the industry obviously hopes will be a five-year "cooling off" period.

Among the most serious flaws in the agreement:

- A grant of regulatory authority to the FDA which is so riddled with loopholes as to be almost illusory.
- Inadequate incentives to reduce youth smoking, including provisions which may even increase competition in the illegal market.
- Limitations on future liability which stack the deck against the industry's victims.
- Payments which the industry can easily absorb as a cost of doing business.
- Severely limited enforcement authority over marketing regulations, with no provision for monetary penalties, attorneys fees, actual damages or private rights of action.
- Temporary preemption of state content disclosure statutes and permanent preemption of more stringent penalties for tobacco licensees.
- Retreat from the second-hand smoke standards contained in the pending OSHA regulations.
- Document disclosures which fall short of a clean break with past covers.

In addition to these flaws, the settlement document is incomplete. It is simply silent on dollars and cents issues such as how the industry payments will be apportioned among public and private plaintiffs, among sub-categories of those groups, and among the private plaintiffs' attorneys.

TITLE I: REFORMATION OF THE TOBACCO INDUSTRY

A. Restrictions on Marketing and Advertising: The proposal incorporates the existing FDA regulations and, in addition, bans the use of human images and cartoon characters, extends the advertising ban to stadia and ads directed outside from retail locations, further restricts point of sale ads, bans movie and TV product placement payments and the direct or indirect "glamorization" of tobacco use in media appeals to minors (e.g. the current "It's a Woman Thing" rock music campaign).

The FDA would be locked into this scheme for five years, except under "extraordinary circumstances." Thereafter the agency could review and revise "under applicable agency procedures."

Comments: The drafters deliberately put the best news first, even moving the logically first "scope" of legislation" section to Title V. The negotiating Attorneys General promised to deliver "FDA Plus," and have in fact exceeded the FDA's *current* advertising and marketing restrictions (although not necessarily the restrictions the FDA could impose when the agency's authority in this area is ultimately upheld in the courts). Even so, the agency would be locked into these restrictions for five years. Marketing has been the tobacco companies' historic genius, and if there is one area where they've shown they can outfox regulators, this is it. In addition, the industry's experience in countries where sales remain strong despite equally tough or tougher regulation makes it easy for them to concede "FDA Plus" and give the negotiating plaintiffs an important cosmetic victory. The industry is even now launching a sophisticated direct mail campaign directed at young women (see attached Exhibit 1), using a mammoth data base built up in anticipation of the FDA regulations. Any doubts in this area must be resolved against the industry.

We believe no advertising and promotion should be permitted, in light of what we now know about the tobacco industry and its products. While it is often argued that cigarettes are a "lawful product," they may only be so because of the conspiracy at issue here. A ban on advertising would be consistent with the nature of the product and the companies' misconduct. Other issues:

- No penalties are provided for violations of Title I marketing restrictions. The lack of meaningful penalties was an almost uniform criticism of last summer's Moore/Scruggs proposal. We have proposed civil penalties of up to $100,000 per violation, actual damages, attorneys fees and private enforcement standing, none of which are present here. The lack of incentives to enforce seriously diminish the effectiveness of the proposed marketing regulations, as they do with any law.

- Some of the "restrictions" may be illusory. For example, the point-of-sale advertising restrictions would permit outlets such as convenience stores to display 10 2' x 2' signs - 40 square feet of point-of-sale ad messages, more than most carry now in any event.

- We know from the Liggett experience that highly significant terms can be embedded in definitions. The proposal does not contain a definitions section, and therefore leaves key terms subject to later interpretation by the drafters. Among significant terms: what is "advertising?" Does it include direct mail, which is the industry's next big advertising frontier?

- A significant omission in the advertising and marketing regulations is the failure to deal with the cigarette package (except through expanded warning labels provided in Section B). Market research has shown that teens are extraordinarily brand sensitive: witness Starter jackets, Guess jeans, team logo caps, the Nike swoosh. Part of the allure of smoking for teens is the brand logo identification. The cigarette package is a brand accessory, as is obvious from the success of Marlboro gear, Camel jackets and the like. On the other hand, black and white generic packaging is decidedly uncool. A good settlement would ban all advertising and promotion; an acceptable one would at least provide for generic packaging.

- This section, through the "extraordinary circumstances" test, (FDA can only change regulations under "extraordinary circumstances" during the first five years), sets up the first of a blizzard of potential fact questions--to wit, what constitute "extraordinary circumstances" justifying an early revision to the regulations?--which, given the industry's propensity to litigate every possible advantage, could well paralyze even an aggressive regulator. A better deal would build in procedural or evidentiary advantages for the regulators, rather than the tobacco companies, or contain industry agreements not to challenge certain features, either directly or through surrogates.

- The proposal itself notes that Title I restricts advertising and marketing "in ways that have previously been challenged on First Amendment grounds." While the companies themselves may agree, in consent decrees, to such restrictions, other affected parties, such as outdoor advertising companies, could still challenge the statute and, arguably, the consent decrees themselves. Groups such as vending machine companies have already announced that they believe the bans on vending machines deprive them of property without just compensation. They demand compensation and say they will challenge the deal if they don't get it. Collateral challenges not only cloud the political picture but could nullify or delay key parts of the agreement.

B. Warnings, Labeling and Packaging: The agreement provides new, rotating warnings on cigarettes and smokeless packages. The warnings would occupy 25% of the front package panel, although on certain flip-top boxes (Marlboros) it would be smaller. The FDA would be required to promulgate rules governing the testing, reporting and disclosure of tobacco smoke constituents, this authority being transferred from the Federal Trade Commission.

Comments: The proposal would not, as we have previously recommended, repeal the preemptive provisions of the existing Federal Cigarette Labeling and Advertising Act. The FDA rulemaking proceeding would offer the industry another shot at disputing, litigating and possibly diluting the proposed standards. It is uncertain whether the label warnings deter smoking. They clearly will strengthen the industry's assumption of risk defense, and on balance, probably favor the industry more than consumers.

C. Restrictions on Access to Tobacco Products: This is another area where the negotiators claim "FDA Plus." The agreement incorporates the existing FDA regulations on youth access and, in addition, bans all vending machine sales and self-service displays except in adults-only facilities. In other facilities, products must be "out of reach of consumers."

Comment: This claim of "FDA Plus" appears to be mistaken. The FDA rule already bans self-service.

D. Licensing of Retail Tobacco Product Sellers: The agreement would mandate minimum federal standards for licensing, to be enforced by federal, state and local authorities and funded by the "Industry Payments." Anyone selling tobacco products directly to consumers would need a license. The penalty scheme would preempt more stringent state and local sanctions. Penalties for violations are set forth in detail in Appendix II to the agreement. Licensing fees would cover state administrative costs. There would be a "comparable" licensing program for U.S. government facilities such as military posts, and for Indian lands (Appendix III to the agreement).

Comments: The tobacco licensing sanctions are a significant breach of faith with the concept of no or minimal preemption: The sanctions listed in Appendix II would be mandatory, and "shall not exceed" the listed penalties, which could be significantly less severe than those just signed into law in Minnesota. It is a truism of tobacco control that the industry favors preemption of local standards whenever it can get them because they are community appropriate, effective, and difficult for the industry to control through lobbying.

Even apart from our general opposition to preemption, this is inadequate substantive law. It is a bald return to the days when Philip Morris trumpeted its own retailer sanctions program--which never resulted in any sanctions at all while we were tracking it.

E. Regulation of Tobacco Product Development and Manufacturing. Section E "impose[s] a regulatory regime to govern the development and manufacturing of cigarettes and smokeless tobacco products, including FDA approval of the ingredients...and...standards for reducing the level of certain constituents, including nicotine." Because of the length and complexity of this section, comments will follow each provision as necessary.

