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Pediatric Study Costs Rose Substantially from 2000 as Complexity Grew, According to Tufts Center for the Study of Drug Development

BOSTON – March 13, 2007 – The average cost to complete pediatric research on already marketed prescription drugs, in response to a request from the U.S. Food and Drug Administration (FDA), increased nearly eight times between 2000 and 2006, according to findings released today by the Tufts Center for the Study of Drug Development.

The increase, in nominal dollars, from \$3.93 million in 2000 to \$30.82 million in 2006, is consistent with the general increase in cost, length, and complexity for developing new drugs, Tufts CSDD said.

The analysis also found that during the first 10 years of an FDA program that seeks to encourage pediatric research, such studies have been undertaken on more than 100 diseases and conditions and have led to new labeling for 120 new or already approved drugs for use in children.

“While the cost to complete pediatric studies has soared, drug companies are not letting that get in their way,” said Tufts CSDD Associate Director Christopher Milne. “The *Best Pharmaceuticals for Children Act* seems to be doing its job, which is to generate more pediatric studies. The bottom line is that better prescribing information and more formulations are being developed for children.”

To improve U.S. labeling of prescription drugs for children, the FDA since 1998 has managed a program in which it asks pharmaceutical companies to conduct pediatric studies on marketed products in exchange for six additional months of market protection, known as pediatric exclusivity, for all of its products that contain the active ingredient being studied. The *Best Pharmaceuticals for Children Act*, which authorizes this program, is due for renewal in October.

The Tufts CSDD findings were based on a survey conducted last fall by Milne and Laura Faden, following up on a similar survey undertaken by Tufts CSDD in 2000.

Since the pediatric exclusivity program began, the FDA reports that it has issued 336 requests for 782 studies involving 46,000 children. During the same time, the cumulative number of pediatric studies completed and subsequently accepted by the FDA, rose from 58 in 2000 to an estimated 568 in 2006, according to Tufts CSDD.

The study, reported in the March/April *Tufts CSDD Impact Report*, released today, also found that:

- Efficacy/safety studies, the most resource-intensive and expensive type of study, now account for 40% of all pediatric studies conducted, up from 25% in 2000.
- Time required to complete a study and submit a final report nearly doubled since 2000.
- The mean number of patients required for studies in response to an FDA request was up 178% between 2000 and 2006, and the mean number of studies per request rose 60%.

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 on related topics, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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