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Streamlined Development Process for Certain New Drug Applications Is Not Facilitating Shorter Approval Times

BOSTON – March 8, 2017 – The 505(b)(2) approval pathway for new drug applications in the United States, aimed at avoiding unnecessary duplication of studies performed on a previously approved drug, has not led to shorter approval times, according to a recently completed analysis conducted by the Tufts Center for the Study of Drug Development.

"While the 505(b)(2) regulatory pathway has been highly successful in bringing new therapies to market from 2009 through 2015, drug products approved under this pathway had a longer average approval time compared to new molecular entities approved during the same period," said Joseph A. DiMasi, director of economic analysis at Tufts CSDD and principal investigator for the study.

The 505(b)(2) pathway allows for a more streamlined development and approval process by enabling drug sponsors to seek approval from the Food and Drug Administration (FDA) using data, such as FDA findings of safety and effectiveness, previously generated for a reference drug. It not only allows developers to leverage information used to support earlier approvals, but also can reduce the data required for the new drug application.

"Our findings suggest that drug developers should not anticipate a 505(b)(2) application will necessarily result in a shorter approval time or limited FDA requirements," DiMasi said. "As with any drug development program, it's important to engage proactively with the FDA to better understand the data needed to bridge a 505(b)(2) program with the approved reference product."

Key findings from the study reported in the March/April Tufts CSDD Impact Report, released today, include the following:

- 505(b)(2) applications accounted for 63% of 451 original new drug applications approved by the FDA during 2009-15.
- Mean approval time for 505(b)(2) applications was nearly five months longer compared to approval time for new molecular entities (NMEs).
- 505(b)(2) applications received substantially fewer expedited review designations than NMEs during the same period.
- The percentage of 505(b)(2) drugs approved on the first review cycle was substantially lower than for all NMEs.

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About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development 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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