Executive Summary

In the last three years, Congressional hearings, FDA's investigation, and litigation have disclosed numerous internal documents from the tobacco industry. These documents have revealed extensive industry efforts to manipulate and control nicotine levels in cigarettes, as well as tobacco company research on marketing tobacco products to children. Yet despite these extensive disclosures, little evidence has emerged about the role played by the tobacco industry's lawyers in concealing information from the public.

Now new evidence is emerging that suggests that secret documents, which the companies claim are protected by the attorney-client privilege, may be the most damaging tobacco industry documents of all. This evidence suggests that tobacco attorneys created and participated in an elaborate scheme to defraud and deceive the American public for over 30 years.

To date, the involvement of the tobacco lawyers has been hidden from the public by the companies' invocation of the attorney-client privilege. Courts that have reviewed portions of these documents *in camera*, however, have concluded that they contain evidence of a decades-long crime or fraud. Recently, courts have found:

- Industry attorney-client documents "revealed the most explicit admissions" that tobacco company lawyers participated in a "program to further the alleged ongoing fraud and deception" and that the tobacco companies and their lawyers "specifically abused the attorney-client privilege in their efforts to effectuate their allegedly fraudulent scheme." *Haines v. Liggett Group Inc.*, 140 F.R.D. 681, 695 (D.N.J. 1992), *vacated*, 975 F.2d 81 (3rd Cir. 1992).

- Tobacco company lawyers carried out and planned "fraudulent activities and

undertook to misuse the attorney/client relationship to keep secret research and other activities related to the true health dangers of smoking." *State of Florida v. American Tobacco Co.*, Civ. Action No. CL 95-1466 AH (Palm Beach County, Fla., filed Feb. 21, 1995).

- The government established "a reasonable basis to believe that the crime-fraud exception to the general rule of privilege should be invoked." Plaintiffs made a "*prima facie* case to invoke the crime-fraud exception." *Minnesota v. Philip Morris*, Civ. Action No. C1-94-8565 (Ramsey County, Minn., filed Aug. 18, 1994).

- The plaintiffs established probable cause that "a fraudulent purpose existed" in the tobacco industry's attorney-client documents; these documents "furthered the fraud perpetrated on the public." *Sackman v. Liggett Group, Inc.*, 920 F. Supp. 357, 368 (E.D.N.Y. 1996), *vacated on other grounds*, 167 F.R.D. 6 (E.D.N.Y. 1996).

The minority staff of the Committee on Government Reform and Oversight has obtained a small number of the secret attorney-client documents. The documents obtained and analyzed by the minority staff are some of the attorney-client documents of Liggett & Myers Tobacco Company. These documents contain important evidence of one tobacco company's efforts to conceal health information from the public – and they illustrate the central role played by tobacco lawyers in these efforts.

Specifically, these documents show that the Liggett attorneys:

- Recognized that Liggett had developed a new cigarette with "major health benefits" but advised that Liggett not market the cigarette because it "may incite accelerated cancer litigation which may, in turn, result in infinite liability." As an apparent result, Liggett never marketed the new cigarette.

- Censored Liggett's communication of health risks to doctors because such a communication could "knock the props from under us" in future litigation.

- Intervened to prevent Liggett managers from making public statements about human health effects that would contradict "our position that there is no scientific proof of any cause and effect relationship between smoking and human health."

- Reviewed scientific research by Liggett and other companies to insure that it

would not "ricochet to our detriment."

Despite their significance, these documents may not be the most important Liggett documents. For example, they do not contain any of the so-called "joint defense" documents, which describe the joint legal strategies of Liggett and other tobacco companies.

Although the documents described in this report are only a tiny fraction of the tobacco industry's attorney-client documents, their import is substantial. They appear to be evidence of potential significant corporate crime or fraud. The policy implication is clear: the attorney-client documents still being held secret by the tobacco industry should come to light. Until these attorney-client documents are made public, the full truth about the tobacco industry's attempt to defraud the public will never be known.

Discussion

I. Recent Court Rulings on Crimes or Fraud by the Tobacco Industry

It appears that lawyers have been at the heart of a tobacco industry strategy to cast doubt on whether smoking causes cancer and to keep detrimental research on human health effects from the public. Lawyers can function largely out of view, because they can shield their work product behind the attorney-client privilege. Several courts, however, have recently been presented with attorney-client documents for *in camera* review. These courts have determined that the tobacco industry's attorney-client documents contain evidence of a tobacco industry crime or fraud -- and should therefore be disclosed.

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

The attorney-client privilege protects confidential communications between an attorney and a client for the purpose of obtaining legal advice. This privilege extends solely to legal advice given by a legal advisor acting in the capacity of a lawyer. Scientific information does not become privileged merely because it is incorporated into a communication between an attorney and client. *Upjohn Co. v. United States*, 449 U.S. 383, 395-96 (1981).

The joint defense privilege is an extension of the attorney-client privilege. *United States v. Schwimmer*, 892 F.2d 237, 243 (2d Cir. 1989). The joint defense privilege

protects communications between different persons or entities "when the communications are 'part of an on-going and joint effort to set up a common defense strategy.'" *Eisenberg v. Gagnon*, 766 F.2d 770, 787 (3rd Cir. 1985), *cert. denied*, 474 U.S. 946 (1985).

