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The U.S. Remains Preferred Market for Launching New Products, According to Tufts Center for the Study of Drug Development

BOSTON – Nov. 12, 2008 – While the number of annual new drug approvals in the United States has declined during the past decade, the U.S. remains the preferred market for launching new products, according to a recently completed analysis conducted by the Tufts Center for the Study of Drug Development.

The study found that new U.S. drug approvals dropped to 48 in 2005-07, from a peak of 110 in 1996-98.

During 2005-07, the most recent period for which information is available, drugs first marketed in the U.S. accounted for 75% of all new drugs approved worldwide, an all time high, according to Tufts CSDD. This was a marked change from the 1987-89 period, when only 20% of new drugs were first marketed in the U.S.

“The United States has become the country of choice to introduce new prescription drugs to the market due, in large part, to the size of the pharmaceutical market, the positive environment for innovation, and the lack of price controls,” said Tufts CSDD Director Kenneth I Kaitin. “For example, because many countries limit the prices that drug companies can charge for their products, they turn to the U.S.”

He noted that the decline in new drug approvals reflects the increasingly time-consuming, risky, and expensive nature of drug development, which is related to the industry’s focus on developing new medicines to treat a host of chronic and complex diseases.

The Tufts CSDD analysis, reported in the November/December *Tufts CSDD Impact Report*, released today, also found that:

- * Combined clinical and approval times for new drugs developed in the U.S. have dropped to the lowest level since the late 1990s.
- * Since enactment of *Prescription Drug User Fee Act of 1992*, average approval times declined generally and reached their lowest three-year average (1.1 years) in 2005-07.
- * Following a jump in clinical times for priority and standard drugs in 2002-04, those numbers in 2005-07 returned to levels similar to those observed in 1996-98 and 1999-01.

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.

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