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Bruce R/Bruce L/
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July 30, 1997

Memorandum

To: Elena Kagan

From: Jennifer O'Connor

Subject: Tobacco Litigation

FYI- Information regarding Union lawsuits and tobacco.

LAW OFFICES

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†NOT A MEMBER OF THE BAR

July 14, 1997

DELIVERED BY HAND

Mr. David Nexon
Minority Staff Director for Health
c/o Senator Ted Kennedy's Office
United States Senate
527 Senate Hart Office Building
Washington, D. C. 20510

Re: *Tobacco Settlement*

Dear David:

I am writing to follow-up our brief discussions concerning the efforts of a national coalition of Taft-Hartley, multiemployer health and welfare funds to obtain reimbursement of their costs for health care provided to participants and beneficiaries who suffer from tobacco-related diseases. The organization is called the Coalition for Workers' Health Care Funds. Enclosed is a copy of the Coalition's mission statement and some other materials. My law firm is serving as national coordinating counsel for the Coalition.

We took to heart your comment that all multiemployer funds should file claims for reimbursement. Statewide class action lawsuits have been filed by multiemployer funds in 15 States thus far: Massachusetts, Rhode Island, California, Washington, Ohio, Maryland, Illinois, New York, Connecticut, Kentucky, Iowa, Louisiana, Hawaii, Oregon and Arizona. Two lawsuits have been filed in New York: one for private sector multiemployer funds, and a second for public sector union plans. Multiemployer plan class actions will be filed shortly in 9 more States: Pennsylvania, Texas, New Jersey, Florida, West Virginia, Colorado, Indiana, Missouri and Tennessee.

Note that these lawsuits are grass-roots efforts. Local multiemployer funds, which are unaffected by the tobacco money that flows so freely in the Nation's capital, are leading the way. The plaintiff funds cover a broad range of worker groups, including laborers, ironworkers, carpenters, teachers, plumbers, seafarers, electricians, machanists, sheet metal workers, teamsters, and industrial workers.

As we discussed, the multiemployer funds' claims are essentially the same as the reimbursement claims made by the State Attorneys General. The Attorneys General demanded reimbursement for the tobacco-related health care costs incurred by State employee health plans as well as by the Medicaid programs. The "global"

settlement agreement between the Attorneys General and the tobacco companies that is currently before Congress provides many billions of dollars in reimbursement to the States' health plans and programs.

Multiemployer funds, however, were not represented at the settlement table that produced that agreement, and the agreement provides no reimbursement to the funds. Worse, the agreement purports to, in effect, shut the court house doors to multiemployer funds' reimbursement lawsuits.

The Coalition will be sending a formal request to Senator Kennedy and Chairman Jeffords for an opportunity to testify at the Labor & Human Resources Committee hearing that has been scheduled for September. Our funds merely want a fair opportunity to press their claims for recompense; if not in Congress, in the courts unfettered by the restraints that the "global" settlement agreement would impose on the funds.

From a public health standpoint, reimbursement would enable multiemployer funds to provide smoking prevention and cessation programs for their participants and beneficiaries and reduce the cost burdens of tobacco-related disease on the funds and the workers whose labor finances the funds. Our funds cover worker groups (e.g., construction workers, seafarers) who were targeted by tobacco marketing and have higher rates of tobacco usage and tobacco-related disease. The children covered by multiemployer funds are more at risk for smoking and other tobacco usage.

To friends who express some concern about taking on the "labor friendly" tobacco industry, I simply ask: How can anyone object to multiemployer funds obtaining reimbursement when the tobacco companies have already agreed to reimburse State employee health plans?

I would be pleased to discuss this matter with you again at your convenience.

Sincerely,

James S. Ray

JSR/mlk
cc: Susan Green, Esq. (w/ encl)

NEWS:

FROM THE COALITION FOR WORKERS' HEALTH CARE FUNDS

BACKGROUND

The Coalition for Workers' Health Funds is a grouping of labor-management health and pension trust funds created under the Taft-Hartley Act of 1947.

The purpose of the coalition is to provide coordination at the national level for funds throughout the nation seeking reimbursement through the civil justice system from tobacco companies for monies paid out as a result of smoking-related illnesses suffered by American workers and their family members.

There are approximately 2000 such funds in the 50 states, the District of Columbia and Puerto Rico paying the medical and hospital bills of some 30 million Americans: workers, retirees and their families. The industries represented are characterized by small employers and transient and intermittent work patterns , e.g. building and construction, trucking, maritime, service and clothing.

The funds are financed by contributions resulting from collective bargaining agreements entered into between working men and women and their employers.

The lineage of these funds can be traced to the passage in 1947 of the Taft Hartley Labor Relations Act. Their mission is to promote health and safety in the workplace and guarantee that a worker's medical and hospital bills would be paid.

From the beginning these funds have also had, as a prime focus, workplace safety because it was in this area that workers suffered the most. Great strides have been made in improving workplace safety conditions.

Indeed, such progress has been made that, in 1996, for the first time, statistics showed fewer accidents per capita in the construction industry than in the nation's manufacturing sector.

1920 L STREET, N.W. • FOURTH FLOOR • WASHINGTON, D.C. 20036-5004

BACKGROUND 2-2-2-2-2-2

As progress has neem made in improving safety in the workplace the trustees of these funds began to look more closely at medical expenses that were non-safety related.

In every instance they found that by far the greatest cause of medical bills came from tobacco-related diseases. Coupled with the discovery that workers covered by the funds consumed tobacco at a rate roughly double that of the national average, it soon became apparent that something had to be done.

In September of 1996, a number of funds began to explore the question of filing class action suits against the tobacco companies to recover costs incurred for tobacco-related illnesses. The first such suit was filed in May, 1997 and others followed quickly.

The money to operate these funds is negotiated at the bargaining table, thus, every dollar spent treating tobacco-related diseases is a dollar that comes out of the worker's pay check.

Fund trustees have a fiduciary duty to manage costs in the best manner possible. They also have a moral duty to safeguard the health and safety of the workers.

These suits are an effort to fulfill both obligations.

#####

Coalition for Workers' Health Care Funds Update

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July 8, 1997

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Senate Judiciary Committee Off to Fast Start

Sen. Hatch Chairs First Hearing on Tobacco Agreement

The Senate Judiciary Committee, on Thursday, June 26, held the first of what is expected to be a lengthy series of congressional hearings to examine the "global" agreement entered into between the tobacco companies and attorneys general for 40 states.

Attracting a full line up of senators and massive press coverage the committee heard from a panel of three witnesses.

They were Michael Moore, Attorney General of the state of Mississippi, lead spokesman for the 40 attorneys general who signed on to the agreement; Matthew Myers, executive vice-president and general counsel for the National Campaign for Tobacco Free Kids and Meyer Kaplow, an attorney representing the tobacco companies.

The following are excerpts of statements taken verbatim from the transcript of the committee hearing.

Excerpts from a statement read by Sen. Orrin Hatch (R-UT)

The proposed settlement also raises a myriad of challenging legal and constitutional questions, including the profound ramifications for our civil justice system embodied in proposed changes affecting class action lawsuits, punitive damage awards, and tobacco advertising.

As provocative as this agreement's possibilities are, the questions it immediately raises are very complicated. In the end, however, what we must settle on is whether this is a good deal.

Excerpts from a statement read by Sen. Patrick Leahy (D-VT)

The very existence of this settlement agreement is a credit to our civil justice system. In fact, without the use of class action and the likelihood of punitive damage recoveries, does anyone believe that the tobacco companies would have ever come to the negotiating table or offered to contribute $368.5 billion over the next 25 years? Without the willingness of private attorneys acting on behalf of their clients, taking significant financial and professional risks, and pursuing these matters so diligently, we would not be here today. At a time when some are trying to limit legal rights and remedies through national legislation, this proposed agreement reminds us that our state-based tort system remains one of the greatest and most powerful vehicles for justice anywhere in the world.

When tobacco companies were

(See, *Committee*, Page 3)

More Hearings Scheduled

Sen. Orrin Hatch (R-UT), chairman of the Senate Judiciary Committee, has announced the committee will hold a series of hearings on the tobacco agreement. The committee is expected to share jurisdiction with several other committees in the process of turning the agreement into federal legislation.

The announcement said the first hearing will deal with the legal implications of the agreement. It will be held on Wednesday, July 16.

The second will deal with public health issues. It will be held on Wednesday, July 30.

Inside:

Who's On First in the Tobacco Wars: Identifying the Key Players 2

How Others See the "Global" Tobacco Settlement Agreement 3

Who's On First in the Tobacco Wars: Identifying the Key Players

The agreement reached between the tobacco companies and the attorneys general has rapidly become one of those gigantic and far reaching administrative/ legislative/media minuets that periodically consume official - and unofficial - Washington, D.C. as it tries to come to grips with an issue of overriding public policy.

UPDATE will endeavor to keep its readers abreast of developments in this ongoing saga as well as identify the key players, their affiliations and where they stand on the issue.

The White House

President Clinton has ordered a review of the agreement. It will be conducted jointly by **Donna Shalala**, Secretary of Health and Human Services and **Bruce Reed**, Director of the White House Office of Domestic Policy.

These two have divided the agreement into smaller packages by subject matter and staffed by working groups.

The first of these deals with regulatory issues and the second deals with liability for cigarette manufacturers. A third deals with the effect the agreement will have on the federal budget. The fourth group will study the economic impact of the agreement on the tobacco industry. That study will be conducted by the President's Council of Economic Advisors.

Public Health Groups

Former Surgeon General of the United States, **Dr. C. Everett Koop** and former Administrator of the Food and Drug Administration (FDA) **David Kessler**, were requested by Congress to head up a group called the **Advisory Committee on Tobacco Policy and Public Health**.

It is widely believed that any recommendations forthcoming from these two will carry considerable weight with members of Congress.

The major public health groups represented on this committee are: **The American Medical Association**; **The American Cancer Society**, the **American Heart Association** and the **National Campaign for Tobacco Free Kids**.

Their current statements are in line with a position taken by Dr. Koop and Mr. Kessler. These hold that from a public health perspective the agreement has serious flaws that need to be fixed.

For the most part their misgivings are directed at language that appears to sharply circumscribe the ability of the FDA to regulate the contents of cigarettes.

Mr. Matthew Meyers, executive vice president and general counsel of the National Campaign for Tobacco Free Kids, who participated in the negotiations that led to the agreement, has been consistently supportive of the pact as written.

Attorneys General

Michael Moore, Attorney General of the State of Mississippi, has been the lead spokesperson for the attorneys general. Moore points out to critics of the agreement that perfection is not often achieved in the real world and that, while flawed, the deal represents the best that could be achieved under the circumstances.

Capitol Hill

Rep. Henry Waxman (D-CA), an influential member of the House on tobacco issues is, thus far, the lone voice categorically in opposition to the agreement, regardless of what modifications it may undergo.

Sen. Orrin Hatch (R-UT), Chairman of the Judiciary Committee, has long been critical of the tobacco industry. He has moved quickly to assert his committee's jurisdiction in the matter. His public statements make it appear that, while he has reservations about several aspects of the agreement, he believes it can be improved by modifications.

Rep. Newt Gingrich (R-GA), Speaker of the House of Representatives, has been critical of some aspects of the settlement. He has told Republican House Members not to expect to have to deal substantively with the issue any time before September at the earliest.

Sen. Edward M. Kennedy (D-MA), ranking minority member of the Labor and Human resources Committee and a member of the Judiciary Committee has criticized aspects of the agreement. In general he has adopted the position that it is too easy on the tobacco industry and, in particular, fails to provide enough money to pay for health insurance for uninsured children.

Sen. Dick Durbin (D-IL), has long been critical of the tobacco industry. He has criticized the deal and has been critical of the National Campaign for Tobacco Free Kids for its position of support.

Rep. Thomas Bliley (R-VA), Chairman of the House Commerce Committee, another committee with apparent jurisdiction, represents a tobacco growing district and has a long history of support for the industry.

Sen. Wendell Ford (D-KY), Senate minority whip who holds the number two Democratic leadership position, represents another tobacco growing state. He has been a longtime supporter of the tobacco industry.❑

(*Committee*, Continued from pg.1)

fighting any and all lawsuits against them, a combination of legal challenges by private citizens and public officials were pursued against great odds. Men and women whose lives were cut short by cancer, heart disease and other adverse health consequences from tobacco deserved better treatment than the years of obstruction and denial by the tobacco industry. Only now as the internal documents are being discovered and the legal tide is beginning to turn have tobacco companies decided to change their strategy and pursue a settlement. The tobacco industry did not agree to this settlement out of some new found sense of public duty. The truth is that giant tobacco corporations were beginning to lose in court and after President Clinton initiated tough new regulatory efforts.

Three fundamental concerns

On my first reading on the 68-page agreement, I am struck by three fundamental concerns on the limits of this agreement; the limits of liability, the limits on disclosure and the limits on jurisdiction.

First, I am concerned about the agreement's sweeping limits on the ability of ordinary citizens to sue tobacco companies. The agreement would ban punitive damages and class actions on past conduct in exchange for payment of $60 billion. That payment appears to have been structured so as to be tax-deductible for the tobacco companies, unlike true punitive damages. For lawsuits based on future conduct of the tobacco industry, the agreement would ban class action lawsuits and impose other restrictions on the rights of individuals to seek legal recourse. The possibility of punitive damages and class action lawsuits are two important factors that brought us to this point. Class actions make it possible for individuals to band together to take on the powerful tobacco conglomerates in ways that an individual could not afford to take on alone. Punitive damages are awarded to punish egregious behavior - like the deceit or concealment of research that some have accused tobacco company officials of practicing.

Excerpts from statement of Sen. Edward M. Kennedy (D-MA)

The financial settlement reportedly offered by the tobacco industry - $300 billion over 25 years - sounds enormous at first blush. People hear the $300 billion and don't register the "25 years." They are offering $12 billion a year. That number pales in comparison to the harm the industry causes. According to the Congressional Office of Technology Assessment, cigarettes cost the United States $68 billion a year in health care costs and lost productivity. 419,000 Americans die each year due to smoking-related illnesses. Smokers lose an average of 15 years of their life. At current smoking rates, 10.5 million people will die prematurely due to tobacco during those years. Collectively, they will have lost 157 million years of life. Suddenly the industry's settlement offer does not sound large anymore.

Right to justice

We also hear that the industry wants blanket immunity from suits for its decades of willful wrongdoing as the price of a settlement. If

(See, *Committee*, Page 4)

How Others See the Tobacco Agreement

The "global" agreement between the tobacco companies and attorneys general for some 40 states has prompted close examination by a variety of interest groups as well as Members of Congress and the White House.

After more than two weeks of discussion, some seven main areas of interest within the agreement have been identified:

- Constraints on the ability of individuals, organizations and government officials to sue tobacco manufacturers in the future.
- The adequacy of $1 billion in annual funding to help any American smoker who wants to quit.
- The adequacy of measures to enforce a dramatic reduction in use of tobacco products by children.
- Whether the FDA's ability to regulate nicotine and tobacco products would be inhibited under the deal.
- Whether the amount of money designated for public health initiatives to reduce tobacco use is adequate.
- The settlement's lack of international tobacco control measures.
- Constraints on disclosure of tobacco industry documents.

(*Committee*, Continued from pg.3)

that is the price, there will be no settlement. It would be unconscionable to deny people poisoned by tobacco their day in court. Each year, millions of Americans discover that they have diseases caused by smoking. In too many cases, it is beyond our power to restore their health. We must never permit the tobacco industry to extinguish their right to justice as well.

"The financial settlement reportedly offered by the tobacco industry - $300 billion over 25 years - sounds enormous at first blush. . . That number pales in comparison to the harm the industry causes. . . Smokers lose an average of 15 years of their life. At current smoking rates, 10.5 million people will die prematurely due to tobacco during those years. Collectively, they will have lost 157 million years of life. Suddenly the industry's settlement offer does not sound large anymore."

Sen. Edward M. Kennedy (D-MA)

Excerpts from a statement read by Sen. Dick Durbin (D-IL)

As long and as difficult as these negotiations have been, this agreement is not written in stone. It is important to understand that the final deal, if there is one, is not the deal cut in secret between tobacco lawyers and state attorneys general. That is only the starting point. We will not rubber-stamp any deal, no matter how extensive. That is not our job.

This agreement must be reviewed and the final arbiters are the American people. And we here in Congress have a responsibility to the American people to review the terms of the agreement and to improve it, to make certain that the final result is in the best interests of the health of our nation.

Excerpts from a statement read by Mr. Meyer Kaplow

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

The following excerpts from the agreement were entered into the hearing record:

Title VIII. Civil Liability.

The following provisions would govern actions for civil liability related to tobacco and health.

A. General

1. Present attorney general actions (or similar actions brought by or on behalf of any governmental entity), parens patriae and class actions are legislatively settled. No future protection of such actions. All "addiction"/dependence claims are settled and all other personal injury actions are reserved. As to signatory states, pending Congressional enactment, no stay applications will be made in pending actions, based upon the fact of this resolution, without mutual consent of the parties.

Agreement for civil liability. Protocol manufacturers not jointly and severally liable for liability of non-protocol manufacturers. Trials involving both protocol and non-protocol manufacturers to be severed.□

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Coalition for Workers' Health Care Funds Update

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July 1, 1997

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Mission Statement of the Coalition for Workers' Health Care Funds

Representing the Labor-Management Health Funds that Provide Health Care for 30 Million Americans: Workers, Retirees and Their Families

Thirty million Americans - workers, retirees, and their family members - rely on labor-management, multiemployer health funds for health care coverage.

That is, these collectively bargained trust funds pay the hospitals, doctors, and other health care professionals who provide medical care, prescription drugs, and health services to workers, retirees and dependents.

Multiemployer funds play a vital role in the health care system of our nation, as recognized in current law and in various legislative proposals advanced by Congress and the Clinton Administration.

But for these pooled, non-profit health funds, a great many more workers and their families would lack employment-based health care coverage and would have to depend on government programs for medical and related care.

These funds cover millions of workers in industries characterized by small employers and transient work patterns: *e.g.* building and construction, trucking, maritime, service, and clothing.

Several of these worker groups have been specifically targeted by the tobacco industry's marketing, and have higher than average rates of smoking and tobacco-related disease.