However, neither the attorney-client nor joint defense privilege provide an absolute protection from disclosure. The crime-fraud exception to these privileges is a legal concept that prevents lawyers from using the privileges as a shield behind which they participate in an ongoing crime or fraud. The attorney-client privilege "'ceases to operate ... where the desired advice refers not to prior wrongdoing, but to future wrongdoing.' It is the purpose of the crime-fraud exception to the attorney-client privilege to assure that the 'seal of secrecy' between lawyer and client does not extend to communications 'made for the purpose of getting advice for the commission of a fraud' or crime." *United States v. Zolin*, 491 U.S. 554, 563 (1989).

Courts have held that the crime-fraud exception applies to substantial abuses of the attorney-client relationship, continuing illegality, false suggestions and the suppression of truth, other misconduct, and any form of deception or deceit. *See, e.g., In re Sealed Case*, 754 F.2d 395, 399 (D.C. Cir. 1985); *International Telephone and Telegraph Corp. v. United Telephone Company of Florida*, 60 F.R.D. 177, 180 (M.D. Fla. 1973); *In Re Westinghouse Electric Corporation Uranium Contracts Litigation*, 76 F.R.D. 47, 57 (W. D. Pa. 1977); *Volcanic Gardens Management Co. v. Paxson*, 847 S.W.2d 343, 347 (Tex. App. 1993); *Central Constr. Co. v. Home Indemnity Co.*, 794 P.2d 595, 598 (Alaska 1990).

B. Judicial Rulings on the Participation by the Tobacco Industry's Lawyers in Crime or Fraud

Recently, both federal and state courts have found that a significant number of privileged tobacco documents fall within the crime-fraud exception to the attorney-client privilege. In the words of one judge, these documents "speak for themselves in a voice filled with disdain for the consuming public and its health." At least five different courts have recently ruled that the tobacco industry's attorney-client documents contain evidence of a crime or fraud by the tobacco industry.

1. *Haines v. Liggett Group*

The first court to consider whether the tobacco industry's attorney-client documents are evidence of a crime or fraud was the federal district court in the *Haines* case. The judge in this case conducted an *in camera* review of a set of 1500 attorney-client documents from the tobacco industry. *Haines v. Liggett Group, Inc, et al.*, 140 F.R.D. 681 (D.N.J. 1992), *vacated.* 975 F.2d 81 (3rd Cir. 1992), *on remand,* 814 F. Supp. 414 (D.N.J. 1993). This court found that its *in camera* inspection of selected documents "supports plaintiff's contentions of the explicit and pervasive nature of the alleged fraud by defendants and defendants' abuse of the attorney-client privilege as a means of effectuating that fraud." *Id.* at 689.

The court's review "revealed the most explicit admissions" that the tobacco company lawyers participated in a "program to further the alleged ongoing fraud and

deception." *Id.* at 695. The court found that the tobacco companies and their lawyers "specifically abused the attorney-client privilege in their efforts to effectuate their allegedly fraudulent scheme." *Id.* at 695.

The judge concluded that "the documents speak for themselves in a voice filled with disdain for the consuming public and its health." *Id.* at 684. According to the court, "despite the industry's promise to engage independent researchers to explore the dangers of cigarette smoking and to publicize their findings, the evidence clearly suggests that the research was not independent: that potentially adverse results were shielded ...; that the attorney-client privilege was intentionally employed to guard against such unwanted disclosure: and that the promise of full disclosure was never meant to be honored, and never was." *Id.* at 684.

The *Haines* court held that certain tobacco documents being withheld as secret demonstrated a fraud on the public perpetrated by lawyers and that these documents should be available for use at trial. The case, however, never went to trial, because tobacco company appeals, which vacated the ruling on procedural grounds, and other legal tactics delayed the action. Ultimately, the plaintiff's counsel, which had incurred millions of dollars in fees, could no longer afford to pursue the case.

2. *Florida v. American Tobacco Co.*

In the last two years, renewed attempts have been made in litigation to disclose the secret attorney-client documents. Once again, courts have found that the crime-fraud exception applies after reviewing the documents.

For example, on April 9, 1997, the special master in the *State of Florida v. American Tobacco Co.*, Civ. Action No. CL 95-1466 AH (Palm Beach County, Fla., filed Feb. 21, 1995), ordered the production of certain privileged Liggett documents because they demonstrate that the tobacco company "engaged in extensive efforts to hide ... the health hazards associated with cigarettes" from the public and that it "misled and defrauded the public and public health officials regarding the relationship between smoking and health." The master found that the documents also show that the tobacco company lawyers carried out and planned "fraudulent activities and undertook to misuse the attorney/client relationship to keep secret research and other activities related to the true health dangers of smoking."

The special master's ruling was upheld by the Circuit Court judge in April 1997.

3. *Minnesota v. Philip Morris*

The most important lawsuit to date considering the evidence of crime or fraud in the attorney-client documents is the lawsuit brought by the Minnesota Attorney General. In *State of Minnesota v. Philip Morris Inc.*, Civ. Action No. C1-94-8565 (Ramsey County, Minn., filed Aug. 18, 1994), the State of Minnesota and Blue Cross and Blue Shield of Minnesota sued all the major cigarette companies. Although the defendants' document production in this case is far from complete, the tobacco companies claim over 150,000 documents are privileged (amounting to over ½ million

pages).[1]

Based on a review of the privilege logs and the documents produced to date, the Minnesota court concluded that the state had established "a reasonable basis to believe that the crime-fraud exception to the general rule of privilege should be invoked." The court found that the tobacco companies released public statements "intended to minimize or reduce fears that smoking is dangerous to one's health." According to the court, it would be improper to permit the tobacco industry's use of "health-related research which supports [its] economic interests" in "advertising and public relations campaigns" while at the same time allowing the industry to assert claims of "privilege for research which may lead to the opposite conclusion." The court concluded that the tobacco companies have an "obligation to disclose" the hazards of tobacco products, which "cannot be eliminated by the assertion of attorney-client privilege."

