First-in-class drugs in competitive development races with later entrants

83% of later-in-class drugs in Phase II or later when first-in-class drug approved

- 48.5% of 40 pharmacologic classes had three or more entrants at the end of 2014.
- Half of all competitive entries within a pharmacologic class for classes where the first compound was approved 1998-11 occurred in less than 2.7 years; only 2.3 years for 2005-11.
- For pharmacologic classes with at least three approved compounds, competition occurred relatively rapidly, particularly for fourth entrants.
- More than half of all later-in-class drugs received a priority rating from the FDA.
- Nearly all pharmacologic classes had a product patent on at least one later-in-class drug filed in the United States or elsewhere before the first-in-class drug was approved.
- About 90% of all later-in-class drugs had at least initiated Phase I clinical testing abroad or in the U.S. prior to U.S. marketing approval for the first-in-class drug.

Drug development has become more competitive than ever, with new prescription drugs enjoying marketing exclusivity for shorter times – an average of only 2.3 years for 2005-11 approvals. Consistent with earlier Tufts CSDD studies of the competitive landscape for new drug and biologics development, the race for exclusivity goes to the drug sponsor that can receive marketing approval for a new product before others do, regardless of when competitors initiated development on products that ultimately received approval. The latest Tufts CSDD analysis, reported here, found that for first-in-class drugs approved during 2005-11, nearly all later-in-class drugs had begun Phase I testing or had an IND filed with the U.S. Food and Drug Administration (FDA) before the first-in-class drug was approved. The bottom line: Marketing exclusivity is won by developers who can shorten development time and be first to market.

This study examined 40 multiple-entrant pharmacologic classes that produced 108 new drug approvals, in which the first-in-class drug received approval from 1998 through 2011. See Tufts CSDD Impact Report 2009 September/October:11[5].