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*Expediting the Drug Approval Process: An Analysis of the FDA Modernization Act of 1997*

51 Admin. L. Rev. 1249 (1999)

Abstract by Hyla Kaplan

The author examines various provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) relating to expedited drug approval. The author discusses the competing tension between the need for production and approval of safe and effective drugs for the public, and the need for rapid approval of new drugs. Traditionally, the Food and Drug Administration (FDA) has been very slow in approving new and beneficial drugs, while other countries have been able to put new drugs on the market much more rapidly. FDAMA, which made significant changes to the Federal Food, Drug, and Cosmetic Act of 1938, was passed by Congress in order to prevent the marketing of unsafe products and to review and approve new drugs more rapidly.

The passage of FDAMA indicates a desire on the part of the FDA to expedite the approval process. However, the FDA still maintains total control over the approval of prescription drugs, and is reluctant to allow other experts in the field to review new drugs that would expedite the approval process. The new provisions are meant to not only expedite the approval process but also to expedite the drug development process. The author believes that FDAMA will be effective in expediting the approval of new drugs. But the author notes concerns as to whether public health will suffer as a result. Ideally, this problem can be avoided by encouraging drug manufacturers to focus on the quality as well as the quantity of drugs.