2. Tobacco will remain a "drug", and "device" under the FDCA. Tobacco products will receive a new classification as "Class II" devices.

Comment: We need to determine the effect of the creation of this new "Class II" classification within the overall context of the FDCA.

3. Sale of tobacco products "to adults in the form that conforms to Performance Standards established for tobacco products pursuant to Section 514 of the FDCA shall be permitted notwithstanding" specified sections of 21 U.S.C.

Comment: Again, the significance of this language is not clear from the text of the agreement. The other sections must be consulted and the meaning of this parsed in light of the referenced sections of federal law.

4. The FDA would approve and require substantiation of health claims.

Comment: The manufacturer would have the burden of showing a "significant" risk reduction, but there is no guidance as to what constitutes "significant." FDA would be authorized to adopt more lenient health claim standards for tobacco than for other products if it determined that "such advertising would reduce harm and promote the public health" under rules it is required to promulgate.

5. Manufacturers would notify FDA of new risk reduction technology and cross license such technology to other companies also covered by the obligations for a "commercially reasonable fee." FDA could require introduction of technologically feasible, less hazardous products after a formal, APA rule making, or the licensing of such technology to another company which promises to bring it to market "within a reasonable time."

Comments: Cross licensing only to "other companies also covered by the obligations" would create an enormous potential barrier to entry of new companies wanting to aggressively produce safer cigarettes. This barrier will inevitably strengthen the Big Five's current shared monopoly. Even among this group, disputes over what constitutes a "commercially reasonable fee" , and the APA rulemaking required to force introduction of new features, could significantly delay introduction of safer products. A better approach would be to declare all existing risk reduction technologies subject to forfeiture for the companies' past misconduct in suppressing them, and

for the FDA to own and license the technology to all comers. Future innovations--the product of legitimate, competitive research--should be subject to cross-licensing for a reasonable fee.

6. FDA could promulgate "Performance Standards" to reduce harm, but not prohibit "the sale to adults of traditional tobacco products in the basic form as described in the August 28, FDA Rule...." This authority is subject to significant restrictions, however. For "no fewer than twelve years" the agency could not eliminate nicotine or other components, and could only reduce it if could show in a rulemaking process, by "substantial evidence" that:

(a) the reduction would "result in a significant reduction of the health risks...,"

(b) technological feasibility, and

(c) that the change would "not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard, taking into account the number of dependent tobacco product users and the availability of alternative products."

After the initial 12-year period, the agency could set additional standards, but must make its case by a preponderance of the evidence, in a forum of the tobacco manufacturer's choosing, showing (b) and (c), above, and (a) "significant overall reduction of the health risks to tobacco consumers as a group."

Section 5 also sets a maximum 12 mg. "tar" yield effective within 3 years.

Comments: This section embodies significant limitations on FDA jurisdiction. Drs. Koop and Kessler have publicly questioned whether the FDA would ever be able to make the showing required to even reduce, let alone eliminate, nicotine; and the chairman of BAT Industries told the Wall Street Journal that, because of the contraband provisions in particular, he's not worried about the FDA ever regulating nicotine. This section not only requires a potentially impossible evidentiary showing, including proving a negative (no "significant" demand for contraband) but also heightens the agency's normal evidentiary burden "substantial evidence," in the first instance, rather than "arbitrary and capricious," rising to "preponderance of the evidence" in a forum of the manufacturer's choosing for additional limitations, after the initial 12-year period.

In addition, the wording of the section--its reference to options of "a manufacturer" (singular) implies that the FDA would not be able to make the required showing across the board, but rather on a manufacturer-by-manufacturer or even brand-by-brand basis -- an impossible burden, in practice.

To further complicate the agency's job, in any judicial review "the deference accorded to [its] findings shall depend upon the extent to which the matter at issue is within the Agency's field of expertise." Matters such as the operations of contraband markets are not necessarily within the FDA's field of expertise.

Finally, even if the FDA is able to make the required Herculean showings, any final action on nicotine elimination would have to be phased in, and would be delayed for at least two years to give Congress an opportunity to overrule it.

Taken together, the above restrictions on FDA authority over nicotine are significant and unacceptable, and contrary to what the negotiators promised on numerous occasions: full and unfettered FDA authority to do whatever is necessary to solve the problems of tobacco and the public health. This elaborate, formal rule-making process hasn't been used for almost a generation, according to press reports. The last use involved regulation of the number of peanuts used in peanut butter: it took ten years. Other comments:

- The legal consequences of the language permitting continued sales of "traditional tobacco products. . . as described in The . . . FDA rule," must be examined. Because the FDA rules do not apply to products containing no nicotine, the intent appears to be to perpetuate nicotine in tobacco products.

7. The industry would be subject to good manufacturing practice standards for the first time. Tobacco farmers "will face no greater regulatory burden than the producers of other raw products regulated by the federal government."

Comments: Good manufacturing standards are needed but so is more study needed to determine whether food standards are appropriate. Standards are <u>not</u> a substitute for FDA regulation over components. Under Title V, state regulation of manufacturing standards is largely preempted.

F. Non-tobacco Ingredients: Manufacturers would disclose ingredient information to the public "under regulations comparable to what current federal law requires for food products." They would also provide confidential lists of added ingredients, substances and compounds to FDA, by quantity in each brand. Manufacturers would have five years, for each ingredient, to provide a safety assessment, consistent with regulations to be promulgated. The FDA then has 90 days to approve or disapprove; the failure to disapprove constitutes approval. Not all ingredients would have to be publicly disclosed under the food laws, and non-disclosable information would be confidential, stored in locked cabinets, etc. Companies would be required to adopt procedures for the selection, testing, use, etc. of ingredients.

Comments: As with nicotine, this section would give the FDA nominal authority, but imposes so many obstacles that real regulation will be impossible.

- This section F is home to one of the most ludicrously one-sided provisions in the entire proposal: the tobacco companies get five years to prepare safety assessments of hundreds of ingredients. When that mountain of evidence is filed, the FDA has all of 90 days to review, approve or disapprove, with the failure to disapprove equaling approval. Clearly, the

manufacturers need much less time, and the FDA much more. Given the vast information the industry already has on its own ingredients, the companies should need no more than 90 days to submit all existing data, with the FDA able to act without restrictions as reliable information becomes available.

- State disclosure laws have been a huge issue for the industry in recent months. This section acknowledges the existence of such laws, but requires only that the companies must disclose all ingredients "which they *have been* compelled to publicly disclose" in compliance therewith. (So far, of course, there are none, since the industry has challenged the constitutionality of the laws and delayed their enforcement.) Buried in Title V is a five-year preemption of state disclosure laws such as those in Massachusetts and Minnesota. This settlement would set content disclosure back from existing law. Even after five years states must apparently apply for an "exemption" from preemption.

- The language regarding the obligation to disclose ingredients is unclear. In particular, it is unclear whether the companies would have to disclose the components of smoke, and test the safety of ingredients when burned. But see III.B. 4 which indicates that there will be "disclosure of tobacco smoke constituents." For example, licorice--a common flavoring--is perfectly safe to eat, but harmful when burned and inhaled. Information should be provided on burned cigarettes.

