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Drug Sponsors' Regulatory Experience Was Mixed During PDUFA IV, According to Tufts Center for the Study of Drug Development

BOSTON – May 9, 2012 – Drug sponsors experienced a mixed regulatory burden under the FDA Amendments Act, which was also the fourth iteration of the Prescription Drug User Fee Act (PDUFA IV), according to new research from the Tufts Center for the Study of Drug Development.

The analysis found that, since 2007, the regulatory burden decreased for new drug applications (NDA) and biologics license applications (BLA) approvals, but increased for supplemental new drug applications (sNDA) and biologics license approvals (sBLA), while regulatory outsourcing by sponsors also increased.

Tufts CSDD conducted the research in advance of ongoing Congressional deliberations on reauthorizing the Prescription Drug User Fee Act (PDUFA) for another five years. Drug sponsors have been paying user fees to the FDA since enactment of PDUFA in 1992.

"While user fees have helped to streamline and speed up the drug review and approval process in the Untied States over the last two decades, certain requirements on developers remain especially problematic," said Christopher-Paul Milne, associate director at Tufts CSDD, who conducted the assessment. "PDUFA V provides an opportunity to resolve some of these issues and concerns."

The Tufts CSDD study, reported in the May/June *Tufts CSDD Impact Report* and released today, also found that:

- Spending on outsourced regulatory services by developers rose 167% between 2007 and 2010.
- The difference between optimal and sub-optimal sponsor experiences with the FDA review process was less for NME/newBLAs than for sNDA/sBLAs.
- Ten of 21 regulatory activity variables were considered significant by sponsors, when optimal and sub-optimal approvals were compared on a disparity index.

To conduct the study, Tufts CSDD convened an industry working group comprised of eight top companies, which led to the development of pilot studies that provided data for the analyses.

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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