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U.S. Approvals of Supplemental Drug Indications Have Been Rising Steadily, According to Tufts Center for the Study of Drug Development

BOSTON – March 8, 2011 – New or modified indication approvals for existing prescription drugs have steadily increased in the United States since the late 1990s, according to an analysis recently completed by the Tufts Center for the Study of Drug Development.

The number of new or modified indication approvals—consent by the Food and Drug Administration (FDA) to market drugs for other than the original indication, based on additional clinical studies—increased 17% from 1998-03 to 2004-09, Tufts CSDD found.

Drug developers, facing patent expirations on many drugs over the next few years and stagnant growth in new approvals in the U.S. and worldwide, are looking for new revenue sources, and supplemental approvals for existing products may be one such source.

"New-indication approvals can translate into revenue growth, but exactly how much depends on the use and the number of competitor products, and therefore that growth can vary widely," said Joseph A. DiMasi, director of economic analysis at the Tufts CSDD and author of the study.

He added, "Many companies are working to find the right balance between investing R&D resources in finding new indications for existing drugs and developing novel compounds."

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

* The number of new or modified indications per drug (originally approved 1963-2009) ranged from 1 to 20 from 1998 to 2009.

* Pediatric indications drove approvals in the 1998-09 period, with those approvals growing by 107% from 1998-03 to 2004-09.

* Antiinfective and central nervous system drugs each accounted for at least one-fifth of all new or modified indication approvals from 1998 to 2009.

* Mean regulatory approval phase time for new or modified indications declined by 21% from 1998-03 to 2004-09 (from 13.6 months to 10.8 months).

While doctors in the U.S. may prescribe a drug "off label," drug companies may only market a prescription medicine for its intended use as approved by the FDA, which is described on the drug's packaging label.

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 Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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