Multiemployer funds have incurred billions of dollars in health care costs for individuals suffering from tobacco-related disease. These costs to the funds are ultimately borne by the covered workers who have seen a growing share of their

(See ***Mission***, Page 4)

Workers' Health Care Funds in 14 States File Suit Against Big Tobacco Seeking Reimbursement

Workers' health care plans in 14 states and the District of Columbia have filed class action lawsuits against the tobacco industry asking for reimbursement for funds spent on tobacco-related illnesses and money for smoking cessation and prevention programs.

Some of the suits have been filed in state courts and others in federal court. As of July 1, 1997 actions had been filed in Arizona, California, Hawaii, Illinois, Iowa, Kentucky, Louisiana, Massachusetts, Maryland, New York, Ohio, Oregon, Rhode Island, and Washington.

The plaintiff funds provide health care coverage for laborers, carpenters, electricians, seafarers, engineers, painters, teamsters, sheet metal workers, plumbers and pipe fitters, ironworkers, transport workers, teachers, office employees, machinists, wood workers, and other groups.

It is expected that additional suits in other states will be filed shortly. ■

In This Issue:

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Benefits From Tobacco Settlement Limited to State Employee Plans: Private Sector Plans Shut Out.....3

Costs: Workers Pay Through the Nose for Tobacco - And Through the Lungs and Heart.....3

Civil Liability Aspects of the Global Tobacco Settlement

Analysis Expected to be Both Lengthy and Complicated

The civil liability aspects of the global tobacco settlement agreement entered into between attorneys general for some 40 states and the tobacco industry are lengthy and complicated.

Certain portions of the agreement seek to limit the ability of some potential plaintiffs to file civil liability suits against the tobacco industry subsequent to the date the agreement was signed. Other portions would limit the kinds of lawsuits that could be brought in the future.

It was not immediately clear what effect, if any, the terms of the agreement would have on efforts by workers' health care funds in the 50 states to use the courts to recover monies spent paying claims for tobacco-related illnesses. The final say, of course, resides with Congress which will conduct an exhaustive investigation into the deal.

Already, the Senate Committee on the Judiciary, chaired by Sen. Orrin Hatch (R-UT) has held a preliminary hearing based on the fact that it has jurisdiction over the civil liability aspects of the agreement.

In that hearing there was substantial criticism of the agreement by members of the committee who feared its terms were too lenient on the tobacco industry.

Attorneys acting on behalf of the Workers' Coalition for Health care Funds are studying the 68-page agreement in an effort to determine what effect, if any, it would have on class action lawsuits filed by funds in some 14 states as of press time.

The following is a verbatim excerpt of those portions of the agreement devoted to the area of civil liability as published in the June 25, 1997 editions of The New York Times.

The following provisions would govern actions for civil liability related to tobacco and to health:

1 - Present Attorney General actions (or similar actions brought by or on behalf of any governmental entity), *parens patriae* and class actions are legislatively settled. No future prosecution of such actions. All "addiction"/dependence claims are settled and all other personal injury claims are reserved. As to signatory states, pending Congressional enactment, no stay applications will be made in pending actions, based upon the fact of this resolution, without mutual consent of the parties.

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 defendant's consent. Action removable by defendant to federal court upon receipt of application to, or order of, state court providing for trial or other procedure in violation of this provision.

3 -Permissible parties:

Plaintiffs:

a. Claims of individuals, or claims derivative of such claims, must be brought either by the person claiming injury or the claimant's heirs.

b. Third-party payer (and similar) claims not based on subrogation that were pending as of June 9, 1997.

c. Third-party payer (and similar) claims not based on subrogation of individual claims; no extrapolations, etc.

Defendants:

a. Maintained only against companies, their assigns, any future fraudulent transferee and/or entity or suit designated to survive defunct manufacturer....

b. Manufacturers of agents agencies and liable vicariously for acts (including advertising attorneys). ■

COALITION FOR WORKERS' HEALTH CARE FUNDS UPDATE

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DAVID A. JEWELL
EDITOR

Labor-management, multi-employer health care funds cover 30 million Americans; workers, retirees and their dependents.

For the most part they cover workers in small-employer industries with transient work patterns, such as building and construction, trucking, maritime, service and clothing.

These groups have been targeted by tobacco industries' marketing and advertising policies. Workers in these groups suffer from higher rates of tobacco-related illnesses than the national average.

Workers Pay Through the Nose for Tobacco- And Through the Lungs and Heart

The cost of smoking only begins when a worker pays for a package of cigarettes. The costs to workers' health far outstrips the cost to their pocketbooks.

This is particularly true when it comes to health care funds covering workers in the construction industry who have for many years been targeted by cigarette marketing and advertising campaigns. Statistics show clearly they have much higher than average rates of smoking and tobacco-related diseases.

A study by one multiemployer health fund covering mostly construction workers in the American Northwest showed that, in 1994 more than 26% of the workers covered received treatment for smoking-related diseases. For their family members the figure was seven percent.

This is a multiple tragedy - first for the workers and their families and next for their health care fund which faces increasingly rising costs - costs that are paid for with money that would otherwise have gone into the workers' pay packets.

Figures contained in the broad-based national Health Interview conducted by the federal government bears out these shocking statistics.

They show that 47 percent of construction workers are smokers compared with 24 percent of all white collar occupations and 39 percent of all blue collar occupations combined. Even more worrisome are statistics which show a sharply lower rate of blue collar workers who succeed in kicking the smoking habit.

In an article entitled *Targeting of Cigarette Advertising in U.S. Magazines, 1959-86*, investigators from the University of Michigan showed that tobacco companies targeted blue collar workers in their advertising and promotional strategies. ■

Benefits From Tobacco Settlement Limited to State Employee Health Plans

Private Sector Workers' Plans Shut Out

The global tobacco settlement agreement signed by some 40 state attorneys general and the tobacco industry would *not* benefit labor-management health care funds covering working families in the private sector.

Men and women employed in construction, trucking, food, clothing, service and maritime industries, their families and retired workers - some 30 million strong - would receive *no* reimbursement for their billions of dollars in tobacco-related disease costs under the secretly negotiated agreement between the states and tobacco companies.

On the other hand, state public employee health plans and Medicaid programs would be paid hundreds of *billions* of dollars by the tobacco companies to reimburse the costs of health care for government employees and public assistance recipients suffering from tobacco-related illnesses.

Moreover, the so-called global settlement calls for federal legislation to close the courthouse doors to lawsuits against the tobacco companies by those not party to the negotiations and to protect the tobacco companies from normal legal remedies.

However, attorneys acting on behalf of the Workers' Coalition for Health care Funds are studying the complex 68-page agreement in an effort to determine what effect, if any, it would have on class action lawsuits filed by funds in some 14 states as of press time. These actions seek reimbursement for workers' funds for money already paid for tobacco-related diseases. ■

Labor-management, multiemployer health funds –

o are non-profit trust funds administered by representatives of the covered workers and their employers;

o are financed by collectively bargained contributions which employers pay on behalf of their workers as part of the compensation for their labor;

o pay the hospital, doctor and pharmacy bills of 30 million Americans - workers, retirees and their family members;

o provide health coverage for workers in industries characterized by transient, intermittent work patterns and small employers (e.g. construction) many of whom would not have on-the-job- health care coverage but for these funds and would be dependent upon government health programs;

o enable workers to move from employer to employer, and state to state without losing health care coverage;

o cover worker groups targeted by tobacco companies' marketing campaigns; and

o are regulated by federal law.

(Mission, Continued from pg. 1)
compensation package absorbed by the collectively bargained contributions needed by the funds to keep pace with increases in health care costs.

These funds have claims against the tobacco companies for reimbursement of their health care costs for tobacco-related disease. Reimbursement would enable the funds to provide smoking prevention and cessation programs for covered individuals, as well as reduce the cost burdens of tobacco-related disease on the funds and the covered workers.

Reimbursement Sought

The funds' claims are essentially the same as the reimbursement claims asserted by the 40 or so states that have filed suit against the tobacco companies. The states' lawsuits seek reimbursement of the costs incurred by the states' employee health plans and Medicaid programs in providing health care to government employees and public assistance recipients.

The settlement agreement negotiated between the states' attorneys general and the tobacco companies provides for reimbursement to the states' employee health plans and Medicaid programs, as well as relief for certain private lawsuits brought by attorneys who were party to the settlement negotiations. Multiemployer funds, which were not represented in the negotiations, would not receive reimbursement under the settlement agreement.

Multiemployer health funds provide coverage for some 30 million Americans and play a vital role in our nation's health care system

The settlement agreement presumes to "legislatively settle" some lawsuits and to severely limit access to the courts and the relief available for cases not resolved by the agreement.

For example, the agreement prohibits the filing or continuation of class actions against the tobacco companies, and further protects the tobacco companies from punitive damages for past wrongdoing. To the extent that the agreement purports to apply these limitations to the claims of multiemployer funds, it cannot be justified.

Before the settlement agreement was reached, multiemployer funds in several states filed class action lawsuits against the tobacco companies seeking reimbursement of health care costs. Several more reimbursement class actions will be filed shortly by multiemployer funds in other states. These lawsuits are similar to the reimbursement lawsuits filed by the states' attorneys general.

Equal Treatment

The Coalition for Workers' Health Care Funds has been formed to represent these funds and coordinate their activities with regard to their reimbursement claims. The Coalition's mission is to seek for multiemployer funds equal treatment with the states' health care plans and programs with regard to reimbursement from the tobacco companies. While pursuing all available recourse through the courts, the Coalition intends to inform Members of Congress, the Administration, interest groups, and the public about the concerns of the multiemployer fund community. It would be in the best interests of all concerned -the Federal Government, the states, the tobacco companies, the public health community, and the millions of families relying on multiemployer health funds - for the tobacco companies to provide fair reimbursement to multi-employer funds. ■

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Union health-care funds suing tobacco companies

Richmond Times-Dispatch
Wednesday, July 09, 1997
BY PETER HARDIN
Times-Dispatch Washington Correspondent

WASHINGTON As the tobacco industry pushes for a landmark $368.5 billion settlement of 40 state lawsuits, it's facing a new wave of litigation from trade union health-care trust funds.

Health-care trust funds have filed class-action lawsuits against tobacco companies in 16 states since May to recoup expenses for smoking-related sicknesses, and lawsuits are likely to be filed in nine or 10 other states, an attorney helping to coordinate the lawsuits said yesterday.

Philip Morris Cos., one of the targeted companies, believes the lawsuits are premised on flawed legal and factual theories and the plaintiffs won't prevail, company lawyer Valerie Kilhenny said.

"The suits are wrong, and the members will lose, and this is wasteful of valuable fund assets," Kilhenny said in a telephone interview.

Brian McQuade, chairman of the newly created Coalition for Workers' Health Care Funds, said its several hundred members were bypassed by the recent tobacco settlement proposal.

"The recently announced 'global' settlement of similar suits filed by state attorneys general and the tobacco industry does not take into account the 30 million men, women and children covered by the (trust) funds," McQuade said at a news conference.

"Our workers, more than any other class of Americans, have been targeted by the advertising and marketing campaigns of the tobacco industry," McQuade said. "The percentage of smokers among our members is roughly double the national average," at 44 percent to 45 percent, he added.

The coalition is made up of health-care trust funds for workers in industries characterized by transient, intermittent work patterns, including construction, trucking, maritime, service and clothing. The trust funds pay hospital, doctor and pharmacy bills for workers, retirees and family members.

Robert J. Connerton, a Washington lawyer helping the trust fund plaintiffs, said the new lawsuits are similar to those filed by attorneys general in 40 states.

In addition to pressing the lawsuits, Connerton said the health-care trust funds intend to work hard on Capitol Hill to protect their position.

The coalition is unhappy with limits on legal liability for tobacco companies proposed in the settlement, which must get

approval from Congress and President Clinton to become effective.

Critics to issue report

The proposed accord would eliminate punitive damage awards against the tobacco companies for past conduct. It also would prohibit both the filing of new class-action lawsuits against the tobacco industry and the continuation of existing ones, according to coalition officials.

Since the settlement proposal was unveiled June 20, it has come under fierce criticism from some public health groups.

Today, two leading critics, former Food and Drug Administration Commissioner David Kessler and former Surgeon General C. Everett Koop, were to issue a report by their 22-member advisory panel recommending future tobacco control policy sharply at odds with some provisions of the settlement.

Mississippi settled

One suing state, Mississippi, already has closed a settlement with cigarette makers in the wake of the proposal. It struck an agreement last week, just days before it was scheduled to go to trial. Whether or not Congress and Clinton approve the national accord, Mississippi will collect $3.6 billion over 25 years.

A series of private class-action lawsuits brought by a coalition of plaintiffs' lawyers around the nation also would be settled if the accord is enacted.

The states where health-care trust funds have lodged suits so far include: Arizona, California, Connecticut, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Massachusetts, New York, Ohio, Oregon, Rhode Island and Washington.

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Tobacco Industry Is Sued By Unions for Health Outlays

Wall Street Journal - Interactive Edition
Thursday, July 03, 1997
By MILO GEYELIN
Staff Reporter of THE WALL STREET JOURNAL

A growing number of health-and-benefit funds for construction trade unions are suing the tobacco industry to recover their health-care outlays for treating sick smokers.

There are now 15 such suits, all styled after the so-called Medicaid recoupment suits in which 40 states and the territory of Puerto Rico are seeking to recover billions of dollars in public health-care costs linked to smoking.

The latest lawsuit was filed Tuesday in federal court in Hartford, Conn., by a health-and-benefit fund for the Connecticut Pipe Trades and the International Brotherhood of Electrical Workers, Local 19.

"Basically we're using the same theory that state AGs had when they sued to recoup their cost of treating tobacco-related diseases," said Robert J. Connerton, at Connerton & Ray in Washington, D.C., one of several law firms involved in the Connecticut suit.

Tobacco-industry representatives said they planned to fight the suits the same way they have fought the attorneys general. "We think the plaintiffs are basing their cases on legal and factual theories that are flawed," said Valerie Kilhenny, an in-house lawyer and spokeswoman for Philip Morris Cos. "We just do not think the law permits for persons who were remotely or indirectly injured to collect damages."

Similar suits by union health-and-benefit funds have been filed in more than half a dozen states, including New York and Washington, over the past three months, and more are expected, said Mr. Connerton. The Connecticut Pipe Trades and International Brotherhood of Electrical Workers, Local 19 has some 2,500 members who are participants in the health-and-benefit fund. An estimated 18% are believed to have some form of smoking-related disease, said Mr. Connerton.

New York lawyer Steven Fineman, a co-counsel in the suit, said the number is so high because construction workers smoke more than most people. According to the complaint, the tobacco industry targets blue-collar workers in its advertising and marketing campaigns.

This new wave of suits could complicate the proposed $368.5 billion national settlement that was reached last month by the attorneys general, plaintiffs lawyers and the tobacco industry and that is being reviewed by the White House, Congress and public health groups. Union health-and-benefit funds weren't represented in the talks. And they are researching the constitutionality of provisions in the agreement, which if

enacted into law by Congress, would limit lawsuits.

The proposed settlement bans all punitive damages for past wrongful conduct by the tobacco industry. It also sharply limits suits against tobacco companies filed by insurance companies, health-care providers and benefit plans after June 9. After that date, class-action suits, consolidations of multiple suits into one trial, or the use of statistical models to prove total damages would be banned. Claims for damages would have to proceed case by case, a requirement that would make such third-party suits too wieldy and burdensome to take to trial.

Mr. Fineman said half of the union health-and-benefit-fund suits now pending were filed before the June 9 cutoff. Nevertheless, he added, "If [the agreement] becomes the law, then our cases have real problems."

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NBA beckons for UK and U of L stars – Sports, C1

The Courier-Journal

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METRO
EDITION

Betty Shabazz dies of injuries from fire

Betty Shabazz, the widow of civil-rights leader Malcolm X, died yesterday of burns suffered in a June 1 fire. **Metro, A3**

Blacks, whites have

Union health fund sues tobacco industry

Labor group wants Kentucky medical costs reimbursed

By JOE WARD
The Courier-Journal

Taking a page out of the strategy book of the 40 states that have sued the tobacco industry, the Kentucky Laborers Union health and welfare fund is suing to recover money it has spent on members with smoking-related illnesses.

The Laborers Union fund, which represents an estimated 1,700 workers in Kentucky, is the latest fund to join a new, rapidly growing national force on the tobacco litigation front.

The union fund is the first in Kentucky to sue the tobacco industry and joins funds in 11 other states that have filed similar lawsuits in the past month.

The Kentucky suit was filed in U.S. District Court in Louisville last Friday. Attorneys involved in the suits said they expect another eight or nine suits to be filed this week.

"It's picking up steam," said Bob Connerton, a Washington, D.C., attorney whose firm is coordinating the union health-fund suits. Herb Segal, a Louisville labor attorney, is representing the Kentucky Laborers Union fund.

Attorneys for the fund say it is a coincidence that the suit was filed on the very day of the historic $360 billion settlement between the tobacco industry and the attorneys general for the 40 states and others. The 40 states filed suit against the tobacco industry to recover state Medicaid funds spent on smoking-related illnesses.

Segal and Connerton said they don't know at this point what effect the settlement will have on their suit. The tobacco settlement bans future class-action lawsuits.

NO MORE: The powerful Tobacco Institute will cease to exist if the agreement becomes law. **E1**

The fund provides a form of health insurance for Kentucky members of the Laborers International Union of North America and their families. Members of the Laborers Union generally work in construction, employed by any of a number of contractors and builders, and often working for many different employers over the course of a year.

Money to cover benefits is provided by the employers and the fund is ad-

See LABORERS' Page 4, col. 6, this section

Landmark restaurant may soon disappear

Molesters can be held

Laborers' fund sues tobacco industry

Continued from Page One

ministered by a board of trustees with an equal number of members from the union and from the group of employers that have contracts with the union.

CONNERTON, WHOSE firm has coordinated all 12 of the suits filed so far, said determining how much each fund has spent on tobacco-related illnesses is complicated, and the process has not been completed for the Kentucky fund.

But he said tobacco-related illnesses make up about 18 percent of direct fund expenses for a fund in another of the suits — or about $3 million a year for 7,000 workers with 7,000 dependents.