Because of the compelling evidence of crime or fraud, the court in Minnesota required the companies for the first time to submit all 150,000 documents to the court for *in camera* review. To balance efficiency and due process in reviewing these documents, the court fashioned a review process. The allegedly privileged documents will be divided into categories based on the type of privilege claimed (e.g., opinion work product, fact work product, attorney-client, or joint defense), the subject matter, author and recipient. Once categorized, the special master will conduct a hearing on each

[1] As of May 9, 1997, none of the Defendants (except Liggett) had finished their privilege logs. At least one of these companies had at that time apparently listed less than 20% of its attorney-client documents on a privilege log.

category of documents to determine the appropriate application of privilege.

4. Other Recent Cases

Several other recent cases have also rejected the tobacco industry's assertion of attorney-client privileges. For example, in *Sackman v. Liggett Group, Inc.*, 920 F. Supp. 357, 365 (E.D.N.Y. 1996), *vacated on other grounds*, 167 F.R.D. 6 (E.D.N.Y. 1996), the federal magistrate ruled that Liggett had wrongly asserted 123 documents were privileged when they were not. Finding that the plaintiffs "sustained their burden of establishing probable cause that a fraudulent scheme existed and that the documents ... are in furtherance of that fraud," the magistrate in *Sackman* concluded that the crime-fraud exception obviates the assertion of privilege and "mandates disclosure." *Id.* at 369.

The court in *Burton v. R.J. Reynolds Tobacco Co.*, 167 F.R.D. 134, 142 (D. Kan. 1996), also found that a *prima facie* case of fraud had been established. In a subsequent ruling, the magistrate also rejected R.J. Reynold's claims of privilege for memoranda relating to research and development, letters from outside counsel on scientific research, literature reviews prepared by scientists at the direction of counsel, a letter from a consultant for outside counsel, minutes of a research-related meeting, and notes made by employees at industry meetings on smoking and health research. 170 F.R.D. 481, 490 (D. Kan. 1997). The court found that some of these documents "may contain evidence that R.J.R. knew, during the relevant time period, that nicotine was addictive." *Id.* at 490.

Similarly, in *Butler v. Philip Morris*, Civ. Action No. 94-5-53 (Jones County, Miss., filed May 12, 1994), the trial judge reviewed Liggett documents identified as joint defense documents and ordered their production.

II. The Liggett Attorney-Client Documents

To date, there has been virtually no public disclosure of the attorney-client documents that the courts have ruled contain evidence of crime or fraud. As the *Haines* case demonstrates, tobacco companies have guarded their secret attorney-client documents fiercely and employed legal tactics to delay the production of these documents in litigation.

This report pierces this veil of secrecy -- at least to a small extent -- by analyzing some of the attorney-client documents. The minority staff has obtained a set of some of the attorney-client privileged documents of Liggett & Myers Tobacco Company. These secret documents may not be the most important Liggett documents, because they do not include documents showing the joint defense of Liggett and the other tobacco companies. Nevertheless, they suggest that Liggett, acting on the advice of its lawyers, knowingly blocked the marketing of safer tobacco products.

These documents also show that lawyers representing Liggett censored correspondence with the medical community and public statements made by employees. They also show that Liggett's lawyers determined whether scientific research would be funded based on whether it would show cigarette smoking to be dangerous.

A. Suppression of the Marketing of a Safer Cigarette

Two previously secret Liggett attorney-client documents illustrate the role played by lawyers representing Liggett in suppressing the marketing of a "safer" cigarette that the lawyers conceded would "dramatically reduce the incidence of both non-cancerous and cancerous tumors in test mice as compared to the tumor incidence produced by conventional cigarettes." These documents show that Liggett's lawyers advised against marketing the safer cigarette because the cigarette "may incite accelerated cancer litigation which may, in turn, result in infinite liability."

1. The "Initial Observations" Memorandum

The first attorney-client document is an undated memorandum marked "Confidential" and entitled "Some Initial Observations on the Patented Cigarette Project."[2] This document describes Liggett's extensive efforts to determine what constituents of tobacco smoke cause tumors and to develop a safer cigarette that eliminated these hazardous constituents.

According to the memorandum:

> In 1954, Liggett began a contractual relationship with Arthur D. Little, Inc. ("ADL") under which Liggett's Tobacco Research Center and ADL's Life Sciences research laboratory in Cambridge, Massachusetts undertook to jointly investigate the supposed correlation between cigarette smoking and cancer. This research was initiated in the wake of the 1953

[2] Undated memorandum marked "Confidential" and entitled "Some Initial Observations on the Patented Cigarette Project" (hereinafter referred to as the "Initial Observations Memo"). The Initial Observations Memo is included as attachment 1 to this staff report.

demonstration by Wynder, Graham and Croninger that cigarette smoke condensate produces tumors on the skin of susceptible mice when painted on the skin in large amounts.[3]

As described by the lawyers, the "principal thrust" of Liggett's research with ADL was "to determine which substance was responsible for this tumorigenic effect and to ascertain a method -- if possible -- by which the tumorigenic effect could be reduced or eliminated."[4] Lawyers recognized that "[t]he back skin of these specially bred laboratory mice is generally recognized by some medical researchers as having sensitivity characteristics similar to human lung tissue."[5] Liggett expended $13 million on this biological testing program through the end of 1978.[6] In 1997 dollars, this expenditure would be over $30 million.

