New or modified indications for existing drugs have steadily increased in U.S.

*Tufts CSDD study offers comprehensive look at supplemental indication trends*

- New or modified indication approvals in the U.S. increased 17% from 1998-03 to 2004-09.
- Antiinfective and CNS drugs each accounted for at least one-fifth of all new or modified indication approvals from 1998 to 2009.
- During 1998-09 the number of new or modified indications per drug ranged from 1 to 20.
- Mean time from approval of a new drug to approval of a new or modified indication averaged approximately 9 years, with a median time of approximately 8 years.
- 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).
- Mean regulatory approval phase times for new or modified indications during 1998-09 ranged from 8.7 months for antineoplastic drugs to 13.6 months for CNS drugs.

Drug developers seeking new revenue streams have stepped up their efforts to seek regulatory approval for new or modified indications for existing drugs. Those efforts, summarized in this *Tufts CSDD Impact Report*, underscore the enormous pressure on drug firms to expand their markets and bolster sales in the United States.

While new indication approvals can translate into revenue growth, exactly how much growth depends on the indication and the number of competitor products, and therefore can vary widely. Similarly, clinical trials to support new indications can take less time than was required for the original indication since developers often don’t have to conduct Phase I studies to determine the pharmacokinetic and pharmacodynamic actions of the drug. However, time savings is not a given. All that said, many drug companies are working to find the right balance between investing precious R&D resources in finding new indications for existing drugs and developing novel compounds.