Connerton said tobacco-related expenses would be different for each fund because some groups have more smokers than others, and benefits vary from fund to fund. But the numbers for the other fund suggest that the Kentucky fund's tobacco-related expenses might be around $700,000 a year.

The Kentucky suit names the major tobacco companies — including Louisville-based Brown & Williamson Tobacco Corp. and Philip Morris Inc., which has a plant in Louisville — as well as several industry organizations and a public-relations firm.

It charges, as the state suits have, that the tobacco companies conspired to hide the dangers of smoking from their customers and manipulated nicotine levels to keep smokers hooked. And, Connerton said, "it asks for the same sort of relief as the states ask."

The suit "asks for the same sort of relief as the states ask."

Attorney Bob Connerton

Joe Helewicz, Brown & Williamson vice president for corporate communications, said he had not seen the Kentucky suit and could not comment on it. But he noted that, as a class action, it would be barred by the settlement reached last Friday, if the settlement is enacted in its current form.

Connerton is a partner in Connerton & Ray, a Washington firm with national expertise in union health and welfare funds that involve unions that work with multiple employers, where unions and trades unions have such funds," Segal said.

Connerton said fund trustees began asking about last September whether they had a duty to sue the tobacco companies as the states had. The first union suit was filed about a month ago.

In response to an earlier class-action lawsuit against the tobacco industry, the U.S. Supreme Court ruled that class actions must proceed on a state-by-state rather than a national basis. Thus, Connerton said, the funds have filed state by state. In addition to the Kentucky fund, funds in California, Washington, Oregon, Hawaii, Arizona, Illinois, Ohio, Massachusetts, Connecticut, New York and Louisiana are suing the tobacco industry.

Connerton said the suits are being filed as class actions, on behalf of all such funds in each state. In several states, funds other than those that filed have joined in. In Illinois, for example, he said, three funds filed and 22 are now named plaintiffs.

Connerton said he and other lawyers involved in the fund suits are in the dark about the effect on them of last Friday's landmark tobacco settlement, which still needs approval of the White House and the Congress to take effect.

RICHARD DAYNARD, director of the Tobacco Products Liability Project at Northeastern University School of Law in Boston, noted that news accounts said the settlement would protect the industry from class-action suits.

But Daynard said it is a provision he would be surprised to see survive the scrutiny of the White House. And he said the union funds will amount to a significant group, in part because tobacco-related illnesses among union members are thought to be higher than for the general public.

"I don't know whether the agreement purports to cover us or not," Connerton said. "We've not been contacted by any of the parties (in the settlement negotiations), and they were well aware of our litigation.

"I have a couple of colleagues studying the settlement carefully," he said.

But "when all is said and done," Connerton said, "our funds are every bit as entitled to recoup some of their expenses as the states are."

"We've filed these suits. We're going to continue to file. What happens tomorrow, we basically don't know."

Health Care

Coalition of Health Care Funds Targets Big Tobacco for Compensation of Costs

In an effort to recover the costs of treating smoking-related illness, about 2,000 health funds representing 30 million workers are working together to coordinate efforts.

The approximately 2,000 multiemployer funds—known as Taft-Hartley or collectively bargained funds—have formed a coalition to coordinate litigation against tobacco companies and seek compensation for monies that were spent treating workers' tobacco-related illnesses.

Brian McQuade, president of the Coalition for Workers' Health Care Funds, said at a July 8 news conference that the exact cost for treatment of the illnesses has not yet been determined, but he predicted the amount could match the $368.5 billion settlement reached by state attorneys general with the tobacco industry. The coalition opposes the June 20 settlement negotiated by the state attorneys general, saying it unfairly limits liability suits against the companies.

Robert Connerton, coalition legal counsel, said about 18 percent of the direct costs to the health funds goes toward treating tobacco-related illnesses.

According to Connerton, 16 class action suits have been filed and he expects that number to rise to 25 or 26 in a little over a week.

McQuade said other goals of the coalition include obtaining money for programs to prevent smoking and to help workers quit, as well as to hold down the increase in future medical costs to the funds.

Coalition Challenges Recent Agreement. McQuade and Connerton expressed dismay over a clause in the recent agreement by the state attorneys general with the tobacco companies that limits further liability suits against the companies.

McQuade said the parties "neglected to take the men and women of the American labor movement into consideration as they pursued their deliberations."

Connerton said the agreement prohibits everyone else from exercising their rights. "They clearly were not authorized by us to act on our behalf," he said.

According to Connerton, the agreement would make all suits filed before June 9 ineligible to be filed as class actions, which affects six of the funds' suits. In addition, it would prohibit any suits filed after that date.

Congress still has to approve the agreement, and McQuade said he believes Congress will not "enact legislation that would leave out tens of millions of American workers and their families."

Workers Targets of Big Tobacco. The coalition, which represents workers in blue-collar industries such as construction, trucking, maritime, service, and clothing, is charging that tobacco companies specifically targeted these workers to encourage them to start smoking.

McQuade said the percentage of smokers among the workers covered by coalition member-plans is double the national average.

Workers covered by the funds begin their trades and crafts at a young age, McQuade added. "This means that the more successful the tobacco companies are in persuading teenagers to take up smoking, the greater will be the financial drain on our health care funds and the deterioration of the health of our members," he said.

McQuade said the coalition's goals can be achieved through direct negotiations with the tobacco companies, a provision for their workers made by Congress, or litigation of the cases in court.

By Amanda J. Crawford

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NEWS:

FROM THE COALITION FOR WORKERS' HEALTH CARE FUNDS

COALITION FOR WORKERS' HEALTH CARE FUNDS

REPRESENTING THE LABOR-MANAGEMENT HEALTH FUNDS THAT PROVIDE HEALTH CARE FOR 30 MILLION AMERICANS: WORKERS, RETIREES AND THEIR FAMILIES

Tobacco Project Mission Statement

Thirty million Americans--workers, retirees, and their family members--rely on labor-management, multiemployer health funds for health care coverage. That is, these collectively bargained trust funds pay the hospitals, doctors, and other health care professionals who provide medical care, prescription drugs, and health services to workers, retirees and dependents.

Multiemployer funds play a vital role in the health care system of our Nation, as recognized in current law and in various legislative proposals advanced by Congress and the Clinton Administration. But for these pooled, non-profit health funds, a great many more workers and their families would lack employment-based health care coverage and would have to depend on government programs for medical and related care. These funds cover millions of workers in industries characterized by small employers and transient work patterns: e.g. building and construction, trucking, maritime, service, and clothing. Several of these worker groups have been specifically targeted by the tobacco industry's marketing, and have higher than average rates of smoking and tobacco-related disease.

Multiemployer funds have incurred billions of dollars in health care costs for individuals suffering from tobacco-related disease. These costs to the funds are ultimately borne by the covered workers who have seen a growing share of their compensation package absorbed by the collectively bargained contributions needed by the funds to keep pace with increases in health care costs.

These funds have claims against the tobacco companies for reimbursement of their health care costs for tobacco-related diseases. Reimbursement would enable the funds to provide smoking prevention and cessation programs for covered individuals, as well as reduce the cost burdens of tobacco-related disease on the funds.

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Mission Statement: Page 2

The funds' claims are essentially the same as the reimbursement claims asserted by the 40 or so States that have filed suit against the tobacco companies. The States' lawsuits seek reimbursement of the costs incurred by the States' employee health plans and Medicaid programs in providing health care to government employees and public assistance recipients.

The settlement agreement negotiated between the States' Attorneys General and the tobacco companies provides for reimbursement to the States' employee health plans and Medicaid programs, as well as relief for certain private lawsuits brought by attorneys who were party to the settlement negotiations. Multiemployer funds, which were not represented in the negotiations, would not receive reimbursement under the settlement agreement.

The settlement agreement presumes to "legislatively settle" some lawsuits and to severely limit access to the courts and the relief available for cases not resolved by the agreement. For example, the agreement prohibits the filing or continuation of class actions against the tobacco companies, and further protects the tobacco companies from punitive damages for past wrongdoing. To the extent that the agreement purports to apply these limitations to the claims of multiemployer funds, it cannot be justified.

Before the settlement agreement was reached, multiemployer funds in several States filed class action lawsuits against the tobacco companies seeking reimbursement of health care costs. Several more reimbursement class actions will be filed shortly by multiemployer funds in other States. These lawsuits are similar to the reimbursement lawsuits filed by the States' Attorneys General.

The Coalition for Workers' Health Care Funds has been formed to represent these funds and coordinate their activities with regard to their reimbursement claims. The Coalition's mission is to seek for multiemployer funds equal treatment with the States' health care plans and programs with regard to reimbursement from the tobacco companies. While pursuing all available recourse through the courts, the Coalition intends to inform Members of Congress, the Administration, interest groups, and the public about the concerns of the multiemployer fund community.

It would be in the best interests of all concerned--the Federal Government, the States, the tobacco companies, the public health community, and the millions of families relying on multiemployer health funds--for the tobacco companies to provide fair reimbursement to multiemployer funds.

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NEWS:

FROM THE COALITION FOR WORKERS' HEALTH CARE FUNDS

FOR IMMEDIATE RELEASE 07-08-97
CONTACT: David A. Jewell (202) 293-1735

LABOR-MANAGEMENT HEALTH FUNDS JOIN HANDS TO SUE BIG TOBACCO – SEEKING REIMBURSEMENT FOR MEDICAL BILLS

Washington, D.C., July 8, 1997 — A grouping of labor-management operated multiemployer health care funds (Taft-Hartley Funds) in 14 states with class action lawsuits pending against the tobacco industry, today announced the creation of a coalition to coordinate their activities at the national level.

"These funds are the last line of defense against ruinous health care costs for some 30 million Americans: workers, retirees and their families, and the time has come for the tobacco industry to reimburse these funds for the billions of dollars they have spent to treat tobacco-related illnesses," said Brian McQuade, Chairman of the coalition.

"The goal in filing these suits is threefold: recompense for the money spent by the funds in treating tobacco-related diseases; to obtain funding for smoking cessation and smoking prevention programs and to hold down the increase in medical costs to our funds," said McQuade.

"The recently announced 'global' settlement of similar suits filed by state attorneys general and the tobacco industry does not take into account the 30 million men, women and children covered by the Taft-Hartley funds. For some reason, they neglected to take the men and women of the American labor movement into consideration as they pursued their deliberations. However, the pact they signed is now before Congress which will, of course, have the final say.

"What remains to be done, as the terms of this agreement are considered by Congress, is to make sure that the legitimate interests of the millions of workers, retirees and their families are taken into consideration," he added.

(MORE)

2-2-2-2-2-2

There are approximately 2000 Taft-Hartley labor-management multiemployer funds in the 50 states, the District of Columbia and Puerto Rico. They provide basic health care coverage for 30 million Americans: workers, retirees and their families. They cover workers in industries characterized by small employers and intermittent and transient work patterns such as building and construction, trucking, maritime, service and clothing.

"Our workers, more than any other class of Americans, have been targeted by the advertising and marketing campaigns of the tobacco industry. Unfortunately, these campaigns have been successful. The percentage of smokers among our members is roughly double the national average," said McQuade.

"If there is any segment of American society that has been victimized by the tobacco industry and which has paid the price of that victimization from its own pocketbook it is the men and women who rely on these labor-management funds. I cannot for an instant imagine that Congress would codify an agreement of this sort and leave out tens of millions of American workers and their families.

"Our members are not seeking any kind of a handout by filing these suits. They are hard working, tax-paying men and women who have prudently striven to take care of their own medical problems without becoming a burden on society. The vast majority of these funds are self-insured. Every dollar spent for tobacco-related health care costs is a dollar that would otherwise have gone into the workers' paychecks.

"I am confident that the very last thing Congress would do would be to enact legislation that left millions of American workers and their families out in the cold.

"We look forward to the national debate on this agreement that will take place in the coming months and the meaningful participation in that debate by ourselves and other elements of the American labor movement," said McQuade.

-30-

NEWS:

FROM THE COALITION FOR WORKERS' HEALTH CARE FUNDS

FACT SHEET

LABOR-MANAGEMENT HEALTH FUNDS: PAYING THE MEDICAL BILLS OF 30 MILLION AMERICANS

Labor-management, multiemployer health funds –

- are non-profit trust funds administered by representatives of the covered workers and of their employers;
- are financed by collectively bargained contributions which employers pay on behalf of their workers as part of the compensation for their labor;
- pay the hospital, doctor and pharmacy bills of 30 million Americans — workers, retirees and their family members;
- provide health coverage for workers in industries characterized by transient, intermittent work patterns and small employers e.g., construction, trucking, maritime, service and clothing; many of whom would not have on-the-job health care coverage but for these funds and would be dependent upon government health programs;
- enable workers to move from employer to employer and State to State, without losing health care coverage; and
- cover worker groups targeted by tobacco companies' marketing campaigns; and
- are regulated by federal laws.

FACT SHEET 2-2-2-2-2

WORKERS' HEALTH FUNDS IN THE FOLLOWING STATES HAVE FILED LAWSUITS AGAINST THE TOBACCO INDUSTRY SEEKING RECOVERY OF TOBACCO-RELATED DISEASE COSTS

Class action lawsuits against the tobacco industry have been filed on behalf of labor-management multimeployer health funds in 14 states and the District of Columbia. They are demanding reimbursement of the costs of providing medical care for workers, retirees and their dependents suffering from tobacco-related illnesses. As of June 30, 1997 lawsuits had been filed by funds in the following states:

CALIFORNIA

Stationary Engineers Local 39 Health & Welfare Trust Fund

HAWAII

Hawaii Health & Welfare Trust Fund for Operating Engineers

ILLINOIS

Central Laborers Welfare Fund
Central Illinois Carpenters Health & Welfare Trust Fund
East Central Illinois Pipe Trades Health & Welfare Fund
Laborers Local #100 Health & Welfare Fund
Laborers Local #231 Health & Welfare Fund
Laborers Local #996 Health & Welfare Fund
Midwestern Teamsters Health & Welfare Fund
NECA-IBEW Welfare Trust Fund
NECA-IBEW Welfare Fund
Northern Illinois & Iowa Laborers Health & Welfare Fund
Operating Engineers #965 Health & Welfare Fund
Painters Local #32 Health & Welfare Fund
Railroad Maintenance and Industrial Health & Welfare Fund
Sheet Metal Workers Local #218 Health & Welfare Fund
Southern Illinois Laborers & Employers Health & Welfare Fund
Teamsters & Employers Welfare Trust of Illinois

IOWA

Iowa Laborers District Counsel Health and Welfare Fund

FACT SHEET 3-3-3-3-3

KENTUCKY

Kentucky Laborers District Council Health and Welfare Fund

LOUISIANA

The ARK-LA-MISS Laborers Welfare Fund

MARYLAND

Seafarers Welfare Plan;
United Industrial Workers Welfare Plan

MASSACHUSETTS

Laborers Health & Welfare Fund

NEW YORK

Laborers Local 17 Health & Benefit Fund
Transport Workers Union New York City Private Bus Lines Health Benefit Trust

OHIO

Ironworkers Local Union No. 17 Insurance Fund
IBEW Local No. 38 Health & Welfare Fund
Ohio Laborers District Council-Ohio Contractors' Association
Insurance Fund

OREGON

Laborers-Employers Health & Welfare Trust Fund
School District No. 1 Health & Welfare Trust Fund
Northwest Forest Products Association Woodworkers District
Lodge 1, IAM
AFL-CIO Health & Welfare Plan
United Assoc. Union Local No. 290 Plumbers
Steamfitters and Shipfitters Retiree Health & Welfare Plan
United Association Union Local No. 290 Plumbers, Steamfitters and Shipfitters Retiree Health & Welfare Plan
Office and Professional Employee International Union Local No. 11 Health & Welfare Plan

FACT SHEET 4-4-4-4-4-4-4

WASHINGTON

The Northwest Laborers-Employers Health & Security Trust Fund
The Carpenters Health & Security Trust of Western Washington

ARIZONA

RHODE ISLAND

NOTE: *As a class, all individual Health & Welfare Funds in these states have the option of becoming named Plaintiffs and many are in the process of so doing..*

July 8, 1997

13TH STORY of Level 1 printed in FULL format.

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May 25, 1997, Sunday, Final Edition

SECTION: OUTLOOK; Pg. C01

LENGTH: 1838 words

HEADLINE: Why My Jury Let R.J. Reynolds Off

BYLINE: Laura T. Barrow

BODY:

On May 5, a civil jury in Jacksonville, Fla., found R.J. Reynolds Tobacco Co. was not liable for the death of smoker Jean Connor, 49. Outlook asked the forewoman, Laura T. Barrow, to describe how the six-member jury reached its verdict and how she felt about being thrust into one of the most important public health battles of the decade.

As the jury forewoman, it was my job to hand the verdict to the bailiff. I was so nervous that I was shaking. The bailiff took our decision to the judge; I thought I saw a flicker of surprise on his face, but then it was gone. The clerk of the court read the verdict aloud to a packed courtroom.

This was the final scene in the courtroom where the family of Jean Connor was suing R.J. Reynolds Tobacco Co. for wrongful death. Connor had smoked two Reynolds brands, Winston and Salem, for 20 years before her death from lung cancer in 1995. Tobacco has been one of the most talked-about topics in the national media, but we six jurors were asked to do more than just talk about it. We had to make a decision about who was mostly to blame for Jean Connor's death: the company that manufactured and marketed the cigarettes, or the woman who smoked them.

Each of us knew that once our verdict in the company's favor was announced, the decision -- and how we reached it -- would come under intense scrutiny. Still, we didn't want to talk about it right away. We were satisfied that we had come to the right decision based on the legal instructions, but we were emotionally drained. All six of us had agreed that upon being dismissed, we wanted to leave together and not stop to talk to the press. What we said after that was up to us.

When I received the summons to appear for jury duty on April 7, 1997, I was excited. I had been called once before, but wasn't even picked for a jury pool. This time, I hoped to see something interesting. Be careful what you wish for.

Jury selection began with 50 of us filling out questionnaires about our smoking history, careers, family, views on regulatory issues and whether we had read certain books (including, of course, John Grisham's bestselling novel about a tobacco trial, "The Runaway Jury"). That eliminated half of us. Then we were questioned more closely. Ron Motley, an attorney for Connor's estate, was very theatrical and looked us right in the eye. He asked each of us if we had such strong views about smoking litigation that we could not keep an open mind; those who admitted they couldn't were dismissed.