G. Compliance and Corporate Culture. The stated purpose of this section is to "forc[e] a fundamental change in the way the tobacco industry does business." Specifics:

- Create annually reviewed compliance plans to identify ways to reduce youth consumption, and provide incentives for development of reduced risk products.
- Protect "Whistleblowers" to the extent permitted by current federal law.
- Promulgate corporate principles, designate compliance officers, report to shareholders on progress.
- A rein on lobbyists, who could not weigh in on tobacco issues "without the manufacturer's express authorization." Lobbyists and agents must also have knowledge of the compliance obligations and the consent decrees.
- Companies subject to fines and "scarlet letter" advertising for breach of their obligations.
- Within 90 days, dissolve and disband the Tobacco Institute and the Council for Tobacco Research. Any new trade associations subject to regulation

Comments: Not much change requiring actual results here, except for the last point, the key disbanding of the CTR and TI. These two organizations have been little more than agencies of unlawful conspiracy for decades, and their dissolution is consistent with antitrust practice in similar cases. However, even this provision will be meaningless unless carefully implemented by consent decrees. TI's Walker Merriman has said that he anticipates business as usual under this agreement. Among the specifications needed to reform future trade associations:

- CTR and TI records must be turned over to the FDA or to a receiver, who would, among other things, disclose any evidence of misconduct.
- Regulatory and public interest representation on any new group's board.
- Open records and visitation rights by law enforcers (DOJ, FTC, and selected states).

Note that other "corporate culture" reforms, discussed during the negotiations, are not included. Example: putting outsiders, or tobacco control people, on the companies' boards of directors.

H. Effective Dates:

TITLE II: "LOOK BACK" PROVISIONS/STATE ENFORCEMENT INCENTIVES

Title II contains three provisions intended to reduce youth smoking:

- Targets for the reduction of underage tobacco use, with separate criteria for cigarettes and smokeless tobacco. The targets are based on a "base percentage" of underage smokers age 13 and up who smoke (in the case of cigarettes) on a daily basis.
- Sanctions, in the form of "mandatory" FDA-imposed "surcharges for failure to meet the targets. The sanctions are subject to rebates for good faith attempt to comply.
- A state enforcement scheme, including funding for enforcement, but also sanctions against states where the tobacco industry fails to meet youth access reduction targets.

The tobacco-use reduction targets are:

	Year 5	Year 7	Year 10
Cigarettes	30%	50%	60%
Smokeless	25%	35%	45%

Reductions will be measured from estimated levels over the last decade.

Comments: This section is a sham. It recites that a "central aim of this legislation is to achieve dramatic and immediate reductions in the number of underage consumers"; but the targeted reductions are neither dramatic nor immediate. The target reduction levels are too low, the first "lookback" is too late, the sanctions too light and riddled with loopholes, and the state enforcement "incentives" would penalize the states for tobacco industry misconduct.

- **The target reduction levels are too low.** In our December, 1996 outline for a tobacco settlement we proposed as a goal the substantial elimination of youth smoking. Clearly, there will continue to be some underage smokers, just as there are underage users of alcohol and illicit drugs. But the proposed settlement goals fall unacceptably short of "zero

> tolerance." To concede in advance that, after 10 years of supposedly intensive efforts, 40% of the number of young smokers will still smoke, is to concede the ineffectiveness of the marketing and access restrictions. This concession--this confidence on the part of the tobacco industry--is explicit in the statements of B.A.T. Industries Chairman Martin Broughton, who told the *Wall Street Journal*. "My expectation is we will fail to meet them [the targets]." The targets for reducing smokeless tobacco use are even further off the mark, a decrease of less than half.

The inadequacy of the benchmarks is magnified by the fact that the baseline percentage includes an artificially small population -- those kids age 13 - 17 who use cigarettes *every day*. The Centers for Disease Control and Prevention's Youth Risk Behavior Surveillance System (YRBSS) lists as "current" users 9 - 12 grade students having smoked *at least once in the last 30 days* (34.8% of the total subject population). "Frequent" 9 - 12 grade users, in the CDC definition, have smoked cigarettes on 20 or more of the last 30 days (16.1% of the total). The YRBSS does not have a category for daily users under age 18.

What this all means is that while in everyday conversation and ordinary understanding we count as "smokers" almost 35% of high school students, the proposed settlement will only measure reduced used among a much smaller percentage of "daily smokers."

It might be argued that it is likely to be more difficult to reduce the smoking of "daily smokers," since they are the most likely to be addicted. In this view, the narrow definition could be an advantage for the states, since it would logically be harder for the industry to meet the targets and therefore make sanctions more likely. One could further argue that the total package of marketing limitations and access restrictions would reduce smoking more among more occasional, less addicted, child smokers, and that the targets if anything undercount the effectiveness of the restrictions.

The problem with viewing this as an advantage is that the failure to meet targets won't hurt the tobacco companies, because the surcharges are too low and too riddled with loopholes. In the meantime, basing the discussion about smoking rates on an artificially small population of "smokers" vastly understates the magnitude of the youth smoking problem, further reducing pressure on the tobacco companies and their distribution system.

Compounding this problem is the fact that the Michigan data used to create smoking rate data counts only smokers <u>in school</u>. The incidence of smoking among dropouts is much higher (e.g., in a study of teens in detention homes, up to 83%).

We have supported and continue to support the youth tobacco use reductions in the Waxman Bill, which calls for a 20% reduction after two years, with annual 20% reductions thereafter until the sixth year, when the final 10% target is achieved. Penalties would be a $1 per-pack "non-

compliance fee" for the first violation, rising $1 for consecutive years' violations. Fees would fund tobacco enforcement and education.

- **The first lookback measurement is too late.** The settlement would require measurements, and the possible imposition of sanctions, after the fifth full year of the settlement and annually thereafter. Five years is the same period that the FDA regulations would be frozen, and state content disclosure laws preempted. The industry is obviously hoping that this five years will be a cooling off period during which public outrage will disappear and the political winds will blow in their favor. Close analysis of this proposal makes it clear that a five-year cool off period is a major element of tobacco industry strategy.

- **The permissible FDA surcharge would not discourage the tobacco companies from marketing to kids.** Here's how the calculation would be made, under the rules set out in Appendix V. B., in a hypothetical situation which assumes that the settlement legislation were effective December 31, 1997:

(1) The FDA establishes a base percentage, pretty much any time after the legislation goes into effect. It finds that 10% of the kids in the defined population smoke every day. (This is a hypothetical but realistic figure based on YRBSS findings that 16.1% of 9th - 12th graders are "frequent" smokers.) (App. V. A. 1.) Using Centers for Disease Control 1991 figures for illegal, underage sales, those 10% of underage smokers buy a total of 225 million packs of cigarettes. Note that the agency does *not* measure by brand or manufacturer, as the Waxman Bill would, but rather total smoking numbers.

(2) On January 1, 2003, the FDA looks back at smoking rates in the same population during the previous year, the fifth full year after the settlement. Under the proposal, the target reduction for that year is 30%. (V. A.3.; B. 1.)

(3) The FDA finds (hypothetically) that the number of underage smokers for the year 2002 is 9% -- that's a one-point reduction, or 10% of the original 10%. (V. B.1.(a) (i - ii)). Since the target reduction is 30%, the variance between the two percentages, and the basis of the surcharge, is 20%.

(4) The surcharge would be $80 million for each percentage point of variance, or $1.6 billion ($80 million x 20) (V.B.1.(b). Note that even had youth smoking actually *increased* two points, and the presumptive surcharge were $3.2 billion, it would be reduced to $2 billion because there is a surcharge cap. V.B.1.(b)(4). No matter how badly they perform, the companies will pay no more than $2 billion.

