

Philip Morris Challenges FDA Jurisdiction

The documents in R033PRA are Bates #2501211673 (19950810) and #2501211686 (19950810). The first document is a Philip Morris press release announcing the filing of a lawsuit against the Food and Drug Administration. The second document is a report regarding the question of jurisdiction over the regulation of cigarettes.

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In August of 1995 The Food and Drug Administration (FDA), under the leadership of Commissioner David Kessler, asserted jurisdiction over tobacco products that would limit access and advertising of those products to minors. The response of the tobacco industry was swift and litigious. On August 10, 1995 five major cigarette manufacturers, joined by retailers and advertisers, filed suit against the FDA. They were attempting to stop the FDA from pursuing a course of action they felt was "...clearly...illegal."

In its public statement announcing the lawsuit against the FDA, PM argues that all Americans shared a common goal with respect to youth smoking. They say that "...minors should not smoke and should not have access to cigarettes." In their view this goal would be best achieved by a combination of regulation at the state level and voluntary efforts by the industry. They are particularly troubled by the Clinton Administration's decision to assert jurisdiction in light of the fact that in June Philip Morris had committed itself to a comprehensive program that would prevent kids from obtaining cigarettes and sanction retailers who sold them cigarettes. This approach, they argue would deal with the problem of youth smoking, but would not become "...the threat to personal liberty...that the FDA regulation would create." In the final analysis, however, the industry asserts that the lawsuit is not about youth smoking, but instead about the federal government's attempt to even more severely restrict or even ban "...the sale of cigarettes to adults."

Philip Morris' internal document on this subject deals mainly with the question of the legality of the FDA's assertion of jurisdiction. It argues that only congress could change the law to allow FDA authority to regulate cigarettes. They cite precedent in which the court found that even though a product may have a pharmacological effect on the body, that was not enough to establish FDA's jurisdiction. Furthermore, the author(s) detail then current legislation to support their contention that FDA's assertion of jurisdiction was illegal. Finally, the authors claim the FDA would not have the authority to implement the very regulations it proposed.