Through this research, Liggett learned that "the tumor-causing activity of cigarette smoke condensate is primarily initiated by the polycyclic aromatic hydrocarbon [PCAH] fraction of the condensate."[7] As a result, Liggett initiated "an effort ... to reduce the quantity of the PCAH fraction in smoke condensate."[8] According to Liggett's lawyers, "several hundred materials were added to tobacco and the

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[3] Initial Observations Memo at 2.

[4] Initial Observations Memo at 2.

[5] Initial Observations Memo at 5.

[6] Initial Observations Memo at 2.

[7] Initial Observations Memo at 2.

[8] Initial Observations Memo at 3.

mixtures were combusted."[9]

Liggett's efforts ultimately proved successful, according to Liggett's lawyers. The memorandum states that Liggett learned that "[p]alladium, an inert metal, apparently inhibits the formation of PCAH molecules by blocking molecular linkage of carbon, hydrogen, and oxygen."[10] According to the lawyers, the "palladium catalyst was the most effective in reducing the amount of the PCAH fraction in the [smoke] condensate."[11]

Liggett also learned through this research that "use of tobacco blends high in nitrogen found in burley, and conventional tobacco blends supplemented with nitrogen in the form of nitrate salts similar to those in burley, further reduced the PCAH fraction of the condensate."[12] Tests of smoke concentrates "showed that a treated tobacco level of 0.75% nitrate nitrogen combined with a palladium catalyst of 400 ppm (between 0.01% and 0.1% of the tobacco weight) achieved an effective reduction of up to 88% of non-cancerous tumors and up to 100% of cancerous tumors in comparison to concentrates from untreated control cigarettes."[13]

According to the lawyers, Liggett conducted extensive additional research. Liggett developed "a special filter to remove the increased nitrogen oxide and other

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[9] Initial Observations Memo at 3.

[10] Initial Observations Memo at 3.

[11] Initial Observations Memo at 3.

[12] Initial Observations Memo at 3.

[13] Initial Observations Memo at 3.

Liggett wanted to market LARK to medical doctors by providing them with information supporting the filter's success removing materials that "are largely responsible for the inhibitory effect on the cilia induced by unfiltered and conventionally filtered cigarette smoke,"[29] but Liggett's lawyers intervened to censor the company's communication with the doctors. In a privileged memo of September 16, 1963, Liggett's lawyers commented on a proposed letter to U.S. medical doctors promoting the LARK cigarette.[30] One of Liggett's lawyers, Mr. Haas, who subsequently became Liggett's general counsel, stated:

> As I have stated with respect to other releases in the past there is one feature of the current proposal which could serve to 'knock the props from under us' in future litigation. We have consistently maintained in court that the results of animal experimentation cannot be directly extrapolated to human beings. In my opinion the doctors receiving the suggested letter in its present form would get the impression, and rightly so, that the Company now says that animal experimentation in the cilia studies is of definite benefit to man.[31]

C. Censorship of Public Statements

Liggett's lawyers also prevented company employees from making statements to the press linking smoking with human health. For example, in a memo dated January 16, 1969, Liggett's lawyer Fred Haas wrote to Liggett executives J. Old and S. White

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[29] Draft Liggett letter to physicians, enclosed with transmittal letter dated March 8, 1963, from William W. Bates, Jr. to Charles J. Kensler (hereinafter referred to as the "Draft Letter"). The Draft Letter is included with this staff report as attachment 4.

[30] Memorandum dated September 16, 1963, from Fred P. Haas to Frank H. Horan (hereinafter referred to as the "Haas Memo"). The Haas Memo is included with this staff report as attachment 5.

[31] Haas Memo.

about a quote in *Fortune* attributed to a Liggett official. According to Mr. Haas, a Liggett official told *Fortune* that "it's gas, not tar, that is the major cigaret health hazard."[32] Mr. Haas wrote that this statement was contrary to Liggett's position that "there is no scientific proof of any cause and effect relationship between smoking and human health."[33] Mr. Haas then stated that Liggett should take steps to prevent such statements from being made in the future:

> I have spoken with the Marketing people along these lines since the beginning, and it is disturbing that such a remark could be attributed to anyone here. I think it incumbent upon us to find out if anyone in the Company actually did make this statement and to caution Brand Management once again.[34]

D. Control of Company Funded Research

Liggett's attorneys were also actively involved in reviewing the outside research projects funded by the company. Their goal, as revealed in the attorney-client documents, was to insure that the outside research funded by Liggett did not demonstrate a link between smoking and any health problem.

For example, in a memo to Liggett executives M.E. Harrington and K. McAllister dated February 2, 1971, Liggett's general counsel Fred Haas recommended that Liggett fund a Washington University research proposal on immunologic aspects of

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[32] Memorandum dated January 16, 1969, from F.P. Haas to J. Old, Re: Page 6 Relative to LARK Brand (hereinafter referred to as the "Fortune Memo"). The Fortune Memo is included with this staff report as attachment 6.

[33] Fortune Memo.

