BACKGROUNDER

How the Tufts Center for the Study of Drug Development Pegged the Cost of a New Drug at $2.6 Billion

BOSTON – Nov. 18, 2014 – The Tufts Center for the Study of Drug Development used a sophisticated analytical methodology to estimate the average cost of developing and gaining marketing approval for new prescription medicines to be $2,558 million. Here, briefly, is how it was done.

DATA

Ten drug firms of varying size, which together accounted for 35% of top 50 firm pharmaceutical sales and pharmaceutical R&D expenditures, provided data on clinical phase expenditures and development phase times for a randomly selected sample of self-originated investigational drugs and biologics that first entered human testing during from 1995 to 2007. Of the 106 investigational compounds included in the project dataset, 87 were small molecule chemical entities (including three synthetic peptides), and 19 were large molecule biologics (10 monoclonal antibodies and nine recombinant proteins). In aggregate, cost data for all phases entered were available for 94 of the 106 compounds (89%). Data were also collected from the cost survey participants on their aggregate annual pharmaceutical R&D expenditures from 1990 to 2010.

ANALYSIS

The full, risk-adjusted estimated cost per approved new compound is based on a number of estimates of various components of the drug development process, including the following:

Clinical period expected costs for investigational drugs – Given the high failure rates for new drug development, costs were analyzed in expected value terms, with totals depending on how far the compound proceeds in development (specifically, how many clinical period phases there are in which the drug was tested). Estimated expected clinical period cost per investigational drug is the weighted average of estimated mean clinical phase costs, where the weights are estimated probabilities that a randomly selected compound will enter a given clinical testing phase.

Clinical success, phase transition and phase attrition rates – To determine the level of resources spent by industry per approved new compound from estimates of cost per investigational compound, Tufts CSDD developed and applied an estimate of the likelihood that an investigational compound will eventually be approved for marketing. Clinical approval success rates are based on information on compounds of top-50 firms for compounds that met study inclusion criteria. This, in turn, required estimates of clinical phase transition rates (the likelihood that an investigational drug will proceed in testing from one phase to the next).

The overall clinical approval success rate was calculated as the product of estimated phase transition probabilities. A phase transition rate was estimated as a ratio, where the numerator is the number of compounds that entered a phase and moved on to the next phase and the denominator is the total number of drugs that entered the phase and either were abandoned in the phase or moved on to the next phase. Results also enabled estimates of phase attrition (failure) rates, which were used to develop an estimated distribution of failures across phases.

These probabilities were used to estimate expected costs per investigational compound. Costs per approved new drug were estimated by dividing cost per investigational drug by the estimated overall clinical success rate.

Out-of-pocket discovery and pre-human development costs – The drug discovery and development process typically involves high fixed costs, meaning that substantial expenditures incurred prior to clinical

testing cannot be directly linked to work on specific compounds. Aggregate level data at the firm level were used to infer cost per drug for R&D incurred prior to human testing. Specifically, annual expenditure data for each surveyed firm on spending on pre-human R&D and on human testing from 1990 to 2010 were obtained, and the ratio of pre-human R&D expenditures to human testing expenditures was determined based on an appropriate lag structure between the distributions of costs for pre-human and for clinical testing (on average, pre-human R&D expenditures occur years prior to the associated human testing costs).

Capitalized costs: development times and the cost of capital – Since drug development is a very lengthy process, a full cost estimate for new drug development needs to account for differentials between when investments are made and when potential returns are earned. Therefore, the cost estimate capitalizes the stream of out-of-pocket costs to the date of marketing approval. Tufts CSDD constructed a timeline from estimated average phase lengths and the average gaps and overlaps between successive phases, using data on development histories provided by the survey firms on the investigational compounds selected for the survey. The periods considered were the time from synthesis to human testing, the lengths of the three clinical phases, and the length of time from submission of a new drug application (NDA) or biologics license application (BLA) to NDA/BLA approval.

Given an estimated development and approval timeline and estimates of how out-of-pocket R&D expenditures are distributed over that timeline, costs were capitalized at a discount rate of 10.5%, the expected return that investors must forego during development when they invest in pharmaceutical R&D instead of an equally risky portfolio of financial securities. The discount rate used was an average company cost of capital.

Total capitalized cost per investigational drug is the sum of the capitalized preclinical and clinical cost estimates. This result was divided by the estimated overall clinical success rate for an estimate of total capitalized cost per approved new drug, yielding an estimate of the full resource and time costs expended by industry to discover and develop a new drug to the point of marketing approval.

For an overview on how drugs are developed, check the FDA's New Drug Development and Review Process.

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

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