(5) The $1.6 billion is the "joint and several liability" of the manufacturers, payable in proportion to market share -- not specifically market share of the underage market, but of the overall market. (V.B.3.) Thus, Philip Morris would pay about half, or $800 million; RJR about

a quarter, or $400 million, etc. Note that because the surcharge for youth smoking is not based on the brands kids actually smoke, there would be no individual brand/manufacturer accountability for "excess" youth smoking. On the contrary, even if the sanctions were genuinely punitive, the joint and several liability provides a positive incentive to gain a disproportionate share of the youth market, since any surcharge payment is based on total market share. Lorillard, for example, with something around 7% of the overall cigarette market, would be better off for grabbing a 50% share of the illegal market, since Philip Morris would pay 50% of the surcharge.

(6) The manufacturers apply for abatements of the surcharge under V.D. Each must show by a preponderance that it "acted in good faith and in full compliance with" applicable law, and "pursued all reasonably available measures" to meet the targets. The attorneys general are entitled to participate, and the FDA may bring forward any evidence that the companies tried to undermine enforcement. Because the companies carefully paper their files, having left their ad agencies to do the dirty work, the FDA has no basis to do anything except rebate 75% of the surcharge, with interest. The companies get back $1.2, and end up paying, in the aggregate, $400 million. When the tax savings are figured in, the failure to meet target by 20% in year 5 would cost the industry something around $250 million. To put that figure in perspective:

- In 1991, the industry sold a CDC- estimated 225 million packs to underage smokers, earning a profit from those sales of around $190 million. If those sales declined 10%, as in the hypothetical, profits from illegal sales would still be $171 million, at current profit levels.
- In 1996 the cigarette companies sold 24 billion packages of cigarettes: they would have to raise prices between one and two cents per pack to recoup, collectively, a $250 million surcharge.
- Even after ten years and a successful 60% reduction in cigarette sales to kids, if the cigarette companies maintained only their current profitability (foregoing the greater short-term profits from increased prices) they would make around $76 million in profit on illegal sales.
- As far as the companies are concerned, given (a) their ability to raise prices to recoup a surcharge, and (b) the $2 billion yearly cap, it is still in their interest to try to hook as many kids as possible, to protect long-term sales. If, by the end of year five, underage smoking goes up 2 percentage points, it might as well go up 20. With the cap, the penalty is the same.

(7) "Upon final completion and review of any abatement petition" -- which would be years after payment if the industry exercises its right to litigate the abatement issues -- the FDA would grant 90% of surcharge amounts to state and local government public health agencies, to be spent on youth smoking reduction activities. With litigation over the abatements a near certainty, if this legislation were enacted in 1997, the states would probably receive the first grant money for youth smoking reduction no sooner than the year 2006. There is no explanation of why the agency could not grant out uncontested money right away. See V.C.

(8) In subsequent years the surcharge would be further reduced "to prevent double counting of persons whose smoking had already resulted in the imposition of a surcharge in previous years (to the extent that there were not underage smokers of comparable age in those previous years on whom a surcharge was not paid because of the cap...)." This language is unclear and must be redrafted so that it may be assessed.

- **The state enforcement incentives mandate enforcement of youth access laws, but could punish the states for tobacco industry misconduct.** Under Appendix VI, "states" must conduct a youth access enforcement campaign which includes:
    - A no-sales-to-minors act
    - Random, unannounced inspections of retailers at least monthly
    - At least 250 such inspections per year for each million of population
    - Annual reports to the FDA, detailing enforcement activity , methods and strategies
    - Designating a "single state agency" accountable for results.

It is not clear whether the efforts of local governments would be counted toward these objectives or whether they would literally be the responsibility of the state governments and only the state governments.

For the states to get continued FDA grant money to enforce the youth access laws, the FDA would have to find that the state "pursued all reasonably available measures to enforce" the no sales to minors laws. However, the agency would "find presumptively" that the state had *not* used such measures unless the retail compliance checks found at least 75% compliance after the fifth year, 85% after 7 and 90% after 10 years. App. VI.

FDA would reduce grant moneys 1% for each percentage point by which the state fell short of its goal. The money would be redistributed to states that had exceeded performance targets.

In a parallel to the procedures for rebates of industry surcharges, the states could petition for rebates, attempt to show "good faith and full compliance", and potentially get back up to 75% of the withheld amounts.

Comments: It is inappropriate to penalize the states for failing to meet standards which are ultimately within the control of the tobacco companies and their chain of distribution. We don't take money away from local law enforcement because the police have failed to stamp out 90% of illegal drug use, or because some people still drink and drive. The states are the cops in the youth access enforcement world -- it is inappropriate and counterproductive to take enforcement funding away from them when, as noted above, the sanctions against tobacco companies will leave them with ample incentive to continue to sell to kids. Doing so would likely increase access in those areas where industry non-compliance is already highest.

Moreover, the percentage compliance targets may be unrealistic. From figures we put together early this year, based on enforcement experience in Minnesota, 85% compliance appears to be a reasonable, high level in an area with a strong ordinance and significant enforcement. Setting the targets any higher than that may be a setup for failure.

It is entirely appropriate to hold the states responsible for having and implementing an intelligent enforcement program, and to sanction the states for not conforming to the process. But to punish the states because the tobacco retailers are still violating the law, despite an enforcement program which conforms to federal standards, and in an environment where the companies still have an incentive to addict young people, is wrong.

TITLE III: PENALTIES AND ENFORCEMENT; CONSENT DECREES; NON-PARTICIPATING COMPANIES

- **A. Penalties and Enforcement:** The legislation would be enforceable by the states and the federal government. In addition, FDA could contract authority to the states. States could proceed under consumer protection "or similar statute[s]", but could not "impose obligations or requirements beyond those imposed by the legislation (except where [it] does not specifically preempt additional state-law obligations), and would be limited to" penalties provided. State enforcement proceedings under the Act or "predicated on conduct violating the Act" would be removable to federal court.

Comments: As discussed above, the lack of enforcement authority is a fatal flaw for this proposal. In addition, the extent of preemption here is far from clear. It appears, though, that a state suing under its own consumer protection "or similar" laws (left undefined) for conduct which also violates the Act, would (a) end up in federal court, (b) be limited in breadth and interpretation by the substance of the Act, (c) and be limited by the inadequate penalties of the Act. Removal to federal court of state enforcement actions is an unacceptable infringement on state sovereignty and a departure from principles of federal jurisdiction.

- Civil penalties of up to $10 million per violation for breach of obligation to disclose certain health-related research or information to the FDA are provided. This section must be worded so as not to preclude more severe existing sanctions, such as criminal penalties for filing false reports with regulators. Criminal penalties should be provided if this conduct is not now clearly covered under the federal criminal code.

B. Consent Decrees. Certain terms will be reiterated in consent decrees. The decrees would take effect only after enactment of the legislation. Among the terms which would be effective both through the legislation and the consent decrees are marketing restrictions, trade association dissolution, lobbying restrictions, tobacco smoke constituent and ingredient disclosure, money payment obligations for the states' "reasonable share" and similar terms.

Excluded from consent decrees will be product design and testing, manufacturing standards and look-back provisions.

States are entitled only to injunctive relief in enforcing consent decrees, and are prohibited from seeking criminal or monetary sanctions. Consent decrees remain enforceable regardless of later changes in the legislation, with certain exceptions, and will contain waivers of defenses of unconstitutionality of consent decree and legislative provisions.

Comments: The sole remedy of injunctive relief for violation of the consent decrees is a significant, unwarranted and unacceptable limitation. States should at a minimum have the ability to enforce consent decrees in accordance with local law, to recoup attorneys fees and costs, and to get the same penalty as provided for the original violation. As drafted, this overbroad consent decree provision would discourage state enforcement. It leaves unanswered the question of how to treat conduct which violates both a decree and a substantive statute. With no penalties provided for the advertising and marketing restrictions, injunctive relief may be the only relief--and no deterrent at all to misconduct.