[34] Fortune Memo.

cancer.[35] Mr. Haas stated that funding this research "warrants our serious consideration" and that he did "not see how it could ricochet to our detriment since the smoking habit has no part in the study and, as I said at the outset, the project is not involved in finding causation."[36]

Mr. Haas also wrote an internal memo to Liggett executives M.E. Harrington and K. McAllister on a research proposal submitted by Harvard's Channing Laboratory to be sponsored as a "special project" of the Council of Tobacco Research, an industry trade group.[37] In his memo recommending the funding, Mr. Haas stated that the main researcher at the Harvard Project, Dr. Gary Huber, "made it clear that no research would be based on the hypothesis that smoking causes any disease."[38]

III. The Attorney-Client Documents that Remain Secret

The secret attorney-client documents reviewed in this staff report provide just a glimpse of the central role played by tobacco industry lawyers in blocking the marketing of "safer" tobacco products and concealing information about the health risks of

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[35] Memorandum dated February 2, 1971, from F.R. Haas to M.E. Harrington and K. McAllister, Re: Proposal on Research Dealing With Immunologic Aspects of Cancer (hereinafter referred to as the "Washington University Proposal"). The Washington University Proposal is included with this staff report as attachment 7.

[36] Washington University Proposal at 3.

[37] Memorandum dated July 6, 1972, from F.P. Haas to M.E. Harrington and K. McAllister, Re: Proposed Research Project - Channing Laboratories (hereinafter referred to as the "Harvard Project Proposal"). The Harvard Project Proposal is included with this staff report as attachment 8.

[38] Harvard Project Proposal at 4.

cigarettes.

The minority staff has obtained an index of over 3,500 Liggett attorney-client documents that discuss joint legal strategies between Liggett and other tobacco companies.[39] The volume of these "joint defense" documents far exceeds the number of documents reviewed by the minority staff. However, none of the Liggett documents that discuss Liggett's joint defense strategy have been reviewed by the minority staff, nor have any of these documents been made public.

Moreover, the Liggett documents themselves are only a small part of the universe of the secret attorney-client documents. According to the judge in the Minnesota litigation, there are more than 150,000 attorney-client documents that need to be reviewed for evidence of a crime or fraud, but have never been released to the public.

Until the entire set of attorney-client documents of the tobacco industry are disclosed, the full truth about the tobacco industry's attempt to defraud the public will never be understood.

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[39] The index containing the joint defense documents is available for inspection at the minority office of the Committee on Government Reform and Oversight, room B-350A Rayburn House Office Building.

irritant substances from the palladium-treated cigarette's smoke."[14] Liggett also determined that "the amount of palladium carried by the smoke through the filter is virtually nonexistent."[15] In fact, the document notes that "even at slightly higher levels, there is no indication that the palladium has any toxic effect" and that palladium has not "been shown to produce toxic effects even among workers in palladium refining or manufacturing operations."[16]

Thus, Liggett's lawyers concluded their analysis of the palladium cigarette by stating that "it seems clear that some major health benefits can be predicted."[17]

2. The Greer Memorandum

Although Liggett's lawyers were apparently convinced that the palladium cigarette offered significant health benefits, the lawyers were not convinced that the product should be marketed. To the contrary, as a second attorney-client document demonstrates, they argued strenuously against the marketing of the cigarette because of their concern that such an effort would imply that other Liggett products were dangerous. The second document is a draft memorandum from Joseph H. Greer, Liggett's Vice President and General Counsel, to Robert Hooker, another Liggett

[14] Initial Observations Memo at 4.

[15] Initial Observations Memo at 6.

[16] Initial Observations Memo at 6.

[17] Initial Observations Memo at 6.

lawyer.[18] The Greer Memo provides Liggett's legal analysis of whether:

> In the event that this Corporation manufacturers, markets and advertises a cigarette containing a blend of tobacco treated with a catalyst which purportedly substantially reduces the biological effect of 'tar' ... as proven by mice painting tests that reduced the number of carcinogenic tumors appearing on the catalyst-blend painted mice as compared to the controls, what risks does this Corporation take with regard to governmental and civil action and possible resulting liability?[19]

The Greer Memo demonstrates that Liggett's chief lawyer advised Liggett that there were serious and perhaps overwhelming litigation risks associated with marketing the palladium cigarette. Specifically, Mr. Greer concluded that "in the case of civil litigation aimed at cancer of the lung, emphysema, heart disease, etc., the running of a catalyst cigarette advertisement making reference specifically or impliedly to reductions in health hazards may incite accelerated cancer litigation which may, in turn, result in infinite liability."[20]

Liggett's lawyer also expressed the concern that marketing of the new cigarette "may further substantiate that this Corporation has a great deal more scientific and medical knowledge concerning lung cancer and cancer in general that it previously had."[21] The consequences would be that "a more significant warning could be required for our present products to the public or negligence on this Corporation's part would

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[18] Draft Memorandum of Law dated October 18, 1977, from Joseph H. Greer to Robert Hooker (hereinafter referred to as the "Greer Memo"). The Greer Memo is included with this staff report as attachment 2.

[19] Greer Memo at 1.

[20] Greer Memo at 8.