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I had revealed on my survey that I was an ex-smoker. Motley asked if it had been difficult to quit. When I said, "No," he quoted Mark Twain: "Quitting smoking is easy. I've done it hundreds of times myself." (We heard that quote quite a few times during the trial.)

My smoking history did not keep me off the jury, which included six members and two alternates. Although we were supposed to represent a "cross section" of the community, the eight of us shared striking similarities. All of us were married. None were full-time smokers. Four of us worked for large corporations, two for medium-sized companies, one for a large retailer and one was a teacher. The oldest was a woman in her forties. At 26, I was the youngest. None of us could believe we had been picked.

The judge, Bernard Nachman, was a delightful man who wore a bow tie. He instructed us not to discuss the case with anyone, including each other, and not to read or watch anything that might relate to the case. (Sometimes he would jokingly read a list of TV shows we could watch.) We were so scared of being sequestered that we followed his orders religiously. We all had visions of what happened to the jury in a famous recent case in Los Angeles.

Opening statements left no doubt about the battle lines. Woody Wilner, a sarcastic man who was one of Connor's attorneys, set the stage for the plaintiff's case by describing Connor, how she began smoking in 1961 at the age of 14, the details of her suffering and why Reynolds should be held responsible for her death. Paul Crist, an attorney for Reynolds, argued that smoking is a personal choice and that Connor knew the risks.

Connor's attorneys went through a slew of witnesses: doctors who testified about the nature and causes of her disease, a marketing professor who brought some recently uncovered internal documents, a scientist fired from Reynolds 30 years ago, Connor's daughter -- and, via videotape, Connor herself.

The plaintiff's biggest gun was Allan Feingold, a pulmonary physician from Miami. He brought a dozen or so books with him, each at least six inches thick. They kept falling on the floor. Feingold, with a touch of arrogance, said if another doctor claimed Connor's illness was anything other than lung cancer caused by smoking, he would be "a liar." By the time he finished, not only was I convinced about Connor's cancer, I also swore that if I ever needed a pulmonary doctor, he would top my list.

Other experts showed us slides of Connor's cells and brought us models of two lungs, one with emphysema and one without. It turned out that they were freeze-dried human lungs. We didn't feel the need to inspect them individually.

Richard Pollay, a marketing professor from Canada, brought documents from a public relations firm Reynolds used in the 1950s, Hill & Knowlton. They became known as "the Hill Papers." The documents, along with others offered by the plaintiff, seemed quite damning on the surface. They proved that yes, Reynolds was quite aware of the health risks associated with smoking. Their scientists had done follow-up research and communicated the findings to company executives. And no, Reynolds did not publicly acknowledge the risks. The company even tried to create doubt about the claims.

But the evidence also showed that smokers were aware of the dangers. We saw articles after article describing the risks, beginning in the late 1950s, from

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Reader's Digest, Life magazine, Time magazine and the local Jacksonville papers. So the public knew. And Connor knew. She even testified to it on the videotape. She said "the enjoyment outweighed the risks."

The Reynolds defense case consisted of testimony from a pathologist from California, a historian, a psychiatrist and David Townsend, a top Reynolds chemist. Perhaps the least effective Reynolds witness was an "expert" physician, who brought no books with him and said he had never read any of the Surgeon General's reports about smoking. He said "just because someone smokes and gets cancer doesn't mean that smoking caused the cancer."

Townsend, an extremely charismatic man, made the biggest impact on us. He described the company's research on minimizing carcinogens in cigarettes and its efforts to develop safer products. He showed us a pack of Premier cigarettes, which were test marketed in the late 1980s as safer than other cigarettes because they heated tobacco rather than burned it. Premier failed because "consumers wouldn't accept them." He seemed honest and forthright, and his testimony helped tipped the scales in favor of the tobacco company.

At this point we lost our second juror due to a family emergency, leaving us with the minimum of six. The judge ordered us to eat healthy and look both ways before crossing the street.

Then it was our turn. Deliberations began with each of us verbalizing our thoughts without interruption. We all agreed that Connor knew the risks of smoking; we also agreed that the Reynolds executives knew more than they were telling. A couple of people said they wouldn't mind awarding the family a minimal amount of money, "just so we wouldn't appear to completely side with Reynolds." One juror said, "I wish we could fine Reynolds a lot of money and give it to a charity like the American Cancer Society." Another, however, was adamant that the plaintiff deserved nothing.

We dissected the verdict form and our jury instructions. We were asked to decide two very specific and related questions:

Was Reynolds negligent and, if so, was that a cause of Connor's death?

Did Reynolds make a defective and unreasonably dangerous product?

We all agreed that Reynolds had disregarded a moral responsibility to its customers. The company knew cigarettes can cause lung cancer; it chose not to disclose this and even raised doubts about it. But Reynolds's actions did not negate the fact that the risks were widely known. Did this release Reynolds from all liability? Not in our minds. But that question was not on our verdict form.

Was Reynolds making a defective or unreasonably dangerous product? According to the judge's instructions, a product is not unreasonably dangerous if it performs as safely as a consumer could expect. As one juror put it, "Even if there were no warnings at all, how can you take smoke into your body and not know it's bad for you?"

According to the judge's instructions, a manufacturer has a duty to warn consumers if the risks of a product are better known to the company than to the consumer. But, we were told, a manufacturer does not have a duty to warn if the hazards are "common knowledge."

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We also discussed the issue of addiction. Could this be linked to the defective product claim? Two doctors told us that cigarettes are addictive. The Surgeon General has proclaimed they are addictive. I believe they're addictive. But exactly how addicting are they? We were instructed not to set aside our common sense. Those of us who had smoked analyzed our own situations. I quit smoking the first time I tried. So did the other ex-smoker. The social smokers said they didn't find it too difficult not to smoke every day. And, most importantly, Connor was able to quit smoking on her first try.

Motley and Wilner had claimed that Reynolds "targets" a certain amount of tar and nicotine needed to sustain addiction -- what they called the "Secret of Salem." Townsend, the Reynolds scientist, said the company didn't. Whom to believe?

Another issue: Would it have made a difference if the company had put tar and nicotine levels on its packages 20 years ago? Does anyone really pay attention to the ingredients on a can of Coke? We decided that better labeling would not have changed Connor's decision to smoke.

As we realized where the jury instructions and our reasoning was leading us, some jurors were rather disturbed. One cried, saying that Connor "knew the risks" but "they [Reynolds] were wrong." It had been difficult to separate our personal feelings from the job we had to do. After all, it is absolutely tragic to lose a mother or sister. But we weren't asked to make an emotional judgment; we were asked to make a legal decision, based on the evidence and the law.

As I look back on it now, I realize what a valuable experience this was. It's amazing to me that you can throw six strangers together and have them work as cohesively and cooperatively as we did. Motley had implored us to "do the right thing." I believe that's exactly what we did.

GRAPHIC: Illustration, gayle hegland for The Washington Post

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9-16-97
Legal

This memorandum sets forth our evaluation of the legal and policy ramifications of Appendix VIII to the proposed tobacco settlement, as well as possible alternatives to that proposal that would provide a mechanism to resolve privilege claims over documents otherwise required to be placed in a national tobacco document depository. Part I addresses the proposal contained in Appendix VIII, part II addresses legislation proposed by Congressman Waxman, the Tobacco Accountability Act, and parts III and IV discuss other alternatives.

I. APPENDIX VIII

As currently drafted, Appendix VIII establishes, through legislation, a national tobacco document depository available to the public and consisting of tobacco industry documents concerning various smoking and health-related issues. Privileged and trade secret materials are exempt from disclosure into the depository. The proposal establishes a three-judge panel to resolve conclusively all privilege claims over documents otherwise required to be placed in the depository. The legislation is intended to "provide for binding, streamlined and accelerated judicial determinations with nationwide effect . . . over the legitimacy of claims of privileges or protections."

By way of background, we understand it has been the widespread practice of at least some of the tobacco manufacturers to cloak what are essentially scientific documents and studies under the attorney-client or work product privileges. Upon the allegations of crime or fraud by various plaintiffs, courts have conducted in camera reviews of some of these documents and concluded that the privileges were improperly invoked to shield evidence of crime or fraud. It is therefore the goal, of at least the plaintiffs and the FDA, that Appendix VIII provide an effective mechanism to pierce fraudulent, or at least improper, claims of privilege.

The efficacy of Appendix VIII is difficult to evaluate fully because the proposal is vague in certain key respects . First, while the depository would include all documents produced to the plaintiffs by the manufacturers in specified actions, it would also include certain additional existing documents of unspecified "manufacturers or trade associations." Moreover, the proposal does not anticipate the possibility that one or more of the specified plaintiffs may opt out of the settlement. The confusion about who is covered by the proposal's requirements is compounded by the provision that the determinations of the three-judge court "shall be binding upon all federal and state courts in all litigation in the United States," and the requirement that all disputes concerning privilege claims, except those in pending cases that can be resolved prior to the three-judge court's review, be resolved through the process set forth in the Appendix -- provisions that, on their face, do not appear to be limited to the parties to the settlement..

Second, the proposal does not define key terms, including "privileged," "trade secret," and "confidential." While the proposal refers, for example, to the Uniform Trade Secrets Act, 18 U.S.C. § 1905, as providing controlling law for the three-judge panel, section 1905 does not provide a definition of the terms used in this proposal, but rather makes release of confidential information by a federal employee a federal crime.

Third, it is unclear whether the mechanism described in this proposal would override the

FDA's existing authority, under the FDCA, to obtain access to documents containing trade secret, confidential, or privileged information.

Fourth, while the proposal creates a judicial body authorized to resolve conclusively all privilege claims over the documents, it does not specify which law the panel is to apply.

Aside from these ambiguities, which may simply be the result of careless drafting, there are substantive problems with the proposal. First, the three-judge panel would consist of Article III judges appointed by the Judicial Conference. It is not clear, however, whether there would be "cases or controversies" over which this panel would have jurisdiction. For example, paragraph 4 purports to create a process of accelerated judicial review for "any public or private person or entity" to challenge "any claims of privilege or trade secrecy before the three-judge panel." These challenges could arise outside the context of litigation.

Second, the proposed three-judge panel is an inappropriate use of Article III judges that is not warranted by the nature of the responsibilities they would have. The Department has historically opposed the creation of three-judge panels as clumsy procedures that only generate more litigation about whether a particular action is properly heard by the panel in question. These objections apply equally to this proposal.

Third, the proposed preclusive effect of the panel's rulings (subject to review only through certioriari) is particularly troubling from a legal and policy perspective. It seems fundamentally unfair to bind all future litigants who are not parties to this settlement and who may not be parties to any specific dispute resolved by the panel. This is particularly so where the privilege in question is qualified (such as work product) and would require the panel to balance the need of a particular litigant for the document against the purpose served by the privilege to determine whether the document should be disclosed. In addition, counsel for the Minnesota Attorney General has advised us that, if this provision requires all of their pending or future privilege disputes to be resolved by this panel, the effect would be an inordinate delay in the trial of their case (Minnesota v. Philip Morris Inc., No. C1-94-8565 2d Dist.), to their detriment. There a special master is currently conducting an in camera review of over one million pages of documents based on the crime-fraud exception, and the pace of that review is geared toward their trial date. The panel, by contrast, would not have the same incentive to resolve any privilege disputes at issue in their litigation in a timely manner that would ensure their current trial schedule is met.

Finally, we question whether the proposal would provide an effective mechanism to pierce fraudulent or improper claims of privilege. Toward that end, the legislative proposal would create an accelerated process with a right of intervention by any member of the public, and would authorize in camera review without any prima facie showing as a prerequisite (unlike the procedure used in the crime-fraud exception, which requires the contesting party to first make a showing that such review may reveal evidence of crime or fraud). Given the volume of documents that are likely to be subject to in camera review (in the Minnesota action over one million documents are currently under review by a special master), it is unrealistic to expect that such review will streamline the process; if anything it is likely that resolution of privilege

disputes will be delayed as the panel wades through an enormous volume of documents.

Moreover, the proposal in essence accepts the status quo. The tobacco manufacturers can continue to claim privilege with the same ease and over the same documents they have withheld as privileged in pending litigation. The proposal would require them to prepare a privilege log with all of the descriptive detail required by the Minnesota court, but the Federal Rules of Civil Procedure currently impose this requirement. And we have been advised by counsel for the Minnesota Attorney General that their court's privilege log standard should not be the standard, as it is grossly deficient. Apart from providing for accelerated and easily accessible in camera review, the proposal does not alter substantively the requirements the manufacturers must meet to sustain a privilege claim.

II. CONGRESSMAN WAXMAN'S PROPOSED "TOBACCO ACCOUNTABILITY ACT"

On June 12, Representative Waxman introduced a bill in the House of Representatives (H.R. 1881 or "Waxman Bill"), which, like Appendix VIII, would require tobacco manufacturers to submit documents relating to the health effects of tobacco products and the marketing of such products to children to a central body, to be made available to the public. But, rather than providing a central judicial or quasi-judicial procedure for addressing the manufacturers' claims that certain of these documents are protected by the attorney-client privilege, the Waxman Bill would simply abrogate the manufacturers' right to assert that privilege (as well as their right to assert the work product privilege). Although this proposal certainly streamlines the process of resolving privilege claims (by ruling them out legislatively), it raises significant constitutional and policy concerns, particularly with respect to its abrogation of the attorney-client privilege.

A. The Waxman Bill

The Waxman Bill would establish a "Tobacco Accountability Board," consisting of five members with expertise on tobacco and public health, appointed for six-year terms by the Secretary of Health and Human Services. H.R. 1881 § 2. The Bill requires the tobacco manufacturers to submit to the Board all documents relating to the health effects of tobacco products, the manipulation of nicotine in tobacco products, and the sale or marketing of tobacco products to children. Id. § 3(a). The Bill also requires the manufacturers to submit the 150,000 "attorney-client" documents which the manufacturers have been ordered to produce to the court for in camera review in the Minnesota tobacco litigation.

The Waxman Bill would require the Board to make all of the documents submitted by the manufacturers available to the public, with the exception only of trade secret information, H.R. 1881 § 3(b) & (c), thereby eliminating the manufacturers' existing right to protect attorney-client communications from disclosure.[1/]

[1/] In addition, the Bill would vest the Board with broad power to investigate all matters relating to the tobacco industry and public health; it would give the Board enforceable subpoena power

A staff report accompanying the Bill, entitled "Secret Attorney-Client Documents are Evidence of Potential Crimes or Fraud by the Tobacco Industry," explains that the Bill's abrogation of the manufacturers' right to assert the attorney-client privilege is based on: (1) a handful of attorney-client documents from Liggett & Myers Tobacco Company which appear to contain evidence of crime or fraud on the part of the manufacturers; and (2) rulings of several courts in tobacco litigation, finding that tobacco manufacturers and their attorneys have abused the attorney-client privilege to shield from the public important evidence of the dangerous health effects of smoking.

B. The Attorney-Client Privilege and the Crime-Fraud Exception

The attorney-client privilege is based in common law and, as the Supreme Court has emphasized, is essential "to encourage full and frank communication between attorneys and their clients" and that the privilege thereby promotes "broader public interests in the observance of law and administration of justice." Upjohn Co. v. United States, 449 U.S. 383, 389 (1981). The privilege, however, does not protect attorney-client communications made in order to "get[] advice for the commission of a fraud or crime." United States v. Zolin, 491 U.S. 554, 563 (1989). This "crime-fraud exception" is meant to prevent parties from abusing the attorney-client privilege to shield unlawful activity.

The Supreme Court has held that in camera inspection is an appropriate mechanism for determining the applicability of the crime-fraud exception, and that such inspection is permissible if the party raising the crime-fraud exception makes an initial showing to support a good faith belief that such review may reveal evidence of crime or fraud. Zolin, 491 U.S. at 572. However, regardless of whether a court engages in in camera review, courts have held that, because of the importance of protecting attorney-client communications, the party asserting the privilege must be given an opportunity to present evidence and argument in its defense, before a court may order disclosure of those communications under the crime-fraud exception. See, e.g., Haines v. Liggett Group, Inc., 975 F.2d 81, 97 (3d Cir. 1992).

C. Constitutional Concerns

Because the Waxman Bill eliminates tobacco manufacturers' existing right to protect legitimate attorney-client communications, with no opportunity for judicial review, based on a congressional finding that certain of the manufacturers' documents are subject to the crime-fraud exception, the Bill presents a potential violation of the Constitution's Bill of Attainder Clause (Art. I, § 9). A bill of attainder is a law that "legislatively determines guilt and inflicts punishment without provision of the protections of a judicial trial." Selective Service System v. Minnesota PIRG, 468 U.S. 841, 846-47 (1984). The Clause is based on separation of powers principles and reflects "the Framers' belief that the Legislative Branch is not so well suited as politically independent judges and juries to the task of ruling upon the blameworthiness and of,

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and the authority to conduct full evidentiary hearings; and it would require the Board to report annually to Congress. H.R. 1881 §§ 4, 5, 7.

and levying appropriate punishment upon, specific persons." United States v. Brown, 381 U.S. 437, 444 (1965).

Legislation which, like H.R. 1881, applies to a specific class of persons and deprives them of a previously enjoyed right without the protections of a judicial trial may be a bill of attainder if, given "the type and severity of the burdens imposed," it cannot be said to further nonpunitive goals. One could argue that the purpose of the Waxman Bill is not to punish the manufacturers, but to make important evidence of fraud available to the public and to protect the public from future attempts by the manufacturers to withhold evidence of the dangers of tobacco products. Those goals assume, however, that the manufacturers are guilty of such fraud; and, as such, could be construed as punitive within the meaning of the Bill of Attainder Clause, especially in light of the burden imposed — mandatory disclosure of all attorney-client communications and all work product material. See Brown, 381 U.S. at 458-59 (punishment barred by Bill of Attainder Clause includes inflicting deprivation on some blameworthy individual in order to prevent his future misconduct).

The congressional staff report accompanying the Waxman Bill, which conveys the staff's determination that certain attorney-client documents are subject to the crime-fraud exception and therefore that the manufacturers should lose the very important right to assert that privilege, is further indication that the bill would constitute a "legislative determin[ation] of guilt that inflicts punishment . . . without provision of the protections of a judicial trial." Selective Service, 468 U.S. at 846.

