Large pharma success rate for drugs entering clinical trials in 1993-04: 16%

Share of licensed products in development portfolios peaked in 1999-01

- Nearly three-quarters of the drugs in the portfolios of the top pharmaceutical firms that reached clinical testing from 1993-07 originated in and were developed by the firms.
- Of six specific broad therapeutic categories analyzed, oncologic/immunologic and central nervous system (CNS) had the greatest number of drug candidates entering clinical testing over the 1993-07 period.
- For the top 50 firms, the annual rate at which drugs enter clinical testing increased 31% from 1999-01 to 2002-07.
- Systemic anti-infectives had the highest clinical approval success rate for self-originated new drugs, with more than one-quarter of the drugs entering clinical testing during 1993-04 estimated to receive U.S. marketing approval.
- Less than 10% of cardiovascular and CNS drugs entering the clinical testing pipeline during 1993-04 are estimated to attain U.S. marketing approval.

Big pharma, looking to replace expected revenue declines due to scheduled patent expirations for many top-selling products, is not sitting idly by. A recent Tufts CSDD study of the development pipelines of the 50 largest global pharmaceutical firms, summarized in this Tufts CSDD Impact Report, found that these companies have been bringing more products into their development pipelines in recent years, even though only one in six self-originated compounds entering clinical testing was expected to eventually attain marketing approval (down from one in five in previous Tufts CSDD studies). The companies also appear to have become more aggressive in terminating unpromising candidates, as the share of new self-originated drugs that were terminated during Phase I and Phase II clinical testing increased from 1993-98 to 1999-04.

Perhaps as important, the largest firms have been looking outside their labs to identify and license potential drug candidates developed by others to take through clinical testing. In recent years, however, that development path seems to have fallen out of favor somewhat. After peaking at 28% in the 1999-01 period, licensed products as a share of the total development portfolios of big pharma dropped to just under 16% in 2005-07.