BY
UST

August 2, 1995

FDA's Backdoor Prohibition of Tobacco Products

FDA's Proposal. According to media reports, Dr. Kessler has submitted to the White House a proposal which classifies nicotine in tobacco products as a "drug" within the meaning of the Federal Food, Drug, and Cosmetic Act (FDC Act). Those same reports, and comments by certain anti-tobacco activists, suggest that FDA may legally regulate nicotine as a "drug" but not require that tobacco products meet the full statutory requirements for "drugs." According to this view, FDA has some discretion to impose regulations governing access to tobacco products and to ban purportedly youth-oriented promotions, such as Joe Camel.

The Problem. The fact is that the FDA does not have the broad discretion that would be needed for the agency to legally carry out Dr. Kessler's proposal which he claims is only designed to prevent access to tobacco products by youth and avoids banning tobacco products altogether. On the contrary, the law is absolutely clear that once the FDA has determined that a product is subject to FDA regulation at all, the agency is prohibited from authorizing use of the product in ways that are not

explicitly permitted by the statute. Accordingly, it would be illegal for the FDA to classify nicotine as a "drug" yet create a regulatory regime in which the sale of tobacco products as "drugs" was affirmatively authorized, subject to distribution and advertising restrictions. The only regulatory regime the FDC Act permits is one in which drugs must be recognized or approved as "safe and effective" for their intended uses, bear full drug labeling, and be made in pharmaceutical grade facilities.

Reasons. The FDA has only the authority that is specifically described in the FDC Act. Unlike some laws, such as the Federal Communications Act, the FDC Act does not give the FDA a general mandate to create whatever regulatory system the agency believes is desirable as a policy matter. Rather, the FDC Act contains specific requirements and prohibitions.

Among the FDC Act's requirements is that any product defined as a "drug" must be either recognized by experts as "safe" and "effective" for its intended uses or approved by the FDA as "safe" and "effective." Anyone marketing a drug that is neither recognized nor approved as "safe and effective" breaks an explicit prohibition with criminal penalties.

Under the FDC Act, any product defined as a "drug" must also meet detailed manufacturing, labeling and other requirements or else be considered "adulterated" or "misbranded." Anyone marketing an adulterated or misbranded drug likewise commits a prohibited act.

The FDA has tried several times to exempt categories of products classified as a "drug" from the specific requirements and prohibitions of the FDC Act while regulating them in other ways. These attempts have been overruled by the courts as flagrant violations of the FDA's very limited administrative discretion to issue regulations "for the efficient enforcement of" the FDC Act:

- The FDA deferred the "effectiveness" requirement of the FDC Act for prescription drugs it had determined did not meet the statutory test. Held: Illegal. "[I]t could not be clearer that the [FDA Commissioner] must begin the procedures to withdraw a drug when he concludes that there is no substantial evidence of efficacy." American Public Health Association v. Veneman, 349 F.Supp. 1311, 1315 (D.C. D.C. 1972).

- The FDA prohibited dispensing methadone from retail pharmacies on safety grounds without withdrawing it from hospitals. Held: Illegal. "FDA's discretion under the Act's NDA provisions is limited to either approving or denying NDA's and nowhere is FDA empowered to approve an NDA upon the condition that the drug be distributed through specified channels." American Pharmaceutical Association v. Weinberger, 377 F.Supp. 824, 829 n.9 (D.C. D.C. 1974), aff'd, 530 F.2d 1054 (D.C. Cir. 1976).

- The FDA let generic drugs be marketed before issuing a formal approval. Held: Illegal. "[T]he Court holds that the FDA's policy of permitting new drugs to be marketed without an approved new drug application contravenes the clear statutory requirement of preclearance mandated by 21 U.S.C. § 355. . . ." Hoffman-LaRoche, Inc. v. Weinberger, 425 F.Supp. 890, 894 (D.C. D.C. 1975).

- The FDA exempted over-the-counter (OTC) drugs from the effectiveness requirement to allow time to complete testing. Held: Illegal. "The Commissioner's OTC regulations formally authorize the continued marketing of Category III drug products (i.e., products found not

to meet the effectiveness requirement] in the absence of an administrative determination that those products are, today, generally recognized by experts as safe and effective. This flies in the face of the statutory scheme." Cutler v. Kennedy, 475 F.Supp. 838, 854 (D.C. D.C. 1979).

In all of these cases, the FDA was ordered by a court to regulate drugs only in the ways specifically provided by the FDC Act, despite the agency's belief that there were good policy reasons for utilizing a different approach.

In another case, the FDA was told by the Department of Justice that a similar "alternative" regulatory approach was illegal, because, very simply, the FDC Act did not authorize it, however good an idea it was. That case did not involve a "drug" but a "food additive," which is another category of FDA-regulated product for which the FDC Act establishes very specific procedures and standards.

The FDA had determined that nitrite as a food preservative was subject to the absolute prohibition of the Delany Clause. However, because nitrite protected against deadly botulism, the FDA proposed "to exercise enforcement discretion to permit nitrites . . . over the period of gradual and indefinite phasing

out of their use." An opinion prepared for the Attorney General observed:

> The public health considerations underlying the desire to permit the continued addition of nitrites . . . are clearly important. But the balancing of these competing health risks is a matter for the Congress in determining whether to amend the Food and Drug Act, not for the [FDA Commissioner] in administrating the law.

43 Op. Att'y Gen. No. 19 at 28 (1979). The FDA proposal was therefore illegal, because it "would constitute the establishment of a tolerance in direct contravention of the evident congressional judgment that there should be no tolerance. . . . Such regulations would . . . not be consistent with the Food and Drug Act or further its 'efficient enforcement.'" Id. at 19-20.

These examples demonstrate that any attempt by Dr. Kessler to fashion a politically popular regime to reduce access by youth short of requiring tobacco products to meet all applicable drug requirements of the FDC Act, including safety and effectiveness, would be illegal. Therefore, if FDA asserted jurisdiction, Dr. Kessler would have no choice but to ban tobacco products because, even if he personally wished to refrain from doing so, the courts would not permit that result and the Department of Justice could not defend such a position.