It should be noted, however, that legislation which achieved the same end but was premised instead on a congressional finding that the public's need for these documents outweighed the manufacturers' need to maintain their privileged status would probably pass constitutional muster, particularly because the attorney-client and work product privileges are not constitutionally based.

In addition to presenting a possible bill of attainder, the Waxman Bill might also implicate the manufacturers' Sixth Amendment right to effective assistance of counsel, to the extent that the Bill might require the manufacturers to reveal attorney-client communications regarding potential criminal proceedings against the manufacturers. In light of the Supreme Court's recognition that the attorney-client privilege is essential to the administration of justice, the Bill could be seen as hindering the manufacturers' right to obtain effective legal representation in criminal cases[2/].

D. Policy Concerns

[2/]In addition, at least one court has suggested that interference with the ability to protect essential attorney-client communications might raise basic due process concerns. See Haines v. Liggett Group, 975 F.2d 81, 97 (3d Cir. 1992). We question that conclusion, however, as the right to assert the privilege in the first place is not of constitutional dimension, but arises from common law.

Even if the Bill's potential constitutional infirmities could be overcome, any legislative abrogation of the attorney-client privilege may raise policy concerns within the government. As discussed above, the attorney-client privilege is essential to ensure full and open communication between clients and their legal counsel. The privilege "recognizes that sound legal advice or advocacy serves public ends and that such advice or advocacy depends upon the lawyer's being fully informed by the client." Upjohn, 449 U.S. at 389. The government, no less than private litigants, relies on this privilege to protect and promote the ability of government agents to communicate openly with government attorneys. These concerns would be minimized, however, if the legislation were based on a specific finding that the health concerns raised by tobacco manufacturers' products and the corresponding need of the public to have access to documents that deal with those concerns outweigh the manufacturers' need to protect attorney-client communications.

The Waxman Bill's abrogation of the manufacturers' right to assert the work product privilege — which protects confidential written materials prepared by attorneys or their agents in the course of legal representation — should raise similar policy concerns within the government. Unlike the attorney-client privilege, the work product privilege is qualified and may be overcome by a showing of substantial need for the materials. See, e.g., Fed. R. Civ. P. 26(a)(3). Thus, the Waxman Bill's abrogation of work product privilege is less likely to engender the same degree of constitutional concern as its abrogation of the attorney-client privilege. Nonetheless, as the Supreme Court has noted, the work product doctrine is crucial to enable attorneys to represent clients well, and is based on "strong public policy." Upjohn, 449 U.S. at 398 (citations omitted). The government most likely would oppose any congressional attempt to restrict its ability to invoke this privilege.

For all of these reasons, the Waxman Bill, or any similar proposal to abrogate the tobacco manufacturers' right to assert the attorney-client privilege or the work product privilege, does not appear to be a wise approach.

III. ALTERNATIVE PROPOSAL TO CREATE TOBACCO DOCUMENT DEPOSITORY AND REVIEW BOARD

As an alternative to Appendix VIII and the Waxman Bill, we have come up with a rough outline for legislation which would provide a central, public tobacco document depository and would create a central process to streamline evaluation of the manufacturers' privilege claims, without denying them their existing right to judicial review of those claims.

The principal elements of such legislation are:

▸ Creation of a central "Article II" Board, consisting of [3] members with expertise in tobacco and health, appointed by [either the Secretary of Health and Human Services or by FDA] for [ ] year terms.

▸ The tobacco manufacturers must submit to the Board all documents in their custody or control that relate in any way to: (1) any health effects caused by or associated with the use of

tobacco products; (2) the use of nicotine in tobacco products; or (3) the sale or marketing of tobacco products to children. These submissions must be made within 90 days of the passage of this Act. Thereafter, tobacco manufacturers shall be under a continuing obligation to submit to the Board any newly-created documents that fall under any of the above three categories.

▸ The manufacturers must include with their submission to the Board a separate submission of any material which they claim to be subject to the attorney-client, attorney work product, or trade-secret privileges. Those submissions of allegedly privileged material must be segregated, if feasible, into the following initial categories: attorney-client communications; opinion work product; ordinary or "fact" work product; trade-secret privilege. Where appropriate, the Board will consider whether these documents must be further divided into sub-categories, such as those ordered by the court in Minnesota v. Philip Morris Inc., No. C1-94-8565 (Minn. Dist. Ct., 2d Dist., filed May 22, 1997), including, for example:

-all documents as to which a previous claim of privilege was denied.

-all documents that on their face show no evidence that they were written or received by an attorney.

-all scientific research or reports on smoking and health or information relating to smoking and health, and memoranda regarding the same.

▸ Along with any submission of allegedly privileged documents, manufacturers must provide a detailed privilege log which includes, for each document as to which a privilege is claimed, a description of the document, including author, person(s) to whom it is addressed, purpose of the document, and general subject matter, along with an explanation for why the document, or a portion of it, is privileged and a statement as to whether any previous claim of privilege was denied. This privilege log must be signed and sworn by a person with knowledge of the contents, pursuant to 28 U.S.C. § 1746.

▸ As soon as practicable, the Board will make available to the public all documents as to which the manufacturers do not claim a privilege.

▸ The Board will review any privilege claims asserted by a manufacturer, and, applying federal privilege law, will make a determination as to whether the material is subject to the claimed privilege. In conducting this review, the Board may, in its discretion, engage in in camera review of any documents. The Board will notify the manufacturer in writing of its final determination, and will include in that notification a brief explanation of the basis for that determination.

▸ A manufacturer may obtain judicial review in federal district court [in the District of Columbia? or any federal district court, subject to venue requirements of 28 U.S.C. § 1391] of any final Board determination. The Board's findings of fact shall be reversed by the court only if clearly erroneous. The Board's legal conclusions shall be reviewed de novo by the court. Judicial review under this section must be sought within 60 days of the date of the Board's final

determination.

▸ If, after a manufacturer has obtained judicial review and has pursued all appeal rights, the final judgment is that a document is not privileged, the Board will disclose that document to the public, and the manufacturer will be estopped from claiming that the document is privileged in any other proceeding. If a manufacturer fails to seek timely judicial review of a final determination by the Board that a document is not privileged, the Board will disclose the document to the public, and the manufacturer will be estopped from claiming that the document is privileged in any other proceeding.

▸ If the Board determines that a document is privileged, the Board may not disclose it to the public, and the document shall be returned to the submitting manufacturer. Current or future litigants who seek to challenge a manufacturer's assertion of that privilege in any legal proceeding will not be bound by the Board's final determination.

▸ Nothing in this section precludes the disclosure of relevant information, including information that is privileged or a trade secret, to other federal agencies, as permitted or required by any other provision of federal law.

▸ Any person who violates a requirement of this chapter shall be liable to the United States for a civil penalty in an amount not to exceed [$10,000] for each such violation, and not to exceed [$1,000,000] for all such violations adjudicated in the same proceeding. Civil penalties under this paragraph shall be assessed by the Board, by an order made on the record after the opportunity for a hearing. A party against whom the Board assesses a civil penalty under this paragraph may seek judicial review of that penalty in federal district court, as provided in Paragraph [ ] of this Section.

This approach has several advantages. First, it does not raise the same constitutional concerns; no privilege is abrogated and the manufacturers are provided a process to resolve all privilege claims, with full review in the district and appellate courts. Moreover, the panel's conclusion that a particular document is privileged does not have a preclusive effect, but leaves future litigants free to challenge the claim of privilege in subsequent litigation.

Second, the panel would consist of Article II officials, not Article III judges, and the effectiveness of its review would be reinforced by its sanction authority. Moreover, as with Appendix VIII of the proposed settlement, our alternative would permit in camera review without first requiring a showing of potential crime or fraud. This review would be facilitated by the requirement that the manufacturers produce to the panel all documents in their possession and control, even those over which they claim a privilege. Although such review could be enormously time-consuming, given the vast quantity of documents potentially involved, it would be concurrent with any judicial review in pending litigation and would not, therefore, delay the trial schedules of ongoing cases. In addition, to facilitate in camera review and resolution of privilege claims, the panel would be authorized to require manufacturers to segregate their privileged documents into substantive categories that are most likely to correspond to categories of documents where the privilege has been improperly invoked.

Third, this alternative makes it clear that the FDA would retain its ability under existing law to access privileged or trade-secret protected information.

Notwithstanding these advantages, we question whether, in the final analysis, such a panel would meet one of the stated goals of Appendix VIII — providing a mechanism for accelerated and streamlined determinations over privilege claims. As the Minnesota Attorney General's office has pointed out, review of this volume of documents by an outside panel that need not accommodate trial schedules is unlikely to result in timely determinations.

IV. RETAIN THE STATUS QUO

Finally, there is at least a serious question whether any legislation is warranted. The experience in the Minnesota action illustrates that courts currently have the ability to review and resolve privilege claims over large volumes of documents in an expeditious manner. The crime-fraud exception provides an effective mechanism to pierce the privilege. Even where fraud or crime is not at issue, the Federal Rules of Civil Procedure authorize sanctions for misuse of the discovery process, which would include improper use of privileges. Moreover, where these privilege issues arise in multi-district litigation, discovery disputes are transferred to one judge for resolution.

By contrast, Appendix VIII, the Waxman Bill, and our proposed alternative all present fairly cumbersome vehicles by which to resolve privilege questions that do not ultimately ensure any greater success in piercing improper privilege claims or streamlining the dispute resolution process.

THE WHITE HOUSE
WASHINGTON

From the Office of:

The Domestic Policy Council

Elena Kagan
Deputy Assistant to the President
for Domestic Policy

TO: Jerry Mande

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MESSAGE: For Monday Mtg.

Please call (202) 456-5584 if there are any problems with the transmission.

U.S. Department of Justice

DRAFT

Washington, D.C. 20530

June 30, 1997

Memorandum

To: Stephen Preston, George Phillips

Fr: Michael Raab

Re: Preemption Issues Raised By Proposed Tobacco Settlement

This memorandum considers preemption issues presented by the Proposed Resolution dated June 20, 1997, which provides for the settlement of numerous lawsuits relating to tobacco products. Part I of the memorandum briefly summarizes current law governing the preemption of state and local requirements regarding medical devices. Part II provides a preliminary analysis of relevant provisions of the Proposed Resolution.

I. Current Law.

Section 521(a) of the Federal Food, Drug and Cosmetic Act of 1938, as amended ("Act"), preempts any state-law "requirement" with respect to a medical device that is "different from, or in addition to," federal requirements imposed under the Act. 21 U.S.C. 360k(a). The Supreme Court has held that Section 521(a) does not preempt state common-law claims that are premised on the failure of a medical device to satisfy federal requirements. *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240, 2255 (1996); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). However, state-law requirements that are more stringent than specific counterpart requirements imposed under federal law are subject to preemption under Section 521(a). See *id.* at 2257-2258; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment); 21 C.F.R. 808.1(d).

Section 521(b) of the Act permits States and their political subdivisions to apply to the FDA for an exemption from Section 521(a). 21 U.S.C. 360k(b). The FDA can exempt a state-law requirement if (1) the requirement "is more stringent than" its federal counterpart or (2) the requirement "is required by compelling and local conditions" and "compliance with the

requirement would not cause the device to be in violation of" any federal requirement applicable under the Act. 21 U.S.C. 360k(b).

The existence of an express preemption provision such as Section 521 does not foreclose the possibility of implied "conflict" preemption. See *Freightliner Corp.* v. *Myrick*, 115 S. Ct. 1483, 1487-1488 (1995). Such preemption can occur when compliance with both the state and federal requirements is impossible, *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142-143 (1963), or where the state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).

II. Proposed Resolution.

The Proposed Resolution (p. 13) would subject tobacco products to regulation under the Act as Class II medical devices. Absent a specific legislative exemption, state and local requirements with respect to such devices therefore would be subject to preemption under the terms of Section 521. As explained below, the Proposed Resolution appears to envision that Section 521 would apply to requirements governing the design and manufacture of tobacco products, but not with respect to other requirements applicable to such products.

a. In apparent reference to Section 521, the Proposed Resolution provides (p. 33) that "the provisions of [the Act] designed to provide uniformity in product manufacturing and design requirements relating to medical devices will apply to tobacco products * * *." Thus, the Proposed Resolution appears to anticipate that state and local requirements relating to the manufacture and design of tobacco products would be subject to preemption under Section 521(a).

The Proposed Resolution (p. 33) would permit the FDA to grant exemptions from preemption (presumably under Section 521(b) of the Act) for state and local requirements "relating to performance standards or good manufacturing practices." But the Proposed Resolution would alter the scope of the agency's authority under Section 521(b) in two respects. First, the Proposed Resolution provides (p. 33) that States and localities could "adopt additional or different requirements relating to performance standards or good manufacturing practices * * * only * * * if the requirement[s] would not unduly burden interstate commerce." Under current law, an exemption may not be granted if "the [FDA] Commissioner determines that the granting of an exemption would not be in the best interest of public health, taking into account the potential burden on interstate commerce." 21 C.F.R. 808.25(g)(3). By requiring only that the Commissioner "tak[e] into account" the possible burden on interstate commerce in deciding whether an exemption is warranted, rather than expressly prohibiting

exemptions where a state-law requirement "unduly burden[s]" interstate commerce (p. 33), the current regulation appears to vest the FDA with broader discretion than the statute contemplated by the Proposed Resolution.[1]

Second, the Proposed Resolution (p. 33) would prohibit States and localities from applying for exemptions for requirements relating to the "non-tobacco ingredients" included in tobacco products until five years after the effective date of implementing legislation. That limitation appears to be related to the requirement (p. 19) that manufacturers submit a safety assessment for each non-tobacco ingredient in their tobacco products within five years after enactment of implementing legislation.

b. As explained above, the Proposed Resolution (p. 33) provides for the preemption of state and local requirements relating to the design and manufacture of tobacco products under terms that are generally consistent with Section 521. However, outside the design and manufacture context, the Proposed Resolution envisions a significantly broader role for States and localities. The Proposed Resolution is intended to "[e]nsure that * * * the States [will] have the regulatory flexibility to address issues of particular concern to public health officials, such as youth tobacco usage and tobacco dependence" (p. 2),[2] and (p. 3) that state and local governments will have authority to regulate exposure to tobacco smoke in public places.[3] But the Proposed

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[1] Moreover, the FDA can alter its regulation; the agency obviously could not amend the proposed statutory restriction.

[2] See also Proposed Resolution, p. 11 ("*Without preventing state and local governments from imposing stricter measures*, the [contemplated federal] legislation would incorporate every access restriction of the FDA Rule, and more." (emphasis added)); *id.* at 12 ("The [contemplated federal] legislation would mandate minimum federal standards for a retail licensing program that the federal government and state and local authorities would enforce through funding provided by the Industry payments."); *id.* at 32 ("While setting a federal 'floor' for tobacco control measures in many substantive areas, this legislation preserves, to the maximum extent, state and local government authority to take additional tobacco control measures that further restrict or eliminate the product's use by and accessibility to minors."); *ibid.* ("The legal authority of a state or local government to further regulate, restrict or eliminate the sale or distribution of tobacco products, and to impose state or local taxes on such products, also remains unchanged.").

[3] Proposed Resolution, p. 3 (proposing to "[e]stablish a minimum federal standard with tough restrictions on smoking in (continued...)

Resolution does not propose any specific legislative exemption from Section 521 for state and local requirements relating to such matters. And Section 521(a) by its terms applies to "any requirement" applicable to a medical device, 21 U.S.C. 360k(a); it is not limited to requirements relating to a device's design and manufacture. Thus, unless Congress enacts such an express limitation for tobacco products, it is by no means clear that States could enforce the type of requirements envisioned under the Proposed Resolution, absent an exemption from the FDA under Section 521(b).[4]

c. The Proposed Resolution (p. 33) calls for continued "national uniformity of warning labels, packaging and labeling requirements, and advertising and promotion requirements related to tobacco and health," as required under current law.[5] The Proposed

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[3](...continued)
public places with enforcement funding from the Industry Payments, *while preserving the authority of state and local governments to enact even more severe standards*." (emphasis added)); *id.* at 32 ("This legislation also permits state and local governments to enact measures that further restrict or eliminate employee and general public exposure to smoking in workplaces and in other public and private places and facilities.").

[4] However, the FDA interprets Section 521(a) to apply only where there is a specific counterpart federal requirement applicable to the device. See 21 C.F.R. 808.1(d); see also *Medtronic, Inc.*, 116 S. Ct. at 2257-2258; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment). Under that interpretation, in order to determine whether a particular state or local requirement is preempted, it would be necessary to determine whether relevant federal directives imposed under the proposed legislation satisfy that threshold requirement.

[5] We are aware of two federal statutes that preempt state and local regulation of warning labels on tobacco products. The Federal Cigarette Labeling and Advertising Act, as amended, specifies the content and format of the warning labels that must be placed on packages of cigarettes, 15 U.S.C. 1333, and provides that "[n]o statement relating to smoking and health, other than the statement required by [15 U.S.C. 1333], shall be required on any cigarette package." 15 U.S.C. 1334(a). The Act further provides that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." 15 U.S.C. 1334(b). The Comprehensive Smokeless Tobacco Health and Education Act of 1986 specifies the content and format of warning labels that must be placed on packages of smokeless tobacco, 15 U.S.C. 4402, (continued...)

Resolution (p. 33) would also provide the FDA with "express authority to require changes in the language of the warnings" required under federal law, as long as the agency provided public notice and an opportunity for hearing prior to adopting those changes. Accordingly, state and local requirements with respect to those matters would continue to be preempted.

d. The Proposed Resolution (p. 44) provides that the sale of tobacco products to consumers by an unlicensed seller "shall be a criminal violation, and be subject to minimum penalty of $1,000, or imprisonment, for 6 months, or both, if an individual, or in the case of a corporation, by a maximum penalty of $50,000." The Proposed Resolution (p. 44) further authorizes States to adopt more stringent penalties. Section 521(a) should not prevent States from enforcing such penalties. That provision addresses the preemption of state and local "requirements," 21 U.S.C. 360k(a); it does not purport to preempt state and local remedies or penalties that encourage compliance with federal requirements. Cf. *Medtronic, Inc.*, 116 S. Ct. at 2255 ("The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law"); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part) ("Section [521] does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.").

