

BACKGROUNDER: Tufts Center for the Study of Drug Development Committed to Informing the Public Debate on Drug Development

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BOSTON – (November 2001) – When members of Congress want a reliable assessment of the pace and nature of new drug development, they ask the Tufts Center for the Study of Drug Development. So do executives of pharmaceutical and biotechnology companies. And so do a wide range of independent organizations.

Since its founding in 1976, the Tufts Center for the Study of Drug Development, affiliated with Tufts University, has been the leading independent source, both in the U.S. and abroad, for information about the efficiency and productivity of the research-based drug industry and the impact of government initiatives on the drug development process.

“The Tufts Center helps inform the public debate on drug development as we are the sole source of strategic information that helps pharmaceutical developers, regulators, and policy-makers understand and improve the process by which new drug products are developed and brought to market,” explains Tufts Center Director Dr. Kenneth I. Kaitin. He added, “With industry mergers, fragmenting markets, political change, price restrictions, and growing generic competition greatly increasing pressure on pharmaceutical and biotech companies to develop new drugs more quickly, it’s vital for industry, regulatory agencies, and legislative bodies to understand how well the industry is responding to these changes.”

Widely respected as an independent source of information on drug development, the Tufts Center is widely quoted in the business, trade, and general press. The Tufts Center has a strong record of producing path-breaking research studies. For example:

- In 1979, the Tufts Center developed the first comprehensive study of the cost to develop a new drug. Updated regularly, most recently in November 2001, this number is cited worldwide as the official estimate of the cost of new drug development.
- Tufts Center data and testimony at Congressional hearings was instrumental in the development of the FDA Modernization Act of 1997 (FDAMA), the Drug Price Competition/Patent Term Restoration Act of 1984, and the Orphan Drug Act of 1983.
- The Tufts Center developed the first comparison of biotechnology product discovery, development, and marketing rates in the U.S., Europe, and Japan. Last year, the Tufts Center published the first comparative analysis of new drug and biopharmaceutical approval times in the U.S. and Europe.

Founded in 1976 to Rationalize Investment in Drug Development Dr. Louis Lasagna, dean of the Sackler School of Graduate Biomedical Sciences at Tufts University, founded the Center in 1976 because, he believed, rapid industry growth created a need for the public and industry to rationalize investments in drug development.

That need exists today, notes David J. Pizzutti, M.D., divisional vice president for medical affairs at Abbot Laboratories: “There’s a lot of pressure on the industry from Congress, from patients, and from providers, and the Center really is the only place to go to get unbiased, academically grounded information regarding the development of pharmaceuticals.” Kaitin, director of the Tufts Center since 1998, leads a team of eight research professionals and four support staff, who are experts in pharmacology, economics, biotechnology, law, and public policy. As an academic, non-profit research organization, the Tufts Center pursues its research mission, in part, through the generous, unrestricted financial support of sponsors, which includes pharmaceutical and biopharmaceutical companies, contract research organizations, trade associations, and

other organizations committed to advancing the understanding of drug development activity in the U.S. and internationally.

In addition to its research and publication work, the Tufts Center conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums on related topics throughout the year. Based in Boston, Mass., the Tufts Center for the Study of Drug Development is on the Web at <http://csdd.tufts.edu>. For more information, call the Tufts Center at 617-636-2170.

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