The decrees would presumably be entered in the courts where the individual state actions are venued, although the proposal does not specify.

C. **Non-participating Companies.** The ostensible purpose of this section is to equalize the market as among those companies which participate in the deal and those that don't. Non-participants would not be subject to the advertising restrictions, which might, the agreement recites, be subject to constitutional challenges by those companies which have not waived their rights. Instead, "non-participants" would be subject to youth access restrictions, general "regulatory oversight, a "user fee equal to the portion of the payments by participating manufacturers allocated to fund public health programs and...access restrictions," and a future liability escrow reserve payment one-and-a-half-times as large as "the annual payment required of participating manufacturers." In addition, non-participating manufacturers would not have the civil liability protections which are one of the main inducements for the companies to participate in this settlement. Similarly, the retailers and distributors who deal with non-participating companies would not be granted liability protection.

Comment: On the surface it seems fair not to place the settling companies at a competitive disadvantage by requiring some obligations of non-participating manufacturers. Below the surface, however, this section appears to be the cigarette cartel's naked attempt to erect barriers to new competition: the civil liability reserve payments are 150% of those expected of settling companies -- they would pay dearly for the right not to be bound by "FDA Plus" advertising and marketing restrictions. While it is fair that the non-participants have no statutory immunity, the withholding of immunity from distributors and retailers would discourage them from dealing with a non-participant, an additional barrier to entry.

We care about potential competition among tobacco companies because the defendants have in the past suppressed competition in new product development. Anything which solidifies the defendants' shared monopoly permits them to continue their collusion, grants unwarranted market protection, and effectively rewards them for their past misconduct.

- This section is plainly inconsistent with the negotiating states' obligations to Liggett under the existing settlement agreement with that company. Liggett would likely be a non-participant under this provision, as would new companies. Section 5 of the Liggett settlement requires the Attorneys General "to exercise best efforts to ensure that the financial terms...of any global settlement are no more onerous on...Liggett than the financial terms...of the agreement." The AG's are also required to use their best efforts in Congress to ensure that Liggett gets the benefit of its bargain. Liggett can withdraw from the agreement if these terms are not met.

Section 16.1 of the Liggett Agreement sets out "the intent of the parties...that the Settling Defendants enjoy a preferred position with respect to Non-Settling Tobacco Companies..." There follow a complex set of formulae designed to give Liggett the same kind of competitive advantage which the other companies seek in this proposal. This section C therefore sets up a "dueling most favored nations" situation. What are the conflicts? Which agreement controls? What are the States' obligations? What are the consequences if Liggett withdraws?

TITLE IV: NATIONWIDE STANDARDS TO MINIMIZE INVOLUNTARY EXPOSURE TO ENVIRONMENTAL TOBACCO SMOKE

The proposal would establish minimum federal standards for smoking in public places and workplaces, without preempting stricter state or local standards. A "public place" is any building "regularly entered by 10 or more individuals at least one day per week." Smoking would only be allowed in areas with a direct outside exhaust, maintained at negative pressure compared to surrounding areas, and with no recirculation of air.

No employee would be required to enter a smoking area while smoking is occurring. Bars and restaurants (except "fast food" restaurants) are exempt. It is not clear from the draft whether the "no employee required to enter" exception would apply to bars and restaurants, i.e. whether as a condition of employment a waitperson could be required to serve the smoking section.

OSHA would be required to issue and enforce regulations, with enforcement funded by the industry payments.

Comments: In dealing with second-hand smoke, the settlement proposal takes several steps back from the indoor air quality (IAQ) regulations proposed by the Occupational Safety and Health Administration. OSHA published notice of the proposed rules--which comprehensively govern IAQ in the workplace, including environmental tobacco smoke-- in April, 1994. Final action has been delayed, however, because the second-hand smoke provisions prompted the tobacco industry to engineer the largest public response to proposed regulations in the agency's history: over 100,000 comments, the bulk of the material from the tobacco industry.

The settlement would retreat from the proposed OSHA rules in the following ways:

- The rules would cover restaurants, bars and hotels (29 CFR 1910.1033(a)); the settlement would exempt them, except for "fast food restaurants" catering largely to minors.
- The rules require enclosed, ventilated areas under negative pressure (id. at (e)(1)(ii)); separate rooms, in other words. The settlement does not require the smoking areas to be separately enclosed.
- The rules would require posted signs stating that smoking is restricted to designated areas (id. at (e)(1)(vi)); the settlement doesn't.
- Coverage is potentially different, with the OSHA rules applying to "all indoor non-industrial work environments," and the settlement to "public places."

Taken together, the differences between the proposed rules and the settlement make the settlement significantly less effective in combating the country's third leading cause of preventable death. Smoking will still be allowed in restaurants, bars and hotels; and deletion of the requirement of enclosed smoking areas means inevitable exposure.

As Stan Glantz says, such designated smoking areas are the equivalent of signs requesting that swimmers urinate only in the shallow end of the pool. Finally, note that the costs of enforcing the reinvented OSHA would come out of the total settlement fund, and thus be subtracted from the amount available for victims.

TITLE V: SCOPE AND EFFECT

This section establishes the scope of the FDA's jurisdiction, the relationship between the FDA and other federal agencies which regulate tobacco products, and the general interplay between federal and state laws. By logic and custom it should be at the beginning of the proposed legislation instead of the advertising and marketing restrictions. Although short, this Title is complicated.

A. Scope of FDA Authority. This assigns regulatory responsibility and limits jurisdiction. It provides:

- The settlement legislation would apply to "all product sold in U.S. commerce."
- Applies to "new entrants" and "imports"
- The Bureau of Alcohol, Tobacco and Firearms would retain fiscal authority over tobacco products while the FTC would cede tar, nicotine and carbon monoxide testing to the FDA.
- FDA would have no jurisdiction over tobacco "growing, cultivation or curing."

Comment: Limitation of FDA jurisdiction to products "sold in U.S. commerce" is a clever way of saying that none of the FDA's standards will apply overseas. In other words, this bill ducks the international marketing issues, leaving the companies free to target children in other countries. At a minimum the industry should be required to stop targeting children abroad.

- Coverage of "new entrants" and "imports" raises the issues of market fairness addressed above. The rationale for covering new entrants and imports in the settlement generally varies depending on the provision at issue. The current defendants want their potential competitors to be at least as burdened by the settlement legislation as they are. In fact, as discussed above, they are clearly attempting to use the settlement to entrench their shared monopoly by creating unnecessary barriers to entry. It is fair and appropriate to include potential competitors in the FDA's regulation, or in any other provisions which have a public health content, since the newcomers too will be making and selling a dangerous product. It is also appropriate to tax or otherwise affect the price of their products, since, from the public health point of view, the more cigarettes cost, the better.

- Transfer of product testing from the FTC to FDA is an appropriate recognition of the latter agency's health and smoking related expertise.

B. State Authority. This section states the general relationship between state and local regulation, on the one hand, and federal regulation, on the other.

Section 1 purports to preserve state and local authority to control youth access "to the maximum extent"; specifically preserves local rights to enact more stringent second-hand smoke exposure standards; and preserves general state regulatory authority. It provides special rules for Indian tribes and federal facilities.

Section 2 continues the Cigarette Labeling Act, including the state preemptions that act contains, and further incorporates Food Drug and Cosmetic Act standards, including provisions which preempt state standards which would "unduly burden interstate commerce." Under this clause, "no [state] exemption relating to ingredients," "as described in Title 1 (F)" may be applied for five years. This language preempts state content disclosure laws, or at least delay

their effective date, for the initial five-year period when FDA regulation over marketing and advertising restrictions is itself frozen under Title I.