The Proposed Resolution also would subject a tobacco product licensee to civil sanctions for any violation of the provisions of state licensing laws regarding sales to minors. State sanctions could not exceed the penalty schedule set out in the Proposed Resolution. (p. 44.) Assuming that Section 521(a) would not preempt the substantive requirements imposed by the state licensing laws, that provision should not bar the imposition of the specified civil penalties to enforce those requirements. However, the FDA has informed us that the proposed schedule prescribes more lenient penalties than those currently imposed by many States. That schedule (if enacted) would preempt more stringent provisions of state law.

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[5](...continued)
and provides that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by [15 U.S.C. 4402], shall be required by any State or local statute or regulation to be included on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product." 15 U.S.C. 4406(b). However, the Act further provides that "[n]othing in this chapter shall relieve any person from liability at common law or under State statutory law to any other person." 15 U.S.C. 4406(c).

e. The Proposed Resolution provides (p. 26) that "[s]tate enforcement actions — whether brought under the [federal legislation contemplated by the Proposed Resolution] or a State's consumer protection law could not impose obligations or requirements beyond those imposed by the [contemplated federal] legislation (except where the legislation does not specifically preempt additional state-law obligations) * * *." It is not entirely clear how that rather convoluted statement can be reconciled with Section 521, which generally preempts more onerous state-law requirements, but authorizes the FDA to grant exemptions from preemption. It appears that the statement is intended to preempt state requirements that are more stringent than those imposed by the contemplated federal legislation, except where the legislation does not specifically provide for such preemption. To accomplish that objective, an express legislative provision precisely limiting the scope of Section 521 would appear to be necessary.

The Proposed Resolution further provides (p. 26) that state enforcement actions "would be limited to the civil and criminal penalties established by the legislation and by the prohibition on duplicative penalties." The limitation to "penalties established by the [contemplated federal] legislation" appears to be in some tension with the Proposed Resolution's treatment of retailer penalties (p. 44), which, as discussed above, prescribes the maximum civil penalties that States can impose, but permits States to adopt criminal penalties that are more stringent than those imposed under federal law.[6]

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[6] The reference to "the prohibition on duplicative penalties" (p. 26) is unclear. The Double Jeopardy Clause bars the imposition of both civil and criminal penalties in some circumstances. See *United States v. Halper*, 490 U.S. 435 (1989). It is uncertain whether the reference to "the prohibition on duplicative penalties" is intended to encompass any greater restrictions.

PENALTIES

	PROPOSED SETTLEMENT	EXISTING LAW (under North Carolina District Court decision)
Overview of Enforcement Mechanisms	The proposed settlement appears to add a number of possible enforcement mechanisms to existing methods under the FDCA, although it is not absolutely clear whether all of the existing mechanisms are retained. (See Questions below). State enforcement appears to be more constrained than it is under existing law because of restrictive preemption provisions, caps on penalties, and a removal provision.	A violation of FDA's tobacco regulations renders the tobacco product misbranded, and the FDCA, among other things, prohibits the introduction into interstate commerce of a misbranded device. FDA's regulations are enforceable to the extent that they are upheld by the courts (e.g., advertising restrictions are currently in limbo). FDA's assertion of jurisdiction does not greatly affect state regulation of tobacco products.
Enforcement Agencies	FDA, DOJ, States. (p.26)	FDA, DOJ, States.
State Enforcement	The proposal prohibits state penalties and requirements duplicative or beyond those in legislation; no preclusion for matters not covered. (p.26) State enforcement incentives apply. (pp.58-60)	Limited preemption of state laws that impose specific requirements more stringent than analogous federal requirements. 61 Fed. Reg. at 44548. No preemption of penalties. State enforcement incentives in place under Synar amendments.
Removal	State enforcement actions removable to federal court. (p.26)	N.A.
Criminal Penalties	Criminal penalties "based on" FDCA and Title 18. (p.26)	Prohibited act: 1 year and/or $1,000; 2d offense or violation committed with intent to defraud or mislead - 3 years and/or $10,000. 21 U.S.C. § 333(a). Title 18 applies.

Civil Penalties	Civil penalties "based on" FDCA. (p.26)	Civil money penalty of maximum $15,000 per violation, $1 mil per proceeding for violations of FDCA device provisions. 21 U.S.C. § 333(f).
Disclosure Penalties	Penalty of $10 mil per violation for failure to disclose to FDA health research and information. (p.26)	No comparable blanket disclosure requirement.
Injunctive Relief	Presumably available to the extent that tobacco restrictions are imposed under the FDCA.	Injunctive relief available to restrain violations. 21 U.S.C. § 332.
Seizure	Presumably available to the extent that tobacco restrictions are imposed under the FDCA.	An adulterated or misbranded device is subject to seizure at any time. 21 U.S.C. § 334(a)(2).
Lookback	If targets for reduction of underage tobacco use are not met, industry is subject to a penalty of up to $2 bil, but could receive up to a 75% abatement of that amount. (p.24)	No comparable provision, but the agency retains the authority to propose and issue additional regulatory requirements in a future rulemaking proceeding to further reduce youth tobacco use. 61 Fed. Reg. at 44542.
Compliance Plans and Corporate Principles	Fines and penalties (including "Scarlet Letter" advertising) if companies breach their obligations relating to the development, implementation, and enforcement of compliance plans and corporate principles - up to $25k per day, to a maximum of $200k. (p. 23)	US Sentencing Guidelines Chapter 8 establish an incentive for companies to adopt and implement such compliance steps.
Compliance Reporting	Manufacturer subject to fines and penalties if its compliance officer fails to furnish to FDA reports by its employees of violations by retailers or distributors.	N.A.

Retailer Penalties	<u>Unlicensed Seller</u> Individual: minimum of $1,000 and/or 6 months. Corp.: max of $50,000. (p.44) Violation of State <u>licensing laws</u> 1st: $500 or 3 day suspension. 2d: $1,000 or 7 day suspension. 3d: $2,000 or 30 day suspension. 4th: $5,000 or 6 mo. suspension. 5th: $10,000 or 1 yr. suspension. 6th: $25,000 or revocation. 10th: permanent revocation. (p.44)	Civil money penalty of maximum $15,000 per violation, $1 mil per proceeding for violations of FDCA device provisions. 21 U.S.C. § 333(f). FDA has announced that for underage tobacco sales it intends to issue a warning for the first violation, and seek a penalty of $250 for the second violation. - only for ID - additional penalties available for other violations.
Consent Decrees	Consent decrees setting out certain terms of the agreement are enforceable only through injunctive suits - after a violation is established and another injunction entered, criminal or civil penalties could be imposed.	N.A.
National Protocol	Contract to provide enforcement rights to all states. (pp.26-27)	N.A.

<u>Questions and Observations</u>:

- Proposal states that "[c]ivil and criminal penalties for violations of the legislation based on those governing other drugs or devices regulated under the Food, Drug, and Cosmetic Act and, where applicable, under Title 18 of the U.S. Code." (p. 26) From this language, it is unclear whether the drafters intended to incorporate all existing penalty provisions or whether "based on" suggests a looser connection. Thus, it is uncertain whether the specific penalty provisions outlined in the proposal are intended to be a substitute for, or an enhancement of, the existing penalties. If they are intended to be in addition to existing provisions, then restrictions that are imposed pursuant to the settlement and under

the FDCA should be enforceable in the same manner as other medical device requirements.

- Appendix II addresses "violation of the provisions of the State licensing laws regarding sales to minors." (pp. 44-45) It is again unclear whether this is meant to be a substitute for civil money penalty proceedings under 21 U.S.C. § 333(f) and 21 C.F.R. Part 17. The maximums for FDA's civil money penalties are $15,000 per violation and $1 million per proceeding. The fines listed in Appendix II range from $500 to $25,000, but there is no provision for aggregating multiple violations. FDA would be interested in aggregating violations with respect to chain retail stores.

Fran 7-11-97
Legal

TITLE VIII: CIVIL LIABILITY

Description of Key Provisions:

Civil Liability for Past and Future Conduct.

° *Scope.* The agreement seeks to resolve the treatment of actions for civil liability relating to tobacco for those manufacturers agreeing to make consensual payments to settle or partially settle various pending actions (the "participating companies"). For such participating companies, present Attorney General actions, *parens patriae* and class actions would be resolved by the agreement and there would be no future prosecution of such actions. While the agreement also purports to settle all "addiction"/dependence claims, individual suits are not settled by the agreement. However, with respect to such individual actions, the agreement provides that there will be individual trials only, *i.e.*, there will be no class actions or other forms of multi-case litigation without the defendant's consent, and that removal of state actions to Federal court will only be at the option of the defendants. The limitations on civil liability envisioned in the agreement would not apply to "nonparticipating companies," *i.e.*, those not entering in the agreement, who instead would be required to established escrowed reserve funds to cover their potential liability payments.

° ***Funds Available for Payment.*** In essence, the agreement creates a fund from which judgments and settlements are to be provided for. Under Title VI of the agreement, the participating companies would agree to make annual payments into the fund in perpetuity, the amount of which payments would be determined by formula. Under the formula, the annual payment would equal a "base annual payment," escalating gradually from $6 billion in the first year of the agreement to $15 billion in the ninth year of the agreement and thereafter, corrected for inflation and essentially increased or decreased by a percentage corresponding to the ratio by which the volume of tobacco sales increased or decreased as compared to sales in 1996 ("the base year"). The $10 billion "up front commitment" payment made by the participating companies at the outset of the agreement apparently would not be available for the payment of judgments and settlements. (See accompanying flow chart for more details on this formula.)

° ***Limitations on payouts.*** Only 33 percent of the base annual payments would be available for the payment of judgments and settlements ("the annual aggregate cap"). If the aggregate amount of judgments and settlements for a given year exceeds the annual aggregate cap, the excess does not have to be paid that year and rolls over to be paid in future years. With respect to individual judgments for more than $1 million dollars, amounts in excess of $1 million will not be paid in the year the judgment occurs unless every other judgment/settlement can be satisfied within the annual aggregate cap. Excess amounts will roll forward, without interest, to be paid at a rate of $1 million per year until the first year that the annual aggregate cap is not exceeded, at which time, the remainder of such

judgments will be paid in full. In the event the annual aggregate cap is not reached in any year, a Commission appointed by the President will determine the appropriate allocation of the surplus amount.

Punitive Damages and Joint and Several Liability.

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° ***Punitive Damages***. With respect to past conduct (*i.e.*, conduct taking place prior to the effective date of the Act), all punitive damages claims would be resolved as part of the overall settlement and no punitive damages would be awarded in individual tort actions. Punitive damages could be awarded with respect to future conduct (*i.e.*, conduct taking place after the effective date of the Act.)

° ***Joint and Several Liability***. With respect to past conduct, the agreement appears to envision a side arrangement under which the "participating companies" would agree to be jointly liable for civil liability. The participating companies would not be jointly and severally liable for the liability of "nonparticipating companies." Trial involving both participating and nonparticipating companies would be severed.

Unresolved Issues:

° ***Allocating the Annual Payments Among Manufacturers***. The agreement does not specify how the annual payments will be allocated among manufacturers. Title III of the agreement appears to envision that the allocation would be made based on market shares, reflecting the percentage of participating and nonparticipating manufacturers in that market. It is unclear, however, whether the agreement would look to market shares in 1996 or some other year and whether the allocation would change as market shares fluctuate. If the allocation of annual payments is based upon the actual market share of both participating and nonparticipating manufacturers, it is also unclear what portion of the base annual payment will actually be paid into the fund, as nonparticipating manufacturers will not be required to pay into the fund, but rather will be required to establish separate escrow accounts.

° ***Who Pays Judgments and Settlements Initially: Participating Manufacturers or the Fund***. The agreement is unclear as to whether judgments and settlements will be paid directly from the fund created by the agreement, by the individual defendants, or some combination of both. Different language in the agreement implies different results. For example, the language regarding the annual aggregate cap (at page 41), appears to envision that judgments and settlements will be paid directly from the fund. Yet, the next paragraph in the agreement indicates that "[a]ny judgments/settlements run against defendant, but give rise to 80-cent-on-the dollar credit against annual payment in the year paid,"

seemingly suggesting that defendants will make payments and offset them against their liability to the fund.

- ***Ensuring Adequate and Prompt Funding for Judgments/Settlements***. Given the way the formula works here, it is unclear exactly how much funds will be available to cover judgments and settlements. Among the variables affecting the availability of such funds are the following: (i) how the annual payments will be allocated among participating and nonparticipating manufacturers; (ii) how the annual payments will be affected by the provisions that potentially decrease the payments for reductions in annual sales; and (iii) whether surplus from some years will be available to pay judgments in later years. It might be advisable to obtain an accurate economic forecast of how the fund will likely fluctuate over time.

- ***Meaning of the 80-Cent-on-the-Dollar Provision***. As noted above, one of the more opaque provisions in the agreement provides that: "[a]ny judgments/ settlements run against defendant, but give raise to 80-cent-on-the-dollar credit against annual payment in year paid." This provision is apparently designed to give defendants an incentive to defend against individual suits, by requiring them to bear 20 percent of the cost of any judgments or settlements, with the fund effectively reimbursing the defendant for the other 80 percent. However, it is unclear how this provision works in combination with the provisions in the agreement that limit annual payouts, *to wit*, the annual aggregate cap limitation and the provision for individual judgments above $1 million. As indicated above, these latter provisions seem to envision that payment will be made from the fund.

- ***Phasing and Interest on Delayed Payments***. Several issues are raised by the provisions that potentially delay the payment of judgments and settlements that exceed the annual aggregate cap and $1 million plus judgments: (i) is interest paid on amounts that exceed the annual aggregate cap that are rolled over for payment to future years (the agreement is silent on this point, although elsewhere it explicitly indicates that no interest will be paid on the roll over of $1 million plus judgments); (ii) the agreement leaves open how the aggregate cap will be applied -- while the agreement seemingly envisions a "first-in-time" rule, under which judgments and settlements early in the year will absorb the aggregate cap, leaving later judgments and settlements to be rolled over if they exceed the cap, this is not explicit; and (iii) the agreement seems to indicate that the delayed payment of amounts in excess of the aggregate cap takes precedence over the payment of judgments and settlements in excess of $ 1 million, but leaves open an interesting question -- plaintiffs with judgments or settlements in excess of $1 million appear to be entitled to receive at least $1 million per year (at least beginning in the year after the year in which the judgment or settlement is first entered), while plaintiffs with judgments or settlements below $1 million are

entitled to payment only to the extent funding is available under the annual aggregate cap.

Other Observations:

In General

° The combined effect of the annual aggregate cap and the limitations on the payment of judgments and settlements in excess of $1 million could significantly delay payment of judgment and settlements to some plaintiffs. If the judgments and settlements entered against the participating companies are well in excess of the annual aggregate cap and if a number of those judgments or settlements exceed $1 million, plaintiffs (particularly those with judgments and settlements below $1 million) could potentially wait years before receiving any payment, even if they had substantial out-of-pocket expenditures. In evaluating this agreement, it thus seems essential that we either develop spreadsheets that compare the expected payouts against the availability of funds or obtain the spreadsheets used by the parties to the agreement in establishing the listed annual payments.

° There may be difficulty in determining whether suits claiming injury or damage relate to conduct taking place after the effective date of the Act, particularly where the injury or damage is caused by continuing conduct taking place both before and after the effective date.

° There does not appear to be any transitional provisions in the agreement regarding pending individual tort actions. If the agreement were deemed to apply to those actions (which seems likely), and to deprive the plaintiffs of punitive damages, it could raise Fifth Amendment issues. The critical question would be whether the plaintiffs would be viewed as having a property interest in a punitive damage claim that had not finally been resolved. While courts have been reticent to find such interests generally, problems could arise if the agreement were deemed to apply to cases pending on appeal, where a plaintiff, at the time of enactment, already had a judgment that included punitive damages. Somewhat less weighty Fifth Amendment issues might be also be raised if the agreement is viewed as delaying the payment of claims in a way that diminishes their value.

° In light of the Supreme Court's recent decision on the Brady bill in Printz v. United States, 1997 WL 351180 (June 27, 1997), certain provisions in the agreement may invite constitutional challenge on federalism grounds. Particular concerns are raised by those provisions in the agreement that would impose purely procedural, non-outcome determinative rules -- banning class actions and mandating severability of some trials -- on state courts. While there are no cases that specifically address the constitutionality of such provisions, in several cases,

the Supreme Court has emphasized the importance of state control of state judicial procedures.

Punitive Damages

° The purpose of punitive damages is to deter and punish. While the aggregate cap on liability provisions in the agreement are very complex, they appear to limit the amount that ultimately will be paid by the participating companies. If this is true, the agreement has the effect of diminishing the impact of diminishing the interrorem effect of punitive damages -- simply put, if punitive damages are awarded, they would effect only the allocation of the amounts contributed by the companies among damage payments and the other purposes envisioned by the agreement, but apparently would not increase the total amount paid by those companies. Perhaps, punitive damage claims for future conduct should not be subject to the annual aggregate cap.

° Query: given the deferral mechanism in the annual aggregate cap regarding judgments above $1 million, would it make sense to prioritize the payment of claims for large compensatory damage judgments/settlements to ensure that their payment is not delayed by the payment of punitive damage judgments/settlements that use up the available aggregate cap for a given year? It particularly seems odd to allow plaintiffs to collect punitive damages for future conduct if it would delay individuals from collecting compensatory damages for past conduct (conduct for which punitive damages are barred under the agreement).

Funding For Tobacco Litigation Judgments/Settlements

Up Front Commitment Lump Sum Cash Payment ($10 billion) → Not Available for Judgments/ Settlements

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Base Annual Payments (in perpetuity)

Face Amount increased by > 3% or CPI multiplied by Adj. for Volume Increase/ Decrease

Adj. for Vol. Increase: $ Actual Domestic Sales / $ 1996 Domestic Sales

Adj. Vol. Decrease: Actual Domestic Sales (Adult)/ $ 1996 Domestic Sales (Adult). (Any reduction in annual payment will be reduced by 25% of increase above 1996 profits on domestic sales)

33 percent

Annual Aggregate Cap for Judgments/ Settlements

If aggregate judgments/ settlements for year exceed annual aggregate cap, excess rolls over

Amounts > $1 million not paid unless every other judgment/ settlement can be satisfied w/n annual aggregate cap; excess rolls forward w/o interest and is paid at rate of $1 million until cap is not exceeded

Documents 7-2-97 Legal Grp.

