Flawed arithmetic on drug development costs

A study reporting that the median cost of bringing a new drug to market is as low as $59 million has met with considerable controversy. The authors, Donald W. Light of the University of Pennsylvania and the University of Medicine and Dentistry in New Jersey, and Rebecca Warburton, of the University of Victoria in British Columbia, Canada, estimate in the journal *BioSocieties* (**6**, 34–50, 2011) that the figures touted by the industry are inflated. Critics retort that although the authors rightly critique the lack of transparency and limited sample of companies used in previous estimates, Light and Warburton wrongly assume that clinical trial and regulatory review times are decreasing and underestimate drug discovery attrition rates and risk.

Light and Warburton found that net median corporate R&D costs varied from $13 million to $204 million, depending on the type of drug. The resulting $59.4 million estimate is for the average drug, not just new medical entities, and does not include the cost of discovery, which varies 30-fold. The authors argue that the widely accepted figure from the 2003 study by the Tufts Center for the Study of Drug Development in Boston is inflated. The Tufts economists analyzed cost data for 68 randomly selected drugs from ten pharma companies, and concluded that the average amount spent per drug was $802 million in 2000. This gave rise to an adjusted figure of $1.32 billion often cited by industry groups. But Light says that the numbers are unverifiable because the original data were not fully disclosed. "We have a few points of independent comparison, like the cost of trials or the length of trials, where we get a peek into the black box, and it seems like [their] data are very skewed." Although some agree that the Tufts study has some flaws, they point out that the new paper adds very little to the ongoing debate on the 'real' cost of pharmaceutical research.

"[When I] look at $50 million from the Light and Warburton study, that study doesn't appear to be in the right zip code," says Bruce Booth, a partner at Atlas Venture, a venture capital fund in Cambridge, Massachusetts. Booth adds that the size and duration of clinical trials—both factors that affect the cost of a drug—can vary vastly depending on whether the drug is for a major disease like diabetes or for a rare or orphaned disease. So, a single point estimate for cost, such as an average or mean as stated in both studies masks the reality that every drug and every company is different. Bernard Munos, of Indianapolis-based Eli Lilly, authored a study in *Nature Reviews Drug Discovery* (**8**, 959–968, 2009), where he calculated the cost to range between $4 billion and $14 billion. Although some of Light and Warburton's criticisms are founded, he says, the paper itself doesn't do much more than "take pot shots at the industry without bothering to check if there is evidence to support their claims a priori." A more rigorous analysis of available data, such as the costs, sizes and durations of current clinical trials, would make Light and Warburton's arguments more credible, Munos says, pointing out that the US clinical trials database (http://www.clinicaltrials.gov/) could be one resource for finding such information. "When the data are available, it's your responsibility to let the data speak, and they don't do it," he says.

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R&D figures contested

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