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Biotech Drug Approvals in the U.S. Nearly Doubled in the Last Decade, According to Tufts Center for the Study of Drug Development

BOSTON – May 10, 2011 – U.S. regulatory approvals for new biopharmaceuticals nearly doubled in the last decade, compared to the 1990s, according to the Tufts Center for the Study of Drug Development, but drug developers “face substantial challenges” if they are to maintain that pace, the study’s author says.

During the 2000-09 period, 65 biopharmaceutical products received marketing approval from the Food and Drug Administration (FDA), up from 39 in the 1990s and 13 in the 1980s, according to a recently completed Tufts CSDD study.

“While the strong growth in approvals is positive news for biotech companies and patients alike, biopharmaceutical development remains complex and developers face substantial challenges if they are to continue winning approvals at the pace of the last decade,” said Janice Reichert, Ph.D., research assistant professor at Tufts University and author of the study.

To underscore her point, she noted that average, combined clinical and approval phase time for biopharmaceuticals rose to 95 months for the 2000s, up from 77 months in the 1990s.

“Moving forward, developers will be under pressure to further streamline the development process to assure greater consistency across compounds and within disease areas,” Reichert said.

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

- * Recombinant protein products as a share of all new biopharmaceuticals approved by the FDA increased slightly, from 54% in the 1980s to 57% in the 2000s.
- * New biopharmaceutical approvals in the 2000s were more evenly distributed in six therapeutic categories, compared to those of 1980-89 and 1990-99.
- * Neither orphan nor fast track designation had a substantial impact on the average time from initiation of clinical study to FDA marketing approval for new biopharmaceuticals approved in the 2000s.

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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