FOR IMMEDIATE RELEASE

New Approaches to Drug Development Will Drive Drug Company Success, According to Tufts Center for the Study of Drug Development

BOSTON – Jan. 3, 2008 – Drug companies, under significant pressure to develop new prescription medicines faster and at lower cost, are more likely to succeed if they change the way they conduct R&D and manage projects, manufacturing, and marketing, according to the Tufts Center for the Study of Drug Development.

"The most successful developers in the near- and medium-term will be those that evolve their management and information systems to improve access to new development platforms and tools," said Tufts CSDD Director Kenneth I Kaitin, who made his comments with the release today of the Tufts Center's *Outlook 2008* report on near-term pharmaceutical and biopharmaceutical trends.

"In the longer term, the successful companies will be those that radically overhaul their approach to business—from R&D to project management, manufacturing, and marketing," he noted.

Kaitin acknowledged that the changes he advocates pose a high hurdle for drug developers, adding, "The pharmaceutical industry essentially has not changed its R&D paradigm in more than four decades, while nearly every other global industry has undergone major change within the last decade. The drug industry has little choice than to change the way it does business.

Among the near-term trends cited in the Tufts CSDD's *Outlook 2008* report include the following:

* Companies will continue to increase their investments in the development of personalized drugs and biologics, leading to an increased focus on diagnostic companies as potential partners and take-over targets.

* The U.S. Food and Drug Administration (FDA) will be challenged to implement the *FDA Amendments Act of 2007* in the wake of large staff turnovers, a new administration, as well as a vigilant and concerned public and Congress.

* Drug sponsors will focus more attention on simplifying and streamlining study protocols to reduce study conduct delays and improve investigative site adherence and performance.

* Interest in commercial cancer vaccine development will wane in the short term as more targeted cancer therapeutics, such as protein kinase inhibitors and monoclonal antibodies, reach the market.

* U.S. policy makers will increasingly look to postmarketing studies that assess comparative clinical- and cost-effectiveness to make decisions on prescribing guidelines and drug reimbursement.

* The European Medicines Agency and FDA will continue efforts to harmonize regulatory approaches in areas of common interest, such as pandemic vaccines, medicines for children, rare diseases, and cancer.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

--end--

Contact: Tufts Center for the Study of Drug Development
Charlene Neu – 617-636-2187

charlene.neu@tufts.edu