

**NEW YORK PHARMA FORUM PROGRAM**  
**TUESDAY, APRIL 20, 1999**

**SPEAKER:**                   **Bert Spilker, Ph.D., MD, FCP, FFPM**  
Senior Vice President  
Scientific and Regulatory Affairs  
Pharmaceutical Research and Manufacturers of America (PhRMA)

**TOPIC:**                       **Pharmaceutical Regulatory Trends in the U.S.**

Dr. Spilker is the author of 15 books on clinical trial methods and the processes of drug discovery and development. Before joining PhRMA, he was President and co-founder of Orphan Medical, Inc. He is a Clinical Professor of Pharmacy Practice at the University of Minnesota and an Adjunct Professor of Medicine and Pharmacy at the University of North Carolina. Dr. Spilker's career also includes over 20 years of experience at four major pharmaceutical companies (Pfizer, Philips-Duphar, Sterling-Winthrop, and Burroughs Wellcome) in drug discovery, development and management. He has received numerous honors including the FDA Commissioner's Special Citation for work in the orphan medicine arena.

He will speak about the future direction of the FDA under new Food and Drug Administration Commissioner Dr. Jane E. Henney, including possible changes in FDA policy regarding regulatory issues, medical safety, user fees and other issues. Dr. Spilker, who serves on the Steering Committee for the International Conference on Harmonization, will also give an insider's view of what the next stage of international regulatory harmonization will be.