NEW YORK PHARMA FORUM PROGRAM
Wednesday, September 27, 2000

SPEAKER: **Kenneth I Kaitin, Ph.D.**, Director,
Tufts Center for the Study of Drug Development.

TOPIC: **Regulatory Reform and the New Environment for Pharmaceutical Innovation**

Dr. Kaitin is the Director of the Tufts Center for the Study of Drug Development, where he studies national and worldwide trends in pharmaceutical innovation, regulation, and public policy. He is also Assistant Professor of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine. Dr. Kaitin has written extensively on factors that contribute to the slow pace and high cost of pharmaceutical R&D, and the impact of regulatory and legislative initiatives to speed drug development and approval. His articles have been published widely in medical and policy journals.

At this program, Dr. Kaitin will examine the following issues:

- What are the external forces directly affecting drug development in the research-based pharmaceutical industry?
- What are the current metrics for new drug and biopharmaceutical development and approval times?
- How will industry and regulatory authority initiatives for improving performance and efficiency affect the drug development process?

The current worldwide focus on containing health care expenditures and the highly competitive environment in the pharmaceutical industry have placed substantial pressure on drug manufacturers and regulators to improve efficiency and quality in the drug development process. Regulatory reform in many of the world's major markets has created a new dynamic between drug firms and regulatory authorities. With Congressional hearings to reauthorize the collection of user fees scheduled for winter 2001, regulatory initiatives and industry practices are coming into sharper focus.