Comment: This section B is almost false advertising in itself. It purports to preserve maximum state authority over tobacco issues while subtly incorporating numerous unjustified preemptions:

- More restrictive state and local youth access/retailer licensing laws are preempted. Title V. B.1. states that the "legislation preserves, to the maximum extent, state and local government authority to take additional tobacco control measures" restricting youth access. In fact Appendix II contains a mandatory schedule of retailer licensing sanctions which preempt more stringent state and local punishments ("Such sanction shall not exceed the following...." Appendix II, 2.) The schedule conflicts with Minnesota's newly enacted licensing restrictions in that our law provides mandatory penalties (albeit ones which fall below the Appendix II maximums), and permits more severe penalties.

Illustration: For a third offense within 24 months, the settlement would allow (but not require) a maximum penalty of $2,000 and/or a 30-day license suspension. The actual sanction could be a $10 penalty and no suspension. Our approach is to impose a mandatory $250 penalty and minimum seven-day suspension. In other words, the actual sanction could be a $250 penalty and a 60-day suspension. Furthermore, the Minnesota statute would permit local ordinances to be more severe. The legislation would preempt any contrary application of the Minnesota statute or local ordinance. There is nothing in the proposal which explains why this preemption is necessary. The statement in Title V B. 1. that the settlement preserves local youth access restrictions "to the maximum extent" is simply false.

- We have recommended in the past that the FDCA preemption of state advertising restrictions be repealed. This settlement would continue them. V.B.2.
- State ability to set manufacturing performance standards is curtailed. Id.
- In a significant setback to state consumer protection efforts, the settlement would freeze state content disclosure laws for five years after its effective date. Id. This provision would nullify the Massachusetts content disclosure law, which that state has already successfully defended in federal court. It is the tobacco industry's attempt to win in Congress what it has already lost in state legislatures and in federal court. Minnesota's content disclosure law would also be preempted.

TITLE VI: INDUSTRY PAYMENTS

The cash value of the settlement is advertised as $368.5 over 25 years, a more or less arbitrary period of time. The payments actually continue in perpetuity. This figure does not include adjustments for inflation, changes in sales volume and other factors which cannot now be measured. The settlement does not include a present value calculation. Significantly, the proposal does not clearly identify how the money will be divided among the plaintiffs and future

claimants, the source of funds for the various programs, or the use of the "public health trust" designated payments. Assuming the settlement were approved in 1997, and not counting the various adjustments, the tobacco companies would make the following payments:

- $10 billion lump sum cash payment when the President signs the Bill. This payment seems to go all to the States. There is no allocation in the proposal.
- On December 31, 1998, $8.5 billion: A $6 billion "base amount," and $2.5 billion for the public health trust. It appears that the base amount is for all claimants and public health purposes, with the public health funds distributed to various programs in Title VII deducted from the base. It further appears that 1/3 of the base amount would be kept for the civil liability fund. Thereafter, the payments look like this:

Year:	2	3	4	5	6	7	8	9	10
Base:	$7B	8	10	10	12.5	12.5	12.5	15	15
PH Trust:	$2.5B	3.5	4	5	2.5	2.5	2.5	-	-
Total	$9.5	11.5	14	15	15	15	15	15	15

Note again the significance of five years. Just as the controls will start to come off the FDA, the industry's payments will peak, giving them the strongest argument that they are paying their share. The payments are subject to the following adjustments:

- They will increase by 3% or CPI each year, whichever is greater, applied to the previous year's payment.

- If the volume of unit sales decreases from 1996 levels (the "base volume"), then the payment is a percentage of the scheduled payments: actual adult volume divided by base adult volume times the scheduled payment, with a further adjustment for any increased profitability. (Using adult volumes keeps the industry from getting a benefit from reduction in underage sales.)

- Payments have priority in bankruptcy, and this settlement could not be rejected in bankruptcy. VI B.6.

- "In order to promote maximum reduction in youth smoking, the statute would provide for the Annual Payments to be reflected in the prices manufacturers charge for tobacco products." VI B.7.

- Payments would be collected from all sellers of tobacco products. Participants would pay by agreement. Non-signators would be bound by statute; this would include new entrants and others not necessarily involved in the acts and practices complained of in the lawsuits.

- None of the payments are deemed fines or penalties, and all payments (including specifically the youth lookback "penalties)" are deemed to be ordinary and necessary business expenses, and therefore tax deductible.

  Here are two examples showing future payment scenarios:

Example #1: (using only adult figures): If 1997 volume sales decrease from 1996's 24 billion packages of cigarettes (the base volume) to 20 billion, the adjustment fraction is .833 (20 divided by 24), so the first year's payment, instead of being $8 billion, would be $6.667 billion. If, despite the decline in unit sales, the industry's profits increased above a "base year net operating profit" (which is not given in the agreement), then 25% of the increased profits go back into the payments. For example, if the "base year net operating profit" is $7.6 billion, and in 1997, despite the above-hypothesized decline in sales, the industry's total profits are $8 billion, then 25% of that $0.4 billion, or $0.1 billion, would be added to the payments, raising the total to $6.767 billion.

Example #2: Instead of decreasing, 1997 sales increase to 30 billion units. The multiplier would be 1.25 (30÷24) and the total first-year payment would be $10 billion instead of $8 billion.

Comments: Perspectives on the amount of the payments:

(1) If the industry saves $4 billion of its current annual outlay of $6 billion in advertising and marketing; saves $750 million in annual legal fees from fighting the state and class action lawsuits; and deducts all payments from taxes (about $2.64 billion in the first year), its savings and tax benefits will amount to $7.39 billion, or 92.4% of the first year's payment.

(2) The payments are far less than the industry can afford. At a minimum, the cigarette companies can increase prices an average of $2 per pack, raising $32 billion per year.

(3) Some experts suggest prices could be increased significantly more than $2 per pack and still permit the companies to be profitable.

(4) The present value of the 25-year stream of payments is at a 10% discount rate is $135.7 billion with the 3% inflation adjustment. Exhibit 2 shows the present value at a range of assumptions.

(5) The industry's stock increased over 20% in value during the negotiations.

- The mechanisms of the mandatory pass-through of price increases are not spelled out in the settlement. According to information leaked during the negotiations, they were to have been implemented by some exemption from the antitrust laws: Such an exemption would be completely inappropriate for companies with a long and sordid history of antitrust violations, and currently charged with one of the largest, longest, and costliest conspiracies in restraint of trade in the nation's history. Higher prices would indeed diminish youth smoking, but to justify an antitrust exemption on this ground is mere pretext. Youth smoking could and

should be discouraged to the maximum by requiring total industry payments which would boost prices by $2 and more, a level already found to be critical in reducing consumption by underage smokers. If it is deemed desirable to have prices passed through to customers, this must be done carefully by government action, not through any agreements or sanctioned joint action among the companies. To set up a structure for these companies to work together on prices would be akin to government handing a loaded gun to a serial killer.

- In applying the payment obligations to non-defendant tobacco companies -- new entrants, for example -- it is again important to keep the focus on public health goals. It is fair and right to apply restrictions across the board in the public health interest; but neither this legislation nor any proposed settlement is a proper vehicle for helping the defendant tobacco companies entrench their undeserved and unlawful shared monopoly.

- The settlement does not contain a waiver of the federal share of Medicaid recoveries, nor any guarantees that congress or federal agencies will not reduce money otherwise available to the States.