[21] Greer Memo at 10.

result."[22]

Mr. Greer noted that in two of the most recent smoking health cases in which Liggett had been involved, Liggett argued "that such mouse painting tests by Wynder and others were invalid because of a lack of replication and further invalid as a scientific test based on acceptable methodology."[23] Liggett's lawyer postulated that "if this Corporation presented evidence ... that the catalyst-painted mice received 80% fewer carcinogenic tumors than the controls painted with the regular Chesterfield blend, then this Corporation has obliterated its defense."[24]

The Greer memo also indicates that the Liggett lawyers anticipated serious problems with the FTC if the company tried to market the palladium cigarette with "health-related" claims. The lawyers noted that the FTC would require substantiation of any advertising claims and this substantiation would be "a collateral implication that the catalyst cigarette does reduce a health hazard concerning lung cancer."[25] Liggett's lawyers warned that if Liggett made any mouse-painting claims in its ads and had to substantiate the claims in a public FTC hearing, "the claims in cancer litigation as well as in emphysema litigation may be enlarged" and the company's "defenses of contributory negligence and assumption of risk may have been diminished" resulting in

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[22] Greer Memo at 10.

[23] Greer Memo at 8.

[24] Greer Memo at 8.

[25] Greer Memo at 9.

"enormous risks" and potentially "vast amounts of monetary liability."[26]

The recommendation of Liggett's lawyers not to market the palladium cigarette apparently prevailed within the company. Despite the company's conclusion that the new cigarette offered "major health benefits," the palladium cigarette was never sold commercially.

B. Censorship of Correspondence to the Medical Community

The documents obtained by the minority staff also show that Liggett's lawyers determined the appropriate language that could be used by Liggett scientists and company employees when communicating with doctors. Under the guise of privileged communications, Liggett's counsel censored company statements to eliminate statements that conveyed knowledge of adverse health effects caused by smoking.

In the 1960s, Liggett discovered that hydrogen cyanide present in the gas phase of cigarette smoke inhibited ciliary transport in the lungs. Ciliary transport is one of the main mechanisms by which the lungs clear themselves of physical irritants such as smoke particles. Liggett's research director initiated a search for a filter that could capture hydrogen cyanide in the gas phase.[27] This initiative resulted in the Keith filter, which was used in the LARK cigarette.[28]

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[26] Greer Memo at 10.

[27] March 15, 1963, Memorandum entitled "Development of the Three Piece Keith Filter" (hereinafter referred to as the "Keith Filter Memo"). The Keith Filter Memo is included with this staff report as attachment 3.

[28] Keith Filter Memo at 4.

READ 1st

Why/When a Pty ① Refuses ② Docu. OR ② Asserts a Priv.

1. When the other side asks for docus that ~~we~~ are outside the scope of discovery, which are obviously unnecessary, which are requested only to annoy, embarrass or harass.

2. BIG ONE atty-client privilege — communications betw. Coke & their lawyer made for the purpose of furnishing or obtaining legal advice or assistance. The priv. belongs to the client, so only Coke could waive it & hand over a privileged docu., NOT their lawyer.

3. the fed. govt. can withhold docus. that reflect advisory opinions, recommendations & deliberations comprising part of a process by which govt. decisions & policies are formulated ~~to~~ in order that frank discussion among decisionmakers is promoted. This is called the deliberative process privilege.

BIG ONE

4. Work product rule — a party does not have to turn over any notes, working papers, memos, etc. that were prepared by its attorney in anticipation of litigation. The atty's "work product" is privileged and includes any private memos, written statements of witnesses that the atty interviewed, & the atty's mental impressions of the witnesses, situation or whatever.

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In camera — ① judge looks at Coke's docu. to decide whether it is really privileged & shouldn't be given to Pepsi

② judge looks at a party's docu. to decide whether it is admissible at trial.

Burden of Proof

The party raising a privilege has the burden of establishing the existence of the privilege.[24]

Who May Assert

Usually, a privilege may only be asserted by the person holding the privilege. Certainly, one party may not assert a privilege of a non-party witness or another party. When an attorney or doctor is deposed it is unclear who may assert the privilege—the privilege technically belongs to the client, but some courts allow the attorney to assert the privilege if asked about the attorney-client communication.

Waiver of Privilege

Privileges generally are waived by voluntary disclosure,[25] either during discovery or elsewhere. Thus, caution should be exercised in discussing or responding to discovery requests pertaining to privileged matters.

Documents Containing Privileged and Non-privileged Matters

If part of a document contains privileged matters and part does not, a party must provide the non-privileged matter, but may redact the privileged matter.

Privileged Matters to be Introduced at Trial

A majority of courts hold that a party cannot assert a privilege at the discovery stage, then introduce the privileged matter at trial.[26] Consequently, any matter intended to be introduced at trial should be produced during discovery if requested. This principle does not apply to the attorney work product protections.

Particular Privileges

A detailed analysis of every potential privilege is beyond the scope of this book. The following is an overview of the most commonly asserted privileges:

- *Attorney–Client:* The attorney-client privilege applies to all confidential communications between a client and the client's attorney that occur in connection with legal representation or in the process of obtaining legal representation.[27] It applies to communications to an in-house attorney if the attorney is providing legal services. The privilege does not protect communications between one party and the attorney for another party. It does

24. *Heathman v. United States District Court*, 503 F.2d 1032, 1033 (9th Cir.1974).

25. *In re Grand Jury Proceedings Subpoena to Testify to: Wine*, 841 F.2d 230, 234 (8th Cir.1988).

26. *Doe v. Eli Lilly & Co., Inc.*, 99 F.R.D. 126, 127 (D.D.C.1983).

