Marketing Exclusivity for First -in-Class Drugs Has Shortened to 2.5 Years

BOSTON - Marketing exclusivity periods for first-in-class drugs have fallen dramatically in recent decades - from a median of 10.2 years in the 1970s to 2.5 years in the early part of this decade underscoring the competitive nature of drug development, a new study recently completed by the Tufts Center for the Study of Drug Development has found.

According to the study, the average time between first and second follow-on drugs fell even more rapidly - from a median of 16.1 years in the 1960s to 1.1 years in the 2000-03 period.

"Since the early 1990s, nearly one in three follow-on drugs entered clinical testing earlier than did the first-in-class drug," said Tufts CSDD Director of Economic Analysis and study author Joseph A. DiMasi, Ph.D., noting that "distinctions about innovativeness drawn between first-in-class and follow-on drugs may not be meaningful."

He added that, contrary to widespread belief that development of follow-on drugs - sometimes called "me-too" drugs - begins after the first new drug in a therapeutic category receives marketing approval, development of nearly all follow-on drugs begins well before the first-in-class drug receives approval.

"New drug development remains a competitive race, and the first candidate to receive marketing approval to address a specific indication belongs to the sponsor that completes the development gauntlet first," DiMasi said.

The study, reported in the September/October Tufts CSDD Impact Report, released today, also found that:

* Approximately one-half of what turned out to be follow-on drugs had a U.S. or worldwide patent filed before the first-in-class drug had filed any such patents.

* Since the early 1990s, 90% of follow-on drugs had initial pharmacologic testing and 87% were in clinical studies somewhere in the world prior to the first-in-class drug approval.

* The average time for market entry between second and third follow-on drugs also dropped significantly, from a median of 5.1 years in the 1960s to 1.3 years in the 1990s.

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

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