- The stipulation that none of the payments is to be considered a fine or penalty is consistent with the tax benefit to the industry. However, it works against the states in that the proposed settlement does not have a federal Medicaid share waiver. The states would presumptively be able to keep all of any payments designated as fines or penalties, or devoted to non-Medicaid elements of damage. They may well have to pay back the federal share of Medicaid damages.

- Finally, it is critical to note that the obligation to pay is being placed only on domestic cigarette manufacturing. This would leave untouched the contribution potential of their domestic and international affiliates which were bought with unlawful tobacco company profits and are therefore subject to judgment in the pending lawsuits.

TITLE VII: Public Health Funds From Tobacco Settlement As Recommended by the Attorneys General For Consideration By the President and Congress

The proposal would devote substantial payments to tobacco-related public health programs and anti-tobacco promotions. It is not explicit from the document itself, but appears to be the case that this money comes out of the "base payments." There are five sections in this title. A summary of where the money goes, and when:

Year	1	2	3	4	5	6	7	8	9	10
To HHS for Tob Use Reduction	$125M	125	125	225	225	225	225	225	225	225
FDA enfrcmt & state grants	$300M	300	300	300	300	300	300	300	300	300
ASSIST-type state & local funding	$75	75M	100	125	125	125	125	125	125	125
R&D re: stop & no-start methods	$100M	100	100	100	100	100	100	100	100	100
soft landing for sponsorship recips. (teams, events, etc.)	-	75	75	75	75	75	75	75	75	75
Public education, media campaign	$500M	500	500	500	500	500	500	500	500	500
Cessation	$1B	1	1	1	1.5	1.5	1.5	1.5	1.5	1.5
Totals	$2.1B	2.175	2.2	2.325	2.325	(same into future...)				

The secretary of HHS (note: not the FDA) would establish programs for the use of the above money. Among the purposes would be reducing tobacco usage by discouraging underage smokers from starting and helping current users to quit; research and development into health effects of tobacco products and additives, and a multi-media public education campaign designed to "discourage and deglamorize" use of tobacco products. This campaign will be directed by an independent, non-profit organization to be created for this purpose. The Board of this non-profit will grant to non-profit entities with a demonstrated recording of working effectively to reduce tobacco product use and expertise in multimedia communications campaigns.

The Secretary of HHS would also promulgate rules governing cessation programs, including standards for eligible cessation devices, individuals eligible to get cessation money, and procedures to govern the cessation program.

Finally, a Presidential commission would be appointed to distribute tobacco-related medical research from the $25 billion Public Health Trust Fund.

Comments: The agreement is decidedly vague on money distribution issues. It appears from the overall structure of the agreement, but is not clear from the document itself, that the money for the programs listed in the above table would come out of the base payments, and therefore be unavailable as compensation to victims. The language establishing the trust fund seems to imply that the Presidential Commission money would be the trust fund.

If the public health trust fund money is entirely separate, and the money to be used for the anti-tobacco efforts listed the above table is part of the base payment, then the money available for distribution for all potential claimants would be as follows:

Year	1	2	3	4	5	6	7	8	9	10
Amt.	$3.9B	4.825	5.8	7.675	10.175	12.675	12.675	12.675	12.675	12.675
Civil Liability Fund	2.0	2.31	2.64	3.33	3.33	4.125	4.125	5.00	5.00	5.00
Avail. to States, etc.	1.9	2.515	3.16	4.345	6.845	8.55	8.55	8.55	7.675	7.675

- There is no explanation why the development of programs under this Title would reside in the Department of Health and Human Services rather than specifically in the FDA, which will have the smoking and health expertise.

- Some of the research to be funded out of the industry payments is research that the industry ought to be doing in any event, for its own commercial purposes--research into safer product technology, for example. It is probably as well to have this research done outside the industry, with the results presumably available to anyone, without commercial restriction.

- Spending public health dollars on a soft landing for people who relied on tobacco sponsorship dollars is questionable, but the stipulation that they carry "quit tobacco use" messages makes this less objectionable.

TITLE VIII: CIVIL LIABILITY

This Title would preempt -- "legislatively settle," in the euphemism of the proposal--all present and future attorney general or similar governmental entity suits, present and future parens patriae actions, all present and future class actions; and all existing addiction/dependence (i.e. Castano-type) claims.

Third-party payor actions pending as of June 19, 1997 (such as Blue Cross/Blue Shield of Minnesota's claim) would not be settled, but would be subject to limitations governing liability for past conduct.

This Title has two main parts, establishing different rules for past and future conduct.

B. Past Conduct: This section applies to suits arising out of conduct occurring before the effective date of the act. It imposes a number of conditions and limitations on the ability of future (i.e. post-effective date) plaintiffs to recover for the industry's misconduct of the past four decades. Where noted, the same restrictions would also apply to future industry conduct:

(1) No punitive damages in individual tort actions.

(2) Individual trials only: i.e. no class actions, joinder, aggregations, consolidations, extrapolations or other devices to resolve cases other than on the basis of individual trials, without the defendant's consent. If a claim inconsistent with this paragraph were asserted in a state court, the case would be removable to federal court. In addition, under (9), below, an individual could only recover $1 million in a given year, unless there was unpaid money within the industry's aggregate, annual liability payment cap. (This provision also applies to future conduct under Section C., below.)

(3) Except as expressly modified, the Federal Cigarette Labeling and Advertising Act and case law would remain unchanged. (Applies to future conduct.)

(4) No joint and several liability for any of the five negotiating companies which enter into the protocol. Trials involving both protocol and non-protocol companies would be severed -- i.e. tried separately.

(5) No claims based on addiction or dependence (arguably the claims most likely to succeed).

(6) Consistent with the limitations on class actions and other multi-party actions, only certain plaintiffs could sue the tobacco companies: individuals (injured parties or heirs); third-party payors with non-subrogation claims pending as of June 19, 1997 (i.e. BCBSM and the labor unions); third-party payors asserting subrogation claims. Only tobacco manufacturing companies, their designated survivors (as in bankruptcy or mergers/acquisitions), their assigns and future fraudulent transferees, and those vicariously liable for their acts, would be permissible defendants. (Applies to future conduct.)

(7) Cases could be heard in state court unless impermissible claims were asserted, when cases would be removed to federal court. (Also applies to future conduct.)

(8) Development of reduced risk tobacco products after the effective date would not be admissible in evidence or discoverable. (Applies to future conduct.)

(9) Statute of limitations would run from the time of injury or discovery, or notice of a violation. (Applies to future conduct.)

(10) There is an annual payment cap with the following features:

- Annual liability payments to the permissible plaintiffs, whether by settlement or by judgment, would not exceed one-third of the industry's base payments for that year. Thus, in Year 1, for example, the industry could not be required to pay more than $2 billion in individual liability damages. By year 9 the cap would rise to $5 billion.
- Excess liability would roll over and be credited 80 cents on the dollar to the annual payments required in the year paid (thus snowballing the cumulative unpaid liability).
- No individual could collect more than $1 million in a year, unless all unsatisfied judgments had been paid that year (i.e. if there was room under the cap). Unpaid amounts on individual judgments would roll forward, with interest. (Applies to future conduct.)

(11) If the cap is not reached in a given year then a Presidential Commission will decide how to allocate unused money. (Note that this implies that there is a fund, with money paid in by the industry -- the "cap" concept itself seems to imply only a limitation on liability. The settlement does not appear to elsewhere require the establishment of an annual payment fund.) (Applies to future conduct.)

(12) Manufacturers control insurance claims, and any insurance payments go 80% to the annual payments. Manufacturers pay defense costs, but retain any defense cost insurance payments.

