molecular pharmaceutics

editorial

Molecular Pharmaceutics: The NIH Roadmap and the FDA Pipeline Problem

Two government reports focusing on "big science" issues will impact molecular pharmaceutics research. One is NIH Roadmap: Accelerating Medical Discovery to Improve Health (www.nihroadmap.nih.gov), and the other is the recent FDA report Innovation−Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products (http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html). The NIH Roadmap process, initiated in May 2002 by Elias A. Zerhouni, M.D., Director of NIH, aims to identify major opportunities in biomedical research that no single NIH institute could tackle alone, and must be addressed by the agency as a whole to make the biggest impact on the progress of medical research. The FDA report provides an analysis of the "pipeline problem", the recent slowdown, rather than the expected acceleration, in innovative medical therapies reaching patients. The NIH Roadmap seeks to deepen understanding of biology, stimulate interdisciplinary research teams, and reshape clinical research to accelerate medical discovery and improve people's health. The FDA report, on the other hand, identifies the pipeline problem as due to the fact that the applied sciences needed for medical product development have not kept pace with the tremendous advances in basic sciences, concluding that a new product development tool kit is needed.

Both reports seem to be based on a general feeling and undercurrent in public opinion that medical research has been slow in translating basic research into direct patient benefits and that pharmaceutical products cost too much. The heightened public expectation is no doubt due, in part, to the highly promoted human genome project and the attendant implications and implied benefits of this enormous undertaking for improving human health. While it is agreed that these benefits will eventually materialize, both reports suggest that current roadblocks are needlessly hindering their timely arrival.

The NIH Roadmap initiative will have a significant impact on the research enterprise, promoting wide access and availability to resources and technologies, facilitating novel partnerships between disciplines, and re-engineering the clinical research enterprise. The FDA is planning an initiative that will identify the most pressing development problems, while highlighting areas with the greatest opportunities for accelerating improvements in public health.

Molecular pharmaceutics research will contribute to and benefit significantly from these initiatives, being by nature multidisciplinary and focused on problems of medical import. Both reports emphasize the need for research and the development of new and innovative ways to translate basic research into medical benefit for people. *Molecular Pharmaceutics* will contribute to these "big science" issues by serving as a forum for researchers focused on molecular mechanistic drug delivery advances. We have much to contribute.

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