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Enforcement Agencies	FDA, DOJ, States. (p.26)	FDA, DOJ, States.
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Removal	State enforcement actions removable to federal court. (p.26)	N.A.
Criminal Penalties	Criminal penalties "based on" FDCA and Title 18. (p.26)	Prohibited act: 1 year and/or $1,000; 2d offense or violation committed with intent to defraud or mislead - 3 years and/or $10,000. 21 U.S.C. § 333(a). Title 18 applies.

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

Retailer Penalties	Unlicensed Seller Individual: minimum of $1,000 and/or 6 months. Corp.: max of $50,000. (p.44) Violation of State licensing laws 1st: $500 or 3 day suspension. 2d: $1,000 or 7 day suspension. 3d: $2,000 or 30 day suspension. 4th: $5,000 or 6 mo. suspension. 5th: $10,000 or 1 yr. suspension. 6th: $25,000 or revocation. 10th: permanent revocation. (p.44)	Civil money penalty of maximum $15,000 per violation, $1 mil per proceeding for violations of FDCA device provisions. 21 U.S.C. § 333(f). FDA has announced that for underage tobacco sales it intends to issue a warning for the first violation, and seek a penalty of $200 for the second violation.
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the FDCA should be enforceable in the same manner as other medical device requirements.

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

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.

Legal - penalties 7/2

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Consent Decrees	Consent decrees setting out certain terms of the agreement are enforceable only through injunctive suits - after a violation is established and another injunction entered, criminal or civil penalties could be imposed. ← extra step.	N.A.
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