Role of Drug Metabolism in Drug Research and Development

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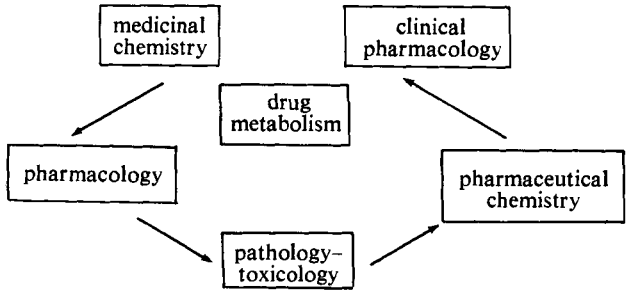
Recent years have witnessed within the pharmaceutical industry a remarkable burgeoning of the activities clustered under the heading "Drug Metabolism." Increasingly, we are asked to provide answers to such questions as: What structural modifications lead to increased absorption, prolonged half-life, and reduced toxicity? Does the drug cross the placental barrier and pose a teratogenic risk? What is the optimum dosing regimen to achieve and maintain therapeutic levels? What animal species will best predict human toxicity?

Through involvement in almost every phase of drug research and development, seemingly visionary expectations have been aroused of what can be achieved by metabolic studies. Can drug metabolism meet these expectations? What is the relevance of metabolic studies—and relevance implies timing—to the various phases of drug research and development? These issues were the stimulus for this Symposium.



Scheme I—Drug research and development sequence

The goals were, first, to clarify, define, and describe drug metabolism, and, second, to intercalate its diverse activities within that complex progression of events simplified in Scheme I—the logic of drug research and development. The Symposium papers[1] follow the "critical path" represented by the arrows presenting those metabolic studies most appropriate to each stage of preclinical and clinical drug testing.

The diversity of the drugs dealt with by the authors emphasizes an important point: each drug must prescribe its own treatment. Without this kind of flexibility, the system loses relevance, and that is the import of this Symposium.

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[1] The article "Evaluation of Comparative Studies" by R. L. Swarm was not submitted for consideration for publication.