Comments: The limitations on actions and on payments, in the aggregate, take away significant incentives for individuals and their lawyers to pursue claims against the tobacco companies. The ban on multi-party actions and non-subrogation theories; the unavailability of the possibility of punitive damages for what is arguably this Century's worst corporate misconduct; limitations on recoveries payable in a given year; the inconvenience of separate proceedings, and the apparent inability to pursue non-tobacco assets to satisfy a judgment all combine to make it unlikely that the tobacco manufacturers will face anything approaching the full and just consequences of their actions. The ban on addiction and dependence claims is armor plating for the industry's weakest spot in individual cases. It would ban precisely those cases where the industry's "assumption of risk" defense is strongest. Other comments:

- Presumably, the Presidential Commission referred to in this Title is the same one which would allocate program dollars under the preceding Title.

- We in the past have recommended that the preemptive provisions in the existing Federal Cigarette Labeling and Advertising Act be repealed. This section would leave the preemption intact, along with the case law which has interpreted in many cases favorably to the industry.

C. Future Conduct: In addition to the provisions identified above as applying to future conduct, there could be no third-party payor, non-subrogation claims.

TITLE IX: BOARD APPROVAL

This agreement is subject to approval by the tobacco companies boards of directors.

Appendix VIII - Public Disclosure of Past and Future Tobacco Industry Documents and Health Research

The proposed settlement establishes one centralized document depository in Washington D.C. and one method of obtaining review of materials alleged to be privileged or trade secret data *for all cases in state or federal court in the United States*. The only exception is for disputes in pending cases that *can be resolved* prior to the time the three-judge panel established by the Congress has an opportunity to *begin to review* claims. (It is not clear what will happen to Mississippi's documents as a result of the settlement in that case.)

The national depository in Washington D.C. will include:

- all documents produced by CTR, TI and the tobacco manufacturers in pending litigation, including the Minnesota litigation
- all indices of documents regarding smoking and health research as defined by the court's order in the Minnesota litigation
- any additional existing documents (which somehow have not been produced) regarding: health research, addiction or dependency, safer/less hazardous cigarettes, studies of smoking habits of minors, and the relationship between advertising or promotion and youth smoking.

These documents will have no confidentiality designations of any kind and will be available to members of Congress, state and federal agencies, and the public.

No documents for which the industry asserts attorney-client privilege, work product or trade secret protection will be placed in the depository. The industry will *as soon as practicable* conduct a good faith, de novo, document-by-document review of all documents previously withheld on grounds of privilege to:

- identify and place in the depository documents which the reviewer determines should not be privileged and
- create *new privilege logs* with all of the detail required by the Minnesota litigation.

Anyone who wishes to challenge the industry's continued assertion of privilege or trade secret protection must file a claim with a three-judge panel of Article III federal judges appointed by the Judicial Conference. The decision of the three-judge panel is binding on all state and federal courts in all litigation in the United States, and may be reviewed only via a petition for certiorari to the United States Supreme Court (28 U.S.C. § 1254). The one exception is for those disputes that have already been resolved by other federal or state courts prior to the time the three-judge panel has had an opportunity to begin to review privilege claims.

The panel will review claims of privilege in accordance with ABA/ALI Model Rules and/or federal common law with respect to privilege and the Uniform Trade Secrets Act with respect to trade secrecy. No prima facie showing is required to obtain in camera review. The panel may appoint a special master(s) to hear claims by any public or private party, subject to a right of intervention by any other interested party. If the panel rules in favor of disclosure, the panel will consider whether costs and attorneys' fees should be assessed against the entity claiming the privilege, and may impose such additional costs or sanctions as the panel deems appropriate.

The industry will have a continuing obligation to disclose to the FDA and the depository:

- any future original laboratory research relating to the health or safety of tobacco products, including all laboratory research relating to ways to make tobacco products less hazardous to consumers (except trade secret information need not be produced to the depository)
- any future studies of the smoking habits of minors or documents which refer to the relationship, if any, between advertising and promotion and underage smoking.

Comments: The removal of any confidentiality designation from the documents already produced is good; the system for determining remaining privilege claims appears designed to slow the discovery process down in a very significant way. Concerns which come to mind on first reading of the proposed settlement summary include:

(1) Would the proposal take jurisdiction away from Judge Fitzpatrick and the Special Master to complete the process they have now begun for review of the industry's assertions of privilege? What does the fine print say about when the three-judge panel gets exclusive jurisdiction? It makes little sense to wrest jurisdiction from the Minnesota court if its review is ongoing (but not yet fully "resolved") prior to the time the three-judge panel has had an opportunity to "begin to review privilege claims." What do these terms mean for us?

(2) Why does the industry need another "document-by-document" review of its assertions of privilege to prepare a new privilege log in as soon as practicable a time frame as it can? Judge Fitzpatrick estimated conservatively that if a person took only five minutes to review each of the documents for which the industry has claimed privilege, the review would take a very long time. Does the proposal

contemplate that privilege determinations would simply be held in abeyance as the industry completes its re-review of the documents? Is the provision for re-review an implicit concession by the industry that it has over-claimed privileges? The defendants have already produced privilege logs in the Minnesota litigation and are under a current obligation to provide all of those privileged documents to the Minnesota depository's secure facility this month. The Minnesota court's process for review of defendants' privilege assertions is well underway and should not be disturbed by whatever new process is contemplated by the settlement.

(3) What does the "trade secret" protection for laboratory research keep confidential from the public in the future? Is this an exception that will swallow the rule of disclosure for research on safer cigarettes? Will the FDA be given access to this information (even if it is not publicly available)?

This settlement requires far less of the big companies than we will be able to get in our litigation, or than Liggett did. To get any kind of deal the companies should make a clean break with past lies. Without such disclosure, Congress will not know what abuses need to be regulated, and we will continue the absurd national policy of legislating on lies.

AG:80540 v1

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Jerold Mande
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FOLDER TITLE:
Tobacco: Minnesota [6]

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b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[001]

STATE OF MINNESOTA

OFFICE OF THE ATTORNEY GENERAL

HUBERT H. HUMPHREY III
ATTORNEY GENERAL

102 STATE CAPITOL
ST. PAUL, MN 55155-1002
TELEPHONE: (612) 296-6196

August 14, 1997

Jerry Mande, Senior Advisor to the Director
Office of Science and Technology Policy
Old Executive Office Building, Room 436
17th and Pennsylvania
Washington, DC 20502

2 pages via fax

Dear Mr. Mande:

Enclosed is a list of attendees for a meeting with the White House Tobacco Working Group on Friday, August 15, 1997.

The attendees are as follows:

Hubert H. Humphrey III: Attorney General, Minnesota
(b)(6)

Eric A. Johnson: Executive Assistant to the Attorney General, Minnesota
(b)(6)

Leslie Sandberg: Press Secretary to the Attorney General, Minnesota
(b)(6)

*As I indicated by phone, Ms. Sandberg will not attend the meeting but will assist in coordinating the media requests we've received for post-meeting interviews.

Roberta Walburn: Esq., Robins, Kaplan, Miller & Ciresi
(b)(6)

Tom Downey: Chairman, Downey Chandler, Inc.
(b)(6)

[001]

Carmen Mercedes Shepard; Chief Deputy Attorney General, Maryland
(b)(6)

Peter George Angelos; Private Counsel, State of Maryland
(b)(6)

Hervey Russell Smouse; Private Counsel, State of Maryland
(b)(6)

Thank you very much for your assistance in helping coordinate this meeting.

Best regards,

Eric A. Johnson
Executive Assistant to the Attorney General

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