Cigarette Firms Challenge FDA's Right To Restrict Minors' Access to Tobacco

By TIMOTHY NOAH
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — The five major U.S. cigarette manufacturers, in a jointly submitted statement to the Food and Drug Administration, will argue that the FDA exceeded its legal authority when it issued a proposed rule aimed at restricting minors' access to tobacco products.

The five cigarette makers — Philip Morris Cos.' Philip Morris U.S.A. unit, RJR Nabisco Holdings Corp.'s R.J. Reynolds Tobacco Co. unit, B.A.T Industries PLC's Brown & Williamson unit, Loews Corp.'s Lorillard Tobacco Co. unit and Brooke Group Ltd.'s Liggett Group unit— waited until today, the final day of the rule's comment period, to submit their massive response to the Clinton administration's proposed regulation, which was issued last August. The 12-volume response runs nearly 2,000 pages, with an additional 40,000 pages' worth of appendices.

In preparing the joint document, the tobacco companies and their Washington-based trade association, the Tobacco Institute, relied on a considerable amount of high-priced legal talent from such law firms as Arnold & Porter; Covington & Burling; Wiley, Rein & Fielding; and Williams and Connolly, to name a few. Attorneys for these firms and others worked busily through the New Year's weekend to meet today's deadline.

The tobacco industry has challenged the FDA rule in court, and its submission to the FDA offers something of a preview of the arguments it will make when the matter comes to trial.

Oftentimes when the federal government proposes a regulation, industry uses the comment period to suggest alternative ways that the regulation might be implemented, or its goals achieved. But the tobacco companies aren't taking that tack in their response. Rather, they are arguing at every turn that the proposed rule, if implemented, would violate U.S. law and even the U.S. constitution.

The proposed regulation, as issued last summer, declares that cigarettes are a drug-delivery device, and therefore subject to jurisdiction by the FDA. The text of the regulation and its appendices also cite various company documents to argue that the tobacco industry, contrary to its public statements, is aware that nicotine is addictive and has sought to manipulate the amount of nicotine delivered in cigarettes. The proposed rule says tobacco companies should be required to fund a $150 million-per-year advertising campaign to warn children of the health dangers of smoking; proposes banning cigarette sales from vending machines; and proposes various restrictions on tobacco product advertising deemed accessible to minors.

The FDA has estimated the annualized cost of its rule to manufacturers and retailers at $230 million per year over fifteen years. It has estimated the benefits at $2.9 billion to $4.3 billion, measured mainly in lives saved. But the tobacco industry's submission will maintain the costs of the rule are considerably greater.

The tobacco industry document will begin from the premise that the Food, Drug and Cosmetic Act, which created the FDA, and the 1976 medical device amendments to that act, do not grant the FDA statutory authority to regulate cigarettes.

The document will also argue that nicotine does not fit the legal definition of a drug, and that its effects do not fit the legal definition of addiction. But the joint response won't address specific evidence unearthed by the FDA and others that tobacco company officials, in internal documents, have stated that cigarettes are addictive. Instead, particular issues raised by these internal documents will be addressed in separate submissions by the affected companies.

A spokesman for the FDA, which hasn't seen the industry submission yet, declined to comment.