Marketing exclusivity for first-in-class drugs has shortened to 2.5 years

Follow-on approvals underscore competitive nature of new drug development

- 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 2000-03 period.

- 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 2000-03.

- Nearly one-third of all follow-on drugs have received a priority rating from the United States Food and Drug Administration (FDA).

- 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.

- Patent filings for follow-on drugs often occur in advance of first-in-class patent filing.

In contrast to popular 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, the fact is that development of nearly all follow-on drugs actually begins well before the first-in-class drug is approved. New drug development remains a competitive race, and the first candidate to receive marketing approval belongs to the sponsor that completes the development gauntlet first.

A new Tufts CSDD study, summarized here, suggests that distinctions about innovativeness drawn between first-in-class and follow-on drugs may not be meaningful. Indeed, since the early 1990s, nearly one in three follow-on drugs had entered clinical testing earlier than did the first-in-class drug. In addition, 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. These findings highlight the fact that, in the highly competitive pharmaceutical market, drug companies are, in effect, more often engaged in development races than in after-the-fact imitation.