3 judge panel - privilege claims.

July 1, 1997

TO: John Dwyer & Alexa Verveer

FROM: Anne Weismann

RE: Comments on Appendix VIII to Tobacco Settlement

We have taken a quick look at the settlement provision that would, through legislation, establish a three-judge panel to resolve conclusively all privilege claims over documents that would otherwise be required to be placed in the national tobacco document depository and have the following comments. As a general matter, we think the proposal creates a judicial entity with an uncertain status, and represents a fairly unwieldy attempt to resolve discrete issues that are better resolved either through the existing judicial system, or a less cumbersome method.

First, we question whether there would be "cases or controversies" over which this panel would have jurisdiction under Article III of the Constitution. It is far from clear that the legislation would create a right for which judicial review would be available to redress an alleged denial of that right. Moreover, while the agreement speaks generally about "disputes," the scope of the disputes covered by the proposed legislation is unclear. For example, paragraph 4 purports to create a process of accelerated judicial review for "any public or private person or entity" to challenge "any claims of privilege or trade secrecy before the three-judge panel."

Second, it is unclear whether the ruling of the three-judge panel would have a preclusive effect. Paragraph 3 provides that the adjudications of the panel "shall be binding upon all federal and state courts in all litigation in the United States." It is unclear whether the intent was to make the panel's rulings have a collateral estoppel effect, or to make them non-appealable.

Third, the Department has historically opposed the creation of three-judge panels as clumsy procedures that only generate more litigation about whether a particular action is properly heard by the panel in question. I understand that most recently the Department opposed the creation of a three-judge panel in the Judicial Reform Act. We see no reason to deviate from this position here.

As to alternatives, we know of no other statute that creates an alternative scheme to resolve comparable issues. The JFK Assassination Records Collection Act of 1992 establishes an Assassination Records Review Board that is empowered to collect government records, as defined therein. Disclosure of particular records or portions of records may be postponed based on certain enumerated grounds (e.g., personal privacy interests, classified information), and the Board is empowered to "consider and render decisions on a determination by a Government office to seek to postpone the disclosure of assassination records." In the tobacco litigation, by contrast, the documents to be placed in the repository are expressly non-governmental; i.e., "the tobacco industry's corporate records."

The Department's concerns with the creation of a three-judge panel could be alleviated if,

alternatively, the legislation created a special court, made up of three to five district judges, designated by the Chief Justice, to hear cases individually raising claims of privilege. Such a court could be similar in concept to the Temporary Emergency Court of Appeals, and would have the advantage of creating a unified body of law. A single judge of the court could hear and decide any case, although the court could sit en banc to resolve significant or recurring issues. Even such an approach strikes us as a fairly extreme solution, given that claims of privilege are hardly unique to the current judicial system.

Another alternative would be to limit, through legislation, the privileges that can be claimed with respect to these documents. Anticipating that the bulk of the privileges claimed would be attorney work product, the legislation could provide explicitly that such privileges cannot be asserted with respect to any document that is required to be placed in the repository. While such legislation will not eliminate entirely disputes that may arise over privileges, it will limit their volume and scope considerably. In addition, the legislation could provide that disputes over privilege claims (in the context of litigation) must first be presented to mediators for attempted resolution. Again, while such an approach will most likely not eliminate all disputes requiring judicial resolution, it will help limit their volume and scope.

Alternatively, the settlement could adopt the approach used in multi-district litigation, where discovery disputes are transferred to one judge for resolution.

Let me stress that these are our preliminary thoughts only. We understand you are under a tight time-frame for response. Given more time, we would be happy to explore these and other alternatives more fully.

7-2-97
Legal Grp.

PUNITIVE DAMAGES

Provision: All punitive damages claims resolved as part of overall settlement. No punitive damages in individual tort actions. This provision would not apply to suits for relief arising from future conduct -- "i.e., suits claiming injury or damage caused by conduct taking place after the effective date of the Act."

Observations:

° The purpose of punitive damages is to deter and punish. While the aggregate cap on liability provisions in the agreement are very complex, they appear to limit the amount that ultimately will be paid by the participating companies. If this is true, the agreement has the effect of diminishing the impact of diminishing the interrorem effect of punitive damages -- simply put, if punitive damages are awarded, they would effect only the allocation of the amounts contributed by the companies among damage payments and the other purposes envisioned by the agreement, but apparently would not increase the total amount paid by those companies. Perhaps, punitive damage claims for future conduct should not be subject to the annual aggregate cap.

° Query: given the deferral mechanism in the annual aggregate cap regarding judgments above $1 million, would it make sense to prioritize the payment of claims for large compensatory damage judgments/settlements to ensure that their payment is not delayed by the payment of punitive damage judgments/settlements that use up the available aggregate cap for a given year? It particularly seems odd to allow plaintiffs to collect punitive damages for future conduct if it would delay individuals from collecting compensatory damages for past conduct (conduct for which punitive damages are barred under the agreement).

° There may be difficulty in determining whether suits claiming injury or damage relate to conduct taking place after the effective date of the Act, particularly where the injury or damage is caused by continuing conduct taking place both before and after the effective date.

° There does not appear to be any transitional provisions in the agreement regarding pending individual tort actions. If the agreement were deemed to apply to those actions (which seems likely), and to deprive the plaintiffs of punitive damages, it could raise Fifth Amendment issues. The critical question would be whether the plaintiffs would be viewed as having a property interest in a punitive damage claim that had not finally been resolved. While courts have been reticent to find such interests generally, problems could arise if the agreement were deemed to apply to cases pending on appeal, where a plaintiff, at the time of enactment, already had a judgment that included punitive damages.

7-2-97 Legal Grp.

DRAFT

LICENSING

I. Introduction

ATF has extensive experience in licensing the alcohol, tobacco, and firearms industries for specified statutory purposes. ATF licenses approximately 3,800 distilled spirits plants, wineries, and breweries; 140 manufacturers of tobacco products and cigarette papers; 14,500 alcohol beverage wholesalers and importers; 200 tobacco export warehouse proprietors; and nearly 135,000 firearms and explosives licensees.

II. Issues to Consider in Evaluating the Licensing Provisions of the Proposed Agreement

A. A comprehensive regulatory scheme for retailers requires licensing at all levels of the distribution chain.

Any licensing scheme should be tailored to meet its specific goals. For example, ATF's licensing of tobacco manufacturers serves the primary purpose of collecting and protecting the revenue generated by a production tax collected from the manufacturer. To achieve this goal, there is no need to license wholesalers or retailers. In contrast, ATF licenses the entire distribution chain of the firearms industry because the primary purpose of the gun control laws is to prevent sales of guns to particular classes of persons, such as felons, and comprehensive record keeping on all transactions is essential to the national firearms tracing system.

The proposed settlement suggests that the primary goals of a licensing system are to facilitate FDA regulation with respect to access, advertising, and labeling. These goals require a comprehensive licensing scheme that will provide accountability for compliance with the licensing scheme. Record keeping requirements must be sufficient at each level to enable the licensing agency to trace the commodity from the manufacturer to the retailer. Without these controls, there is a "weak link" in the distribution chain that can result in the diversion of the commodity into the stream of unlicensed commerce or noncompliance with regulatory requirements.

However, the system proposed does not license all levels of the distribution chain. Manufacturers and wholesalers that do not sell to consumers would not require a license. Potential for diversion from points earlier in the distribution chain to illegal consumption or for noncompliance with regulatory requirements would be great, particularly when effective controls are imposed at the retail level.

B. The licensing scheme should have enforceable criteria for obtaining a license.

Setting criteria to limit the distribution system has the prophylactic effect of saving enforcement resources and helping ensure the integrity of the licensing and regulatory system. To avoid illicit trading, licenses should be given only to persons who actually intend to engage in the business the license authorizes. Keeping ineligible persons out of the business can also be achieved through licensing fees and inspections. Several years ago, when firearms licenses cost only $10 per year and there was almost no enforcement of the requirement that licensees actually engage in business, the number of licensees blossomed to over 260,000, making enforcement difficult. Raising the fee to $200 and strictly enforcing the licensing requirements has lead to a decrease of about 60% in the number of licensees over a four year period, greatly enhancing ATF's ability to enforce the gun control laws.

The proposed scheme makes compliance with the proposed legislation a condition of obtaining and holding that license. However, there is no mention of an investigative authority to determine whether an applicant is eligible for a license or, for that matter, to determine whether a licensee is maintaining compliance with the proposed legislation.

C. The licensing system needs an effective enforcement arm.

Because a licensing system produces an incentive to traffic unlawfully in the licensed commodity, a sophisticated enforcement arm is needed to investigate unlawful commerce outside the licensed distribution channels. An effective and fair enforcement arm raises the level of voluntary compliance through education of the licensees and deterrence; in contrast, uneven application leads to resentment and non-compliance on the part of licensees, and ultimately, to litigation.

Certain enforcement tools are necessary to effective licensing enforcement. Periodic inspections ensure that the licensees comply with the system. A sensible range of meaningful sanctions for non-compliance give the licensing agency the needed flexibility to deal with different types of violations. These sanctions can include suspension or revocation of the license, civil fines or penalties, or criminal penalties.

The penalty set out in the proposal for unlawful sale of tobacco products without a license is a misdemeanor. A criminal misdemeanor is not a great deterrent -- particularly if the illicit sale of tobacco products becomes highly profitable. Moreover, it is very difficult to obtain prosecution of a misdemeanor given scarce prosecutorial resources.

It is unclear whether the penalties and other sanctions imposed for the sale of tobacco products to underage persons are criminal or civil in nature. Moreover, it is not clear how to count violations for purposes of imposing these sanctions.

D. The proposal leaves unresolved critical funding and resource issues.

An agency charged with administering a licensing system must have adequate resources to process and investigate applications for licenses to ensure that ineligible persons do not improperly receive them. ATF's experience shows that time spent investigating applicants is repaid many fold by avoiding later enforcement actions. Significant resources must also be devoted to the education and inspection of licensees. Costs associated with data processing support are also significant. Costs of a licensing system are particularly high when enforcement is at the retail level, given the number of potential licensees involved, the frequency of turnover, and the diverse locations where business is conducted.

Resources needed for the proposed scheme will be very substantial. FDA estimates that there are on the order of 700,000 retail dealers in tobacco products in the United States. Given that ATF taxes 450,000 retail liquor dealers (stores, bars , restaurants, etc.), almost all of whom sell tobacco products, this may be an underestimate. Costs relating to the processing and investigation of applications alone will be extensive. Costs associated with investigating violations and taking action against violators could even be greater. For example, ATF regulates nearly 135,000 firearms and explosives licensees, using nearly 430 inspectors and roughly 50 people to process license applications. The cost of administering this licensing system is approximately $38 million per year. This estimate does not include the costs of establishing a new system from scratch, nor does it include litigation costs associated with defending challenges to system; actions to suspend or revoke licenses; or criminal investigations and prosecutions.

The proposal states that the enforcement of the licensing scheme would be funded through industry payments, and that licensing fees would cover the administrative costs of issuing State licenses.

However, the agreement does not appear to contemplate any audit authority to account for payments of monies used to enforce the system, nor does it specify whether the federal government or Indian tribes would recover the costs of non-enforcement aspects of licensing programs they administer..

E. The proposal will require cooperation between the federal government and the States.

In order to avoid confusion, misinformation and duplication of efforts, it is necessary to vest responsibility for licensing in one agency. However, cooperation and communication with other agencies is often essential to ensure the licensing agency has all relevant information. In particular, commodities licensed by the Federal government may also be regulated by State and local governments. Cooperation, information sharing and communication with those State and local agencies is essential in order to regulate a commodity effectively. This is particularly true when enforcement resources are stretched to the limit at both the Federal and State level. ATF has entered into approximately 40 memoranda of understanding with States calling for the exchange of information pertaining to alcohol and tobacco products.

III. Legal Issues

A. Tenth Amendment Concerns with the Imposition of Federal Standards on the States

According to the proposed agreement, Federal legislation would mandate "minimum Federal standards" for a retail licensing scheme. The agreement is ambiguous about how this would be done, but presumably the following are possibilities:

- The Federal government could be the licensor, exercising its power under the commerce clause;
- The Federal government could preempt the field, but allow the states to adopt and enforce their own regulations conforming to the Federal standard;
- The States could design their own licensing schemes with advisory Federal guidance; or
- The spending power could be used to give incentives to the States to comply with the Federal standard.

The language of the proposed tobacco settlement agreement appears to contemplate legislation under which the Federal government would set minimum standards for licensing laws that states would be required to adopt as state law and required to enforce through funding provided by the tobacco industry. In its recent decision striking down certain portions of the Brady act, the Supreme Court made clear that the Tenth Amendment bars the Federal government from requiring states to enact or enforce a Federal mandate. *Printz v. United States*, No. 95-1478, 1997 U.S. LEXIS 4044 (June 27, 1997). Thus, the licensing scheme cannot be implemented simply by the passage of a Federal law requiring states to adopt Federal prescribed licensing laws and to enforce them.

However, there are other constitutionally permissible models for Congress to encourage state participation in a Federal scheme. Congress can make compliance with Federal standards a precondition for continued state regulation in an otherwise preempted field. *Printz*, *supra.* at 27, *discussing Hodel v. Virginia Surface Mining & Reclamation Assn., Inc.*, 452 U.S. 264 (1981) and *FERC v. Mississippi*, 456 U.S. 742 (1982); *see also New York v. United States*, 505 U.S. 144, 161-3 (1992) . There is no question that under its Commerce Clause authority Congress could establish a nationwide Federal licensing system for tobacco products, to be administered by Federal agencies. Under *Hodel*, Congress could then allow states to adopt and enforce their own regulations if they

complied with Federal standards. If the agreement provides for industry payments to the Federal government for licensing, Congress could finance a Federal licensing system through such payments.

A somewhat more difficult question is whether Congress could through Federal legislation condition the receipt of payments from the tobacco industry to the states, or some portion of those payments, on the states' adoption of licensing laws that complied with Federal standards. Under the Spending Clause, Congress may condition the receipt of Federal funds on the States' undertaking certain action. *Printz, supra*, (O'Connor , J. concurring). In *South Dakota v. Dole*, 483 U.S. 203 (1987), the Supreme Court upheld, as a valid exercise of the Spending Power, a Federal law reducing the percentage of Federal highway funds received by States that failed to enact a law barring consumption of alcohol by persons under 21. Likewise, in *New York v. United States, supra.*, the Supreme Court upheld financial incentive provisions of a Federally mandated waste disposal law applying to the States but struck down provisions forcing the State to take title involuntarily to such wastes.

However, the Court has cautioned that if the Federal financial incentive is too powerful it may be deemed not to be a condition but to be impermissible coercion. *South Dakota v. Dole*, 483 U.S. at 211, *citing Stewart Machine Co. v. Davis*, 301 U.S. 548, 590 (1937). The Fourth Circuit, sitting en banc, recently struck down a funding condition imposed by the Department of Education on the receipt of funds under the Individuals with Disabilities Education Act (IDEA). *Comm. of Virginia Dept. of Education v. Riley*, 106 F. 3d 559 (4th Cir. 1997). While the majority held only that the statute did not clearly and expressly authorize the condition imposed, six judges joined an opinion holding that the threat of withdrawal of all IDEA funds if the state did not change its policy of refusing to provide tutors to disabled students expelled from school "begins to resemble impermissible coercion, if not forbidden regulation," in violation of the Tenth Amendment. *Id.* at 569-72. The six seemed moved not only by the size of the amount at issue but also by the area in which the Federal government had sought to influence the state's choice.

Some aspects of the proposed settlement might prove problematic to Federal regulation of state licensing under a Spending Clause approach. First, the industry payments may not be Federal funds subject to the Spending Power -- if, for example, the agreement itself provides for licensing-related payments from the tobacco companies to the states, or otherwise constrains the Federal government's use of the licensing funds. Second, the size of the payments involved may be quite large, so that even in the unlikely event that the states were willing to have industry payments for licensing made to the Federal government and doled out to the states under Federal law, the courts might find the legislation coercive. Finally, not all states are participating in this settlement, and the courts might be particularly skeptical of the legislation as applied to a non-signatory state.

B. Due Process Concerns with Suspension and Revocation

The licensing scheme also provides for a suspension of the retail license (after the first offense) and revocation (after the sixth or subsequent offense). Since a license is a property interest protected by the Fifth Amendment, Due Process requires that the licensees be afford an opportunity for a hearing before the license may be suspended or revoked. *See Bell v. Burson*, 402 U.S. 535 (1971). This applies to both state and Federal licensing procedures because the due process clause is made applicable to the states by the Fourteenth Amendment. Accordingly, the enabling legislation must establish a procedure (administrative and/or judicial) giving the licensee notice of the charges and an opportunity to be heard.

C. Licensing on Native American Lands

Using a framework adopted from the Clean Air Act (a *Hodel* - model scheme), the proposed agreement provides for licensing provisions governing sales on Native American lands and

commerce in tobacco products by members of Indian tribes. The proposed agreement provides that the federal government would decide for each tribe whether the licensing provisions would be set by the federal government, set by the state subject to federal standards, or set by the tribe subject to federal standards which incorporate state law. (*See* Appendix III.)

These provisions do not appear to raise additional Constitutional concerns. First, as discussed above, the *Hodel* model of federal-state interaction appears to have been reaffirmed in the Printz case. We are not aware of any constitutional concerns that would arise from the imposition of a federal licensing system or federal standards on Indian tribes, even if the federal standards incorporated state law. The state could also set the licensing requirements: it is well-established that State taxation and regulatory laws can apply to members of Indian tribes and can apply in Indian country. *See, e.g., New York State Department of Taxation v. Attea*, 114 S. Ct. 2028 (1994) (State can require Indian cigarette traders to register with state and tax cigarettes intended for off-reservation consumption). For example, State liquor licensing laws apply to Indians. *See id.*; *Rice v. Rehner*, 463 U.S. 713 (1983).