27. *Diversified Industries, Inc. v. Meredith*, 572 F.2d 596, 612 (8th Cir.1977).

not protect documents or other physical evidence provided to the attorney (other than written communications to the attorney), nor does it protect information or evidence gathered by the attorney from other sources or notes and memoranda prepared by the attorney (but see the discussion of attorney-work product under Rule 26(b)(3)).

- *Self-Incrimination:* The Fifth Amendment to the United States Constitution provides all persons (whether or not parties to a litigation) with a privilege against testifying in a manner that would tend to incriminate them.[28] The privilege applies at depositions,[29] interrogatories, requests for admission, and production of documents,[30] as well as at trial. Corporations may not assert the privilege, but corporate representatives may assert it if their testimony would incriminate them personally, regardless of whether they are testifying in their individual or representative capacities.[31] There can be no penalties or sanctions for properly exercising the Fifth Amendment privilege. However, in a civil proceeding it appears that opposing parties may comment on a party's exercise of the Fifth Amendment (in contrast to the prohibition on such comments in a criminal proceeding).[32]
- *Governmental Privileges:* The United States and the individual States must produce all relevant, non-privileged matter, just as any other party.[33] However, the United States has some extra privileges:
  - *Governmental Informer Privilege:* The United States has a qualified privilege to refuse to reveal the identity of an informer.[34] When the privilege is asserted, the court will balance the litigant's need for the information against the government's interest in protecting its informer's identity. The privilege belongs to the government, and protects only the identity of the informer, not the information provided by the informer. The government may not assert the privilege if it intends for the informer to testify at trial.
  - *Government's Privilege for Military or State Secrets:* The United States has a qualified privilege for matters that involve military or state secrets. In order to

28. *De Vita v. Sills,* 422 F.2d 1172 (3d Cir.1970).

29. *In re Folding Carton Antitrust Litigation,* 609 F.2d 867 (7th Cir.1979).

30. *Gordon v. Federal Deposit Ins. Corp.,* 427 F.2d 578, 580 (D.C.Cir.1970).

31. *United States v. Kordel,* 397 U.S. 1, 8, 90 S.Ct. 763, 767, 25 L.Ed.2d 1 (1970).

32. *Baxter v. Palmigiano,* 425 U.S. 308, 96 S.Ct. 1551, 47 L.Ed.2d 810 (1976).

33. *United States v. Procter & Gamble Co.,* 356 U.S. 677, 681, 78 S.Ct. 983, 986, 2 L.Ed.2d 1077 (1958).

34. *Roviaro v. United States,* 353 U.S. 53, 59, 77 S.Ct. 623, 627, 1 L.Ed.2d 639 (1957).

assert the privilege, the head of the department that has control over the matter must lodge a formal claim of privilege. The court will then rule on the privilege by balancing the litigant's need against the government's interest in keeping the matter secret.[35]

- *Government's Statutory Privilege:* Some statutes require governmental agencies and other entities to file certain documents or reports, and designate the submissions as confidential. Under these statutes, the privilege is generally absolute. A common example is income tax returns. Under the regulation,[36] the United States receives and keeps tax returns, but is not required to produce them to private litigants. Note that the privilege belongs to the United States only—the individual filing the return may be required to produce it (although other objections, such as relevance, might apply).
- *Executive Privilege:* The Executive branch of the United States government has a general qualified privilege, grounded in the need for the executive branch to gather information. The privilege generally must be asserted by the head of the relevant department. The court will then balance the litigant's need against the governmental interest asserted.[37]

- *Other Privileges:* In some states, communications with spouses, physicians, clergy, journalists, accountants, and social workers are privileged.

RULE 26(b)(2). LIMITATIONS

CORE CONCEPT

Rule 26(b)(2) provides the court with authority to limit discovery that is unreasonably cumulative or duplicative, is obtainable from another source more conveniently, or is unduly burdensome or expensive given the nature and circumstances of the case.[38] The court may also limit discovery if the party seeking the discovery has had "ample opportunity" to obtain the information during prior discovery.

APPLICATIONS

Motion for Protective Order

A party seeking to have the use of certain discovery procedures limited should make a motion for a protective order under Rule 26(c). The motion must be accompanied by a certification

35. *United States v. Reynolds,* 345 U.S. 1, 73 S.Ct. 528, 97 L.Ed. 727 (1953).

36. 26 C.F.R. § 301.6103(a–1(c)).

37. *United States v. Nixon,* 418 U.S. 683, 94 S.Ct. 3090, 41 L.Ed.2d 1039 (1974).

38. *See Leyh v. Modicon, Inc.,* 881 F.Supp. 420 (S.D.Ind.1995)(EEOC investigator not compelled to appear for deposition because such investigators would spend all their time testifying).

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 of 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.

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.

2/17 ?

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.

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

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⑥ doesn't alter the requirements ~~the~~ manus. must ~~the~~ meet ~~to~~ sustain a privilege claim.

2 Solutions

1.) ~~Alternative~~ Proposal

— Art. II Bd. — 3 people w/ expertise in tob. + health picked by HHS +/or FDA

— TI gives all docus. + new ones as they come up — privileged ~~stuff~~ is given separately ~~+~~ w/a detailed log

— Bd applies federal privilege law — Bd's finding can be ~~reversed~~ reviewed de novo + reversed by a fed dt. ct. only if clearly erroneous

— ruling ~~applies to~~ binds manus. in future proceedings. ~~future~~ π's aren't bound by a ruling in the manu's favor.

