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Letters...

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The Price of Success

THE COST OF INNOVATION. The recent article published in the Feb. 7, 2011, issue of the journal BioSocieties for The London School of Economics and Political Science is causing quite a stir. The authors — Donald W. Light of Stanford University and University of Medicine and Dentistry of New Jersey and Rebecca Warburton of University of Victoria in Canada — challenge the gold standard of R&D costs put forward by the Tufts Center for the Study of Drug Development.

The new study claims Tufts' estimates are artificially high and make no adjustment for taxpayer subsidies or tax deductions/credits specifically tied to R&D expenditures, which would reduce net R&D costs for a company. The authors also question the inclusion of cost of capital, or the costs of returns from funds that would have been invested in the stock market, were the R&D project not undertaken.

Tufts used a rate of return of 11% compounded annually, which is higher than the 3% called for by U.S. government guidelines. The authors calculate a net mean cost of $80.3 million per approved drug and net median cost of $59.4 million per approved drug, which includes the lower guidelines for cost of capital. In our reader question this month, we want to know whether the authors' of the new study have a case for their suggestion that R&D cost estimates are artificially high? Send your comments to feedback@pharmavoice.com.

Shortly following the release of the BioSocieties' study, PhRMA, along with Burrill & Company, released its annual state of the industry. The industry trade organization estimates that America's biopharmaceutical research companies invested a record $67.4 billion last year in the research and development of new medicines and vaccines — an increase of $1.5 billion from 2009. Furthermore, PhRMA member companies alone spent an estimated $49.4 billion on biopharmaceutical R&D last year, a 6.5% increase over 2009. Burrill analysis shows that additional biopharmaceutical research companies in the United States spent an estimated $18.0 billion on R&D in 2009.

The increase in R&D spending is expected to increase as more and more companies continue to invest in postapproval research studies, which are becoming bigger and more expensive. As noted in this month's Forum, late-phase or registry studies can run for five years or more, compared with the 12 months to 18 months for many Phase III trials. This presents significant site and patient retention issues for these longer study durations. And as a result, pharmaceutical sponsors are looking at other ways to use the data generated from these studies to create value for their organizations.

In the end, and whatever the real R&D number is, hopefully patients will benefit from improved outcomes and safety profiles.

Regards,

Taren Grom
Editor

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Their Word...

DENISE MYSHKO
Managing Editor

Sponsors are challenged to come up with ways to get late-phase studies done as quickly and as inexpensively as possible.

ROBIN ROBINSON
Senior Editor

Unlike many technologies, AR and QR codes are a good fit for the needs of the healthcare field.

KIM RIBBINK
Features Editor

The Russian government has taken steps to bolster the domestic pharma sector that are expected to boost the number of global companies establishing a local presence.

CAROLYN GRETTON
Contributing Editor

Education programs that incorporate cutting-edge technology are helping to keep healthcare providers up to date, with the goal of improving patient outcomes.

COMING in May

- mHealth
- HBA Rising Stars
- Emerging Market — South Korea
- Showcase Feature — Market Research