Also, the agreement states that federal taxes or fees (such as the tobacco excise tax) would apply to commerce in tobacco by members of Indian tribes or on tribal lands. Again, this does not seem to raise significant legal concerns. Federal statutes of general applicability apply with equal force to Indians unless the law touches on exclusive rights of self-governance in purely intramural matters, the application of the law would abrogate treaty rights, or Congress intended to exclude Indians. *U.S. v. Baker*, 63 F.3d 1478, 1484-1485 (9th Cir.) *cert. den.*, 116 S.Ct. 824 (1996). For example, the Contraband Cigarette Act applies to Indian tribes. *U.S. v. Gord*, 77 F.3d 1192 (9th Cir. 1996).

However, it might be difficult for a Federal agency or State to enforce a licensing scheme given current sovereignty issues or the volatile nature of investigations occurring on these lands.

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Document Disclosure Issues Affecting FDA

Authority under the FDCA to review documents

FDA has authority under the FDCA to inspect medical device manufacturers. FDA has additional authority pursuant to the Medical Device Amendments of 1976 to inspect records, files, papers, processes, controls, and facilities to determine whether restricted devices are adulterated or misbranded. (Section 704 of the FDCA, 21 U.S.C. 374). The 1976 Amendments also provided FDA with authority to inspect and copy records required under reporting and records requirements, including records concerning compliance with Good Manufacturing Practice (GMP) regulations.

There is no exclusion in the FDCA for documents containing trade secret, confidential, or privileged information. FDA has regulations to protect trade secrets as well as commercial or financial information that is confidential or privileged (21 C.F.R. 20.61).

The inspectional authority for restricted devices does not encompass: (1) financial data, (2) sales data other than shipment data, (3) pricing data, (4) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this chapter), and (5) "research data," except for "data" subject to reporting and inspection under regulations issued pursuant to the provision of the FDCA that requires reports and records of deaths and serious injuries that device may have caused or contributed to. (Section 360i, 21 U.S.C. 519). As part of the 1996 Tobacco Rule, FDA issued an amendment to the relevant regulation that provides that tobacco product manufacturers are required to submit reports under these provisions "only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process." Thus, the tobacco companies could argue that under the current provisions, FDA is not entitled to research data, except for data relating to serious adverse events that are not already well-known.

Documents that FDA needs to have in the future

To effectively evaluate how nicotine in tobacco products should be regulated, regulate the ingredients in tobacco products, and evaluate less hazardous products, FDA needs to have access to a range of documents and sources. Although some of these documents could be obtained under existing FDA authority, others may not be easily obtainable under the FDCA. FDA is continuing to look into the scope of its authority under the FDCA with respect to these documents. Based on preliminary analysis, FDA needs access to documents related to the following issues:

Nicotine Regulation
-the interaction between nicotine and tobacco product components (including both tobacco and smoke)
-nicotine as it relates to product design and manufacturing, tobacco blend, filters, papers used in cigarettes, and pouches or other apparatuses used in smokeless tobacco products
-nicotine descriptions in the context of tobacco leaf purchasing (e.g., breeding

tobacco, methods of producing nicotine, buying practices)
-nicotine in the context or reverse-engineering work (e.g., analyses of a competitor's product)
-analyses of nicotine delivery (e.g., evaluations of how nicotine deliveries can be most accurately measured)
-technology or chemicals that affect the concentration or delivery of nicotine from tobacco products
-biology and psychopharmacology of nicotine

Ingredient Regulation
-identification of constituents in tobacco products and ingredients in smoke
-additives used in products, including the filters, papers, and pouches
-the toxicity and possible adverse effects of ingredients
-research and information on products that result when these ingredients are heated and interact

Less Hazardous Products
-research and development activities involving "safer" products, including law tar, low nicotine, and di-nicotinized products.

Subpoena authority: To have full benefit of the documents described above, FDA should also have access to the people who worked on the relevant research. Expanded subpoena authority would permit this.

Settlement Proposal Provisions

The relevant provisions are extremely vague. The proposed settlement lacks any express provision that would provide FDA with access to the documents that would be needed to effectively regulate tobacco products in the future. To the extent that there are relevant provisions, they are vague and/or drawn very narrowly. Specific concerns:

Research Disclosure Generally: The proposal (page 26) provides penalties of up to $10 million per violation for failure to disclose to FDA "research about tobacco-product health effects," but the relevant provisions (pages 67-68) are narrowly limited to disclosure of "original laboratory research relating to the health or safety of tobacco products" or "relating to ways to make tobacco products less hazardous." This provision encompasses little that would be of use to FDA. To effectively regulate nicotine and tobacco product ingredients, and address issues related to safer products, FDA would also need access to documents that reflect internal discussions and analyses concerning nicotine and tobacco products.

The timing and process for the disclosure of research to FDA is unclear. One sentence further narrows the scope of the provision by providing that manufacturers must provide research "results" to FDA.

The relevant provisions (page 68) also appear to permit companies to withhold "original laboratory research" from FDA based on trade secret privilege. Moreover, the provision for the authority of the 3 judge panel (page 66) appears to contemplate that the federal government will be making "privilege or trade secret" challenges. As

noted, under the FDCA's inspectional authority, documents cannot be withheld from the agency based on trade secret or other privilege.

Review of Previously Unproduced Documents: The proposal directs the companies, TI, and CTR to produce previously unproduced documents related to a number of specific categories (page 64), and to do a good-faith, de-novo, document-by-document review of previously withheld documents (page 65-66). FDA is particularly interested in older documents relating to nicotine research. These provisions appear too narrow, and may not encompass all of the documents FDA would need. In addition, it appears that the companies may withhold from FDA any documents that they deem ""legitimately privileged against disclosure." The proposal later contains provisions that mandate the disclosure of documents relating to certain subjects, irrespective of attorney-client or work product privilege, but these provisions appear to affect future action and documents only.

Safer Products: The proposal (page 14) requires manufacturers to "notify FDA of any technology that they develop or acquire and that reduces the risk from tobacco products," but wording not clear as to what stage in the development process this obligation would start. FDA should have routine inspectional access to all documents relating to the possible and actual development of reduced risk products.

Ingredients: Both the scope of the information concerning ingredients that FDA would have access to and when FDA would have that access are unclear. The proposal (page 19) requires manufacturers to submit, within 5 years of enactment of the proposal, a "safety assessment" for each ingredient currently added to the tobacco product. The proposal (page 20) states that it would "[p]rovide for record keeping regarding ingredients," and "[a]llow FDA access to such records, with protection of proprietary information," but contains only these vague statements. FDA should have access to all information involving ingredients irrespective of when a manufacturer submits the assessment.

Subpoena Authority: The proposal (page 19) provides that the subpoena authority FDA has with respect to manufacturers of medical devices generally would also apply to tobacco product manufacturers. FDA's existing authority is limited to use in proceedings involving civil money penalties. Expanded authority would be appropriate with respect to tobacco products.

FDCA Inspectional Authority: The proposed settlement is vague as to whether existing FDCA inspectional authority would exist. As noted above, however, FDA may not have the authority under existing provisions to obtain all of the documents needed to effectively regulate tobacco products in the future. Because of the unique circumstances and concerns of tobacco product regulation, however, it would be appropriate to adopt provisions that enhance FDA's inspectional authority with respect to tobacco products.

Issues Regarding Provisions for Public Disclosure of Documents

The relevant provisions are on pages 18, 26, 64-68 (appendix VIII).

Documents outside the scope of the proposal

The proposal establishes perimeters for what documents the tobacco industry must disclose, either by making the document public or by including it on a privilege log. In evaluating these provisions, there are two overriding issues: (1) are the proposal's provisions too limited in scope in terms of what they require the companies to disclose, and (2) because the proposal imposes specific obligations on the industry to disclose documents on particular subjects, the companies' view will be that they need not do more; as a result, we may not be able to obtain potentially important documents that we do not currently have any knowledge of.

Vagueness

This portion of the proposed settlement is quite vague and contains internal inconsistencies. The major areas of vagueness are: the subject matter of documents encompassed by the proposal, the timing of the various obligations on the industry, and enforcement mechanisms and penalties.

Undefined terms

The proposal does not define many terms and phrases. Most significantly, it does not define "privileged," "trade secret," and "confidential." In the context of the controlling law for the three judge panel, the proposal refers to the ABA/ALI Model Rules and principles of federal law as well as the Uniform Trade Secrets Act, 18 U.S.C. 1905. The ABA/ALI Model Rules may not contain adequate definitions. Section 1905 is the provision that makes release of confidential information by a federal employee a federal crime; it does not provide a definition of the terms used in this proposal.

Limiting words and terms

The proposal contain many words and terms that limit the scope of provisions. For example, under the proposal, "corporate records" "from the files of the tobacco industry" would be disclosed (pp. 18, 64). Relevant documents could be in a range of locations and forms. Of particular interest to FDA are documents from the 50s, 60s, and 70s. These documents could be in the possession of associations, companies, or individuals, in the United States and elsewhere, that are no longer directly connected to a tobacco company.

The proposal also uses lists of examples rather than descriptive terms to define a class or category. For example, the proposal names specific groups that can view the records that will be placed in the depository. An alternative would be to simply say "individuals and groups."

The proposal limits the class of affected documents by naming categories of documents or using qualifying terms. The proposal uses different qualifying terms interchangeably. For example, in some places, the proposal refers to documents

related to "smoking and health, addiction or nicotine dependency, safer or less hazardous cigarettes and underage tobacco use and marketing." In other places, the proposal refers only to "smoking and health" documents. Beyond vagueness issues, the listed categories appear too narrow. "Smoking and health" could, for example, exclude certain documents involving nicotine.

The proposal variously uses the terms "privileged," "trade secret," "confidential," and "non-public." In certain provisions, the selected term seems intentional (and unduly restrictive), but the interchangeability of terms in other provisions creates vagueness as to the proposal's meaning.

Oversight of search for previously unproduced documents

The proposal (page 65-66) directs the companies, TI, and CTR to do a good-faith, de-novo, document-by-document review of previously unproduced documents. They are to create a comprehensive privilege log of all documents that they deem to be "legitimately privileged against disclosure." This provision grants them wide discretion to determine whether a document should be withheld. It is not clear what would happen if the companies fail to provide a privilege log that meets the standards set out by the Minnesota court.

The timing of this review is unclear. The provision is contingent on the settlement of all the State Attorney General actions, and does not anticipate the possibility that one or more states might opt not to settle.

One issue is whether only documents that contain confidential trade secret information should be permitted to be withheld from public disclosure, or whether other categories of documents can also be withheld.

Another issue is whether a special master should be involved in the evaluation of some privilege claims at this stage, instead of waiting for a challenge and utilizing the three judge panel to evaluate all claims. (In Minnesota, a special master is currently reviewing 550,000 pages of documents for which attorney-client privilege has been asserted. The plaintiff State of Minnesota invoked the criminal fraud exception to attorney-client privilege, and believes that many of these documents will be made public. They anticipate that the special master's review will be done in August.)

National tobacco document depository: form and oversight

The proposal would require tobacco manufacturers, CTR and TI to establish and finance a national depository of documents in the Washington, D.C. area that is open to the public. The provision is vague. The relationship between this provision and the section that requires CTR and TI to be disbanded is unclear. Also, it is not clear when the depository will be established.

One issue is whether a government or independent entity should have oversight over the Depository's creation and running. Another issue is whether an electronic depository, accessible through the Internet, would be preferable.

National adjudication of privilege claims

The proposal's goal is to have national, "binding, streamlined and accelerated judicial determinations" of privilege and trade secret claims. One issue is whether this is an appropriate goal.

The mechanism proposed also raises many issues:

-It is not clear how long the court will be in existence (i.e., is there any point at which privilege issues related to tobacco documents would again be made in individual state and federal courts)

-Is this an appropriate use of Article III judges

-The appointment process is unclear (the Judicial Conference has only administrative responsibilities)

-Tenure of judges is unclear (would they rotate, have other judicial responsibilities, or be life-appointees); the multi-district litigation scheme may provide a model

-Because decisions are appealable only through *cert.*, the panel's decisions would, as a practical matter, be the final word

-Timing of when "national adjudication" would begin, and the affect on pending cases is unclear

-Unclear is whether a privilege that has already been decided on by a state or federal court can be re-litigated

-Applicable law is unclear (e.g., what case law would apply)

-Appointment and role of special masters is unclear

-Scope of authority is extremely broad: "the panel's adjudications shall be binding on all federal and state courts *in all litigation* in the United States"--this could encompass anti trust and other litigation

-Standard for refusing attorney fees (to be paid by manufacturers only) would probably be easily met by the companies

-High potential for a large volume of cases. Because there appears to be no standing requirements, and no prima face showing is required for *in camera* review, it is likely that every document for which a privilege has been claimed would be reviewed by the court

-Unclear whether proceedings would be *in camera*, public, or some combination

Disclosure of laboratory research

One issue is that this may discourage research into safer products. Another issue this that there may be takings concerns if research is made public. The companies will have the incentive to shield research from public disclosure by tailoring their research to the trade secrets exception (e.g., do formula-based research). In addition, the companies will likely contract more research in foreign countries. Further, it is not clear at what point in the research process the research is to be released to FDA or the public.

PENALTIES

	PROPOSED SETTLEMENT	EXISTING LAW (under North Carolina District Court decision)
Overview of Enforcement Mechanisms	The proposed settlement appears to add a number of possible enforcement mechanisms to existing methods under the FDCA, although it is not absolutely clear whether all of the existing mechanisms are retained. (See Questions below). State enforcement appears to be more constrained than it is under existing law because of restrictive preemption provisions, caps on penalties, and a removal provision.	A violation of FDA's tobacco regulations renders the tobacco product misbranded, and the FDCA, among other things, prohibits the introduction into interstate commerce of a misbranded device. FDA's regulations are enforceable to the extent that they are upheld by the courts (e.g., advertising restrictions are currently in limbo). FDA's assertion of jurisdiction does not greatly affect state regulation of tobacco products.
Enforcement Agencies	FDA, DOJ, States. (p.26)	FDA, DOJ, States.
State Enforcement	The proposal prohibits state penalties and requirements duplicative or beyond those in legislation; no preclusion for matters not covered. (p.26) State enforcement incentives apply. (pp.58-60)	Limited preemption of state laws that impose specific requirements more stringent than analogous federal requirements. 61 Fed. Reg. at 44548. No preemption of penalties. State enforcement incentives in place under Synar amendments.
Removal	State enforcement actions removable to federal court. (p.26)	N.A.
Criminal Penalties	Criminal penalties "based on" FDCA and Title 18. (p.26)	Prohibited act: 1 year and/or $1,000; 2d offense or violation committed with intent to defraud or mislead - 3 years and/or $10,000. 21 U.S.C. § 333(a). Title 18 applies.

Civil Penalties	Civil penalties "based on" FDCA. (p.26)	Civil money penalty of maximum $15,000 per violation, $1 mil per proceeding for violations of FDCA device provisions. 21 U.S.C. § 333(f).
Disclosure Penalties	Penalty of $10 mil per violation for failure to disclose to FDA health research and information. (p.26)	No comparable blanket disclosure requirement.
Injunctive Relief	Presumably available to the extent that tobacco restrictions are imposed under the FDCA.	Injunctive relief available to restrain violations. 21 U.S.C. § 332.
Seizure	Presumably available to the extent that tobacco restrictions are imposed under the FDCA.	An adulterated or misbranded device is subject to seizure at any time. 21 U.S.C. § 334(a)(2).
Lookback	If targets for reduction of underage tobacco use are not met, industry is subject to a penalty of up to $2 bil, but could receive up to a 75% abatement of that amount. (p.24)	No comparable provision, but the agency retains the authority to propose and issue additional regulatory requirements in a future rulemaking proceeding to further reduce youth tobacco use. 61 Fed. Reg. at 44542.
Compliance Plans and Corporate Principles	Fines and penalties (including "Scarlet Letter" advertising) if companies breach their obligations relating to the development, implementation, and enforcement of compliance plans and corporate principles - up to $25k per day, to a maximum of $200k. (p. 23)	US Sentencing Guidelines Chapter 8 establish an incentive for companies to adopt and implement such compliance steps.
Compliance Reporting	Manufacturer subject to fines and penalties if its compliance officer fails to furnish to FDA reports by its employees of violations by retailers or distributors.	N.A.

Retailer Penalties	Unlicensed Seller Individual: minimum of $1,000 and/or 6 months. Corp.: max of $50,000. (p.44) Violation of State licensing laws 1st: $500 or 3 day suspension. 2d: $1,000 or 7 day suspension. 3d: $2,000 or 30 day suspension. 4th: $5,000 or 6 mo. suspension. 5th: $10,000 or 1 yr. suspension. 6th: $25,000 or revocation. 10th: permanent revocation. (p.44)	Civil money penalty of maximum $15,000 per violation, $1 mil per proceeding for violations of FDCA device provisions. 21 U.S.C. § 333(f). FDA has announced that for underage tobacco sales it intends to issue a warning for the first violation, and seek a penalty of $200 for the second violation.
Consent Decrees	Consent decrees setting out certain terms of the agreement are enforceable only through injunctive suits - after a violation is established and another injunction entered, criminal or civil penalties could be imposed.	N.A.
National Protocol	Contract to provide enforcement rights to all states. (pp.26-27)	N.A.

Questions and Observations:

- Proposal states that "[c]ivil and criminal penalties for violations of the legislation based on those governing other drugs or devices regulated under the Food, Drug, and Cosmetic Act and, where applicable, under Title 18 of the U.S. Code." (p. 26) From this language, it is unclear whether the drafters intended to incorporate all existing penalty provisions or whether "based on" suggests a looser connection. Thus, it is uncertain whether the specific penalty provisions outlined in the proposal are intended to be a substitute for, or an enhancement of, the existing penalties. If they are intended to be in addition to existing provisions, then restrictions that are imposed pursuant to the settlement and under

the FDCA should be enforceable in the same manner as other medical device requirements.

- Appendix II addresses "violation of the provisions of the State licensing laws regarding sales to minors." (pp. 44-45) It is again unclear whether this is meant to be a substitute for civil money penalty proceedings under 21 U.S.C. § 333(f) and 21 C.F.R. Part 17. The maximums for FDA's civil money penalties are $15,000 per violation and $1 million per proceeding. The fines listed in Appendix II range from $500 to $25,000, but there is no provision for aggregating multiple violations. FDA would be interested in aggregating violations with respect to chain retail stores.