The respective roles of the public and private sectors in pharmaceutical innovation

December 15 2011

The study identifies the respective contributions of direct and indirect government support in research and development of new pharmaceutical drugs.

Research conducted by Columbia Business School Professor Frank Lichtenberg, Courtney C. Brown Professor of Business, Finance and Economics, Healthcare and Pharmaceutical Management Program, and Bhaven Sampat, Assistant Professor in the Department of Health Policy and Management at the Mailman School of Public Health of Columbia University, identifies the respective contributions of direct and indirect government support in research and development of new pharmaceutical drugs. Although industry supplies the bulk of the funds devoted to research and development, the public sector – primarily the National Institutes of Health (NIH) – supports most of the nation's basic biomedical research.

The research, recently featured in *Health Affairs,* finds direct government funding to be important to research and development for the most innovative new drugs, which typically proceed through the Food and Drug Administration's (FDA) "priority-review" process for approval. However, direct government funding is less important for research and development of so-called standard-review drugs that proceed through the FDA's normal review process. The researchers' analysis can help determine the merits of various policy proposals, such as those that would attempt to recapture a share of drug profits and return them to the government through recoupment or march-in

authority. March-in proposes that taxpayers should not have to pay twice for publicly funded research – once through taxes, and once through monopoly prices or restricted access to drugs.

The paper focuses on patents for drugs approved between 1988 and 2005. The analysis studies a range of publicly available data from federal agencies including the Patent and Trademark Office, the National Library of Medicine, the FDA, and the Agency for Healthcare Research and Quality (AHRQ). Of the 478 drugs in the sample, 379 were covered by at least one patent. There were 1,073 distinct patents on these 379 drugs.. The researchers identified public-sector patents to be ones assigned to a government agency, which generally resulted from research conducted inside that agency, and all of those with government interest statements. Most derived from academic laboratories that had received government funding, generally through extramural research grants. The recipients of federal research grants are required to acknowledge government funding in their patent applications.

The researchers' analysis found striking differences between priority-review drugs and standard-review drugs in terms of the proportion receiving a public-sector patent. The direct government role is much more pronounced for the most innovative drugs—those receiving priority review. The data also show that the indirect impact of government funding is much larger than the direct effect. Although fewer than 10 percent of drugs had a public-sector patent, far larger proportions of drugs had patents that cited a public-sector patent, a government publication, or both. In all cases, the public-sector influence was much greater on priority-review drugs than on those receiving a standard review.

Professor Lichtenberg explains the significance of the study. "This analysis underscores why it is important to distinguish between the direct and indirect roles of government funding in pharmaceutical innovation.

For example, policies such as recoupment and march-in would apply only to drugs in whose development the government had played a direct role."

Provided by Columbia Business School