Document Disclosure (FDA) (8/17)

1) Some may not be easily obtainable under the FDCA

FDA needs docus. relating to

① nicotine regulation
② ingredient " "
③ less hazardous prods

Docus should reflect internal discussions & analyses, not just orig. lab research relating to health or safety of tob. prods or to ways of making them safer.

2) trade secret, atty-c privs

FDA needs expanded subpoena authority. Current authority is ltd to proceedings involving civil $ penalties.

(Public)

1. Limits on what types or categories the fob. industry must disclose
   - too limited?
   - are we cutting ourselves off from obtaining important documents that we don't know about?

2. vague @ only matter of docus to be disclosed, timing of disclosure, + enforcement mechanisms + penalties

3. broaden the scope of docus to be disclosed — descriptions like "corporate records" are too limiting.

4. oversight of search for previously unproduced docus by FOIA, + CFR
   - too much discretion for them (what can they withhold?)

3 Judge Panel to pierce fraudulent or improper claims of privilege.

Probs. w/ it

① doesn't anticipate the possibility that 1 or more of the specified Pt's may opt out of the sett.

② are the determinations binding in all litig. in US?

③ may override FDA's existing auth under FDCA to obtain access to docs containing trade secret, confidential, or privileged info.

④ could generate more litig @ whether a particular action is properly heard by the panel

⑤ unfair to bind all future litigants to a panel decision @ a particular time

⑥ slow

Legal - Disclosure
7/2

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.

Party Legal - Disclosure 7/2

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:

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-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

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-nicotine in the context of reverse-engineering work (e.g., analyses of a competitor's product)
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-technology or chemicals that affect the concentration or delivery of nicotine from tobacco products
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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

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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.

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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.

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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.

Document Disclosure:

1. greater sanction auth — perjury if you falsely assert privilege
2. any determination by the bd. of lack of privilege would be binding on future Δ's. A finding of privilege wouldn't be binding on future P's.
3. presumption — makes in camera review accessible; shifts burden by having cos. present the docus. upfront, as were not wondering what to ask for.
4. Mitch talked @ docus that ⑦ L. discussion mtgs. show:
   ① link betw. smoking + health
   ② cancer research
   ③ campaigns to target youth
   ④ nicotine/analogues
   ⑤ product development
   ⑥ content/minutes of Phil M. info mtgs. (Richmond mtgs.)

5. consent decrees would be useful here — atty-cl. priv. is a prophylactic not a constitutional right.

— Could we have a fed. enactment to get @ the need for a preliminary showing? This could be justified as remedial.

for fed cts. — not St. cts since pt can't impose on them.

— DOJ thinks FTC should'nt have to come fwd. + ask for docs. Cos. have to put them all in a repository, and they all get looked at.

6. Don't just think @ what FTC's need. Think @ the needs of FDA enforcement. FDA could go further than litigants.

7. Do you want to specify categories for which we abrogate privilege or presume it

isn't privileged?
Ex. – docus @ target kids
not prepared for litigation
Demand info f. them in
order to formulate our response.
Caveat – no telling on the crim.
side, bec. you're dealing w/
the CEO's priv. as an indi-
vidual Δ.
They need to look at case
law @ abrog. priv. – that's
how exceptions were carved
out.
What @ a group that check in
to how well the discl.
is wking.
Sanctions in the form of forced
disclosure.

Conclusions

* DOJ scheme – litigs. can use
this ~~depo~~ deposit. & ots. to get docus.
* no obligation to make a

prima facie case in getting docs from either channel + all this applies to the federal system.

We need a new process/body for the depos to handle challenges and people don't need to litigate it in ct. b/c b's current admin bodies couldn't handle this. We need a new body + new rules.

Litig. has 2 chances to win:

① depos. rules "no priv."
② go to cts.

bd. puts in the "P's side.

DOCU. DISCLOSURE

~~$~~ FDA has their same Illinoy subpoena auth. in civil penality proceedings.

MINN. docus. come to DC depository.

LICENSING

The states were to administer ~~cert~~ the standards set by the feds. So basically you lose a st. r.t. when you break the fed. law. Feds want to be able to yank the federal license.

— Youth access provs. + others → these don't preempt. st. + local govts. if. enacting tougher laws. → You could have double penalties.

~~Batt~~

~~&~~ Cig. Lab. & Prev. Act provs. don't repealed. Ingredient labelling is not preempted. States can still do their own ~~preempts~~ dical laws.

Document —

What @ atty-c privilege w/docus that FDA needs, like research docus. You don't have to go thru the rigamarole if FDA can have the docus under its current authority.

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-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

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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.

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 of 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:

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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.

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Document disclosure
Myers mtg. 7/22

- Int'l Money

- Public Education —
having it stay outside gov't

Matt - $ for state and local —
- hasn't been emphasized
- shows that there's $ for

Int'l $ was a drop dead issue for B&W.

Matt - Documents
W.gard - DeNoble - snuff
- 10 not subject to a-c privilege

Appear willing to give up on older set of industry documents.
Abrogate a-c privilege - make a deal breaker / w/ true exceptions
(A) health / Marketing to kids issues —
(B) don't involve direct - litigation preparation tied to specific case.
(C) Take back X number of years.

Documents under litigation?
What if judge rules - in Minn. case - and it's in appeal.
Matt - if they prevail, it would be nice to get the documents out there.
- We wanted them to let Liggett documents.