

essential action

Access to Medicines Project

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Ensuring Effective Biogenerics Legislation: The Cost-Sharing Approach to Compensation for the Cost of Clinical Trials is Preferable to Data Exclusivity

If U.S. policymakers wish to create an additional incentive in biogenerics legislation specifically for the cost of the clinical trials required to obtain FDA marketing approval of new biologic drugs, there are approaches -- such as sharing the cost of clinical trials -- that satisfy the public policy rationale for providing data exclusivity to innovators, at a much lower cost and while avoiding data exclusivity-conferred marketing monopolies that undermine access to medicines and other public health objectives. If a policy decision were made that innovator companies need investment protections beyond those afforded by the patent system, the cost-sharing approach would be an efficient and pro-public health alternative to the data exclusivity (marketing monopoly) approach. This approach gives generic firms an automatic right to use brand-name originators' data, but requires them to pay a share of the documented costs of generating the data, proportionate to the size of the markets in which they are selling their product.¹

The cost-sharing approach gives generic competitors an automatic right to rely on the registration data generated by originator companies, or marketing approval authorizations based on that data. But it requires the generic entrants to pay for use of the data (or for relying on marketing approvals based on the data). Under the cost-sharing approach, the amount generic competitors pay for using or relying on the data is based on the actual costs of generating the data and the proportionate market share obtained by the generic competitor.

The Key Features of a Cost-Sharing System are:

- The originator of the data must disclose and document the actual costs incurred in generating the data.
- The generic competitor pays a proportionate share of cost.

Avoiding Overcompensation for Test Data

To avoid overcompensation for pharmaceutical test data, or double compensation for originators of data, caps and limits on payment should be applied under this approach:

- If a product is covered by a patent, no registration data compensation is paid;
- When the company that originated the data earns from sales a certain multiple (we propose 20 times) of its cost in generating registration data, it loses its right to data compensation from generic competitors;
- The right to compensation expires five years after marketing approval has been granted to data originators.

The Cost-Sharing System Explained

Here's how the system would work in practice: Innovator A receives marketing approval for biologic pharmaceutical P in 2010. Generic company G1 gains marketing approval in 2012 and immediately gains a 50 percent market share. Stipulate that P is sold only in the United States. A documents clinical

testing costs of \$100 million. G1 must pay \$10 million to A at the end of 2012, at the end of 2013 and the end of 2014.

Now assume another generic entrant, G2 enters the market in 2013. A, G1 and G2 each have a 33 percent market share. G1 and G2 must each pay \$6.67 million to A in 2013 and 2014.

This system would be administratively manageable. A version is already in effect for U.S. approval of agricultural chemicals, although the agrichemical cost-sharing scheme follows only after grant of an initial marketing monopoly.²

Significant Advantages of the Cost-Sharing Approach over Data Exclusivity (Marketing Monopolies)

The cost-sharing approach acknowledges that there are genuine and significant costs associated with conducting clinical trials to obtain marketing approval for biologics. By providing compensation to companies that originate registration data, the cost-sharing approach deals directly with the claim by brand-name companies that "free-riding" by generic entrants will undermine R&D incentives or unfairly situate the originators of registration data.

The cost-sharing approach also narrowly tailors the reward offered to data originators. It provides direct compensation based on the actual cost of data used to obtain marketing approval, ensuring that data originators obtain proportionate compensation for others' use of the results of the originators' investment.

This approach contrasts sharply to the data exclusivity approach, which rewards data originators with effective marketing monopolies. The cost-sharing approach considers an effective marketing monopoly as likely to provide overcompensation for data originators, enabling them to earn many times the cost of their investments, with monopoly rewards unrelated to the size of their investment. The cost-sharing approach also rejects the idea of marketing monopoly as appropriate for an investment-based compensatory scheme – one that is trying to avoid uses of the fruits of originators' investment that may be considered "unfair," but is not trying to reward creative genius in the fashion of patents.

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¹ For more detailed discussions of the cost-sharing approach to investments in pharmaceutical test data, see: Weissman, Robert. "Public health-friendly options for protecting pharmaceutical registration data." *International Journal of Intellectual Property Management*. 2006 Vol 1, Nos 1/2: 113-130, available at <http://www.essentialaction.org/access/index.php?/archives/54-Essential-Action-Publications-and-Papers.html>; and Love James, Rius Sanjuan, Judit, and Weissman Robert. "A cost-sharing model to protect investments in pharmaceutical test data." CPTech (now Knowledge Ecology International - KEI) Policy Brief No. 1, April 3, 2006, revised May 18, 2006, available at: <http://www.cptech.org/publications/recent-publications.html>.

² Section 3(c)(2)(b), 7 U.S.C. 136(a)(c) (2) (B), of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y.